STATE OF IOWA DEPARTMENT OF

Health AND Human

SERVICES

Iowa Medicaid Drug Utilization Review Commission Annual Report of Activities Fee-for-Service Program SFY23

September, 2023

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The Iowa Medicaid Drug Utilization Review Commission

Change Healthcare has developed the following report for the Iowa Department of Health and Human Services. This report provides a summary description of the activities of the Iowa Medicaid Drug Utilization Review Commission, along with an evaluation of the Iowa Medicaid fee-for-service retrospective drug utilization review program. Information contained in this report covers projects completed and evaluated during the time period of July 2022 through June 2023.

Background Information

Established in 1984, the DUR Commission is charged with promoting the appropriate and cost-effective use of medications within the Iowa Medicaid member population. Acting as a professional advisory group, the Commission analyzes medication utilization by the members of Iowa Medicaid and performs educational initiatives to optimize member outcomes. The Commission performs retroDUR and educational outreach through patient-focused reviews and problem-focused reviews. The Commission supports the proDUR program through criteria review and acts as a resource to the DHHS on other issues concerning appropriate medication use. On April 1, 2016, the Iowa Medicaid population transitioned to managed care. With this transition, over 90 percent of the population moved to managed care leaving less than 10 percent of the population in the fee-for-service (FFS) program. Managed Care Organizations (MCOs) participate in the DUR Commission meetings, provide a quarterly prevalence report with information on prescribers, pharmacies and prescription claims information for the DUR Commission to review, and have the ability to provide input during the meetings. Collaboration with the MCOs to develop retroDUR initiatives and educational outreach for the entire Iowa Medicaid population is ongoing. The DUR Commission also engaged in the ongoing development of clinical prior authorization criteria and ProDUR edits.

The MCOs are required to follow the FFS Preferred Drug List (PDL), prior authorization (PA) criteria and utilization edits. Additionally, each MCO utilizes the state's DUR program to comply with federal regulations.

Patient-Focused Reviews

Member medication profiles are generated prior to each DUR meeting for review. The DUR contractor generates member medication profiles through a complex screening process. The first step of the screening process subjects member profiles to a therapeutic criteria screen. If a profile is found to have failed one or more therapeutic criteria, the member profiles are then assigned a level of risk based on their medication history and potential for adverse events regarding medication. The profiles with the highest level of risk are then selected for review. Six months of prescription claims data and medical claims data, if available, are assessed to determine this risk factor.

The member profiles selected from this process are manually reviewed by the Commission, if needed, or the DUR Coordinator to minimize false positives generated by the computer selection process. The Commission or DUR Coordinator identifies situations where educational intervention might be appropriate. Through these interventions, suggestions regarding medication therapy are communicated to the care providers. Templates are developed for suggestions that are frequently communicated to providers. The reviewer may also author an individualized suggestion if a template suggestion is not applicable.

Educational interventions are generally done by letters to prescribers and pharmacists, but may also be done by telephone or in person. The suggestions made by the Commission or DUR Coordinator are educational and informative in nature. Suggestions may be classified as either therapeutic or cost saving in nature. In addition, these suggestions are classified by problem identified for reporting purposes. The classifications are as follows:

- Not Optimal Drug
- Not Optimal Dose
- Not Optimal Duration
- Unnecessary Drug Use
- Therapeutic Duplication
- High Cost Drug
- Drug-Drug Interaction
- Drug-Disease Interaction
- Adverse Drug Reaction
- Patient Overuse
- Patient Underuse
- Therapeutic Alternative
- Missing Drug Therapy
- Not Optimal Dosage Form
- Potential Generic Use
- Inappropriate Billing

Suggestions are intended to promote appropriate and cost-effective use of medications. When suggestions result in cost savings, these savings are calculated based on decreased cost of medications. However, several of these classes of interventions are intended to increase the use of medications. Examples are member underuse and missing drug therapy. In these cases, the addition of medication therapy will increase medication expenditures, but will be beneficial to the member and should result in cost savings in medical services and/or improved quality of life. Cost savings in these situations cannot be calculated due to data limitations. Therefore, these suggestions are considered to have a positive impact on the program with no medication cost savings. Cost savings on medical services are assumed however not calculated.

Providers are invited to respond to the Commissions' suggestions and to request additional information. Reponses are voluntary and response rates are calculated for prescribers and pharmacists.

Once a member's profile is reviewed, it is excluded from the selection process for nine months to eliminate repeat selections. After this waiting period, the current profile for each member is generated and reviewed to determine if the Commission's suggestion was implemented. If so, fiscal considerations resulting from that change are also calculated. The policy regarding these calculations is included in Appendix B.

Problem-Focused Reviews

Problem-focused reviews narrow the emphasis of review to a specific issue that has been determined to be an area where a targeted educational effort to providers may be valuable. Topics for review are selected from findings of patient-focused reviews, from assessments of the monthly paid claims report, from review of the quarterly prevalence report, and medical literature, or from suggestions by Commission members and MCOs. Criteria are developed to identify the members who may benefit from intervention, and educational materials are disseminated to their

providers. Providers are encouraged to voluntarily respond. The member profile is generated again in an appropriate amount of time (typically 6 to 9 months) to determine the impact rate of the intervention, along with any fiscal considerations. The policy regarding these calculations is included in Appendix B.

Administrative Review

The Commission will review utilization data and medical literature to make recommendations to the Department of Health and Human Services (DHHS) regarding policy issues. These recommendations are made to promote the appropriate use of medications and positive member outcomes. Recommendations are made at the request of the DHHS or at the Commission's discretion. All authority to accept or reject DUR Commission recommendations lies with the DHHS. The Commission may make recommendations but does not make policy. Primary areas for recommendations include proDUR, drug prior authorization (PA), coverage of medications, and administrative and billing procedures. The prospective drug utilization review (proDUR) system is currently administered by Change Healthcare and was implemented statewide in July 1997.

The Commission recommends new or updated guidelines for use in the drug prior authorization program. This process is based on reviews of medical literature in addition to comparisons with other public and private sector programs. Input from providers outside the Commission, particularly specialists, is often sought when developing these guidelines. Once developed, the drug prior authorization criteria are sent to the medical and pharmacy associations in the state for comments. After considering these comments, a final recommendation is made to the Department. The Department may or may not accept the recommendation or may alter the recommendation.

The Commission also makes recommendations regarding coverage of medication or devices. As most coverage requirements are defined by OBRA '90, these recommendations generally encourage coverage of optional services. An example would be the coverage of select over-the-counter medications.

The Commission may review pharmacy claims with respect to administrative procedures. Situations where funding for medication can be obtained from other sources are relayed to the Department for their action. For instance, Medicare will pay for immunosuppressive medications for transplant patients and nebulizer solution for dual eligible patients. The Commission also identifies situations where the Department may recover funds from inappropriate billing.

Overall Results

Activities of the DUR Commission were evaluated for SFY23 for interventions performed in the previous or the current fiscal year. Due to the small patient population in the FFS program, savings to the state are significantly less than prior to the transition to managed care. The direct cost savings from all activities of the DUR Commission are calculated to be $16,303.13*. This calculation is based on estimates regarding two types of reviews: patient-focused reviews and problem-focused reviews. These results are also found in Appendix C.

Cost Savings Estimate	$16,303.13*

Patient-focused reviews resulted in $5,491.80* in direct cost savings, or $189.37* per patient evaluated. This estimate is based on the 30 suggestions made by the DUR Commission identified from the review of the medication therapy of 29 patient profiles selected for intervention. Of these 30 suggestions, 8 suggestions were implemented by the providers, resulting in a 27 percent impact rate.

Patient-Focused Profile Review

Suggestions Made	30
Therapy Changed	8
IMPACT RATE	27%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated	$189.37*
Dollars Saved on Medication	$5,491.80*

*Savings reported are pre-rebate, total dollars

Problem-focused reviews resulted in an estimated cost savings of $10,811.33* or $74.56 saved per patient evaluated. This estimate is based on the review of profiles with 145 patients selected for interventions. Therapy was changed for 41 patients, resulting in an impact rate of 28 percent. These interventions are informative in nature.

Problem-Focused Profile Review	
Patients Evaluated	145
Therapy Changed	41
IMPACT RATE	28%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated	$74.56*
Dollars Saved on Medication	$10,811.33*

Comparison to Previous SFY Report

Cost savings estimates for SFY23 ($16,303.13*) are slightly higher than last year ($15,867.81*). This low overall cost savings amount is due largely to the majority of the population being enrolled in managed care. With a fraction of members remaining in FFS, the number of interventions has significantly decreased, limiting the ability to realize a substantial cost savings.

The savings from SFY23 patient-focused reviews ($5,491.80*) were lower than SFY22 ($15,698.97*). The number of suggestions made (30) vs. (37) decreased while the number of suggestions that were accepted (8) vs. (12) from SFY22 also slightly decreased. Again, due to the transition to managed care, cost savings, the number of suggestions made, and the number of suggestions accepted fluctuate year to year. Historically there has been minimal impact from patient-focused reviews; that is attributed to the maturation of the Preferred Drug List (PDL) program and Point of Sale (POS) edits that have been implemented over the years. It is difficult to determine the actual cause for the minimal number of suggestions accepted. Due to the voluntary participation of the prescriber and lack of the ability to enforce the educational recommendations made by the DUR Commission, it's possible prescribers do not make the recommended change due to lack of time, or they do not feel it is in the best interest of the patient.

The savings from problem-focused reviews for SFY23 ($10,811.33*) were higher than SFY22 ($168.84*). This was due to one focused review with a higher number of members resulting in a greater impact than in prior years.

*Savings reported are pre-rebate, total dollars

Results by Review Type

Patient-Focused Review

During this evaluation period, 67 educational intervention letters were mailed to prescribers and pharmacies regarding medication therapy. Of this total, 37 letters (55 percent) were mailed to prescribers, and 30 letters (45 percent) were mailed to pharmacies. Providers are invited to voluntarily respond to DUR Commission letters. Providers returned 25 responses to these letters, resulting in an overall response rate by the providers of 27 percent. Of the 25 responses, 13 (52 percent) were from prescribers and 12 (48 percent) were from pharmacies. The overall response rate differed between prescribers and pharmacies; 35 percent for prescribers and 40 percent for pharmacies.

In these 67 educational letters, the DUR Commission made 30 suggestions. Of these suggestions, 30 (100 percent) were therapeutic in nature while zero (zero percent) were cost-saving in nature. The suggested change was implemented in 8 cases, resulting in an overall impact rate of 27 percent.

Of the 30 suggestions, only one type of suggestion accounted for 100 percent of the total; Therapeutic Duplication. Of the 8 changes, the only reason for the Commission's inquiry was Therapeutic Duplication (100 percent). No other single category accounted for any changes.

The suggestion(s) that resulted in change the highest percentage of the time was Therapeutic Duplication (27 percent).

Implementation of therapeutic suggestions resulted in direct drug cost savings of $5,491.80*. Zero cost-savings suggestions were made or implemented, resulting in zero direct drug cost savings*. The total amount saved on medication utilization was calculated to be $5,491.80* for the 29 patients evaluated, or $189.37* per patient.

The complete details of the results of patient-focused studies reported quarterly are also outlined in Appendix D.

Problem-Focused Reviews

Nine problem-focused reviews were evaluated during SFY23. In conducting these reviews, 145 patients were selected for intervention. Of these patients, 41 showed evidence of a positive outcome, resulting in an impact rate of 28 percent.

Results of the focused studies are detailed in Appendix E. A description of the problem-focused review is available in Appendix F. The MCOs perform the same reviews on their members.

*Savings reported are pre-rebate, total dollars

Administrative Review

Prior Authorization

The DUR Commission annually reviews the prior authorization program for clinical appropriateness. Changes are recommended to the Department. During SFY23, the DUR Commission reviewed all therapeutic categories requiring prior authorization as well as therapeutic criteria to support operations of the Preferred Drug List. Recommendations for modifications to existing criteria, recommendations for new prior authorization criteria, and recommendations for removal of prior authorization criteria can be found in Appendix G as well as the Recommendation Letters.

Prospective Drug Review

The DUR Commission reviews and recommends prospective drug utilization review criteria to be used by the Department. Information regarding the DUR Commission recommendations for prospective DUR can be found in the DUR Recommendation Letters in Appendix G and the list of recommendations in Appendix H.

Other Activities

All activities of the DUR Commission can be found in the DUR meeting minutes in Appendix I.

Two newsletters were written and posted to the website by the DUR Commission for the Medicaid provider community during this fiscal year.

The DUR Commission maintains a web site to improve communication with a variety of stakeholders. The web site is found at www.iadur.org. The site contains information regarding upcoming meeting dates, locations, agendas, minutes from the previous meeting, as well as past issues of the provider newsletter, the *DUR DIGEST*. In addition, the web site provides meeting agendas and minutes for the DUR Mental Health Advisory Group.

Rhea Hartley, M.D. began her first term on the DUR in July 2022.

Holly Randleman, Pharm.D. began her first term on the DUR in July 2022.

Lisa Todd, R.Ph. completed one year of her two-year term on the Commission as the MCO representative, leaving early due to a change in her job duties with Amerigroup.

Susan Parker, Pharm.D. retired after over 20 years as the Pharmacy Director for the Department of Health and Human Services at Iowa Medicaid.

Quarterly prevalence reports were developed to allow the DUR Commission to analyze changes in medication use across the entire Medicaid patient population and can be viewed on the DUR Commission website as a part of the meeting materials.

Periodically the DUR Commission will make recommendations to the Iowa Medicaid Pharmacy & Therapeutics Committee regarding the status of a medication on the Preferred Drug List (PDL). Recommendations can be found in Appendix J.

*Savings reported are pre-rebate, total dollars

Links to useful items regarding the DUR Commission can be found in Appendix K, which include the DUR website, DUR newsletters, and Prevalence Reports.

*Savings reported are pre-rebate, total dollars

Appendix A
Commission Members

Iowa Medicaid Drug Utilization Review
Commission Members
2022-2023

John Ellis, Pharm.D.
Dr. Ellis is currently the pharmacy manager at Hy-Vee Pharmacy in Winterset, Iowa, and previously worked at several other Des Moines metro Hy-Vee locations. He received his Doctorate of Pharmacy degree from Drake University, where he is also an Adjunct Assistant Professor of Pharmacy. Dr. Ellis was appointed to the DUR Commission in 2019; Dr. Ellis was reappointed for a second term which will expire in June 2027.

Rhea Hartley, M.D.
Dr. Hartley is currently the Chief Medical Officer at Community Health Centers of Southeast Iowa in West Burlington, Iowa, and recently worked in Kansas as a Staff Physician at Trust Women and Planned Parenthood, ED Physician at Air Capital Emergency Physicians, and Chief Informatics Officer at the Robert J. Dole VA Medical Center. She received her Doctor of Medicine degree from the University of Kansas School of Medicine in 2003, and also has a Master of Science in Health Care Administration from Oklahoma State University. Dr. Hartley was appointed to the DUR Commission in 2022; her first term will expire in June 2026.

Melissa Klotz, Pharm.D.
Dr. Klotz is the pharmacy manager at Medicap Pharmacy in Des Moines, Iowa. Melissa graduated with her Doctor of Pharmacy degree from the University of Iowa College of Pharmacy in 2007, and has experience with hospital, long
term care and retail pharmacy. She has volunteered at Grace Methodist Free Medical Clinic, and also volunteered at Webster City Free Medical Clinic 2009-2010. Dr. Klotz was reappointed to the DUR for a second term in 2021, which will expire in June 2025.

Jason Kruse, D.O.
Dr. Kruse graduated from Des Moines University College of Osteopathic Medicine in 2011. He then completed his internal medicine residency at the University of Iowa Des Moines Campus in 2014, and is board certified in internal medicine. Dr. Kruse currently practices inpatient and outpatient medicine at Broadlawns Medical Center in Des Moines, Iowa. Dr. Kruse was reappointed to the DUR for a second term in 2021, which will expire in June 2025.

Holly Randleman, Pharm.D.
Dr. Randleman is currently an Emergency Medicine Clinical Staff Pharmacist at Iowa Methodist Medical Center in Des Moines, Iowa, and previously worked at Mercy Medical Center as a Clinical Staff Pharmacist. As part of her current role, she reviews and applies guideline-based medicine, specifically hospital policies related to drug therapy and helping to implement new procedures as policies are approved. She received her Doctor of Pharmacy degree from Drake University in 2007. She served on the Iowa Medicaid Pharmaceuticals and Therapeutics Committee from 2013 to 2020, and also has

experience on several hospital, Iowa Pharmacy Association, and Iowa Board of Pharmacy committees. Dr. Randleman was appointed to the DUR Commission in 2022; her first term will expire in June 2026.

Susan Parker, Pharm.D.
Dr. Parker is the Pharmacy Director for the Department of Human Services at the Iowa Medicaid Enterprise and serves as liaison to the Commission. She graduated with a Doctor of Pharmacy degree from Mercer Southern School of Pharmacy in Atlanta, Georgia. She is also a graduate of Gannon University in Erie, Pennsylvania with a Bachelor of Science Degree Physician Assistant. Dr. Parker brings to the Commission a variety of experience in health care as an Iowa Medicaid drug prior authorization pharmacist, community pharmacist, and physician assistant. She is a member of the American Medicaid Pharmacy Administrators Association and the Western Medicaid Pharmacy Administrators Association.

Lisa Todd, R.Ph.
Lisa Todd has been the Pharmacy Account Director for Amerigroup since June 2020. Prior to her Iowa Medicaid role at Amerigroup, she served in many roles as a pharmacist. She was previously the Pharmacy Program Manager for both the Kansas and Nevada Medicaid programs and had retail pharmacy experience at multiple pharmacies including Dillon's Pharmacy and King Pharmacy in Kansas. Lisa Todd is a graduate of Kansas University School of Pharmacy, earning a B.S. in Pharmacy, and also earned a Bachelor of Business Administration and a B.A. in Chemistry from Washburn University. Ms. Todd serves on the DUR Commission as the MCO Pharmacy Director representative, which rotates around the MCOs every 2 years. Ms. Todd's two-year term will expire June 2023.

Charles Wadle, D.O.
Dr. Wadle graduated from Des Moines University of Osteopathic Medicine and then completed his residency at the University of Nebraska Medical Center in Omaha. Dr. Wadle is currently Section Chief of Outpatient Behavioral Health at Broadlawns Medical Center in Des Moines. He is a Board Certified in Psychiatry by the American Board of Psychiatry and Neurology; Addictions by American Society of Addiction Medicine and American Board of Addiction Medicine; and Quality Assurance by the American Board of Quality Assurance and Utilization Review Physicians. Dr. Wadle also serves on the Iowa Medicaid P&T Committee. Dr. Wadle was reappointed to the DUR Commission for a second term, which will expire in June 2026.

Jason Wilbur, M.D.
Dr. Wilbur graduated from the Saint Louis University School of Medicine in 1999. He then completed his Family Medicine Residency at the University of Iowa, where he was Chief Resident 2001-2002, followed by a Geriatric Medicine Fellowship 2002-2003. He is currently Professor of Clinical Family Medicine for the Roy J. & Lucille A. Carver College of Medicine at the University of Iowa. Prior to that, he was Medical Director of the Family Medicine Clinic in Iowa City from 2006 to 2011. The University of Iowa Hospitals and Clinics awarded him the Above and Beyond Reward in 2006 and again in

2007, along with the Teacher of the Year Award, presented by the University of Iowa Family Medicine residents, in 2008. Dr. Wilbur was reappointed for a third term in 2020 which will expire in June 2024.

Appendix B
Evaluation Procedure

EVALUATION OF THE IMPACT OF PROSPECTIVE AND RETROSPECTIVE DRUG UTILIZATION REVIEW INTERVENTIONS

The goal of Drug Utilization Review (DUR) is to evaluate cost savings and provide quality assurance of medication use. The DUR Commission works in conjunction with the pharmacy medical program at the Iowa Medicaid Enterprise to contribute to the overall success of the program. The Drug Utilization program:

- Evaluates three areas of activity including Patient-focused Drug Utilization Reviews, Problem-focused Drug Utilization Reviews, and Administrative Activities.
- Examines only direct drug costs. DUR evaluation does not have the ability to quantify its impact on other health services such as hospitalizations, ER visits, and physician visits.
- Reports pre-rebate savings since access to supplemental rebates is not within the scope of the DUR program.
- Often provides recommendations that are qualitative, such as improved health outcomes, rather than quantitative in nature.

As a general principle, evaluations are based upon an observed change in the targeted prescribing or dispensing pattern, as well as changes seen in therapy of the individual patients. One evaluation approach is to observe and quantify changes in prescribing due to a given intervention compared to a control group of providers who do not receive the intervention. The intervention's impact on prescribing may be more readily detectable by this method and could be measured by comparing the two groups of patients or prescribers. However, it is very difficult to design a scientifically sound control group given the many variables surrounding patient care. Therefore, in most instances the DUR Commission has chosen to forego use of a control group to achieve the greatest impact. Although the evaluation of the intervention may be less scientific, intervention on behalf of all the patients is more desirable. In this instance, prescribing trends may not be available for comparison, but savings and benefit can still be quantified at the individual patient level.

<u>Patient-focused DUR</u>

Patient-focused DUR concentrates efforts on specific suggestions made about an individual patient. Each suggestion, or template, attempts to make a change in therapy. These changes are either therapeutic or cost-saving in nature; however, these situations are not necessarily mutually exclusive. A therapeutic change -- one that improves the patient's therapy in some way -- may also produce cost savings. Cost-saving changes are attempted when a patient is not receiving a medication in the most economical form. The intervention does not change the medication but points out that the same medication could be given in a more cost-effective manner. Each template and intervention is evaluated to determine if the proposed change was implemented and, if so, what economic implications can be calculated.

The calculation relating to therapeutic and cost saving interventions is tabulated by comparing a member's initial profile with the member's re-review profile. Each member

profile is a six-month snapshot of medications covered by the Medicaid program. Pertinent information such as patient name and ID, date of service, drug name, strength, and quantity, RX number, day supply, prescriber and pharmacy ID, total price submitted, and amount paid appear on each profile. There are nine to twelve months in between the initial and re-review profiles to accommodate for provider review, response, and implementation for therapeutic and or cost changes. For each intervention, the total amount paid on the initial profile for any one intervention is noted. According to the intervention at hand, the re-review profile is evaluated for change. The amount paid on the re-review profile for the same intervention is also noted. A comparison between the profiles is calculated by subtracting the total amount paid from the initial profile with the total amount paid from the re-review profile. This calculation is then annualized multiplying the number by 2 to get the pre-rebate annualized savings.

All savings for patient-focused review are based on annualized savings for one year only. Reporting on patient-focused interventions will provide the following information:

- Total number of templates mentioned
- Number of templates that were therapeutic in nature
- Number of templates that were cost-saving in nature
- Total number of changes implemented
- Number of changes that were therapeutic in nature
- Number of changes with positive impact without savings
- Number of changes that were cost-saving in nature
- Total dollars saved from therapeutic changes
- Total dollars saved from cost-saving changes
- Total dollars saved
- Impact of interventions expressed as a percentage

All templates are described by one of sixteen classifications. These classifications indicate the general type of intervention addressed by the template. Reports will also include a breakdown by classification (therapeutic or cost-saving) of the templates used in the patient-focused letters. This data will show which templates are cited most often, result in change most often, and result in higher cost savings.

Templates that are therapeutic in nature include:

- Not Optimal Drug
- Not Optimal Dose
- Not Optimal Duration of Use
- Unnecessary Drug Use
- Therapeutic Duplication
- High Cost Drug
- Drug-Drug Interaction
- Drug-Disease Interaction
- Adverse Drug Reaction
- Patient Overuse
- Patient Underuse

- Therapeutic Alternative
- Missing Drug Therapy

Templates that are cost saving in nature include:
- Not Optimal Dosage Form
- Potential Generic Use
- Inappropriate Billing

Problem-focused DUR

Problem-focused DUR concentrates efforts on a specific problem or trend in prescribing. While patient-focused reviews may address a multitude of situations, a problem-focused review addresses only one concern. The DUR Commission uses guidelines, literature and peer-group prescribing to identify particular clinical situations that need addressed. This process ensures that each intervention is unique due to the subject matter and may differ in steps of evaluation.

Reporting for problem-focused interventions will include the types of intervention done and the resulting savings. Savings are always calculated based on one year of therapy only and are calculated in the same manner as explained in the patient-focused DUR section.

Administrative Review

The Drug Utilization Review (DUR) program is a component of the Pharmacy Medical Division of the Iowa Medicaid Enterprise (IME). DUR contributes expertise and information that leads to implementation in other programmatic areas including, but not limited to: Prospective Drug Utilization Review, Prior Authorization, Preferred Drug List, and Supplemental Rebates. Although the DUR program impacts all of the different pharmacy programs it is difficult to determine where its impact begins and ends. Therefore, the savings associated with DUR contribution in other pharmacy areas cannot be determined. IME pharmacy programs are listed below along with a DUR impact statement:

- Prospective DUR
  Definition: A process in which a request for a drug product for a particular patient is screened for potential drug therapy problems before the product is dispensed.
  Impact: The DUR Commission reviews scientific literature regarding specific medications and makes recommendations to DHS on appropriate utilization guidelines or parameters.

- Prior Authorization
  Definition: A process for obtaining approval for a drug before the drug is provided to a member, as a precondition for provider reimbursement. Prior authorization is requested at the prescriber level and is a prescriber fax-only system using the forms provided by the Iowa Medicaid Enterprise.
  Impact: The DUR Commission develops sound, cost-effective medication use

guidelines by reviewing peer reviewed medical information from various sources. The Commission seeks outside expertise when necessary and considers public comments prior to recommending prior authorization for appropriate drug use.

- Preferred Drug List (PDL)
  Definition: A list comprised of drugs recommended to the Iowa Department of Human Services by the Iowa Medicaid Pharmaceutical and Therapeutics Committee that have been identified as being therapeutically equivalent within a drug class and that provide cost benefit to the Medicaid program.
  Impact: The DUR Commission makes referrals to and considers requests from the Pharmacy and Therapeutics (P&T) Committee to improve drug therapy.

- Supplemental rebates
  Definition: A rebate given in addition to rebates received under the CMS Rebate Agreement, pursuant to Section 1927 of the Social Security Act (42 USC 1396r-8).
  Impact: The existence of a supplemental rebate and how it may impact the price of a medication is taken into consideration when the DUR Commission makes recommendations.

Appendix C
Overall Program Results

FFS Program Evaluation/Cost Savings Estimates
Iowa Medicaid Retrospective Drug Utilization Review
Annual Report
SFY23

Patient Focused Profile Review

Suggestions Made	30
Therapy Changed	8
Impact Rate	26.67%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated*	$189.37
Dollars Saved on Medication*	$5,491.80

Problem-Focused Profile Review

Suggestions Made	145
Therapy Changed	41
Impact Rate	28.28%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated*	$74.56
Dollars Saved on Medication*	$10,811.33

Cost Savings Estimate*	**$16,303.13**

*Savings reported are pre-rebate, total dollars

Appendix D
Results Patient-Focused

FFS Patient - Focused Reviews

SFY23

Initial Review Date	**October 2021 - September 2022**			
Re-review Date	**July 2022 - June 2023**			
Patient Profiles Reviewed	206			
Patient Profiles Selected for Intervention	29			
Intervention Letters Sent				
Prescribers	37	55.22%		
Pharmacists	30	44.78%		
Total	**67**	100%		
Responses Received				
Prescribers	13	52.00%	**Overall Response Rate**	**37.31%**
Pharmacists	12	48.00%	Prescriber Response Rate	35.14%
Total	**25**	100.00%	Pharmacy Response Rate	40.00%
Total Number of Suggestions				
Therapeutic	30	100.00%		
Cost-Saving	0	0.00%		
Total	**30**	100%		
Total Number of Changes				
Therapeutic	8	100.00%	**Impact Rate**	**26.67%**
Cost-Saving	0	0.00%		
Positive Impact Only	0	0.00%		
Total	**8**	100%		

FFS Patient - Focused Review
Month by Month Breakdown
SFY23

Initial Review Date	**Nov-21**	**Feb-22**	**May-22**	**Aug-22**	**Total**
Evaluation Date	**Aug-22**	**Nov-22**	**Feb-23**	**May-23**	
Patient Profiles Reviewed	63	27	74	42	**206**
Profiles Selected for Intervention	9	6	9	5	**29**
Total Number of Suggstions Made	10	6	9	5	**30**
Therapeutic	10	6	9	5	**30**
Cost Saving	0	0	0	0	**0**
Total Number of Changes Made	2	2	1	3	**8**
Therapeutic	2	2	1	3	**8**
Cost Saving	0	0	0	0	**0**
Positive Impact Only	0	0	0	0	**0**
Total Dollars Saved - Therapeutic Changes	$990.96	$214.00	$147.72	$4,139.12	**$5,491.80**
Total Dollars Saved - Cost Saving Changes	$0.00	$0.00	$0.00	$0.00	**$0.00**
Total Dollars Saved on Medication*	$990.96	$214.00	$147.72	$4,139.12	**$5,491.80**
Total Dollars Saved per Profile Evaluated	$110.11	$35.67	$16.41	$827.82	$189.37

*Savings reported are pre-rebate total dollars.
Does not include MCO population

FFS Medicaid DUR Impact Assessment
Report Patient-Focused Reviews SFY23

Initial Review Date	Nov-21	Feb-22	May-22	Aug-22		
Evaluation Date	Aug-22	Nov-22	Feb-23	May-23	**Total**	
Patient Profiles Reviewed	63	27	74	42	**206**	
Patient Profiles Selected for Intervention	9	6	9	5	**29**	
Letters Sent	22	14	19	12	**67**	100.00%
Prescribers	12	8	10	7	37	55.22%
Pharmacy	10	6	9	5	30	44.78%
Responses Received	9	6	7	3	**25**	100.00%
Prescribers	5	2	4	2	13	52.00%
Pharmacy	4	4	3	1	12	48.00%
Total Number of Templates Mentioned	10	6	9	5	**30**	100.00%
Therapeutic	10	6	9	5	30	100.00%
Cost-Saving	0	0	0	0	0	0.00%
Total Number of Changes Made	2	2	1	3	**8**	100.00%
Therapeutic	2	2	1	3	8	100.00%
Cost-Saving	0	0	0	0	0	0.00%
Positive Impact Only	0	0	0	0	0	0.00%
Total Dollars Saved - Therapeutic Changes	$990.96	$214.00	$147.72	$4,139.12	**$5,491.80**	100.00%
Total Dollars Saved - Cost Saving Changes	$0.00	$0.00	$0.00	$0.00	**$0.00**	0.00%
Total Dollars Saved on Medication*	$990.96	$214.00	$147.72	$4,139.12	**$5,491.80**	100.00%
Total Dollars Saved Per Profile Evaluated	$110.11	$35.67	$16.41	$827.82	**$189.37**	

***Savings reported are pre-rebate, total dollars**

Comment Type
FFS Patient Focused Reviews
SFY23

Initial Review Date	**Nov-21**		**Feb-22**		**May-22**		**Aug-22**			
Evaluation Date	**Aug-22**		**Nov-22**		**Feb-23**		**May-23**		**Total**	
Template Classification	**Suggestions**	**Changes**	**Suggestions**	**Changes**	**Suggestions**	**Changes**	**Suggestions**	**Changes**	**Total Suggestions**	**Total Changes**
Adverse Drug Reaction	0	0	0	0	0	0	0	0	0	0
Drug-Disease Interaction	0	0	0	0	0	0	0	0	0	0
Drug-Drug Interaction	0	0	0	0	0	0	0	0	0	0
High Cost Drug	0	0	0	0	0	0	0	0	0	0
Innapropriate Billing	0	0	0	0	0	0	0	0	0	0
Missing Drug Therapy	0	0	0	0	0	0	0	0	0	0
Not Optimal Dosage Form	0	0	0	0	0	0	0	0	0	0
Not Optimal Dose	0	0	0	0	0	0	0	0	0	0
Not Optimal Drug	0	0	0	0	0	0	0	0	0	0
Not Optimal Duration	0	0	0	0	0	0	0	0	0	0
Patient Overuse	0	0	0	0	0	0	0	0	0	0
Patient Underuse	0	0	0	0	0	0	0	0	0	0
Potential Generic Use	0	0	0	0	0	0	0	0	0	0
Therapeutic Alternative	0	0	0	0	0	0	0	0	0	0
Therapeutic Duplication	10	2	6	2	9	1	5	3	30	8
Unnecessary Drug Therapy	0	0	0	0	0	0	0	0	0	0
Total	**10**	**2**	**6**	**2**	**9**	**1**	**5**	**3**	**30**	**8**

FFS Patient Focused Reviews

SFY23

Template Classification	Total Suggestions	Total Changes	% of Total Suggestions	% of Total Changes	% of Suggestions Changed	% Dollars Saved
Adverse Drug Reaction	0	0	0.00%	0.00%	0.00%	0.00%
Drug-Disease Interaction	0	0	0.00%	0.00%	0.00%	0.00%
Drug-Drug Interaction	0	0	0.00%	0.00%	0.00%	0.00%
High Cost Drug	0	0	0.00%	0.00%	0.00%	0.00%
Inappropriate Billing	0	0	0.00%	0.00%	0.00%	0.00%
Missing Drug Therapy	0	0	0.00%	0.00%	0.00%	0.00%
Not Optimal Dosage Form	0	0	0.00%	0.00%	0.00%	0.00%
Not Optimal Dose	0	0	0.00%	0.00%	0.00%	0.00%
Not Optimal Drug	0	0	0.00%	0.00%	0.00%	0.00%
Not Optimal Duration	0	0	0.00%	0.00%	0.00%	0.00%
Patient Overuse	0	0	0.00%	0.00%	0.00%	0.00%
Patient Underuse	0	0	0.00%	0.00%	0.00%	0.00%
Potential Generic Use	0	0	0.00%	0.00%	0.00%	0.00%
Therapeutic Alternative	0	0	0.00%	0.00%	0.00%	0.00%
Therapeutic Duplication	30	8	100.00%	100.00%	26.67%	100.00%
Unnecessary Drug Therapy	0	0	0.00%	0.00%	0.00%	0.00%
Total	**30**	**8**	100.00%	100.00%	**26.67%**	100.00%

FFS Savings By Template Class

SFY23

Initial Review Date	Nov-21	Feb-22	May-22	Aug-22	
Evaluation Date	Aug-22	Nov-22	Feb-23	May-23	
					Total
Template Classification					
Adverse Drug Reaction	$0.00	$0.00	$0.00	$0.00	$0.00
Drug-Disease Interaction	$0.00	$0.00	$0.00	$0.00	$0.00
Drug-Drug Interaction	$0.00	$0.00	$0.00	$0.00	$0.00
High Cost Drug	$0.00	$0.00	$0.00	$0.00	$0.00
Inappropriate Billing	$0.00	$0.00	$0.00	$0.00	$0.00
Missing Drug Therapy	$0.00	$0.00	$0.00	$0.00	$0.00
Not Optimal Dosage Form	$0.00	$0.00	$0.00	$0.00	$0.00
Not Optimal Dose	$0.00	$0.00	$0.00	$0.00	$0.00
Not Optimal Drug	$0.00	$0.00	$0.00	$0.00	$0.00
Not Optimal Duration	$0.00	$0.00	$0.00	$0.00	$0.00
Patient Overuse	$0.00	$0.00	$0.00	$0.00	$0.00
Patient Underuse*	$0.00	$0.00	$0.00	$0.00	$0.00
Potential Generic Use	$0.00	$0.00	$0.00	$0.00	$0.00
Therapeutic Alternative	$0.00	$0.00	$0.00	$0.00	$0.00
Therapeutic Duplication	$990.96	$214.00	$147.72	$4,139.12	$5,491.80
Unnecessary Drug Therapy	$0.00	$0.00	$0.00	$0.00	$0.00
Total	**$990.96**	**$214.00**	**$147.72**	**$4,139.12**	**$5,491.80**

*additional cost but positive impact assumed

Appendix E
Results Problem-Focused

FFS Problem-Focused Studies

Impact Rate

SFY 2023

Focus	Review Period	Evaluation Period	Patients Evaluated	Positive Impact	Impact Rate
Montelukast without Asthma Diagnosis	08/01/2021 - 10/30/2021	07/01/2022 - 09/30/2022	112	33	29.46%
Two Short-Acting Opioids	07/01/2021 - 09/30/2021	07/01/2022 - 09/30/2022	2	1	50.00%
Two Long-Acting Opioids	07/01/2021 - 09/30-2021	07/01/2022 - 09/30/2022	0	0	#DIV/0!
Concurrent GLP1 RA and DPP4i	10/01/2021 - 01/31/2022	07/01/2022 - 09/30/2022	0	0	#DIV/0!
High Dose Glucocorticoids without Bisphosphonate	10/01/2021 - 01/31/2022	07/01/2022 - 09/30/2022	3	0	0.00%
Duplicate Antipsychotics in Adults	03/01/2022 - 04/30/2022	03/01/2023 - 04/30/2023	2	0	0.00%
SABA Overutilization^	05/01/2021 - 04/30/2022	05/01/2022 - 04/30/2023	22	5	22.73%
High Dose Opioid without Reversal Agent^	07/01/2022 - 7/31/2022	10/01/2022 - 04/30/2023	4	2	50.00%
Duplicate Therapy Stimulants	05/01/2021 - 04/30/2022	05/01/2022 - 04/30/2023	0	0	#DIV/0!
TOTAL			**145**	**41**	**28.28%**

^ Positive Impact Only

FFS Problem-Focused Studies

Savings

SFY 2023

Focus	Review Period	Evaluation Period	Patients Reviewed	Patients Selected	Cost Savings Calculated
Montelukast without Asthma Diagnosis	08/01/2021 - 10/30/2021	07/01/2022 - 09/30/2022	112	112	$10,682.09
Two Short-Acting Opioids	07/01/2021 - 09/30/2021	07/01/2022 - 09/30/2022	2	2	$129.24
Two Long-Acting Opioids	07/01/2021 - 09/30-2021	07/01/2022 - 09/30/2022	0	0	$0.00
Concurrent GLP1 RA and DPP4i	10/01/2021 - 01/31/2022	07/01/2022 - 09/30/2022	0	0	$0.00
High Dose Glucocorticoids without Bisphosphonate	10/01/2021 - 01/31/2022	07/01/2022 - 09/30/2022	3	3	$0.00
Duplicate Antipsychotics in Adults	03/01/2022 - 04/30/2022	03/01/2023 - 04/30/2023	2	2	$0.00
SABA Overutilization^	05/01/2021 - 04/30/2022	05/01/2022 - 04/30/2023	22	22	$0.00
High Dose Opioid without Reversal Agent^	07/01/2022 - 7/31/2022	10/01/2022 - 04/30/2023	4	4	$0.00
Duplicate Therapy Stimulants	05/01/2021 - 04/30/2022	05/01/2022 - 04/30/2023	0	0	$0.00
TOTAL			**145**	**145**	**$10,811.33 ***

*Savings reported are pre-rebate, total dollars.

^ Positive Impact Only

Prepared by the Iowa Medicaid Drug Utilization Review Commission

Appendix F
Descriptions Problem-Focused

Description of Problem Focused Studies
SFY23

Montelukast without Asthma Diagnosis

- Identify members without a diagnosis of asthma, using montelukast.

Two Short-Acting Opioids

- Identify members in SUPPORT Act reports with concurrent use of two chemically distinct short-acting opioids.

Two Long-Acting Opioids

- Identify members in SUPPORT Act reports with concurrent use of two chemically distinct long-acting opioids.

Concurrent GLP1 RA and DPP4i

- Identify members with concurrent use of a glucagon-like peptide receptor agonist (GLP-1 RA) and dipeptidyl peptidase-4 inhibitor (DPP-4i).

High Dose Glucocorticoid without Bisphosphonate

- Identify members taking a high dose glucocorticoid without an oral bisphosphonate.

Duplicate Antipsychotics in Adults

- Identify members in SUPPORT Act reports with more than two chemically distinct antipsychotics.

Duplicate Therapy with Stimulants

- Identify members with more than one chemically distinct stimulant in pharmacy claims.

SABA Overutilization

- Identify members who are overutilizing short-acting beta agonist (SABA) inhalers (albuterol and/or levalbuterol).

High Dose Opioid without Reversal Agent

- Identify members at high risk of opioid overdose, taking ≥ 90 MME per day, without an opioid reversal agent in pharmacy claims history.

Appendix G
Prior Authorization Recommendations

Prior Authorization Criteria Review
SFY23

During the fiscal year ending 2023, the Commission reviewed and made recommendations on the following categories of medications covered under the prior authorization program. Criteria can be reviewed in the following recommendation letters.

DUR Meeting	New PA Criteria	Updated PA Criteria	Removal of PA Criteria
08/03/2022	• Tralokinumab (Adbry) • Ophthalmic Agents for Presbyopia	• Tasimelteon (Hetlioz) • Janus Kinase Inhibitors • Crisaborole (Eucrisa) • Extended Release Formulations • Non-Preferred Drug • Biologicals for Hidradenitis Suppurativa	
11/02/2022	• Maralixibat (Livmarli) • PIK3CA-Related Overgrowth Spectrum (PROS) Treatments • Mavacamten (Camzyos)	• Sedative/Hypnotics, Non-Benzodiazepine • Vericiguat (Verquvo) • Dupilumab (Dupixent) • Viloxazine (Qelbree) • CNS Stimulants and Atomoxetine	
02/01/2023	• Select Topical Psoriasis Agents	• Initial Days' Supply Limit Override • High Dose Opioids	• Nebivolol (Bystolic) • Potassium Binders
05/03/2023		• Viloxazine (Qelbree) • Dupilumab (Dupixent) • Gonadotropin-Releasing Hormone (GnRH Receptor Antagonist, Oral) • Janus Kinase Inhibitors	

IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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August 5, 2022

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid
1305 East Walnut
Des Moines, Iowa 50309

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, August 3, 2022. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Tasimelteon (Hetlioz); Janus Kinase Inhibitors; Tralokinumab-Idrm (Adbry); Crisaborole (Eucrisa); Extended-Release Formulations; Non-Preferred Drug; Biologicals for Hidradenitis Suppurativa; and Ophthalmic Agents for Presbyopia. The DUR Commission members also discussed ProDUR edits for Initial Days' Supply Limit – Benzodiazepines; Benzodiazepine Cumulative Quantity Limit; and quantity limits for select drugs (as detailed below). The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to a May 9, 2022 letter that was sent to them detailing the proposed criteria for Tasimelteon (Hetlioz); Janus Kinase Inhibitors; Tralokinumab-Idrm (Adbry); Crisaborole (Eucrisa); Extended-Release Formulations; Non-Preferred Drug; Biologicals for Hidradenitis Suppurativa; and Ophthalmic Agents for Presbyopia. Also included were details regarding proposed ProDUR edits for Initial Days' Supply Limit – Benzodiazepines; Benzodiazepine Cumulative Quantity Limit; and quantity limits for select drugs.

Tasimelteon (Hetlioz)

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for tasimelteon (Hetlioz®). Requests for doses above the manufacturer recommended dose will not be considered. Payment will be considered under the following conditions:

1. Patient has a diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24), as confirmed by a sleep specialist; and
2. Patient is 18 years of age or older; and

3. Patient has a documented trial and therapy failure with at least one preferred sedative/hypnotic-non-benzodiazepine agent; and
4. Patient has a documented trial and therapy failure with ramelteon (Rozerem®).

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of therapy will be considered when the patient has received 3 months of continuous therapy and patient has achieved adequate results with tasimelteon (Hetlioz®), such as entrainment, significant increases in nighttime sleep, and/or significant decreases in daytime sleep.

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted and stricken)
Prior authorization (PA) is required for tasimelteon (Hetlioz®). *Requests will be considered when patient has an FDA approved or compendia indication for the requested drug.* ~~Requests for doses above the manufacturer recommended dose will not be considered.~~
Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. Patient has a *documented* diagnosis of:
    a. Non-24-Hour Sleep-Wake Disorder (Non-24)~~, as confirmed by a sleep specialist~~; and
        ~~i. Patient is 18 years of age or older; and~~
        ii. Patient has a documented trial and therapy failure with at least one preferred sedative/hypnotic-non-benzodiazepine agent; and
        iii. Patient has a documented trial and therapy failure with ramelteon (Rozerem®)*; or*
    b. *Sleep disturbances in Smith-Magenis Syndrome (SMS); and*
        i. *Documentation of confirmed deletion 17p11.2 (cytogenetic analysis or microarray) or RAI1 gene mutation is provided (attach results); and*
        ii. *Patient has a documented trial and therapy failure with at least one other medication used for sleep disturbances; and*
3. *Is prescribed by, or in consultation with a physician who specializes in the treatment of sleep disorders; and*
4. *Will not be used concurrently with other sleep medications.*

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of therapy will be considered *under the following conditions:*

1. *Patient's use of tasimelteon (Hetlioz®) has been continuous without gaps in treatment;* ~~when the patient has received 3 months of continuous therapy~~ and
2. *Documentation* patient has *experienced a positive clinical response to therapy* ~~achieved adequate results~~ with tasimelteon (Hetlioz®), such as entrainment, significant increases in nighttime sleep, ~~and/or~~ significant decreases in daytime sleep*, and/or nighttime sleep quality*.

Janus Kinase Inhibitors

Current Clinical Prior Authorization Criteria
Prior authorization (PA) is required for Janus kinase (JAK) inhibitors. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis when the following conditions are met:

1. Patient meets the FDA approved age for indication; and
2. Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, biologic DMARDs or potent immunosuppressants (azathioprine or cyclosporine); and
3. Has been tested for latent tuberculosis prior to initiating therapy and will be monitored for active tuberculosis during treatment; and
4. Recommended laboratory monitoring of lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids are being conducted according to the manufacturer labeling; and
5. Patient does not have a history of malignancy, except for those successfully treated for non-melanoma skin cancer (NMSC); and
6. Patient is not at an increased risk of gastrointestinal perforation; and
7. Patient does not have an active, serious infection, including localized infections; and
8. Medication will not be given concurrently with live vaccines; and
9. Follows FDA approved dosing based on indication; and
10. Patient has a diagnosis of:
    a. Moderate to severe rheumatoid arthritis; with
        i. A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate; and
        ii. A documented trial and inadequate response to one preferred TNF inhibitor; OR
    b. Psoriatic arthritis; with
        i. A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
        ii. Documented trial and therapy failure with one preferred TNF inhibitor used for psoriatic arthritis; OR
    c. Moderately to severely active ulcerative colitis; with
        i. A documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and
        ii. A documented trial and inadequate response with a preferred TNF inhibitor; and
        iii. If requested dose is for tofacitinib 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit; OR
    d. Polyarticular Course Juvenile Idiopathic Arthritis; with
        i. A documented trial and inadequate response to intraarticular glucocorticoid injections; and
        ii. A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
        iii. A documented trial and inadequate response with a preferred TNF inhibitor.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

<u>Proposed Clinical Prior Authorization Criteria</u> (changes stricken/italicized and/or highlighted)
Prior authorization (PA) is required for Janus kinase (JAK) inhibitors. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an

FDA approved or compendia indicated diagnosis *for the requested drug* when the following conditions are met:

~~1. Patient meets the FDA approved age for indication; and~~
2. Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, *biological therapies,* ~~biologic DMARDs~~ or potent immunosuppressants (azathioprine or cyclosporine); and
3. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*

~~4. Has been tested for latent tuberculosis prior to initiating therapy and will be monitored for active tuberculosis during treatment; and~~
~~5. Recommended laboratory monitoring of lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids are being conducted according to the manufacturer labeling; and~~
~~6. Patient does not have a history of malignancy, except for those successfully treated for non-melanoma skin cancer (NMSC); and~~
~~7. Patient is not at an increased risk of gastrointestinal perforation; and~~
~~8. Patient does not have an active, serious infection, including localized infections; and~~
~~9. Medication will not be given concurrently with live vaccines; and~~
~~10. Follows FDA approved dosing based on indication; and~~

11. Patient has a diagnosis of:
    a. Moderate to severe rheumatoid arthritis *(baricitinib, tofacitinib, upadacitinib)*; with
        i. A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate; and
        ii. A documented trial and inadequate response to one preferred TNF inhibitor; OR
    b. Psoriatic arthritis *(tofacitinib, upadacitinib)*; with
        i. A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
        ii. Documented trial and therapy failure with one preferred TNF inhibitor used for psoriatic arthritis; OR
    c. Moderately to severely active ulcerative colitis *(tofacitinib, upadacitinib)*; with
        i. A documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and
        ii. A documented trial and inadequate response with a preferred TNF inhibitor; and
        iii. If requested dose is for tofacitinib 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit; OR
    d. Polyarticular Course Juvenile Idiopathic Arthritis *(tofacitinib)*; with
        i. A documented trial and inadequate response to intraarticular glucocorticoid injections; and
        ii. A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
        iii. A documented trial and inadequate response with a preferred TNF inhibitor*; OR*
    e. Ankylosing spondylitis (tofacitinib, upadacitinib); with

i. A documented trial and inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at a maximally tolerated dose for a minimum of at least one month; and

ii. A documented trial and inadequate response with at least one preferred TNF inhibitor; OR

f. Atopic dermatitis; with

i. Documentation patient has failed to respond to good skin care and regular use of emollients; and

ii. A documented adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and

iii. A documented trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and

iv. For mild to moderate atopic dermatitis (ruxolitinib)

a. A documented trial and therapy failure with crisaborole; and

b. Affected area is less than 20% of body surface area (BSA); and

c. Patient has been instructed to use no more than 60 grams of topical ruxolitinib per week; or

v. For moderate to severe atopic dermatitis (abrocitinib, upadacitinib):

a. A documented trial and therapy failure with cyclosporine or azathioprine; and

b. Requests for upadacitinib for pediatric patients 12 to less than 18 years of age must include the patient's weight in kg.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Tralokinumab (Adbry)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for tralokinumab-ldrm (Adbry). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has a diagnosis of moderate to severe atopic dermatitis; and
3. Is prescribed by or in consultation with a dermatologist; and
4. Patient has failed to respond to good skin care and regular use of emollients; and
5. Patient has documentation of an adequate trial and therapy failure with at least one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
6. Patient has documentation of a previous trial and therapy failure with a preferred topical immunomodulator for a minimum of 4 weeks; and
7. Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and
8. Patient will continue with skin care regimen and regular use of emollients.

If criteria for coverage are met, initial authorization will be given for 16 weeks to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy and documentation patient will continue with skin care regimen and regular use of emollients.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Crisaborole (Eucrisa)

Current Prior Authorization Criteria
Prior authorization (PA) is required for Eucrisa (crisaborole). Payment will be considered for patients when the following criteria are met:

1. Patient has a diagnosis of mild to moderate atopic dermatitis; and
2. Patient is within the FDA labeled age; and
3. Patient has failed to respond to good skin care and regular use of emollients; and
4. Patient has documentation of an adequate trial and therapy failure with two preferred medium to high potency topical corticosteroids for a minimum of 2 consecutive weeks; and
5. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
6. Patient will continue with skin care regimen and regular use of emollients.
7. Quantities will be limited to 60 grams for use on the face, neck, and groin and 100 grams for all other areas, per 30 days.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Proposed Prior Authorization Criteria (changes italicized/highlighted/stricken)
Prior authorization (PA) is required for Eucrisa (crisaborole). Payment will be considered ~~for patients~~ when *patient has an FDA approved or compendia indication for the requested drug when* the following criteria are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. Patient has a diagnosis of mild to moderate atopic dermatitis; and
3. ~~Patient is within the FDA labeled age; and~~
4. Patient has failed to respond to good skin care and regular use of emollients; and
5. Patient has documentation of an adequate trial and therapy failure with *one* ~~two~~ preferred medium to high potency topical corticosteroid~~s~~ for a minimum of 2 consecutive weeks; and
6. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
7. Patient will continue with skin care regimen and regular use of emollients.
8. Quantities will be limited to 60 grams for use on the face, neck, and groin and 100 grams for all other areas, per 30 days.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Extended Release Formulations

Current Prior Authorization Criteria
Payment for a non-preferred extended release formulation will be considered when the following criteria are met:

1. Previous trial and therapy failure with the preferred immediate release product of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance and
2. Previous trial and therapy failure at a therapeutic dose with a preferred drug of a different chemical entity indicated to treat the submitted diagnosis.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Proposed Prior Authorization Criteria (changes italicized/highlighted/stricken)
Payment for a non-preferred extended release formulation will be considered *for an FDA approved or compendia indicated diagnosis for the requested drug* when the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. Previous trial and therapy failure with the preferred immediate release product of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance*;* and
3. Previous trial and therapy failure at a therapeutic dose with a preferred drug of a different chemical entity indicated to treat the submitted diagnosis.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Non-Preferred Drug

Current Prior Authorization Criteria
Prior authorization (PA) is required for non-preferred drugs as specified on the Iowa Medicaid Preferred Drug List. Payment for a non-preferred medication will be authorized only for cases in which there is documentation of previous trial and therapy failure with the preferred agent, unless evidence is provided that use of these agents would be medically contraindicated.

Proposed Prior Authorization Criteria (changes italicized/highlighted/stricken)
Prior authorization (PA) is required for non-preferred drugs as specified on the Iowa Medicaid Preferred Drug List. Payment for a non-preferred medication will be *considered for an FDA approved or compendia indicated diagnosis* ~~authorized~~ only for cases in which there is documentation of previous trial and therapy failure with the preferred agent*(s)*, unless evidence is provided that use of these agents would be medically contraindicated. *Request must adhere to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations.*

Biologicals for Hidradenitis Suppurativa

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for biologicals FDA approved for the treatment of Hidradenitis Suppurativa (HS). Patients initiating therapy with a biological agent must:

1. Be screened for hepatitis B and C. Patients with active hepatitis B will not be considered for coverage; and
2. Have not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biologic agent; and
3. Not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and
4. Be screened for latent TB infection. Patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment.

Payment will be considered under the following conditions:

1. Patient has a diagnosis of moderate to severe HS with Hurley Stage II or III disease; and
2. Patient is 18 years of age or older; and
3. Patient has at least three (3) abscesses or inflammatory nodules; and
4. Patient has documentation of adequate trials and therapy failures with the following:
    a. Daily treatment with topical clindamycin;
    b. Oral clindamycin plus rifampin;
    c. Maintenance therapy with tetracyclines (doxycycline or minocycline).

If criteria for coverage are met, initial requests will be given for 3 months. Additional authorizations will be considered upon documentation of clinical response to therapy. Clinical response is defined as at least a 50% reduction in total abscess and inflammatory nodule count with no increase in abscess count and no increase in draining fistula count from initiation of therapy.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized/stricken)

Prior authorization (PA) is required for biologicals FDA approved *or compendia indicated* for the treatment of Hidradenitis Suppurativa (HS). *Payment for non-preferred biologic agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred biologic agent.* Patients initiating therapy with a biological agent must:

1. Be screened for hepatitis B and C. Patients with active hepatitis B will not be considered for coverage; and
2. Have not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biologic agent; and
3. Not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and

4. Be screened for latent TB infection. Patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment.

Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. Patient has a diagnosis of moderate to severe HS with Hurley Stage II or III disease; and
3. ~~Patient is 18 years of age or older; and~~
4. Patient has at least three (3) abscesses or inflammatory nodules; and
5. Patient has documentation of adequate trials and therapy failures with the following:
    a. Daily treatment with topical clindamycin;
    b. Oral clindamycin plus rifampin;
    c. Maintenance therapy with *a preferred* tetracycline~~s~~ ~~(doxycycline or minocycline)~~.

If criteria for coverage are met, initial requests will be given for 3 months. Additional authorizations will be considered upon documentation of clinical response to therapy. Clinical response is defined as at least a 50% reduction in total abscess and inflammatory nodule count with no increase in abscess count and no increase in draining fistula count from initiation of therapy.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Ophthalmic Agents for Presbyopia

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for ophthalmic agents indicated for presbyopia. Requests will be considered when patient has an FDA approved or compendia indication for the requested drug. Payment for a non-preferred agent will be considered when there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has a documented diagnosis of presbyopia; and
3. Patient is aged 40 to 55 years old at start of therapy; and
4. Is prescribed by or in consultation with an ophthalmologist or optometrist; and
5. Patient has documentation of a therapeutic failure with corrective lenses (eyeglasses or contact lenses), unless contraindicated or clinically significant intolerance.

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of therapy will be considered under the following conditions:

1. Patient has a documented improvement in presbyopia defined as the patient gained 3 lines or more in mesopic, high contrast, binocular distance corrected near visual acuity (DCNVA), without losing more than 1 line (5 letters) of corrected distance visual acuity (CDVA); and

2. Patient is not experiencing adverse effects from the drug.

Proposed ProDUR Quantity Limits

Drug	**Proposed Quantity Limit per 30 Days** (unless otherwise stated)
Cibinqo (abrocitinib) 50 mg, 100 mg, 200 mg	30
Olumiant (baricitinib) 1 mg, 2 mg	30
Opzelura (ruxolitinib) 1.5% cream	240 g (4 tubes)
Rinvoq (upadacitinib)15 mg, 30 mg	30
Rinvoq (upadacitinib) 45 mg	28 per 28 days
Xeljanz (tofacitinib) 5 mg, 10 mg	60
Xeljanz (tofacitinib) XR 11 mg, 22 mg	30
ProAir HFA 8.5 g (albuterol)	2 inhalers (17 grams)
ProAir Digihaler (albuterol)	2 inhalers
ProAir Respiclick (albuterol)	2 inhalers
Proventil HFA 6.7 g (albuterol)	2 inhalers (13.4 grams)
Ventolin HFA 18 g (albuterol)	2 inhalers (36 grams)
Xopenex HFA 15 g (levalbuterol)	2 inhalers (30 grams)
Halcion 0.125 mg (triazolam)	30
Halcion 0.25 mg (triazolam)	60
Vuity (Pilocarpine) 1.25% opth. soln.	2.5 mL

Proposed ProDUR Initial Days Supply Limit for Benzodiazepines

The DUR Commission made a recommendation to implement a 7-day initial limit on all benzodiazepines for new users. The ProDUR point-of-sale (POS) edit would limit to an initial 7 days' supply for a benzodiazepine if the requested benzodiazepine is not found in pharmacy claims in the preceding 90 days. Exceptions to this edit include nasal and rectal diazepam, nasal midazolam and clobazam. Prior authorization would be required for use beyond the 7-day allowance. The Commission will develop PA criteria for requests exceeding the initial limit at a future meeting and will be shared with interested parties for comment prior to implementation.

Proposed ProDUR Cumulative Quantity Limit for Oral Benzodiazepines

The DUR Commission made a recommendation to implement a cumulative quantity limit of 4 units per day across the benzodiazepine class for solid oral dosage forms. The quantity limit chart would include the following statement: Benzodiazepines are subject to a cumulative quantity limit of 4 units per day, unless otherwise indicated on the chart.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for Tasimelteon (Hetlioz); Janus Kinase Inhibitors; Tralokinumab-Idrm (Adbry); Crisaborole (Eucrisa); Extended-Release Formulations; Non-Preferred Drug; Biologicals for Hidradenitis Suppurativa; and Ophthalmic Agents for Presbyopia; and the Proposed ProDUR initiatives detailed above.

Sincerely,

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Erin Halverson, R.Ph, IME
Gina Kuebler, R.Ph, IME

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November 4, 2022

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid
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Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, November 2, 2022. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Sedative/Hypnotics, Non-Benzodiazepine; Vericiguat (Verquvo); Maralixibat (Livmarli); Alpelisib (Vijoice); Mavacamten (Camzyos); Dupilumab (Dupixent); Viloxazine (Qelbree); and CNS Stimulants and Atomoxetine. The DUR Commission members also discussed ProDUR quantity limits for select drugs (as detailed below). The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to an August 11, 2022 letter that was sent to them detailing the proposed criteria for Sedative/Hypnotics, Non-Benzodiazepine; Vericiguat (Verquvo); Maralixibat (Livmarli); Alpelisib (Vijoice); Mavacamten (Camzyos); Dupilumab (Dupixent); Viloxazine (Qelbree); and CNS Stimulants and Atomoxetine. Also included were details regarding proposed ProDUR quantity limits for select drugs (as detailed below).

Sedative/Hypnotics, Non-Benzodiazepine

Current Clinical Prior Authorization Criteria

Preferred agents are available without prior authorization (PA) when dosed within the established quantity limits. Requests for doses above the manufacturer recommended dose will not be considered.

PA is required for all non-preferred non-benzodiazepine sedative/hypnotics. Payment for non-preferred non-benzodiazepine sedative/hypnotics will be authorized only for cases in which there is documentation of previous trials and therapy failures with, at a minimum, three (3) preferred agents. Payment for non-preferred non-benzodiazepine sedative/hypnotics will be considered when the following criteria are met:

1. A diagnosis of insomnia; and

2. Medications with a side effect of insomnia (i.e., stimulants) are decreased in dose, changed to a short acting product, and/or discontinued; and
3. Enforcement of good sleep hygiene is documented; and
4. All medical, neurological, and psychiatric disease states causing chronic insomnia are being adequately treated with appropriate medication at therapeutic doses.
5. In addition to the above criteria, requests for suvorexant (Belsomra) will require documentation of a trial and therapy failure with at least one non-preferred agent, other than suvorexant, prior to consideration of coverage.
6. Non-preferred alternative delivery systems will only be considered for cases in which the use of the alternative delivery system is medically necessary and there is a previous trial and therapy failure with a preferred alternative delivery system if available.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted and stricken)
Preferred agents are available without prior authorization (PA) when dosed within the established quantity limits. ~~Requests for doses above the manufacturer recommended dose will not be considered.~~ PA is required for all non-preferred non-benzodiazepine sedative/hypnotics. Payment for *a* non-preferred *agent* ~~non-benzodiazepine sedative/hypnotics~~ will be authorized only for cases in which there is documentation of previous trials and therapy failures with, at a minimum, three (3) preferred agents. Payment for a non-preferred *agent* ~~non-benzodiazepine sedative/hypnotics~~ will be considered *for an FDA approved or compendia indicated diagnosis for the requested drug* when the following criteria are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. A diagnosis of insomnia; and
3. Medications with a side effect of insomnia ~~(i.e., stimulants)~~ are decreased in dose, changed to a short acting product, and/or discontinued; and
4. Enforcement of good sleep hygiene is documented; and
5. All medical, neurological, and psychiatric disease states causing chronic insomnia are being adequately treated with appropriate medication at therapeutic doses*; and*
6. *Will not be used concurrently with a benzodiazepine sedative/hypnotic agent.*
7. In addition to the above criteria, requests for *an orexin receptor antagonist* ~~suvorexant (Belsomra)~~ will require documentation of a trial and therapy failure with at least one non-preferred agent~~, other than suvorexant,~~ prior to consideration of coverage.
8. Non-preferred alternative delivery systems will only be considered for cases in which the use of the alternative delivery system is medically necessary and there is a previous trial and therapy failure with a preferred alternative delivery system if available.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Vericiguat (Verquvo)

Current Clinical Prior Authorization Criteria
Prior authorization is required for vericiguat (Verquvo). Payment will be considered under the following conditions:

1. Patient has a diagnosis of symptomatic chronic heart failure (NYHF class II-IV) with a left ventricular ejection fraction (LVEF) ≤ 45%; and
2. Patient meets one of the following:
    a. Recent hospitalization for heart failure (within the last 6 months); or
    b. Recent need for outpatient intravenous diuretics (within the last 3 months); and
3. Patient is within the FDA labeled age for indication; and
4. Female patients of reproductive potential have been advised to use effective contraception during treatment and for at least one month after the last dose; and
5. Will not be used concomitantly with other soluble guanylate cyclase (sGC) stimulators (e.g. riociguat) or phosphodiesterase type 5 (PDE-5) inhibitors (e.g. sildenafil, tadalafil, vardenafil); and
6. Documentation of prior or current therapy, at a maximally tolerated dose, with one drug from each category below:
    a. Renin-angiotensin system inhibitor (angiotensin converting enzyme [ACEI], angiotensin receptor blocker [ARB], or angiotensin receptor-neprilysin inhibitor [ARNI]); and
    b. Evidence-based beta-blocker (carvedilol, metoprolol succinate, or bisoprolol); and
7. Is dosed based on FDA approved dosing; and
8. Initial requests for Verquvo 2.5 mg and 5 mg tablets will be limited to one 14-day supply for each strength.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

<u>Proposed Clinical Prior Authorization Criteria</u> (changes stricken/italicized and/or highlighted) Prior authorization is required for vericiguat (Verquvo). Payment will be considered *when patient has an FDA approved or compendia indication for the requested drug* under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. Patient has a diagnosis of symptomatic chronic heart failure (NYHF class II-IV) with a left ventricular ejection fraction (LVEF) ≤ 45%; and
3. Patient meets one of the following:
    a. Recent hospitalization for heart failure (within the last 6 months); or
    b. Recent need for outpatient intravenous diuretics (within the last 3 months); and
4. ~~Patient is within the FDA labeled age for indication; and~~
5. Female patients of reproductive potential have been advised to use effective contraception during treatment and for at least one month after the last dose; and
6. Will not be used concomitantly with other soluble guanylate cyclase (sGC) stimulators (e.g. riociguat) or phosphodiesterase type 5 (PDE-5) inhibitors (e.g. sildenafil, tadalafil, vardenafil); and
7. Documentation of prior or current therapy, at a maximally tolerated dose, with one drug from each category below:
    a. Renin-angiotensin system inhibitor (angiotensin converting enzyme [ACEI], angiotensin receptor blocker [ARB], or angiotensin receptor-neprilysin inhibitor [ARNI]); and

b. Evidence-based beta-blocker (carvedilol, metoprolol succinate, or bisoprolol); and
c. *Mineralocorticoid receptor antagonist (MRA); and*
d. *Sodium-glucose cotransporter 2 inhibitor (SGLT2i) indicated for the treatment of heart failure (empagliflozin or dapagliflozin); and*

~~8. Is dosed based on FDA approved dosing; and~~

9. Initial requests for *vericiguat (*Verquvo) 2.5 mg and 5 mg tablets will be limited to one 14-day supply for each strength.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Maralixibat (Livmarli)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for maralixibat (Livmarli). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has a diagnosis of Alagille syndrome (ALGS) confirmed by genetic testing demonstrating a *JAG1* or *NOTCH2* mutation or deletion; and
3. Patient has cholestasis with moderate to severe pruritus; and
4. Is prescribed by or in consultation with a hepatologist, gastroenterologist, or a prescriber who specializes in ALGS; and
5. Documentation of previous trials and therapy failures, at a therapeutic dose, with at least two of the following agents:
    a. Ursodeoxycholic acid (ursodiol)
    b. Cholestyramine
    c. Rifampin; and
6. Patient's current weight in kilograms (kg) is provided.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will require documentation of an improvement in pruritus symptoms and patient's current weight in kg.

PIK3CA-Related Overgrowth Spectrum (PROS) Treatments

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for alpelisib (Vijoice). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has a diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) confirmed by genetic testing demonstrating a *PIK3CA* mutation; and
3. Patient's condition is severe or life-threatening requiring systemic therapy as determined by treating prescriber; and
4. Patient has at least one target lesion identified on imaging.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will be considered with documentation of a positive response to therapy as evidenced by a reduction in sum of measurable lesion volume assessed across 1 to 3 target lesions.

Mavacamten (Camzyos)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for mavacamten (Camzyos). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has a diagnosis of obstructive hypertrophic cardiomyopathy (HCM); and
3. Patient exhibits symptoms of New York Heart Association (NYHA) class II or III symptoms; and
4. Is prescribed by or in consultation with a cardiologist; and
5. Patient has a left ventricular ejection fraction (LVEF) ≥ 55%; and
6. Patient has a peak left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg at rest or with provocation; and
7. Documentation of a previous trial and therapy failure, at a maximally tolerated dose, with all of the following:
    a. Non-vasodilating beta-blocker (atenolol, metoprolol, bisoprolol, propranolol); and
    b. Non-dihydropyridine calcium channel blocker (verapamil, diltiazem); and
    c. Combination therapy with disopyramide plus beta-blocker or disopyramide plus a non-dihydropyridine calcium channel blocker.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Request for continuation of therapy will be considered with documentation of a positive response to therapy as evidenced by improvement in obstructive HCM symptoms.

Dupilumab (Dupixent)

Current Prior Authorization Criteria

Prior authorization is required for Dupixent (dupilumab). Payment will be considered under the following conditions:

1. Patient is within the FDA labeled age for indication; and
2. Patient has a diagnosis of moderate-to-severe atopic dermatitis; and
    a. Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and
    b. Patient has failed to respond to good skin care and regular use of emollients; and
    c. Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
    d. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
    e. Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and
    f. Patient will continue with skin care regimen and regular use of emollients; or
3. Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) OR with oral corticosteroid dependent asthma; and
    a. Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and
    b. Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted; and
    c. Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g. long acting $beta_2$ agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and
    d. Patient must have one of the following, in addition to the regular maintenance medications defined above:
        i. Two (2) or more exacerbations in the previous year or
        ii. Require daily oral corticosteroids for at least 3 days; ~~and~~ *or*
4. Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and
    a. Documentation dupilumab will be used as an add-on maintenance treatment; and
    b. Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:
        i. Nasal corticosteroid spray; and
        ii. Oral corticosteroid; and
5. Dose does not exceed the FDA approved dosing for indication.

If criteria for coverage are met, initial authorization will be given for 16 weeks to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Proposed Prior Authorization Criteria (changes italicized/highlighted/stricken)
Prior authorization is required for Dupixent (dupilumab). *Payment for non-preferred agents will be considered when there is documentation of a previous trial and therapy failure with a preferred agent.* Payment will be considered *when patient has an FDA approved or compendia indication for the requested drug* under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations* ~~Patient is within the FDA labeled age for indication~~; and
2. *Patient's current weight in kilograms (kg) is provided; and*
3. Patient has a diagnosis of moderate-to-severe atopic dermatitis; and
    a. Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and
    b. Patient has failed to respond to good skin care and regular use of emollients; and
    c. Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
    d. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
    e. Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and
    f. Patient will continue with skin care regimen and regular use of emollients; or
4. Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) OR with oral corticosteroid dependent asthma; and
    a. Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and
    b. Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted; and
    c. Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g., long acting $beta_2$ agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and
    d. Patient must have one of the following, in addition to the regular maintenance medications defined above:
        i. Two (2) or more exacerbations in the previous year or
        ii. Require daily oral corticosteroids for at least 3 days; ~~and~~ *or*
5. Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and
    a. Documentation dupilumab will be used as an add-on maintenance treatment; and
    b. Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:
        i. Nasal corticosteroid spray; and
        ii. Oral corticosteroid; ~~and~~ *or*

6. *Patient has a diagnosis of eosinophilic esophagitis (EoE); and*
    a. *Is prescribed by, or in consultation with, an allergist, gastroenterologist, or immunologist; and*
    b. *Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and*
    c. *Patient has signs and symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, food refusal, abdominal pain, heartburn regurgitation, chest pain and/or, odynophagia); and*
    d. *Documentation of previous trials and therapy failures with all of the following:*
        i. *High dose proton pump inhibitor (PPI) for at least 8 weeks; and*
        ii. *Swallowed topical corticosteroid (e.g., fluticasone propionate, oral budesonide suspension); and*
        iii. *Dietary therapy; and*
7. Dose does not exceed the FDA approved dosing for indication.

If criteria for coverage are met, initial authorization will be given for *6 months* ~~16 weeks~~ to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Viloxazine (Qelbree)

Current Clinical Prior Authorization Criteria
Prior authorization is required for viloxazine (Qelbree). Payment will be considered under the following conditions:

1. Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV); and
2. Patient is between 6 and 17 years of age; and
3. Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more current environments (social, academic, or occupational) and
4. Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred amphetamine stimulant; and
5. Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred methylphenidate stimulant; and
6. Documentation of a previous trial and therapy failure at a therapeutic dose with atomoxetine; and
7. Is dosed based on FDA approved dosing, and dose does not exceed 400 mg per day; and
8. Documentation of a recent clinical visit that confirms improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized/stricken)

Prior authorization is required for viloxazine (Qelbree). Payment will be considered *when patient has an FDA approved or compendia indication for the requested drug* under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV); and
3. ~~Patient is between 6 and 17 years of age; and~~
4. Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more current environments (social, academic, or occupational) and
5. ~~Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred amphetamine stimulant; and~~
6. ~~Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred methylphenidate stimulant; and~~
7. Documentation of a previous trial and therapy failure at a therapeutic dose with atomoxetine; and
8. ~~Is dosed based on FDA approved dosing, and~~ ~~d~~*D*ose does not exceed 400 mg per day *for pediatric patients (< 18 years of age) and 600 mg per day for adult patients*; and
9. Documentation of a recent clinical visit that confirms improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

CNS Stimulants and Atomoxetine

Current Clinical Prior Authorization Criteria for ADHD

Prior authorization (PA) is required for CNS stimulants and atomoxetine for patients 21 years of age or older. Prior to requesting PA for any covered diagnosis, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website. Requests will be considered for an FDA approved age for the submitted diagnosis. Payment for CNS stimulants and atomoxetine will be considered under the following conditions:

Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV). Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more current environments (social, academic, or occupational). Documentation of a recent clinical visit that confirms improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD. Adults (≥ 21 years of age) are limited to the use of long-acting agents only. If a supplemental dose with a short-acting agent is needed for an adult in the mid to late afternoon, requests will be considered under the following circumstances: the dose of the long-acting agent has been optimized, documentation is provided a short-acting agent of the same chemical entity is medically necessary (e.g. employed during the day with school in the evening, and will be limited to one unit dose per

day. Children (< 21 years of age) are limited to the use of long-acting agents with one unit of a short acting agent per day.

Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. *If a non-preferred long-acting medication is requested, a trial with the preferred extended release product of the same chemical entity (methylphenidate class) or chemically related agent (amphetamine class) is required.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Proposed Clinical Prior Authorization Criteria for ADHD (changes highlighted/italicized and/or stricken)
Prior authorization (PA) is required for CNS stimulants and atomoxetine for patients 21 years of age or older. Prior to requesting PA for any covered diagnosis, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website. ~~Requests will be considered for an FDA approved age for the submitted diagnosis~~. *Request must adhere to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations.* Payment for CNS stimulants and atomoxetine will be considered *when patient has an FDA approved or compendia indication for the requested drug* under the following conditions:

Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV). Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more current environments (social, academic, or occupational). Documentation of a recent clinical visit that confirms improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD. Adults (≥ 21 years of age) are limited to the use of long-acting agents only. If *a* supplemental dose with a short-acting agent is needed for an adult in the mid to late afternoon, requests will be considered under the following circumstances: the dose of the long-acting agent has been optimized, documentation is provided a short-acting agent of the same chemical entity is medically necessary (e.g. employed during the day with school in the evening, and will be limited to one unit dose per day. Children (< 21 years of age) are limited to the use of long-acting agents with one unit of a short acting agent per day. *Use of an amphetamine agent plus a methylphenidate agent will not be considered for a diagnosis of ADHD.*

Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. *If a non-preferred long-acting medication is requested, a trial with the preferred extended release product of the same chemical entity (methylphenidate class) or chemically related agent (amphetamine class) is required.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Proposed ProDUR Quantity Limits

Drug	**Proposed Quantity Limit per 30 Days** (unless otherwise stated)
Livmarli 9.5 mg/mL (maralixibat)	90 mL
Vijoice 50 mg blister pack (alpelisib)	1 pack (28 tabs) per 28 days
Vijoice 125 mg blister pack (alpelisib)	1 pack (28 tabs) per 28 days
Vijoice 250 mg blister pack (alpelisib)	1 pack (56 tabs) per 28 days
Camzyos 2.5 mg, 5 mg, 10 mg, 15 mg (mavacamten)	30
Qelbree 200 mg (viloxazine)	90

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for Sedative/Hypnotics, Non-Benzodiazepine; Vericiguat (Verquvo); Maralixibat (Livmarli); Alpelisib (Vijoice); Mavacamten (Camzyos); Dupilumab (Dupixent); Viloxazine (Qelbree); CNS Stimulants and Atomoxetine; and the Proposed ProDUR quantity limits detailed above.

Sincerely,

Pamela Smith R.Ph.

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Erin Halverson, R.Ph, IME
Gina Kuebler, R.Ph, IME

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February 1, 2023

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid
1305 East Walnut
Des Moines, Iowa 50309

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, February 1, 2023. At this meeting, the DUR Commission members discussed removal of prior authorization (PA) criteria for Nebivolol (Bystolic) and Potassium Binders, in addition to new or updated PA criteria for Select Topical Psoriasis Agents, Initial Days' Supply Limit Override for Benzodiazepines, and High Dose Opioids. Additionally, the DUR Commission proposed ProDUR quantity limits for select drugs and ProDUR age edits (as detailed below). The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to a November 9, 2022 letter that was sent to them detailing the proposed removal of prior authorization (PA) criteria for Nebivolol (Bystolic) and Potassium Binders, in addition to new and updated PA criteria for Select Topical Psoriasis Agents, Initial Days' Supply Limit Override for Benzodiazepines, and High Dose Opioids. Also included were ProDUR quantity limits for select drugs and ProDUR age edits (as detailed below).

Nebivolol (Bystolic)

Removal of PA criteria due to the availability of a cost effective generic.

Current Clinical Prior Authorization Criteria – *Recommendation to Remove PA Criteria*

Prior authorization is required for Bystolic. Payment will be considered in cases where there are documented trials and therapy failures with two preferred cardio-selective beta-blockers of a different chemical entity at a therapeutic dose. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Potassium Binders

Removal of PA criteria due to the availability of safer, effective products to allow access to the preferred potassium binders without requiring a trial with sodium polystyrene sulfonate (SPS).

Current Clinical Prior Authorization Criteria – *Recommendation to Remove PA Criteria*
Prior authorization (PA) is required for potassium binders subject to clinical criteria. Payment will be considered under the following conditions:

1. Patient is 18 years of age or older; and
2. Patient has a diagnosis of chronic hyperkalemia; and
3. Patient has documentation of a recent trial and therapy failure with sodium polystyrene sulfonate.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Select Topical Psoriasis Agents

Newly Proposed Clinical Prior Authorization Criteria
Prior authorization is required for select topical psoriasis agents. Payment for a non-preferred agent will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following criteria are met:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has a diagnosis of plaque psoriasis with involvement estimated to affect ≤ 20% of the body surface area; and
3. Patient has documentation of an adequate trial and therapy failure of combination therapy with a preferred medium to high potency topical corticosteroid and a preferred topical vitamin D analog for a minimum of 4 consecutive weeks.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Initial Days' Supply Limit Override – Adding Benzodiazepines

Current Prior Authorization Criteria
Requests for medications exceeding the initial days' supply limit require prior authorization. Payment will be considered under the following conditions:

1. Diagnosis is provided; and
2. Medical rationale for exceeding the initial days' supply limit is provided; and
3. Requests for opioids exceeding the 7 day initial supply limit will be considered:
    a. For patients with active cancer, patients experiencing acute sickle cell crises, end-of-life/palliative care, or on an individual case-by-case basis based on medical necessity documentation provided; and
    b. Request must meet all other opioid requirements (quantity limits, morphine milligram equivalents (MME), and the preferred drug list (PDL). If requests do not comply with these requirements, separate, additional, prior authorization is required. Please reference and use the following prior authorization (PA) forms

at www.iowamedicaidpdl.com where appropriate:
   i. Quantity Limit Override Form (exceeds established quantity limit)
   ii. High Dose Opioid PA Form (exceeds established MME limit)
   iii. Short-Acting Opioids PA Form (non-preferred short-acting opioids)
   iv. Long-Acting Opioids PA Form (non-preferred long-acting opioids); or
4. Requests for non-opioid drugs subject to the initial days' supply limit will be considered on an individual case-by-case basis, based on medical necessity documentation provided.

Proposed Prior Authorization Criteria (changes italicized/highlighted/stricken)

Requests for medications exceeding the initial days' supply limit require prior authorization. Payment will be considered under the following conditions:

1. *Patient has an FDA approved or compendia indication for the requested drug* ~~Diagnosis is provided~~; and
2. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
3. Medical rationale for exceeding the initial days' supply limit is provided; and
4. Requests for opioids exceeding the 7 day initial supply limit will be considered:
   a. For patients with active cancer, patients experiencing acute sickle cell crises, end-of-life/palliative care, or on an individual case-by-case basis based on medical necessity documentation provided; and
   b. Request must meet all other opioid requirements (quantity limits, morphine milligram equivalents (MME), and the preferred drug list (PDL). If requests do not comply with these requirements, separate, additional, prior authorization is required. Please reference and use the following prior authorization (PA) forms at www.iowamedicaidpdl.com where appropriate:
      i. Quantity Limit Override Form (exceeds established quantity limit)
      ii. High Dose Opioid PA Form (exceeds established MME limit)
      iii. Short-Acting Opioids PA Form (non-preferred short-acting opioids)
      iv. Long-Acting Opioids PA Form (non-preferred long-acting opioids); or
5. *Requests for benzodiazepines exceeding the 7 day initial supply limit will be considered:*
   a. *For patients with active cancer; end-of-life/palliative care, seizure disorder, or on an individual case-by-case basis based on medical necessity documentation provided; and*
   b. *For patients taking concurrent opioids, the prescriber must document the following:*
      i. *The risks of using an opioid and benzodiazepine concurrently have been discussed with the patient; and*
      ii. *Documentation is provided as to why concurrent use is medically necessary; and*
      iii. *A plan to taper the opioid is provided, if appropriate; and*
   c. *Request must meet all other benzodiazepine requirements (quantity limit, PDL, etc.). If requests do not comply with these requirements, separate, additional prior authorization is required. Please use the following PA forms at www.iowamedicaidpdl.com where appropriate:*
      i. *Benzodiazepines (non-preferred benzodiazepine)*

ii. *Quantity Limit Override (as posted at www.iowamedicaidpdl.com under Billing/Quantity Limits); and*

6. Requests for ~~non-opioid~~ drugs *or drug classes* subject to the initial days' supply limit *not listed above,* will be considered on an individual case-by-case basis, based on medical necessity documentation provided.

High Dose Opioids

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for use of high-dose opioids ≥ 90 morphine milligram equivalents (MME) per day (See CDC Guideline for Prescribing Opioids for Chronic Pain at https://www.cdc.gov/drugoverdose/prescribing/guideline.html). Patients undergoing active cancer treatment or end-of-life care will not be subject to the criteria below. Payment will be considered when the following is met:

1. Requests for non-preferred opioids meet criteria for coverage (see criteria for Long-Acting Opioids and/or Short-Acting Opioids); and
2. Patient has a diagnosis of severe, chronic pain with a supporting ICD-10 code. Requests for a diagnosis of fibromyalgia or migraine will not be considered; and
3. Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and
4. Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants); and
5. There is documentation demonstrating an appropriate upward titration or an appropriate conversion from other opioid medications; and
6. Pain was inadequately controlled at the maximum allowed dose without prior authorization for the requested opioid(s); and
7. Pain was inadequately controlled by 2 other chemically distinct preferred long-acting opioids at the maximum allowed dose without prior authorization; and
8. Chart notes from a recent office visit for pain management is included documenting the following:
    a. Treatment plan – including all therapies to be used concurrently (pharmacologic and non-pharmacologic); and
    b. Treatment goals; and
9. Patient has been informed of the risks of high-dose opioid therapy; and
10. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that use of high-dose opioid therapy is appropriate for this patient; and
11. The patient's risk for opioid addiction, abuse and misuse has been reviewed and prescriber has determined the patient is a candidate for high-dose opioid therapy; and
12. A signed chronic opioid therapy management plan between the prescriber and patient dated within 12 months of this request is included; and
13. The requested dosing interval is no more frequent than the maximum FDA-approved dosing interval; and
14. Patient has been provided a prescription for a preferred naloxone product for the emergency treatment of an opioid overdose; and
15. Patient has been educated on opioid overdose prevention; and
16. Patient's household members have been educated on the signs of opioid overdose and how to administer naloxone; and

17. Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with initial and subsequent requests; and
18. A documented dose reduction is attempted at least annually.

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of high-dose opioid therapy will be considered every 6 months with the following:

1. High-dose opioid therapy continues to meet treatment goals, including sustained improvement in pain and function; and
2. Patient has not experienced an overdose or other serious adverse event; and
3. Patient is not exhibiting warning signs of opioid use disorder; and
4. The benefits of opioids continue to outweigh the risks; and
5. A documented dose reduction has been attempted at least annually, and the prescriber has determined the dose cannot be reduced at this time; and
6. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that continued use of high-dose opioid therapy is appropriate for this patient; and
7. Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with subsequent requests.
8. Patient has been provided a prescription for a preferred naloxone product for the emergency treatment of an opioid overdose; and
9. Patient has been reeducated on opioid overdose prevention; and
10. Patient's household members have been reeducated on the signs of opioid overdose and how to administer naloxone.

Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for use of high-dose opioids ≥ 90 morphine milligram equivalents (MME) per day (See CDC *Clinical Practice* Guideline for Prescribing Opioids for ~~Chronic~~ Pain – *United States, 2022* at https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1.htm_w ~~https://www.cdc.gov/drugoverdose/prescribing/guideline.html~~). Patients undergoing active cancer treatment or end-of-life care will not be subject to the criteria below. Payment will be considered when the following is met:

1. Requests for non-preferred opioids meet criteria for coverage (see criteria for Long-Acting Opioids and/or Short-Acting Opioids); and
2. Patient has a diagnosis of severe, chronic pain with a supporting ICD-10 code. Requests for a diagnosis of fibromyalgia or migraine will not be considered; and
3. Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and
4. Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants); and
5. There is documentation demonstrating an appropriate upward titration or an appropriate conversion from other opioid medications; and
6. Pain was inadequately controlled at the maximum allowed dose without prior authorization for the requested opioid(s); and
7. Pain was inadequately controlled by 2 other chemically distinct preferred long-acting opioids at the maximum allowed dose without prior authorization; and

8. Chart notes from a recent office visit *or telehealth visit* for pain management *are* ~~is~~ included documenting the following:
    a. Treatment plan – including all therapies to be used concurrently (pharmacologic and non-pharmacologic); and
    b. Treatment goals; and
9. Patient has been informed of the risks of high-dose opioid therapy; and
10. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that use of high-dose opioid therapy is appropriate for this patient; and
11. The patient's risk for opioid addiction, abuse and misuse has been reviewed and prescriber has determined the patient is a candidate for high-dose opioid therapy; and
12. A signed chronic opioid therapy management plan between the prescriber and patient dated within 12 months of this request is included; and
13. The requested dosing interval is no more frequent than the maximum FDA-approved dosing interval; and
14. Patient has *documentation of receipt of an* ~~been provided a prescription for a preferred~~ *opioid reversal agent (e.g. as seen in pharmacy claims or documentation from the Iowa PMP of dispensation [attach documentation]) within the prior 24 months of high dose opioid request* ~~naloxone product~~ for the emergency treatment of an opioid overdose; and
15. Patient has been educated on opioid overdose prevention; and
16. Patient's household members have been educated on the signs of opioid overdose and how to administer *an opioid reversal agent* ~~naloxone~~; and
17. Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with initial and subsequent requests; and
18. A documented dose reduction is attempted at least annually.

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of high-dose opioid therapy will be considered every 6 months with the following:

1. High-dose opioid therapy continues to meet treatment goals, including sustained improvement in pain and function; and
2. Patient has not experienced an overdose or other serious adverse event; and
3. Patient is not exhibiting warning signs of opioid use disorder; and
4. The benefits of opioids continue to outweigh the risks; and
5. A documented dose reduction has been attempted at least annually, and the prescriber has determined the dose cannot be reduced at this time; and
6. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that continued use of high-dose opioid therapy is appropriate for this patient; and
7. Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with subsequent requests.
8. Patient has *documentation of receipt of an* ~~been provided a prescription for a preferred~~ *opioid reversal agent (e.g. as seen in pharmacy claims or documentation from the Iowa PMP of dispensation [attach documentation]) within 24 months of high dose opioid request* ~~naloxone product~~ for the emergency treatment of an opioid overdose; and
9. Patient has been reeducated on opioid overdose prevention; and
10. Patient's household members have been reeducated on the signs of opioid overdose and how to administer *an opioid reversal agent* ~~naloxone~~.

Proposed ProDUR Quantity Limits

Drug	**Quantity Limit per 30 Days** (unless otherwise stated)
Bystolic 2.5 mg, 5 mg, 10 mg (nebivolol)	30
Bystolic 20 mg (nebivolol)	60
Lokelma 5 g, 10 g (sodium zirconium cyclosilicate)	34 packets
Veltassa 8.4 g, 16.8 g, 25.2 g (patiromer)	30 packets
Vtama 1% (tapinarof)	60 g (1 tube)

Proposed ProDUR Age Edit

Drug	**Age Edit**
Lokelma (sodium zirconium cyclosilicate)	18 years of age and older
Veltassa (patiromer)	18 years of age and older

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for removal of prior authorization (PA) criteria for Nebivolol (Bystolic) and Potassium Binders, in addition to new or updated PA criteria for Select Topical Psoriasis Agents, Initial Days' Supply Limit Override for Benzodiazepines, and High Dose Opioids, as well as the ProDUR quantity limits and ProDUR age edits.

Sincerely,

Pamela Smith R.Ph.

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid

Cc: Erin Halverson, R.Ph, Iowa Medicaid
Gina Kuebler, R.Ph, Iowa Medicaid

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May 3, 2023

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid
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Des Moines, Iowa 50309

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, May 3, 2023. At this meeting, the DUR Commission members discussed implementation of a 90-day drug supply allowance for select medications in addition to new or updated prior authorization (PA) criteria for Viloxazine (Qelbree); Dupilumab (Dupixent); Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist, Oral; and Janus Kinase Inhibitors. The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to a February 8, 2023 letter that was sent to them detailing the proposed 90-day drug supply allowance for select medications in addition to new or updated PA criteria for Viloxazine (Qelbree); Dupilumab (Dupixent); Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist, Oral; and Janus Kinase Inhibitors.

90-Day Drug Supply Allowance

The DUR Commisison discussed and proposed implementation of a 90-day drug supply allowance of select, cost-effective generic maintenance medications. Details of the proposed policy are as follows:

- Dispensing fee - pharmacy gets one dispensing fee per 90-day supply billed.
- Copayment - member gets charged one copay (if applicable) per 90-day supply billed.
- Member exclusions - none
- Initial fill – quantity would be at the discretion of prescriber, but consideration should be given to dispensing less than a 90-day supply with the initial fill when starting members on new medications or with dose adustments to minimize waste.
- 90-day drug selection process – will include select generic products from MediSpan maintenance drug categories.
- Exclusion criteria -
    - Safety – e.g., risks associated with a particular class
    - Controlled substances
    - Narrow therapeutic index (NTI) drugs

    - Drugs subject to frequent dose adjustments
    - OTC drugs
    - Brand drugs
    - PA drug categories (Clinical PA)
    - Nopreferred or nonrecommended drugs
    - Other therapeutic categories – antibiotics, ophthalmic, otic, and topical products
- Initial categories (select, generic drugs) – blood pressure; cholesterol lowering agents; antidepressants; diabetes mellitus
- Review list annually

Viloxazine (Qelbree)

Current Clinical Prior Authorization Criteria

Prior authorization is required for viloxazine (Qelbree). Payment will be considered under the following conditions:

1. Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV); and
2. Patient is between 6 and 17 years of age; and
3. Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more current environments (social, academic, or occupational) and
4. Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred amphetamine stimulant; and
5. Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred methylphenidate stimulant; and
6. Documentation of a previous trial and therapy failure at a therapeutic dose with atomoxetine; and
7. Is dosed based on FDA approved dosing, and dose does not exceed 400 mg per day; and
8. Documentation of a recent clinical visit that confirms improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted/stricken)

Prior authorization is required for viloxazine (Qelbree). Payment will be considered *when patient has an FDA approved or compendia indication for the requested drug* under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV); and
3. ~~Patient is between 6 and 17 years of age; and~~
4. Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more current environments (social, academic, or occupational) and
5. ~~Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred amphetamine stimulant; and~~

6. ~~Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred methylphenidate stimulant; and~~
7. Documentation of a previous trial and therapy failure at a therapeutic dose with atomoxetine *or a preferred stimulant*; and
8. ~~Is dosed based on FDA approved dosing, and~~ ~~d~~*D*ose does not exceed 400 mg per day *for pediatric patients (< 18 years of age) and 600 mg per day for adult patients*; and
9. Documentation of a recent clinical visit that confirms improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Dupilumab (Dupixent)

Current Clinical Prior Authorization Criteria

Prior authorization is required for Dupixent (dupilumab). Payment for non-preferred agents will be considered when there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. Request adheres to all FDA approved labeling for requested drug and indication including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient's current weight in kilograms (kg) is provided; and
3. Patient has a diagnosis of moderate-to-severe atopic dermatitis; and
    a. Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and
    b. Patient has failed to respond to good skin care and regular use of emollients; and
    c. Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
    d. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
    e. Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and
    f. Patient will continue with skin care regimen and regular use of emollients; or
4. Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) OR with oral corticosteroid dependent asthma; and
    a. Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and
    b. Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted; and
    c. Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g., long acting $beta_2$ agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and
    d. Patient must have one of the following, in addition to the regular maintenance medications defined above:

        i. Two (2) or more exacerbations in the previous year or
        ii. Require daily oral corticosteroids for at least 3 days; or
5. Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and
    a. Documentation dupilumab will be used as an add-on maintenance treatment; and
    b. Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:
        i. Nasal corticosteroid spray; and
        ii. Oral corticosteroid; or
6. Patient has a diagnosis of eosinophilic esophagitis (EoE); and
    a. Is prescribed by, or in consultation with, an allergist, gastroenterologist, or immunologist; and
    b. Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and
    c. Patient has signs and symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, food refusal, abdominal pain, heartburn regurgitation, chest pain and/or, odynophagia); and
    d. Documentation of previous trials and therapy failures with all of the following:
        i. High dose proton pump inhibitor (PPI) for at least 8 weeks; and
        ii. Swallowed topical corticosteroid (e.g., fluticasone propionate, oral budesonide suspension); and
        iii. Dietary therapy; and
7. Dose does not exceed the FDA approved dosing for indication.

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

<u>Proposed Clinical Prior Authorization Criteria</u> (changes highlighted/italicized/stricken)
Prior authorization is required for Dupixent (dupilumab). Payment for non-preferred agents will be considered when there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. Request adheres to all FDA approved labeling for requested drug and indication including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient's current weight in kilograms (kg) is provided; and
3. Patient has a diagnosis of moderate-to-severe atopic dermatitis; and
    a. Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and
    b. Patient has failed to respond to good skin care and regular use of emollients; and
    c. Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
    d. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
    e. Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and

f. Patient will continue with skin care regimen and regular use of emollients; or

4. Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) OR with oral corticosteroid dependent asthma; and
    a. Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and
    b. Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted; and
    c. Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g., long acting $beta_2$ agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and
    d. Patient must have one of the following, in addition to the regular maintenance medications defined above:
        i. Two (2) or more exacerbations in the previous year or
        ii. Require daily oral corticosteroids for at least 3 days; or
5. Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and
    a. Documentation dupilumab will be used as an add-on maintenance treatment; and
    b. Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:
        i. Nasal corticosteroid spray; and
        ii. Oral corticosteroid; or
6. Patient has a diagnosis of eosinophilic esophagitis (EoE); and
    a. Is prescribed by, or in consultation with, an allergist, gastroenterologist, or immunologist; and
    b. Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and
    c. Patient has signs and symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, food refusal, abdominal pain, heartburn regurgitation, chest pain and/or, odynophagia); and
    d. Documentation of previous trials and therapy failures with all of the following:
        i. High dose proton pump inhibitor (PPI) for at least 8 weeks; and
        ii. Swallowed topical corticosteroid (e.g., fluticasone propionate, oral budesonide suspension); and
        iii. Dietary therapy; ~~and~~ *or*
7. *Patient has a diagnosis of moderate to severe prurigo nodularis (PN); and*
    a. *Is prescribed by, or in consultation with an allergist, immunologist, or dermatologist; and*
    b. *Patient has experienced severe to very severe pruritus, as demonstrated by a current* Worst Itch-Numeric Rating Scale (WI-NRS) ≥ 7*; and*
    c. *Patient has ≥ 20 nodular lesions (attach documentation); and*
    d. *Documentation of a previous trial and therapy failure with a high or super high potency topical corticosteroid for at least 14 consecutive days; and*
8. Dose does not exceed the FDA approved dosing for indication.

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Gonadotropin-Releasing Hormone (GnRH Receptor Antagonist, Oral)

Current Clinical Prior Authorization Criteria
Prior authorization (PA) is required for oral gonadotropin-releasing hormone (GnRH) antagonists. Payment for non-preferred oral GnRH antagonists may be considered only for cases in which there is documentation of a previous trial and therapy failure with the preferred agent. Payment will be considered for patients when the following is met:

1. Pregnancy has been ruled out; and
2. Patient does not have osteoporosis; and
3. Request adheres to all FDA approved labeling for requested drug, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
4. Requests for elagolix (Orilissa) will be considered under the following conditions:
    a. Patient has a diagnosis of moderate to severe pain associated with endometriosis; and
    b. Patient has documentation of a previous trial and therapy failure with at least one preferred oral NSAID and at least one preferred 3-month course of a continuous hormonal contraceptive taken concurrently; and
    c. Patient has documentation of a previous trial and therapy failure with a preferred GnRH agonist.
    d. Initial requests will be considered for 3 months. Additional requests will be considered upon documentation of improvement of symptoms
    e. Requests will be considered for a maximum of 24 months for the 150mg dose and six (6) months for the 200mg dose; or
5. Requests for elagolix, estradiol, and norethindrone acetate; elagolix (Oriahnn) or relugolix, estradiol, norethindrone acetate (Myfembree) will be considered under the following conditions:
    a. Patient is premenopausal; and
    b. Patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); and
    c. Patient has documentation of a previous trial and therapy failure with at least one preferred 3-month course of a continuous hormonal contraceptive; and
    d. Patient has documentation of a previous trial and therapy failure with tranexamic acid.
    e. Initial requests will be considered for 6 months. Additional requests will be considered upon documentation of improvement of symptoms.
    f. Requests will be considered for a maximum of 24 months of treatment.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized/stricken)
Prior authorization (PA) is required for oral gonadotropin-releasing hormone (GnRH) antagonists. Payment for non-preferred oral GnRH antagonists may be considered only for cases in which there is documentation of a previous trial and therapy failure with the preferred agent. Payment will be considered for patients when the following is met:

1. Pregnancy has been ruled out; and
2. Patient does not have osteoporosis; and
3. Request adheres to all FDA approved labeling for requested drug, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and

4. Requests for elagolix (Orilissa) *or relugolix, estradiol, norethindrone acetate (Myfembree)* will be considered under the following conditions:
    a. Patient has a diagnosis of moderate to severe pain associated with endometriosis; and
    b. Patient has documentation of a previous trial and therapy failure with at least one preferred oral NSAID and at least one preferred 3-month course of a continuous hormonal contraceptive taken concurrently; and
    c. Patient has documentation of a previous trial and therapy failure with a preferred GnRH agonist.
    d. Initial requests will be considered for 3 months. Additional requests will be considered upon documentation of improvement of symptoms*; and*
    e. Requests will be considered *based on drug, dose, and length of therapy:*
        i. *Orilissa* - ~~for a~~ maximum *duration* of *therapy of* 24 months for the 150mg dose and six (6) months for the 200mg dose*; or*
        ii. *Myfembree - maximum duration of therapy of 24 months; or*
5. Requests for elagolix, estradiol, and norethindrone acetate; elagolix (Oriahnn) or relugolix, estradiol, norethindrone acetate (Myfembree) will be considered under the following conditions:
    a. Patient is premenopausal; and
    b. Patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); and
    c. Patient has documentation of a previous trial and therapy failure with at least one preferred 3-month course of a continuous hormonal contraceptive; and
    d. Patient has documentation of a previous trial and therapy failure with tranexamic acid.
    e. Initial requests will be considered for 6 months. Additional requests will be considered upon documentation of improvement of symptoms.
    f. Requests will be considered for a maximum *duration of therapy* of 24 months ~~of treatment~~.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Janus Kinase Inhibitors

Current Prior Authorization Criteria

Prior authorization (PA) is required for Janus kinase (JAK) inhibitors. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, biological therapies, or potent immunosuppressants (azathioprine or cyclosporine); and
2. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
3. Patient has a diagnosis of:
    a. Moderate to severe rheumatoid arthritis (baricitinib, tofacitinib, upadacitinib); with
        i. A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate; and
        ii. A documented trial and inadequate response to one preferred TNF inhibitor; OR
    b. Psoriatic arthritis (tofacitinib, upadacitinib); with

i. A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
ii. Documented trial and therapy failure with one preferred TNF inhibitor used for psoriatic arthritis; OR

c. Moderately to severely active ulcerative colitis (tofacitinib, upadacitinib); with
i. A documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and
ii. A documented trial and inadequate response with a preferred TNF inhibitor; and
iii. If requested dose is for tofacitinib 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit; OR

d. Polyarticular Course Juvenile Idiopathic Arthritis (tofacitinib); with
i. A documented trial and inadequate response to intraarticular glucocorticoid injections; and
ii. A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
iii. A documented trial and inadequate response with a preferred TNF inhibitor; OR

e. Ankylosing spondylitis (tofacitinib); with
i. A documented trial and inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at a maximally tolerated dose for a minimum of at least one month; and
ii. A documented trial and inadequate response with at least one preferred TNF inhibitor; OR

f. Atopic dermatitis; with
i. Documentation patient has failed to respond to good skin care and regular use of emollients; and
ii. A documented adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
iii. A documented trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
iv. For mild to moderate atopic dermatitis (ruxolitinib)
a. A documented trial and therapy failure with crisaborole; and
b. Affected area is less than 20% of body surface area (BSA); and
c. Patient has been instructed to use no more than 60 grams of topical ruxolitinib per week; or
v. For moderate to severe atopic dermatitis (abrocitinib, upadacitinib):
a. A documented trial and therapy failure with cyclosporine or azathioprine; and
b. Requests for upadacitinib for pediatric patients 12 to less than 18 years of age must include the patient's weight in kg.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

<u>Proposed Clinical Prior Authorization Criteria</u> (changes highlighted/italicized/stricken)

Prior authorization (PA) is required for Janus kinase (JAK) inhibitors. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug*, excluding requests for the FDA approved indication of alopecia areata, vitiligo, or other excluded medical use(s), as defined in Section 1927(d)(2) of the Social Security Act, State Plan, and Rules* when the following conditions are met:

1. Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, biological therapies, or potent immunosuppressants (azathioprine or cyclosporine); and
2. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
3. Patient has a diagnosis of:
    a. Moderate to severe rheumatoid arthritis (baricitinib, tofacitinib, upadacitinib); with
        i. A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate; and
        ii. A documented trial and inadequate response to one preferred TNF inhibitor; OR
    b. Psoriatic arthritis (tofacitinib, upadacitinib); with
        i. A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
        ii. Documented trial and therapy failure with one preferred TNF inhibitor used for psoriatic arthritis; OR
    c. Moderately to severely active ulcerative colitis (tofacitinib, upadacitinib); with
        i. A documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and
        ii. A documented trial and inadequate response with a preferred TNF inhibitor; and
        iii. If requested dose is for tofacitinib 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit; OR
    d. Polyarticular Course Juvenile Idiopathic Arthritis (tofacitinib); with
        i. A documented trial and inadequate response to intraarticular glucocorticoid injections; and
        ii. A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
        iii. A documented trial and inadequate response with a preferred TNF inhibitor; OR
    g. *Axial spondyloarthritis conditions (e.g., a*nkylosing spondylitis *or nonradiographic axial spondyloarthritis)* (tofacitinib*, upadacitinib*); with
        i. A documented trial and inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at a maximally tolerated dose for a minimum of at least one month; and
        ii. A documented trial and inadequate response with at least one preferred TNF inhibitor; OR
    h. Atopic dermatitis; with
        i. Documentation patient has failed to respond to good skin care and regular use of emollients; and

ii. A documented adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
iii. A documented trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
iv. For mild to moderate atopic dermatitis (ruxolitinib)
    a. A documented trial and therapy failure with crisaborole; and
    b. Affected area is less than 20% of body surface area (BSA); and
    c. Patient has been instructed to use no more than 60 grams of topical ruxolitinib per week; or
v. For moderate to severe atopic dermatitis (abrocitinib, upadacitinib):
    a. A documented trial and therapy failure with cyclosporine or azathioprine; and
    b. Requests for upadacitinib for pediatric patients 12 to less than 18 years of age must include the patient's weight in kg.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for implementation of a 90-day drug supply allowance for select medications in addition to new or updated PA criteria for Viloxazine (Qelbree); Dupilumab (Dupixent); Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist, Oral; and Janus Kinase Inhibitors.

Sincerely,

Pamela Smith R.Ph.

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid

Cc: Erin Halverson, R.Ph, Iowa Medicaid
Gina Kuebler, R.Ph, Iowa Medicaid

Appendix H
Prospective DUR Recommendations

Prospective DUR
SFY23

All recommendations are inclusive of brand and generic agents. The following prospective DUR (ProDUR) edits were recommended by the DUR Commission to the Department:

ProDUR Quantity Limits

Drug	**Proposed Quantity Limit per 30 Days** (unless otherwise stated)
Bystolic 2.5 mg, 5 mg, 10 mg (nebivolol)	30
Bystolic 20 mg (nebivolol)	60
Camzyos 2.5 mg, 5 mg, 10 mg, 15 mg (mavacamten)	30
Cibinqo (abrocitinib) 50 mg, 100 mg, 200 mg	30
Halcion 0.125 mg (triazolam)	30
Halcion 0.25 mg (triazolam)	60
Livmarli 9.5 mg/mL (maralixibat)	90 mL
Lokelma 5 g, 10 g (sodium zirconium cyclosilicate)	34 packets
Olumiant (baricitinib) 1 mg, 2 mg	30
Opzelura (ruxolitinib) 1.5% cream	240 g (4 tubes)
ProAir Digihaler (albuterol)	2 inhalers
ProAir HFA 8.5 g (albuterol)	2 inhalers (17 grams)
ProAir Respiclick (albuterol)	2 inhalers
Proventil HFA 6.7 g (albuterol)	2 inhalers (13.4 grams)
Qelbree 200 mg (viloxazine)	90
Rinvoq (upadacitinib) 45 mg	28 per 28 days
Rinvoq (upadacitinib)15 mg, 30 mg	30
Veltassa 8.4 g, 16.8 g, 25.2 g (patiromer)	30 packets
Ventolin HFA 18 g (albuterol)	2 inhalers (36 grams)
Vijoice 125 mg blister pack (alpelisib)	1 pack (28 tabs) per 28 days
Vijoice 250 mg blister pack (alpelisib)	1 pack (56 tabs) per 28 days
Vijoice 50 mg blister pack (alpelisib)	1 pack (28 tabs) per 28 days
Vtama 1% (tapinarof)	60 g (1 tube)
Vuity (Pilocarpine) 1.25% opth. soln.	2.5 mL
Xeljanz (tofacitinib) 5 mg, 10 mg	60
Xeljanz (tofacitinib) XR 11 mg, 22 mg	30
Xopenex HFA 15 g (levalbuterol)	2 inhalers (30 grams)

ProDUR Initial Days Supply Limit for Benzodiazepines

The DUR Commission made a recommendation to implement a 7-day initial limit on all benzodiazepines for new users. The ProDUR point-of-sale (POS) edit would limit to an initial 7 days' supply for a benzodiazepine if the requested benzodiazepine is not found in pharmacy claims in the preceding 90 days. Exceptions to this edit include nasal and rectal

diazepam, nasal midazolam and clobazam. Prior authorization would be required for use beyond the 7-day allowance. The Commission will develop PA criteria for requests exceeding the initial limit at a future meeting and will be shared with interested parties for comment prior to implementation.

ProDUR Cumulative Quantity Limit for Oral Benzodiazepines

The DUR Commission made a recommendation to implement a cumulative quantity limit of 4 units per day across the benzodiazepine class for solid oral dosage forms. The quantity limit chart would include the following statement: Benzodiazepines are subject to a cumulative quantity limit of 4 units per day, unless otherwise indicated on the chart.

ProDUR Age Edit

Drug	Age Edit
Lokelma (sodium zirconium cyclosilicate)	18 years of age and older
Veltassa (patiromer)	18 years of age and older

90-Day Drug Supply Allowance

The DUR Commisison discussed and proposed implementation of a 90-day drug supply allowance of select, cost-effective generic maintenance medications. Details of the proposed policy are as follows:

- Dispensing fee - pharmacy gets one dispensing fee per 90-day supply billed.
- Copayment - member gets charged one copay (if applicable) per 90-day supply billed.
- Member exclusions - none
- Initial fill – quantity would be at the discretion of prescriber, but consideration should be given to dispensing less than a 90-day supply with the initial fill when starting members on new medications or with dose adustments to minimize waste.
- 90-day drug selection process – will include select generic products from MediSpan maintenance drug categories.
- Exclusion criteria -
    - Safety – e.g., risks associated with a particular class
    - Controlled substances
    - Narrow therapeutic index (NTI) drugs
    - Drugs subject to frequent dose adjustments
    - OTC drugs
    - Brand drugs
    - PA drug categories (Clinical PA)
    - Nopreferred or nonrecommended drugs
    - Other therapeutic categories – antibiotics, ophthalmic, otic, and topical products
- Initial categories (select, generic drugs) – blood pressure; cholesterol lowering agents; antidepressants; diabetes mellitus
- Review list annually

Appendix I
Meeting Minutes

Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes August 3, 2022

Attendees:

Commission Members
Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; John Ellis, Pharm.D.; Jason Wilbur, M.D.; Chuck Wadle, D.O.; Holly Randleman, Pharm.D.; Rhea Hartley, M.D.; Susan Parker, Pharm.D.; and Lisa Todd, R.Ph. Amerigroup.
Staff
Pam Smith, R.Ph.
Guests
Erin Halverson, R.Ph., IME; Gina Kuebler, R.Ph., IME; Melissa Biddle, IME; and Emily Rogers, Pharm.D. Iowa Total Care.

Welcome & Introductions

As the Commission was without a chairperson and vice chairperson due to Brett Faine and Kellen Ludvigson's last meeting in May, Pam Smith called the meeting to order at 9:33 a.m. Due to the current federal state of emergency, continually fluctuating numbers of coronavirus cases in various counties, the need for stability and pre-planning for the public, and due to increased workload of our members directly related to the COVID-19 pandemic, the committee finds that it is impossible/impractical to meet in person for the August 3, 2022 meeting and that it must be held electronically. The minutes from the May 4, 2022, meeting were reviewed. Melissa Klotz motioned to accept them, and Jason Kruse seconded. All members were in favor. The recommendation letter sent to DHS after the last DUR meeting and a letter from the P&T Committee requesting development of prior authorization criteria for Adbry and Opzelura were also reviewed. Jason Kruse nominated Melissa Klotz for chairperson, and Melissa Klotz then nominated Jason Kruse for chairperson, as well. Jason Kruse agreed to be vice-chairperson, and Melissa Klotz then agreed to be chairperson. Chuck Wadle motioned to make Melissa Klotz chairperson and Jason Kruse vice-chairperson. Jason Wilbur seconded, and all members in attendance were in favor of the motion. Members were also asked to complete their annual conflict of interest disclosures.

IME Pharmacy Update

The final July 2022 cost of dispensing report is available on the reimbursement section of the website. The report showed the mean cost of dispensing as $10.97 per prescription for all pharmacies including specialty, and $10.18 for all non-specialty pharmacies. The current dispensing fee of $10.38 will remain in place until additional state funding is appropriated in the next Iowa legislative session, and a state plan amendment would also have to be submitted to CMS for approval. Any change would be prospective following approval.

Prevalence Report Summaries

***Amerigroup**:* Lisa Todd provided an overview for ITC's statistics from March 2022 through May 2022, including: total paid amount ($128,899,388); total prescriptions (1,158,376); and unique users (176,907). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy and 4 Walgreens locations made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Caremark Kansas Specialty Pharmacy, Community Walgreens Pharmacy, Caremark Illinois Specialty Pharmacy, and Unity Point at Home. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Inflammatory; Antiasthmatic and Bronchodilator Agents; and Dermatologicals. These were the top five classes by prescription count: Antidepressants, Anticonvulsants, Antiasthmatic and Bronchodilator Agents, ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, and Antipsychotics/Antimanic Agents. Humira (CF) Pen was the most expensive medication, followed by Vyvanse, Trulicity, Vraylar, and Trikafta. Sertraline hcl had the highest prescription count, followed by: omeprazole, trazodone hcl, escitalopram, and fluoxetine.

Iowa Total Care: Emily Rogers provided an overview for ITC's statistics from March 2022 through May 2022, including: total paid amount ($87,114,575.82); total prescriptions (811,170); and unique users (131,310). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy, Broadlawns, and 3 Walgreens locations made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Unity Point at Home, Caremark Kansas Specialty Pharmacy, Nucara Specialty, and CVS. The top 5 therapeutic classes by paid amount were: Anti-TNF-alpha-Monoclonal Antibodies; Sympathomimetics; Insulin; Incretin Mimetic Agents (GLP-1 Receptor Agonists); and Antipsychotics – Misc. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Sympathomimetics; Proton-Pump Inhibitors; and NSAIDs. The most expensive drugs were Humira Pen, Trulicity, Vraylar, Vyvanse, and Trikafta, while sertraline, omeprazole, trazodone, amoxicillin, and atorvastatin and had the top 5 prescription counts.

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from March 2022 through May 2022, including: total amount paid ($2,357,974), unique users (3,685); cost per user ($639.88), number of total prescriptions dispensed (21,855); and percent generic (88.2%). The top 5 therapeutic classes by paid amount were: Anti-Inflammatories, Non-NSAID; Antipsychotics – Atypicals; Anticonvulsants; Muscular Dystrophy Agents; and Antidepressants – Selected SSRIs. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Antihypertensives - Central; and Antiasthmatic – Beta-Adrenergics. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Humira Pen, Evrysdi, Biktarvy, Vyvanse, and Enbrel Sureclick. The five drugs with the highest prescription counts were: trazodone hcl, clonidine hcl, sertraline hcl, escitalopram, and omeprazole.

Comparative Prevalence Report Summary

Pam Smith also created a report that compared the FFS stats with those from each MCO. Its side-by-side statistics showed that $ 218,368,938 was spent in total for 311,902 unique users who had 1,991,401 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Humira Pen was the most expensive drug for FFS and both MCO plans. The top 25 drugs by prescription count were also similar across FFS and both MCO plans, with sertraline in the top spot for both MCOs and third for FFS. When all three plans were combined, Jeffrey Wilharm had the overall highest prescription count at 5,189. All three complete prevalence reports and the comparative summary can be found in the finalized meeting packet posted on https://iadur.org on the Meeting Materials page.

Public Comment

In addition to the written public comments provided to Commission members, posted in the finalized meeting packet on https://iadur.org on the Meeting Materials page and summarized below, they heard oral public comment from the speakers shown below.

Name	Representing	Drug/Topic
Susie Moroney	Novartis	Vijoice
Mariola Vazquez	Leo Pharma	Adbry
James Bauman	Pfizer	Cibinqo & Eucrisa (Atopic Dermatitis)

Written Provider Comments Received: None

Written Manufacturer Comments Received: Humira

Retrospective DUR Data Presentations

High Dose Opioid (> 90 MME) without Opioid Reversal Agent: The Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) requires states have an automated review process in place to identify patients at high risk of opioid overdose without a reversal agent. Current prior authorization criteria for High Dose Opioids, defined as 90 morphine milligram equivalents (MME) per day, requires the prescriber to attest a prescription for a preferred naloxone product for the emergency treatment of an opioid overdose has been provided. As requested at the May meeting, data was pulled to identify members with a claim(s) for an opioid ≥ 90 MME during the month of April 2022, with a look-back at the prior 12, 18 and 24 months to check for naloxone prescriptions in their claim histories, due to the 36-month shelf life. The Commission was also provided a report for the total number of naloxone claims per quarter during the look-back period. The High Dose Opioids PA criteria will be updated to require patients have a paid claim for or documentation of receiving an opioid reversal agent (i.e. documentation from Iowa PMP of dispensation) within a certain time period. Updated criteria will then be brought back for review and approval. Additionally, letters will be sent to prescribers regarding members that do not have an opioid reversal agent in their claims history pointing out the patient's higher risk of opioid overdose due to daily MME, recommending co-prescribing or co-dispensing

of a preferred opioid reversal agent and encouraging the member to have it on-hand for an emergency situation. This may also appear in a future DUR Digest.

Opioid plus Buprenorphine for OUD: The Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) requires states to establish prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state, to identify patients prescribed an opioid after being prescribed one or more drugs used for medication assisted treatment (MAT). Currently, pharmacies receive a ProDUR soft edit regarding the combination. As requested at the May meeting, data was pulled to identify members with concurrent buprenorphine, indicated for the treatment of opioid use disorder (OUD), and an opioid in pharmacy claims, taking days' supply into account due to possible post-operative opioid use. Upon review of the findings, the Commission would like to hold this topic for further future review and take no immediate action. Pam Smith will consult with the MCOs to develop a plan to manage the data and monitor usage, then bring any issues back to the commission if merited.

Retrospective DUR Proposals

LABA without ICS in Asthma: LABAs as monotherapy increase the risk of asthma-related death and should be prescribed only as additional therapy for patients with asthma who are currently taking but are inadequately controlled on an inhaled corticosteroid (ICS). Salmeterol xinafoate inhalation powder (Serevent Diskus) is the only single-ingredient LABA indicated for the treatment of asthma. Pam Smith will run data to identify members with an asthma diagnosis and a claim for Serevent Diskus in their pharmacy claims from May through July 2022 that do not have a claim for an ICS. Results will be brought back to the next meeting.

Concurrent Use of Opioids and Sedatives: Opioids carry an FDA boxed warning of increased risk of respiratory and CNS depression with concurrent use of opioid and CNS depressants such as antipsychotics or sedatives. Currently, there are no hard POS edits to stop this combination or an automated retrospective claims review process for concurrent use of an opioid and sedative. Questions related to this issue appeared in the FFY21 CMS DUR Survey. Pam Smith will research to find more information regarding increased harm with specific drug combinations, along with a more complete list of sedatives that would be included in the claims data search. Findings will be brought back to the next meeting.

Duplicate Therapy with Opioids – Discussion

Though letters were sent to prescribers a year ago, there has been little impact thus far, with 771 unique members across all plans still showing duplicate therapy for 30 days or more in their claim histories between April and June 2022. Pam Smith will research how other states are addressing this issue and bring additional information for specific options back to a future meeting.

Commission Recommendations for Retrospective DUR Agenda Topics

There were no additional topic suggestions.

Prospective DUR

Initial Days Supply Limit – Benzodiazepines: At the May meeting, the DUR Commission made a recommendation to implement a 7-day initial limit on all benzodiazepines for new users. The ProDUR point-of-sale (POS) edit would limit to an initial 7 days' supply for a benzodiazepine if the requested benzodiazepine is not found in pharmacy claims in the preceding 90 days. Exceptions to this edit include nasal and rectal diazepam, nasal midazolam and clobazam. Prior authorization would be required for quantities exceeding 7 days and the Commission will develop PA criteria at a future meeting. No further changes were recommended. As this was the second review, no motion was necessary. The recommendation will be sent to the Department for consideration.

Benzodiazepine Cumulative Quantity Limit: At the May meeting, the DUR Commission made a recommendation to implement a cumulative quantity limit of 4 units per day across the benzodiazepine class for solid oral dosage forms. The limit chart will include a statement, such as "Benzodiazepines are subject to a cumulative quantity limit of 4 units per day, unless otherwise indicated on the chart." No further changes were recommended. As this was the second review, no motion was necessary. The recommendation will be sent to the Department for consideration.

Short-Acting Beta Agonist Quantity Limit: At the May meeting, the Commission voted to implement a quantity limit of 2 canisters per 30 days on SABAs, similar to other states, and to send letters to the providers of members with overuse in their claim histories. No further changes were recommended. As this was the second review, no motion was necessary. The recommendation will be sent to the Department for consideration.

The Commission took a short break and open session resumed at 11:18 a.m.

Prior Authorization

Sedative/Hypnotics, Non-Benzodiazepine: The Commission reviewed the proposed prior authorization criteria as follows:

Preferred agents are available without prior authorization (PA) when dosed within the established quantity limits. PA is required for all non-preferred non-benzodiazepine sedative/hypnotics. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of previous trials and therapy failures with, at a minimum, three (3) preferred agents. Payment for non-preferred agent will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following criteria are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *A diagnosis of insomnia; and*
3. *Medications with a side effect of insomnia are decreased in dose, changed to a short acting product, and/or discontinued; and*
4. *Enforcement of good sleep hygiene is documented; and*

5. *All medical, neurological, and psychiatric disease states causing chronic insomnia are being adequately treated with appropriate medication at therapeutic doses; and*
6. *Will not be used concurrently with a benzodiazepine sedative/hypnotic agent.*
7. *In addition to the above criteria, requests for an orexin receptor antagonist will require documentation of a trial and therapy failure with at least one non-preferred agent prior to consideration of coverage.*
8. *Non-preferred alternative delivery systems will only be considered for cases in which the use of the alternative delivery system is medically necessary and there is a previous trial and therapy failure with a preferred alternative delivery system if available.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Jason Wilbur motioned to accept the criteria as amended, and Jason Kruse seconded. All members were in favor. The recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Vericiguat (Verquvo): The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization is required for vericiguat (Verquvo). Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of symptomatic chronic heart failure (NYHF class II-IV) with a left ventricular ejection fraction (LVEF) ≤ 45%; and*
3. *Patient meets one of the following:*
    a. *Recent hospitalization for heart failure (within the last 6 months); or*
    b. *Recent need for outpatient intravenous diuretics (within the last 3 months); and*
4. *Female patients of reproductive potential have been advised to use effective contraception during treatment and for at least one month after the last dose; and*
5. *Will not be used concomitantly with other soluble guanylate cyclase (sGC) stimulators (e.g. riociguat) or phosphodiesterase type 5 (PDE-5) inhibitors (e.g. sildenafil, tadalafil, vardenafil); and*
6. *Documentation of prior or current therapy, at a maximally tolerated dose, with one drug from each category below:*
    a. *Renin-angiotensin system inhibitor (angiotensin converting enzyme [ACEI], angiotensin receptor blocker [ARB], or angiotensin receptor-neprilysin inhibitor [ARNI]); and*
    b. *Evidence-based beta-blocker (carvedilol, metoprolol succinate, or bisoprolol); and*

c. *Mineralocorticoid receptor antagonist (MRA); and*
d. *Sodium-glucose cotransporter 2 inhibitor (SGLT2i) indicated for the treatment of heart failure (empagliflozin or dapagliflozin); and*

7. *Initial requests for vericiguat (Verquvo) 2.5 mg and 5 mg tablets will be limited to one 14-day supply for each strength.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Jason Kruse motioned to accept the criteria as amended, and Jason Wilbur seconded. All members were in favor. The recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Maralixibat (Livmarli): The Commission reviewed the newly proposed clinical prior authorization criteria as follows:

Prior authorization (PA) is required for maralixibat (Livmarli). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of Alagille syndrome (ALGS) confirmed by genetic testing demonstrating a JAG1 or NOTCH2 mutation or deletion; and*
3. *Patient has cholestasis with moderate to severe pruritus; and*
4. *Is prescribed by or in consultation with a hepatologist, gastroenterologist, or a prescriber who specializes in ALGS; and*
5. *Documentation of previous trials and therapy failures, at a therapeutic dose, with at least two of the following agents:*
    a. *Ursodeoxycholic acid (ursodiol)*
    b. *Cholestyramine*
    c. *Rifampin; and*
6. *Patient's current weight in kilograms (kg) is provided.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will require documentation of an improvement in pruritus symptoms and patient's current weight in kg.

Jason Wilbur motioned to accept the criteria, and Rhea Hartley seconded. All members were in favor. The recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

PIK3CA-Related Overgrowth Spectrum (PROS) Treatments (Vijoice): The Commission reviewed the newly proposed clinical prior authorization criteria as follows:

Prior authorization (PA) is required for alpelisib (Vijoice). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) confirmed by genetic testing demonstrating a PIK3CA mutation; and*
3. *Patient's condition is severe or life-threatening requiring systemic therapy as determined by treating prescriber; and*
4. *Patient has at least one target lesion identified on imaging.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will be considered with documentation of a positive response to therapy as evidenced by a reduction in sum of measurable lesion volume assessed across 1 to 3 target lesions.

Jason Kruse motioned to accept the criteria, and Melissa Klotz seconded. All members were in favor. Melissa Klotz then motioned to accept the recommended quantity limits listed below. Rhea Hartley seconded, and this decision was unanimous as well. The recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

- Quantity limits (per 30 days)
  - 50 mg – 30 tablets
  - 125 mg – 30 tablets (must use combination of 50 mg and 200 mg tablet to obtain 250 mg dose)
  - 200 mg – 30 tablets

Mavacamten (Camzyos): The Commission reviewed the newly proposed clinical prior authorization criteria as follows:

Prior authorization (PA) is required for mavacamten (Camzyos). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*

2. *Patient has a diagnosis of obstructive hypertrophic cardiomyopathy (HCM); and*
3. *Patient exhibits symptoms of New York Heart Association (NYHA) class II or III symptoms; and*
4. *Is prescribed by or in consultation with a cardiologist; and*
5. *Patient has a left ventricular ejection fraction (LVEF) ≥ 55%; and*
6. *Patient has a peak left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg at rest or with provocation; and*
7. *Documentation of a previous trial and therapy failure, at a maximally tolerated dose, with all of the following:*
    a. *Non-vasodilating beta-blocker (atenolol, metoprolol, bisoprolol, propranolol); and*
    b. *Non-dihydropyridine calcium channel blocker (verapamil, diltiazem); and*
    c. *Combination therapy with disopyramide plus beta-blocker or disopyramide plus a non-dihydropyridine calcium channel blocker.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Jason Wilbur motioned to accept the criteria, including a quantity limit of 30 capsules per 30 days across all strengths. Holly Randleman seconded, and all members were in favor. The recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Dupilumab (Dupixent): The Commission reviewed the proposed clinical prior authorization criteria as follows:

Prior authorization is required for Dupixent (dupilumab). Payment for non-preferred agents will be considered when there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient's current weight in kilograms (kg) is provided; and*
3. *Patient has a diagnosis of moderate-to-severe atopic dermatitis; and*
    a. *Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and*
    b. *Patient has failed to respond to good skin care and regular use of emollients; and*
    c. *Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*
    d. *Patient has documentation of a previous trial and therapy failure with a*

topical immunomodulator for a minimum of 4 weeks; and

e. *Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and*
f. *Patient will continue with skin care regimen and regular use of emollients; or*

4. *Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) OR with oral corticosteroid dependent asthma; and*
    a. *Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and*
    b. *Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted; and*
    c. *Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g., long acting $beta_2$ agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and*
    d. *Patient must have one of the following, in addition to the regular maintenance medications defined above:*
        i. *Two (2) or more exacerbations in the previous year or*
        ii. *Require daily oral corticosteroids for at least 3 days; or*
5. *Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and*
    a. *Documentation dupilumab will be used as an add-on maintenance treatment; and*
    b. *Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:*
        i. *Nasal corticosteroid spray; and*
        ii. *Oral corticosteroid; or*
6. *Patient has a diagnosis of eosinophilic esophagitis (EoE); and*
    a. *Is prescribed by, or in consultation with, an allergist, gastroenterologist, or immunologist; and*
    b. *Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and*
    c. *Patient has signs and symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, food refusal, abdominal pain, heartburn regurgitation, chest pain and/or, odynophagia); and*
    d. *Documentation of previous trials and therapy failures with all of the following:*
        i. *High dose proton pump inhibitor (PPI) for at least 8 weeks; and*
        ii. *Swallowed topical corticosteroid (e.g., fluticasone propionate, oral budesonide suspension); and*
        iii. *Dietary therapy; and*
7. *Dose does not exceed the FDA approved dosing for indication.*

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Jason Kruse motioned to accept the criteria as amended, and Melissa Klotz seconded. All members were in favor. The recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Viloxazine (Qelbree): The Commission reviewed the proposed clinical prior authorization criteria as follows:

Prior authorization is required for viloxazine (Qelbree). Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV); and*
3. *Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more current environments (social, academic, or occupational) and*
4. *Documentation of a previous trial and therapy failure at a therapeutic dose with atomoxetine; and*
5. *Dose does not exceed 400 mg per day for pediatric patients (< 18 years of age) and 600 mg per day for adult patients; and*
6. *Documentation of a recent clinical visit that confirms improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Jason Wilbur motioned to accept the criteria as amended and also the recommended quantity limit, and Jason Kruse seconded. All members were in favor. The recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

CNS Stimulants and Atomoxetine: The Commission reviewed the proposed clinical prior authorization criteria as follows:

Prior authorization (PA) is required for CNS stimulants and atomoxetine for patients 21 years of age or older. Prior to requesting PA for any covered diagnosis, the

prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website. Request must adhere to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations. Payment for CNS stimulants and atomoxetine will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV). Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more current environments (social, academic, or occupational). Documentation of a recent clinical visit that confirms improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD. Adults (≥ 21 years of age) are limited to the use of long-acting agents only. If a supplemental dose with a short-acting agent is needed for an adult in the mid to late afternoon, requests will be considered under the following circumstances: the dose of the long-acting agent has been optimized, documentation is provided a short-acting agent of the same chemical entity is medically necessary (e.g. employed during the day with school in the evening, and will be limited to one unit dose per day. Children (< 21 years of age) are limited to the use of long-acting agents with one unit of a short acting agent per day. Use of an amphetamine agent plus a methylphenidate agent will not be considered for a diagnosis of ADHD.

*Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. *If a non-preferred long-acting medication is requested, a trial with the preferred extended release product of the same chemical entity (methylphenidate class) or chemically related agent (amphetamine class) is required.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Chuck Wadle motioned to accept the criteria as amended, and Jason Wilbur seconded. All members were in favor. The recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Tasimelteon (Hetlioz): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for tasimelteon (Hetlioz®). Requests will be considered when patient has an FDA approved or compendia indication for the requested drug. Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*

2. *Patient has a documented diagnosis of:*
    a. *Non-24-Hour Sleep-Wake Disorder (Non-24); and*
        i. *Patient has a documented trial and therapy failure with at least one preferred sedative/hypnotic-non-benzodiazepine agent; and*
        ii. *Patient has a documented trial and therapy failure with ramelteon (Rozerem®); or*
    b. *Sleep disturbances in Smith-Magenis Syndrome (SMS); and*
        i. *Documentation of confirmed deletion 17p11.2 (cytogenetic analysis or microarray) or RAI1 gene mutation is provided (attach results); and*
        ii. *Patient has a documented trial and therapy failure with at least one other medication used for sleep disturbances; and*
3. *Is prescribed by, or in consultation with a physician who specializes in the treatment of sleep disorders; and*
4. *Will not be used concurrently with other sleep medications.*

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of therapy will be considered under the following conditions:

1. *Patient's use of tasimelteon (Hetlioz®) has been continuous without gaps in treatment; and*
2. *Documentation patient has experienced a positive clinical response to therapy with tasimelteon (Hetlioz®), such as entrainment, significant increases in nighttime sleep, significant decreases in daytime sleep, and/or nighttime sleep quality.*

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Janus Kinase Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for Janus kinase (JAK) inhibitors. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. *Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, biological therapies, or potent immunosuppressants (azathioprine or cyclosporine); and*
2. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
3. *Patient has a diagnosis of:*
    a. *Moderate to severe rheumatoid arthritis (baricitinib, tofacitinib, upadacitinib); with*

i. *A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate; and*
ii. *A documented trial and inadequate response to one preferred TNF inhibitor; OR*

b. *Psoriatic arthritis (tofacitinib, upadacitinib); with*
i. *A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*
ii. *Documented trial and therapy failure with one preferred TNF inhibitor used for psoriatic arthritis; OR*

c. *Moderately to severely active ulcerative colitis (tofacitinib, upadacitinib); with*
i. *A documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and*
ii. *A documented trial and inadequate response with a preferred TNF inhibitor; and*
iii. *If requested dose is for tofacitinib 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit; OR*

d. *Polyarticular Course Juvenile Idiopathic Arthritis (tofacitinib); with*
i. *A documented trial and inadequate response to intraarticular glucocorticoid injections; and*
ii. *A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*
iii. *A documented trial and inadequate response with a preferred TNF inhibitor; OR*

e. *Ankylosing spondylitis (tofacitinib, upadacitinib); with*
i. *A documented trial and inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at a maximally tolerated dose for a minimum of at least one month; and*
ii. *A documented trial and inadequate response with at least one preferred TNF inhibitor; OR*

f. *Atopic dermatitis; with*
i. *Documentation patient has failed to respond to good skin care and regular use of emollients; and*
ii. *A documented adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*
iii. *A documented trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
iv. *For mild to moderate atopic dermatitis (ruxolitinib)*

a. *A documented trial and therapy failure with crisaborole; and*
b. *Affected area is less than 20% of body surface area (BSA); and*
c. *Patient has been instructed to use no more than 60 grams of topical ruxolitinib per week; or*

v. *For moderate to severe atopic dermatitis (abrocitinib, upadacitinib):*
   a. *A documented trial and therapy failure with cyclosporine or azathioprine; and*
   b. *Requests for upadacitinib for pediatric patients 12 to less than 18 years of age must include the patient's weight in kg.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Drug	**Proposed Quantity Limit per 30 Days** (unless otherwise noted)
Cibinqo 50 mg, 100 mg, 100 mg tablet	30
Olumiant 1 mg, 2 mg tablet	30
Opzelura 1.5% cream	240 g (4 tubes)
Rinvoq 15 mg, 30 mg tablet	30
Rinvoq 45 mg tablet	28 per 28 days
Xeljanz 5 mg, 10 mg tablet	60
Xeljanz XR 11 mg, 22 mg tablet	30

Tralokinumab-ldrm (Adbry): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for tralokinumab-ldrm (Adbry). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of moderate to severe atopic dermatitis; and*
3. *Is prescribed by or in consultation with a dermatologist; and*
4. *Patient has failed to respond to good skin care and regular use of emollients; and*
5. *Patient has documentation of an adequate trial and therapy failure with at least one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*

6. *Patient has documentation of a previous trial and therapy failure with a preferred topical immunomodulator for a minimum of 4 weeks; and*
7. *Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and*
8. *Patient will continue with skin care regimen and regular use of emollients.*

If criteria for coverage are met, initial authorization will be given for 16 weeks to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy and documentation patient will continue with skin care regimen and regular use of emollients.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Crisaborole (Eucrisa): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for Eucrisa (crisaborole). Payment will be considered when patient has an FDA approved or compendia indication for the requested drug when the following criteria are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of mild to moderate atopic dermatitis; and*
3. *Patient has failed to respond to good skin care and regular use of emollients; and*
4. *Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*
5. *Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
6. *Patient will continue with skin care regimen and regular use of emollients.*
7. *Quantities will be limited to 60 grams for use on the face, neck, and groin and 100 grams for all other areas, per 30 days.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Extended-Release Formulations: The Commission reviewed the prior authorization criteria as follows:

Payment for a non-preferred extended release formulation will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Previous trial and therapy failure with the preferred immediate release product of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance; and*
3. *Previous trial and therapy failure at a therapeutic dose with a preferred drug of a different chemical entity indicated to treat the submitted diagnosis.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Non-Preferred Drug: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for non-preferred drugs as specified on the Iowa Medicaid Preferred Drug List. Payment for a non-preferred medication will be considered for an FDA approved or compendia indicated diagnosis only for cases in which there is documentation of previous trial and therapy failure with the preferred agent(s), unless evidence is provided that use of these agents would be medically contraindicated. Request must adhere to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations.

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Biologicals for Hidradenitis Suppurativa: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for biologicals FDA approved or compendia indicated for the treatment of Hidradenitis Suppurativa (HS). Payment for non-preferred biologic agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred biologic agent. Patients initiating therapy with a biological agent must:

1. *Be screened for hepatitis B and C. Patients with active hepatitis B will not be considered for coverage; and*

2. *Have not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biologic agent; and*
3. *Not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and*
4. *Be screened for latent TB infection. Patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment.*

Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of moderate to severe HS with Hurley Stage II or III disease; and*
3. *Patient has at least three (3) abscesses or inflammatory nodules; and*
4. *Patient has documentation of adequate trials and therapy failures with the following:*
    a. *Daily treatment with topical clindamycin;*
    b. *Oral clindamycin plus rifampin;*
    c. *Maintenance therapy with a preferred tetracycline*

If criteria for coverage are met, initial requests will be given for 3 months. Additional authorizations will be considered upon documentation of clinical response to therapy. Clinical response is defined as at least a 50% reduction in total abscess and inflammatory nodule count with no increase in abscess count and no increase in draining fistula count from initiation of therapy.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

No further changes were currently recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration. However, Jason Kruse would like more information on the study that was referenced in the public comment presented. Pam Smith will reach out to the manufacturer and provide this to the commission once received.

Ophthalmic Agents for Presbyopia: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for ophthalmic agents indicated for presbyopia. Requests will be considered when patient has an FDA approved or compendia indication for the requested drug. Payment for a non-preferred agent will be considered when there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a documented diagnosis of presbyopia; and*
3. *Patient is aged 40 to 55 years old at start of therapy; and*
4. *Is prescribed by or in consultation with an ophthalmologist or optometrist; and*
5. *Patient has documentation of a therapeutic failure with corrective lenses (eyeglasses or contact lenses), unless contraindicated or clinically significant intolerance.*

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of therapy will be considered under the following conditions:

1. *Patient has a documented improvement in presbyopia defined as the patient gained 3 lines or more in mesopic, high contrast, binocular distance corrected near visual acuity (DCNVA), without losing more than 1 line (5 letters) of corrected distance visual acuity (CDVA); and*

Patient is not experiencing adverse effects from the drug.

No further changes were currently recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Miscellaneous

DUR Digest: The Commission members conducted the second review of DUR Digest Volume 34, Number 2.

MedWatch: The Commission members received FDA announcements concerning new Black Box Warnings.

At 12:25, Jason Kruse motioned to adjourn, and Melissa Klotz and John Ellis both seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for November 2, 2022, location to be determined.

Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes November 2, 2022

Attendees:

Commission Members
Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; John Ellis, Pharm.D.; Jason Wilbur, M.D.; Chuck Wadle, D.O.; Holly Randleman, Pharm.D.; Rhea Hartley, M.D.; Susan Parker, Pharm.D.; and Lisa Todd, R.Ph. Amerigroup.

Staff
Pam Smith, R.Ph.

Guests
Erin Halverson, R.Ph., IME; Gina Kuebler, R.Ph., IME; Melissa Biddle, IME; and Emily Rogers, Pharm.D. Iowa Total Care.

Welcome & Introductions

Chairperson Melissa Klotz called the meeting to order at 9:34 a.m. Due to the current federal state of emergency, continually fluctuating numbers of coronavirus cases in various counties, the need for stability and pre-planning for the public, and due to increased workload of our members directly related to the COVID-19 pandemic, the committee finds that it is impossible/impractical to meet in person for the November 2, 2022, meeting and that it must be held electronically. The minutes from the August 3, 2022, meeting were reviewed. Jason Kruse motioned to accept them, and John Ellis seconded. All members were in favor. The recommendation letter sent to DHS after the last DUR meeting was also reviewed.

IME Pharmacy Update

Providers received Informational Letter 2370-MC-FFS related to PDL and prior authorization criteria changes that went into effect October 1, 2022, following the August P&T and DUR Meetings. There were no additional updates.

Prevalence Report Summaries

Iowa Total Care: Emily Rogers provided an overview for ITC's statistics from June 2022 through August 2022, including: total paid amount ($88,493,857.90); total prescriptions (797,260); and unique users (128,701). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy, Broadlawns, and 3 Walgreens locations made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Caremark Kansas Specialty Pharmacy, Unity Point at Home, Nucara Specialty, and Walgreens Community Pharmacy. The top 5 therapeutic classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Inflammatory; Antiasthmatic and Bronchodilator Agents; and Dermatologicals. The top 5 classes by prescription count were: Antidepressants; Antiasthmatic and Bronchodilator Agents;

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from June 2022 through August 2022, including: total amount paid ($2,513,938), unique users (3,532); cost per user ($711.76), number of total prescriptions dispensed (20,784); and percent generic (88.2%). The top 5 therapeutic classes by paid amount were: Anti-Inflammatories, Non-NSAID; Anticonvulsants; Antipsychotics – Atypicals; Antineoplastics – Protein-Tyrosine Kinase Inhibitors; and Antiretroviral Combinations. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Antihypertensives - Central; and GI – Proton Pump Inhibitor. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Humira Pen, Evrysdi, Biktarvy, Emflaza, and Trulicity. The five drugs with the highest prescription counts were: clonidine hcl, trazodone hcl, sertraline hcl, escitalopram, and omeprazole.

Amerigroup*:* Lisa Todd provided an overview for ITC's statistics from June 2022 through August 2022, including: total paid amount ($129,596,815); total prescriptions (1,134,449); and unique users (172,028). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy and 4 Walgreens locations made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Caremark Kansas Specialty Pharmacy, Caremark Illinois Specialty Pharmacy, Community Walgreens Pharmacy, and Unity Point at Home. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Inflammatory; Antiasthmatic and Bronchodilator Agents; and Dermatologicals. These were the top five classes by prescription count: Antidepressants, Anticonvulsants, Antiasthmatic and Bronchodilator Agents, ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, and Antipsychotics/Antimanic Agents. Humira (CF) Pen was the most expensive medication, followed by Trulicity, Vyvanse, Vraylar, and Trikafta. Sertraline hcl had the highest prescription count, followed by: omeprazole, trazodone hcl, escitalopram, and atorvastatin.

Comparative Prevalence Report Summary

Pam Smith also created a report that compared the FFS stats with those from each MCO. Its side-by-side statistics showed that $ 220,604,611 was spent in total for 304,261 unique users who had 1,952,493 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Humira Pen was the most expensive drug for FFS and both MCO plans. The top 25 drugs by prescription count were also similar across FFS and both MCO plans, with sertraline in the top spot for both MCOs and third for FFS. When all three plans were combined, Jeffrey Wilharm had the overall highest prescription count at 4,483. All three complete prevalence reports and the comparative summary can be found in the finalized meeting packet posted on https://iadur.org on the Meeting Materials page.

Public Comment

In addition to the written public comments provided to Commission members, posted in the finalized meeting packet on https://iadur.org on the Meeting Materials page and summarized below, they heard oral public comment from the speakers shown below.

Name	Representing	Drug/Topic
Bradley Jones	AbbVie	Vraylar
Nila Stevens	Sanofi	Dupixent
Jennifer Kammerer	CSL	Veltassa
Mary Claire Wohletz	Merck	Verquvo

Written Provider Comments: Kerendia, Humira, anticonvulsant quantity limits, Xyway

In response to the comment received regarding issues with anticonvulsant quantity limits, the Iowa Department of Health and Human Services (HHS) will be reviewing the quantity limits, specifically on the lower strengths of lamotrigine, as that appears to be the medication giving providers the most access issues. To eliminate the need to keep multiple strengths on hand, Pam Smith suggested that lamotrigine quantity limits be adjusted to the following to accommodate dosing in pediatric patients:

Drug Product	Quantity	Days' Supply
Lamotrigine 25 MG tab & ODT, 50MG ODT, 100MG tab & ODT	120	30
Lamotrigine 150 MG tab	60	30

Retrospective DUR Data Presentations

LABA without ICS: LABAs as monotherapy increase the risk of asthma-related death and should be prescribed only as additional therapy for patients with asthma who are currently taking but are inadequately controlled on an inhaled corticosteroid (ICS). Salmeterol xinafoate inhalation powder (Serevent Diskus) is the only single-ingredient LABA indicated for the treatment of asthma. Data was run to identify members with an asthma diagnosis and a claim for Serevent Diskus in their pharmacy claims from May through July 2022 that do not have a claim for an ICS. Letters will be sent to prescribers of members using Serevent Diskus without an ICS pointing out the increased risks associated of monotherapy use in the treatment of asthma and recommending the addition of an ICS to Serevent Diskus or switch to a combination LABA/ICS product. This topic will be reviewed again in a year. No PA criteria will be implemented for now.

Retrospective DUR Proposals

Concurrent Use of Opioids and Sedatives: Opioids carry an FDA boxed warning of increased risk of respiratory and CNS depression with concurrent use of opioid and CNS depressants such as antipsychotics or sedatives. Currently, there are no hard POS edits to stop this combination or an automated retrospective claims review process for concurrent use of an opioid and sedative. Questions related to this issue appeared in the FFY21 CMS DUR Survey. As requested at the last meeting, Pam Smith researched to find more information regarding increased harm with specific drug

combinations, along with a more complete list of sedatives that would be included in the claims data search. Dosing will be further split out to identify how many members from those initial findings are on high dose opioids (≥ 90 MME) combined with the listed sedatives below, and results brought back to the next meeting.

- o Chloral hydrate
- o Daridorexant
- o Eszopiclone
- o Lemborexant
- o Phenobarbital
- o Ramelteon
- o Suvorexant
- o Tasimelteon
- o Zaleplon
- o Zolpidem

Underutilization of Beta-Blockers in Heart Failure: Evidence based beta-blocker therapy in patients with HFrEF can reduce all-cause and cardiovascular mortality, sudden cardiac death, and heart failure hospitalizations. Use of a beta-blocker proven to reduce mortality (bisoprolol, carvedilol, or sustained-release metoprolol succinate) in patients with chronic HFrEF is recommended for all adult patients with current or prior symptoms of HFrEF, unless contraindicated or not tolerated. Data will be run to identify members with heart failure with reduced ejection fraction, looking for proven beta-blockers, metoprolol tartrate, and Entresto in their claim histories.

Commission Recommendations for Retrospective DUR Agenda Topics

Jason Kruse suggested looking at Chronic Kidney Disease and Diabetes, as there's a strong recommendation to get people on an SGLT2 early, along with an ACE or ARB, to make providers aware of the firm guidance change.

The Commission took a short break and open session resumed at 10:50 a.m.

Prior Authorization

Annual Review of Prior Authorization (PA) Criteria: The Commission reviewed all categories from the October 1, 2022 PA criteria chart. Changes were suggested for the following categories, to be brought to upcoming meetings for further discussion.

PA Category	Recommended Changes
Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors	Is there a reason concurrent use with PCSK9 Inhibitors is not considered?
Biologicals for Arthritis	Hep B guidance discrepancy between this and other Biologicals categories.
Naloxone Nasal Spray	Allow additional if history of overdose? State that rather than just "other reason"? Discuss abstinence and treatment programs.

Nebivolol (Bystolic) – Removal of Criteria: Due to the availability of a cost effective generic, a recommendation was made to remove PA criteria for nebivolol as follows:

Prior authorization is required for Bystolic. Payment will be considered in cases where there are documented trials and therapy failures with two preferred cardio-selective beta-blockers of a different chemical entity at a therapeutic dose. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Jason Wilbur motioned to remove criteria as recommended and implement the proposed quantity limits below, and Jason Kruse seconded. All members were in favor.

- 2.5 mg, 5 mg, 10 mg tablets – 30 tablets per 30 days
- 20 mg tablet – 60 tablets per 30 days

Potassium Binders – Removal of Criteria: Due to the availability of safer, effective products, a recommendation was made to remove PA criteria (shown below) to allow access to the preferred potassium binders without requiring a trial with sodium polystyrene sulfonate (SPS).

Prior authorization (PA) is required for potassium binders subject to clinical criteria. Payment will be considered under the following conditions:

1. *Patient is 18 years of age or older; and*
2. *Patient has a diagnosis of chronic hyperkalemia; and*
3. *Patient has documentation of a recent trial and therapy failure with sodium polystyrene sulfonate.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Jason Kruse motioned to remove criteria as recommended, and Jason Wilbur seconded. However, they also wanted to implement an age edit (18 years of age or older) and quantity limits on both medications, but leave sodium polystyrene sulfonate preferred so as not to restrict access. Recommended quantity limits: Veltassa (patiromer) - 30 packets per 30 days and Lokelma (sodium zirconium cyclosilicate (34 packets per 30 days). All members were in favor.

Select Topical Psoriasis Agents: The Commission reviewed the newly proposed prior authorization criteria as follows:

Prior authorization is required for select topical psoriasis agents. Payment for a non-preferred agent will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following criteria are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of plaque psoriasis with involvement estimated to affect ≤ 20% of the body surface area; and*
3. *Patient has documentation of an adequate trial and therapy failure of combination therapy with a preferred medium to high potency topical*

corticosteroid and a preferred topical vitamin D analog for a minimum of 4 consecutive weeks.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Rhea Hartley motioned to accept the criteria as recommended and to implement the proposed quantity limit for tapinarof (Vtama) of one 60 g tube per 30 days, and Jason Wilbur seconded. All members were in favor. The recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Initial Days' Supply Limit Override, Benzodiazepines: The Commission reviewed updated, proposed prior authorization criteria as follows:

Requests for medications exceeding the initial days' supply limit require prior authorization. Payment will be considered under the following conditions:

1. *Patient has an FDA approved or compendia indication for the requested drug; and*
2. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
3. *Medical rationale for exceeding the initial days' supply limit is provided; and*
4. *Requests for opioids exceeding the 7 day initial supply limit will be considered:*
    a. *For patients with active cancer, patients experiencing acute sickle cell crises, end-of-life/palliative care, or on an individual case-by-case basis based on medical necessity documentation provided; and*
    b. *Request must meet all other opioid requirements (quantity limits, morphine milligram equivalents (MME), and the preferred drug list (PDL). If requests do not comply with these requirements, separate, additional, prior authorization is required. Please reference and use the following prior authorization (PA) forms at www.iowamedicaidpdl.com where appropriate:*
        i. *Quantity Limit Override Form (exceeds established quantity limit)*
        ii. *High Dose Opioid PA Form (exceeds established MME limit)*
        iii. *Short-Acting Opioids PA Form (non-preferred short-acting opioids)*
        iv. *Long-Acting Opioids PA Form (non-preferred long-acting opioids); or*
5. *Requests for benzodiazepines exceeding the 7 day initial supply limit will be considered:*

a. *For patients with active cancer; end-of-life/palliative care, seizure disorder, or on an individual case-by-case basis based on medical necessity documentation provided; and*
b. *For patients taking concurrent opioids, the prescriber must document the following:*
    i. *The risks of using an opioid and benzodiazepine concurrently have been discussed with the patient; and*
    ii. *Documentation is provided as to why concurrent use is medically necessary; and*
    iii. *A plan to taper the opioid is provided, if appropriate; and*
c. *Request must meet all other benzodiazepine requirements (quantity limit, PDL, etc.). If requests do not comply with these requirements, separate, additional prior authorization is required. Please use the following PA forms at www.iowamedicaidpdl.com where appropriate:*
    i. *Benzodiazepines (non-preferred benzodiazepine)*
    ii. *Quantity Limit Override (as posted at www.iowamedicaidpdl.com under Billing/Quantity Limits); and*

6. *Requests for drugs or drug classes subject to the initial days' supply limit not listed above, will be considered on an individual case-by-case basis, based on medical necessity documentation provided.*

Jason Kruse motioned to accept the criteria as amended, and Rhea Hartley seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

High Dose Opioids: The Commission reviewed the updated, proposed prior authorization criteria as follows:

Prior authorization (PA) is required for use of high-dose opioids ≥ 90 morphine milligram equivalents (MME) per day (See CDC Guideline for Prescribing Opioids for Chronic Pain at https://www.cdc.gov/drugoverdose/prescribing/guideline.html). Patients undergoing active cancer treatment or end-of-life care will not be subject to the criteria below. Payment will be considered when the following is met:

1. *Requests for non-preferred opioids meet criteria for coverage (see criteria for Long-Acting Opioids and/or Short-Acting Opioids); and*
2. *Patient has a diagnosis of severe, chronic pain with a supporting ICD-10 code. Requests for a diagnosis of fibromyalgia or migraine will not be considered; and*
3. *Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and*
4. *Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants); and*
5. *There is documentation demonstrating an appropriate upward titration or an appropriate conversion from other opioid medications; and*

6. *Pain was inadequately controlled at the maximum allowed dose without prior authorization for the requested opioid(s); and*
7. *Pain was inadequately controlled by 2 other chemically distinct preferred long-acting opioids at the maximum allowed dose without prior authorization; and*
8. *Chart notes from a recent office visit or telehealth visit for pain management are included documenting the following:*
    a. *Treatment plan – including all therapies to be used concurrently (pharmacologic and non-pharmacologic); and*
    b. *Treatment goals; and*
9. *Patient has been informed of the risks of high-dose opioid therapy; and*
10. *The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that use of high-dose opioid therapy is appropriate for this patient; and*
11. *The patient's risk for opioid addiction, abuse and misuse has been reviewed and prescriber has determined the patient is a candidate for high-dose opioid therapy; and*
12. *A signed chronic opioid therapy management plan between the prescriber and patient dated within 12 months of this request is included; and*
13. *The requested dosing interval is no more frequent than the maximum FDA-approved dosing interval; and*
14. *Patient has documentation of receipt of an opioid reversal agent (e.g. as seen in pharmacy claims or documentation from the Iowa PMP of dispensation [attach documentation]) within the prior 24 months of high dose opioid request for the emergency treatment of an opioid overdose; and*
15. *Patient has been educated on opioid overdose prevention; and*
16. *Patient's household members have been educated on the signs of opioid overdose and how to administer an opioid reversal agent; and*
17. *Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with initial and subsequent requests; and*
18. *A documented dose reduction is attempted at least annually.*

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of high-dose opioid therapy will be considered every 6 months with the following:

1. *High-dose opioid therapy continues to meet treatment goals, including sustained improvement in pain and function; and*
2. *Patient has not experienced an overdose or other serious adverse event; and*
3. *Patient is not exhibiting warning signs of opioid use disorder; and*
4. *The benefits of opioids continue to outweigh the risks; and*
5. *A documented dose reduction has been attempted at least annually, and the prescriber has determined the dose cannot be reduced at this time; and*
6. *The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that continued use of high-dose opioid therapy is appropriate for this patient; and*

7. *Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with subsequent requests.*
8. *Patient has documentation of receipt of an opioid reversal agent (e.g. as seen in pharmacy claims or documentation from the Iowa PMP of dispensation [attach documentation]) within 24 months of high dose opioid request for the emergency treatment of an opioid overdose; and*
9. *Patient has been reeducated on opioid overdose prevention; and*
10. *Patient's household members have been reeducated on the signs of opioid overdose and how to administer an opioid reversal agent.*

Rhea Hartley motioned to accept the criteria as amended, and Holly Randleman seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion. Pam Smith will research private payor and other Medicaid states' criteria, specifically regarding drug screen requirements, to ensure the above is in line with other payors and states.

Sedative/Hypnotics, Non-Benzodiazepine: The Commission reviewed the updated, proposed prior authorization criteria as follows:

Preferred agents are available without prior authorization (PA) when dosed within the established quantity limits. PA is required for all non-preferred non-benzodiazepine sedative/hypnotics. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of previous trials and therapy failures with, at a minimum, three (3) preferred agents. Payment for non-preferred agent will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following criteria are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *A diagnosis of insomnia; and*
3. *Medications with a side effect of insomnia are decreased in dose, changed to a short acting product, and/or discontinued; and*
4. *Enforcement of good sleep hygiene is documented; and*
5. *All medical, neurological, and psychiatric disease states causing chronic insomnia are being adequately treated with appropriate medication at therapeutic doses; and*
6. *Will not be used concurrently with a benzodiazepine sedative/hypnotic agent.*
7. *In addition to the above criteria, requests for an orexin receptor antagonist will require documentation of a trial and therapy failure with at least one non-preferred agent prior to consideration of coverage.*
8. *Non-preferred alternative delivery systems will only be considered for cases in which the use of the alternative delivery system is medically necessary and there is a previous trial and therapy failure with a preferred alternative delivery system if available.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Vericiguat (Verquvo): The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization is required for vericiguat (Verquvo). Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of symptomatic chronic heart failure (NYHF class II-IV) with a left ventricular ejection fraction (LVEF) ≤ 45%; and*
3. *Patient meets one of the following:*
    a. *Recent hospitalization for heart failure (within the last 6 months); or*
    b. *Recent need for outpatient intravenous diuretics (within the last 3 months); and*
4. *Female patients of reproductive potential have been advised to use effective contraception during treatment and for at least one month after the last dose; and*
5. *Will not be used concomitantly with other soluble guanylate cyclase (sGC) stimulators (e.g. riociguat) or phosphodiesterase type 5 (PDE-5) inhibitors (e.g. sildenafil, tadalafil, vardenafil); and*
6. *Documentation of prior or current therapy, at a maximally tolerated dose, with one drug from each category below:*
    a. *Renin-angiotensin system inhibitor (angiotensin converting enzyme [ACEI], angiotensin receptor blocker [ARB], or angiotensin receptor-neprilysin inhibitor [ARNI]); and*
    b. *Evidence-based beta-blocker (carvedilol, metoprolol succinate, or bisoprolol); and*
    c. *Mineralocorticoid receptor antagonist (MRA); and*
    d. *Sodium-glucose cotransporter 2 inhibitor (SGLT2i) indicated for the treatment of heart failure (empagliflozin or dapagliflozin); and*
7. *Initial requests for vericiguat (Verquvo) 2.5 mg and 5 mg tablets will be limited to one 14-day supply for each strength.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Maralixibat (Livmarli): The Commission reviewed the newly proposed clinical prior authorization criteria as follows:

Prior authorization (PA) is required for maralixibat (Livmarli). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of Alagille syndrome (ALGS) confirmed by genetic testing demonstrating a JAG1 or NOTCH2 mutation or deletion; and*
3. *Patient has cholestasis with moderate to severe pruritus; and*
4. *Is prescribed by or in consultation with a hepatologist, gastroenterologist, or a prescriber who specializes in ALGS; and*
5. *Documentation of previous trials and therapy failures, at a therapeutic dose, with at least two of the following agents:*
    a. *Ursodeoxycholic acid (ursodiol)*
    b. *Cholestyramine*
    c. *Rifampin; and*
6. *Patient's current weight in kilograms (kg) is provided.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will require documentation of an improvement in pruritus symptoms and patient's current weight in kg.

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

PIK3CA-Related Overgrowth Spectrum (PROS) Treatments *(Vijoice):* The Commission reviewed the newly proposed clinical prior authorization criteria as follows:

Prior authorization (PA) is required for alpelisib (Vijoice). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*

2. *Patient has a diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) confirmed by genetic testing demonstrating a PIK3CA mutation; and*
3. *Patient's condition is severe or life-threatening requiring systemic therapy as determined by treating prescriber; and*
4. *Patient has at least one target lesion identified on imaging.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will be considered with documentation of a positive response to therapy as evidenced by a reduction in sum of measurable lesion volume assessed across 1 to 3 target lesions.

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Mavacamten (Camzyos): The Commission reviewed the newly proposed clinical prior authorization criteria as follows:

Prior authorization (PA) is required for mavacamten (Camzyos). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of obstructive hypertrophic cardiomyopathy (HCM); and*
3. *Patient exhibits symptoms of New York Heart Association (NYHA) class II or III symptoms; and*
4. *Is prescribed by or in consultation with a cardiologist; and*
5. *Patient has a left ventricular ejection fraction (LVEF) ≥ 55%; and*
6. *Patient has a peak left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg at rest or with provocation; and*
7. *Documentation of a previous trial and therapy failure, at a maximally tolerated dose, with all of the following:*
    a. *Non-vasodilating beta-blocker (atenolol, metoprolol, bisoprolol, propranolol); and*
    b. *Non-dihydropyridine calcium channel blocker (verapamil, diltiazem); and*
    c. *Combination therapy with disopyramide plus beta-blocker or disopyramide plus a non-dihydropyridine calcium channel blocker.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Dupilumab (Dupixent): The Commission reviewed the proposed clinical prior authorization criteria as follows:

Prior authorization is required for Dupixent (dupilumab). Payment for non-preferred agents will be considered when there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient's current weight in kilograms (kg) is provided; and*
3. *Patient has a diagnosis of moderate-to-severe atopic dermatitis; and*
    a. *Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and*
    b. *Patient has failed to respond to good skin care and regular use of emollients; and*
    c. *Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*
    d. *Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
    e. *Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and*
    f. *Patient will continue with skin care regimen and regular use of emollients; or*
4. *Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) OR with oral corticosteroid dependent asthma; and*
    a. *Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and*
    b. *Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted; and*
    c. *Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g., long acting $beta_2$ agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and*
    d. *Patient must have one of the following, in addition to the regular*

maintenance medications defined above:
    i. Two (2) or more exacerbations in the previous year or
    ii. Require daily oral corticosteroids for at least 3 days; or
5. *Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and*
    a. *Documentation dupilumab will be used as an add-on maintenance treatment; and*
    b. *Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:*
        i. Nasal corticosteroid spray; and
        ii. Oral corticosteroid; or
6. *Patient has a diagnosis of eosinophilic esophagitis (EoE); and*
    a. *Is prescribed by, or in consultation with, an allergist, gastroenterologist, or immunologist; and*
    b. *Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and*
    c. *Patient has signs and symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, food refusal, abdominal pain, heartburn regurgitation, chest pain and/or, odynophagia); and*
    d. *Documentation of previous trials and therapy failures with all of the following:*
        i. High dose proton pump inhibitor (PPI) for at least 8 weeks; and
        ii. Swallowed topical corticosteroid (e.g., fluticasone propionate, oral budesonide suspension); and
        iii. Dietary therapy; and
7. *Dose does not exceed the FDA approved dosing for indication.*

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Viloxazine (Qelbree): The Commission reviewed the proposed clinical prior authorization criteria as follows:

Prior authorization is required for viloxazine (Qelbree). Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV); and*
3. *Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more current environments (social, academic, or occupational) and*
4. *Documentation of a previous trial and therapy failure at a therapeutic dose with atomoxetine; and*
5. *Dose does not exceed 400 mg per day for pediatric patients (< 18 years of age) and 600 mg per day for adult patients; and*
6. *Documentation of a recent clinical visit that confirms improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

CNS Stimulants and Atomoxetine: The Commission reviewed the proposed clinical prior authorization criteria as follows:

Prior authorization (PA) is required for CNS stimulants and atomoxetine for patients 21 years of age or older. Prior to requesting PA for any covered diagnosis, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website. Request must adhere to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations. Payment for CNS stimulants and atomoxetine will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV). Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more current environments (social, academic, or occupational). Documentation of a recent clinical visit that confirms improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD. Adults (≥ 21 years of age) are limited to the use of long-acting agents only. If a supplemental dose with a short-acting agent is needed for an adult in the mid to late afternoon, requests will be considered under the following circumstances: the

dose of the long-acting agent has been optimized, documentation is provided a short-acting agent of the same chemical entity is medically necessary (e.g. employed during the day with school in the evening, and will be limited to one unit dose per day. Children (< 21 years of age) are limited to the use of long-acting agents with one unit of a short acting agent per day. Use of an amphetamine agent plus a methylphenidate agent will not be considered for a diagnosis of ADHD.

*Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. *If a non-preferred long-acting medication is requested, a trial with the preferred extended release product of the same chemical entity (methylphenidate class) or chemically related agent (amphetamine class) is required.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Miscellaneous

DUR Digest: The Commission members conducted the initial review of DUR Digest Volume 35, Number 1.

MedWatch: The Commission members received FDA announcements concerning new Black Box Warnings.

At 11:51, Jason Wilbur motioned to adjourn, and Rhea Hartley and Holly Randleman both seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for February 1, 2023, location to be determined.

Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes February 1, 2023

Attendees:

Commission Members
Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; John Ellis, Pharm.D.; Jason Wilbur, M.D.; Chuck Wadle, D.O.; Holly Randleman, Pharm.D.; Rhea Hartley, M.D.; Susan Parker, Pharm.D.; and Lisa Todd, R.Ph. Amerigroup.
Staff
Pam Smith, R.Ph.
Guests
Erin Halverson, R.Ph., IME; Gina Kuebler, R.Ph., IME; Melissa Biddle, IME; and Emily Rogers, Pharm.D. Iowa Total Care.

Welcome & Introductions

Chairperson Melissa Klotz called the meeting to order at 9:32 a.m. Due to the current federal state of emergency, continually fluctuating numbers of coronavirus cases in various counties, the need for stability and pre-planning for the public, and due to increased workload of our members directly related to the COVID-19 pandemic, the committee finds that it is impossible/impractical to meet in person for the February 1, 2023, meeting and that it must be held electronically. The minutes from the November 2, 2022, meeting were reviewed. Jason Wilbur motioned to accept them, and Jason Kruse seconded. All members were in favor. The recommendation letter sent to DHS after the last DUR meeting was also reviewed, along with a letter from the P&T Committee requesting development of specific prior authorization (PA) criteria for Winlevi, due to the concern of hypothalamic-pituitary-adrenal (HPA) axis suppression and lack of long-term safety data.

IME Pharmacy Update

The federal COVID-19 public health emergency will be ending in May, and informational letters will be sent out regarding unwind plans, providing a minimum of 60 days notification before any changes are implemented or reverted back to standard policy. There were no additional updates.

Prevalence Report Summaries

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from September 2022 through November 2022, including: total amount paid ($2,584,295), unique users (3,850); cost per user ($671.25), number of total prescriptions dispensed (21,450); and percent generic (88.7%). The top 5 therapeutic classes by paid amount were: Anti-Inflammatories, Non-NSAID; Antipsychotics – Atypicals; Anticonvulsants; Antineoplastics – Protein-Tyrosine Kinase Inhibitors; and Muscular Dystrophy Agents. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals;

Antihypertensives - Central; and Antiasthmatic – Beta - Adrenergics. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Humira Pen, Evrysdi, Biktarvy, Vijoice, and Vyvanse. The five drugs with the highest prescription counts were: trazodone hcl, clonidine hcl, sertraline hcl, escitalopram, and omeprazole.

Amerigroup*:* Lisa Todd provided an overview for ITC's statistics from September 2022 through November 2022, including: total paid amount ($121,126,342); total prescriptions (1,083,320); and unique users (180,883). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy and 4 Walgreens locations made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Caremark Kansas Specialty Pharmacy, Community Walgreens Pharmacy, CVS Specialty Pharmacy, and Unity Point at Home. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Inflammatory; Dermatologicals, and Antiasthmatic and Bronchodilator Agents. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, and Antipsychotics/Antimanic Agents. Humira (CF) Pen was the most expensive medication, followed by Trulicity, Vyvanse, Vraylar, and Latuda. Amoxicillin had the highest prescription count, followed by: sertraline hcl, omeprazole, trazodone hcl, and escitalopram.

Iowa Total Care: Emily Rogers provided an overview for ITC's statistics from September 2022 through November 2022, including: total paid amount ($91,554,504.95); total prescriptions (835,803); and unique users (143,112). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy, Broadlawns, and 3 Walgreens locations made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Caremark Kansas Specialty Pharmacy, Walgreens Community Pharmacy, Unity Point at Home, and Nucara Specialty. The top 5 therapeutic classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Inflammatory; Antiasthmatic and Bronchodilator Agents; and Dermatologicals. The top 5 classes by prescription count were: Antidepressants; Antiasthmatic and Bronchodilator Agents; Anticonvulsants; ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; and Antihypertensives. The most expensive drugs were Humira Pen, Trulicity, Vraylar, Vyvanse, and Biktarvy, while amoxicillin, sertraline, omeprazole, trazodone, and atorvastatin had the top 5 prescription counts.

Comparative Prevalence Report Summary

Pam Smith also created a report that compared the FFS stats with those from each MCO. Its side-by-side statistics showed that $ 215,265,142 was spent in total for 327,845 unique users who had 1,940,573 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population.

Humira Pen was the most expensive drug for FFS and both MCO plans. The top 25 drugs by prescription count were also similar across FFS and both MCO plans, with amoxicillin in the top spot for both MCOs. When all three plans were combined, Jeffrey Wilharm had the overall highest prescription count at 4,661. All three complete prevalence reports and the comparative summary can be found in the finalized meeting packet posted on https://iadur.org on the Meeting Materials page.

Public Comment

In addition to the written public comments provided to Commission members, posted in the finalized meeting packet on https://iadur.org on the Meeting Materials page and summarized below, they heard oral public comment from the speakers shown below.

Name	Representing	Drug/Topic
Nila Stevens	Sanofi	Dupixent
Erin Hohman	AbbVie	Orilissa and Oriahnn

Written Provider Comments Received: Dupixent (3 different providers)

Written Manufacturer Comments Received: Qelbree

Retrospective DUR Data Presentations

Concurrent Use of Opioids and Sedatives: Opioids carry an FDA boxed warning of increased risk of respiratory and CNS depression with concurrent use of opioid and CNS depressants such as antipsychotics or sedatives. Currently, there are no hard POS edits to stop this combination or an automated retrospective claims review process for concurrent use of an opioid and sedative. Questions related to this issue appeared in the FFY21 CMS DUR Survey. Pam Smith researched to find more information regarding increased harm with specific drug combinations. Data results were split out to identify how many members are on high doses 90 MME or greater combined with these listed sedatives: chloral hydrate, daridorexant, eszopiclone, lemborexant, phenobarbital, ramelteon, suvorexant, tasimelteon, zaleplon, and zolpidem. Letters will be sent to prescribers of all identified members with claims for a sedative from the list above and an opioid with at least one day overlap from August through October 2022.

Underutilization of Beta-Blockers in Heart Failure: Evidence based beta-blocker therapy in patients with HFrEF can reduce all-cause and cardiovascular mortality, sudden cardiac death, and heart failure hospitalizations. Use of a beta-blocker proven to reduce mortality in patients with chronic HFrEF is recommended for all adult patients with current or prior symptoms of HFrEF, unless contraindicated or not tolerated. Beta-blockers proven to reduce mortality in patients with HFrEF include bisoprolol, carvedilol, or sustained-release metoprolol succinate. Data was run to identify members with heart failure with reduced ejection fraction, looking for proven beta-blockers, metoprolol tartrate, and Entresto in their claim histories. Letters will be sent to prescribers of members with heart failure, without a beta blocker and Entresto recommending the addition of a proven beta blocker and Entresto, if not contraindicated. Letters will also be sent to prescribers of members using metoprolol tartrate and recommend a change to metoprolol succinate.

Retrospective DUR Proposals

Contraindications to Metformin: Metformin use is contraindicated in patients with the following:

- Acute or chronic metabolic acidosis including diabetic ketoacidosis with or without coma
- Severe renal impairment (eGFR below 30 mL/min/1.73 m2)
- Hypersensitivity to metformin

The Commission would like to do a look-back to identify members with acute or chronic metabolic acidosis or severe renal impairment taking metformin, to see how big this issue is before taking further action. Dr. Kruse commented that since SGLT2 medications are relatively new, prescribers were hesitant to change patients to those given issues with side effects, but agreed the evidence-based trials were robust and it was important to get members in line with the current guidelines. Pam Smith will bring results back to the next meeting.

Underutilization of SGLT2i in Type 2 Diabetes and Chronic Kidney Disease: Patients with T2D and CKD are at increased risk of cardiovascular events and progression to kidney failure. Preventative treatment strategies that reduce the risk of both kidney and cardiovascular outcomes are vital. Current guidelines recommend use of a SGLT2i with proven kidney or cardiovascular benefit for patients with T2D, CKD, and eGFR ≥ 20 mL/min/1.73 m2. SGLT2i with proven cardiorenal benefit include canagliflozin, dapagliflozin, and empagliflozin. The Commission would like to pull data to identify adult members with type 2 diabetes (T2D) and chronic kidney disease (CKD) without a sodium-glucose cotransporter 2 inhibitor (SGLT2i) in pharmacy claims, and also look at heart failure. Pam Smith will bring results back to the next meeting.

Commission Recommendations for Retrospective DUR Agenda Topics

There were no additional recommendations.

Prospective DUR

90 Day Supply Limit: The DUR Commisison discussed and recommended a 90-day drug supply allowance of select, cost-effective generic maintenance medications (motion by Holly Randleman, second by Jason Wilbur, and all members in favor). Details of the proposed policy are as follows:

- Dispensing fee - pharmacy gets one dispensing fee per 90-day supply billed.
- Copayment - member gets charged one copay (if applicable) per 90-day supply billed.
- Member exclusions - none
- Initial fill – at discretion of prescriber, but consideration should be given to dispensing less than a 90-day supply with the initial fill when starting members on new medications or with dose adustments to minimize waste.
- 90-day drug selection process – will include select generic products from MediSpan maintenance drug categories.
- Exclusion criteria -
    - Safety – e.g., risks associated with a particular class
    - Controlled substances

    - Narrow therapeutic index (NTI) drugs
    - Drugs subject to frequent dose adjustments
    - OTC drugs
    - Brand drugs
    - PA drug categories (Clinical PA)
    - Nopreferred or nonrecommended drugs
    - Other therapeutic categories – antibiotics, ophthalmic, otic, and topical products
- Initial categories (select, generic drugs) – blood pressure; cholesterol lowering agents; antidepressants; diabetes mellitus
- Review list annually
- No change to the existing lost/stolen/destroyed medication policy
- No change to the existing vacation medication policy.

The Commission took a short break and open session resumed at 11:10 a.m.

Prior Authorization

Viloxazine (Qelbree): The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization is required for viloxazine (Qelbree). Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV); and*
3. *Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more current environments (social, academic, or occupational) and*
4. *Documentation of a previous trial and therapy failure at a therapeutic dose with atomoxetine or a preferred stimulant; and*
5. *Dose does not exceed 400 mg per day for pediatric patients (< 18 years of age) and 600 mg per day for adult patients; and*
6. *Documentation of a recent clinical visit that confirms improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Jason Kruse motioned to accept the criteria as amended, and Chuck Wadle seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Dupilumab (Dupixent): The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization is required for Dupixent (dupilumab). Payment for non-preferred agents will be considered when there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient's current weight in kilograms (kg) is provided; and*
3. *Patient has a diagnosis of moderate-to-severe atopic dermatitis; and*
    a. *Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and*
    b. *Patient has failed to respond to good skin care and regular use of emollients; and*
    c. *Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*
    d. *Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
    e. *Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and*
    f. *Patient will continue with skin care regimen and regular use of emollients; or*
4. *Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) OR with oral corticosteroid dependent asthma; and*
    a. *Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and*
    b. *Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted; and*
    c. *Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g., long acting $beta_2$ agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and*
    d. *Patient must have one of the following, in addition to the regular maintenance medications defined above:*
        i. Two (2) or more exacerbations in the previous year or
        ii. Require daily oral corticosteroids for at least 3 days; or
5. *Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and*
    a. *Documentation dupilumab will be used as an add-on maintenance treatment; and*

b. *Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:*
    i. *Nasal corticosteroid spray; and*
    ii. *Oral corticosteroid; or*

6. *Patient has a diagnosis of eosinophilic esophagitis (EoE); and*
    a. *Is prescribed by, or in consultation with, an allergist, gastroenterologist, or immunologist; and*
    b. *Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and*
    c. *Patient has signs and symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, food refusal, abdominal pain, heartburn regurgitation, chest pain and/or, odynophagia); and*
    d. *Documentation of previous trials and therapy failures with all of the following:*
        i. *High dose proton pump inhibitor (PPI) for at least 8 weeks; and*
        ii. *Swallowed topical corticosteroid (e.g., fluticasone propionate, oral budesonide suspension); and*
        iii. *Dietary therapy; or*
7. *Patient has a diagnosis of moderate to severe prurigo nodularis (PN); and*
    a. *Is prescribed by, or in consultation with an allergist, immunologist, or dermatologist; and*
    b. *Patient has experienced severe to very severe pruritus, as demonstrated by a current Worst Itch-Numeric Rating Scale (WI-NRS) ≥ 7; and*
    c. *Patient has ≥ 20 nodular lesions (attach documentation); and*
    d. *Documentation of a previous trial and therapy failure with a high or super high potency topical corticosteroid for at least 14 consecutive days; and*
8. *Dose does not exceed the FDA approved dosing for indication.*

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Jason Kruse motioned to accept the criteria as amended, and John Ellis seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist, Oral: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for oral gonadotropin-releasing hormone (GnRH) antagonists. Payment for non-preferred oral GnRH antagonists may be considered

only for cases in which there is documentation of a previous trial and therapy failure with the preferred agent. Payment will be considered for patients when the following is met:

1. *Pregnancy has been ruled out; and*
2. *Patient does not have osteoporosis; and*
3. *Request adheres to all FDA approved labeling for requested drug, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
4. *Requests for elagolix (Orilissa) or relugolix, estradiol, norethindrone acetate (Myfembree) will be considered under the following conditions:*
    a. *Patient has a diagnosis of moderate to severe pain associated with endometriosis; and*
    b. *Patient has documentation of a previous trial and therapy failure with at least one preferred oral NSAID and at least one preferred 3-month course of a continuous hormonal contraceptive taken concurrently; and*
    c. *Patient has documentation of a previous trial and therapy failure with a preferred GnRH agonist.*
    d. *Initial requests will be considered for 3 months. Additional requests will be considered upon documentation of improvement of symptoms; and*
    e. *Requests will be considered based on drug, dose, and length of therapy:*
        i. *Orilissa - maximum duration of therapy of 24 months for the 150mg dose and six (6) months for the 200mg dose; or*
        ii. *Myfembree - maximum duration of therapy of 24 months; or*
5. *Requests for elagolix, estradiol, and norethindrone acetate; elagolix (Oriahnn) or relugolix, estradiol, norethindrone acetate (Myfembree) will be considered under the following conditions:*
    a. *Patient is premenopausal; and*
    b. *Patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); and*
    c. *Patient has documentation of a previous trial and therapy failure with at least one preferred 3-month course of a continuous hormonal contraceptive; and*
    d. *Patient has documentation of a previous trial and therapy failure with tranexamic acid.*
    e. *Initial requests will be considered for 6 months. Additional requests will be considered upon documentation of improvement of symptoms.*
    f. *Requests will be considered for a maximum duration of therapy of 24 months.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Rhea Hartley motioned to accept the criteria as amended, and Jason Wilbur seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Janus Kinase Inhibitors: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for Janus kinase (JAK) inhibitors. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug, excluding requests for the FDA approved indication of alopecia areata, vitiligo, or other excluded medical use(s), as defined in Section 1927(d)(2) of the Social Security Act, State Plan, and Rules when the following conditions are met:

1. *Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, biological therapies, or potent immunosuppressants (azathioprine or cyclosporine); and*
2. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
3. *Patient has a diagnosis of:*
    a. *Moderate to severe rheumatoid arthritis (baricitinib, tofacitinib, upadacitinib); with*
        i. *A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate; and*
        ii. *A documented trial and inadequate response to one preferred TNF inhibitor; OR*
    b. *Psoriatic arthritis (tofacitinib, upadacitinib); with*
        i. *A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*
        ii. *Documented trial and therapy failure with one preferred TNF inhibitor used for psoriatic arthritis; OR*
    c. *Moderately to severely active ulcerative colitis (tofacitinib, upadacitinib); with*
        i. *A documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and*
        ii. *A documented trial and inadequate response with a preferred TNF inhibitor; and*
        iii. *If requested dose is for tofacitinib 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit; OR*
    d. *Polyarticular Course Juvenile Idiopathic Arthritis (tofacitinib); with*
        i. *A documented trial and inadequate response to intraarticular glucocorticoid injections; and*
        ii. *A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*

iii. A documented trial and inadequate response with a preferred TNF inhibitor; OR

e. Axial spondyloarthritis conditions (e.g., ankylosing spondylitis or nonradiographic axial spondyloarthritis) (tofacitinib, upadacitinib); with

i. A documented trial and inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at a maximally tolerated dose for a minimum of at least one month; and

ii. A documented trial and inadequate response with at least one preferred TNF inhibitor; OR

f. Atopic dermatitis; with

i. Documentation patient has failed to respond to good skin care and regular use of emollients; and

ii. A documented adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and

iii. A documented trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and

iv. For mild to moderate atopic dermatitis (ruxolitinib)

a. A documented trial and therapy failure with crisaborole; and

b. Affected area is less than 20% of body surface area (BSA); and

c. Patient has been instructed to use no more than 60 grams of topical ruxolitinib per week; or

v. For moderate to severe atopic dermatitis (abrocitinib, upadacitinib):

a. A documented trial and therapy failure with cyclosporine or azathioprine; and

b. Requests for upadacitinib for pediatric patients 12 to less than 18 years of age must include the patient's weight in kg.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Jason Kruse motioned to accept the criteria as amended, and Holly Randleman seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Nebivolol (Bystolic) – Removal of Criteria: Due to the availability of a cost effective generic, a recommendation was made to remove PA criteria for nebivolol as follows:

Prior authorization is required for Bystolic. Payment will be considered in cases where there are documented trials and therapy failures with two preferred cardio-selective beta-blockers of a different chemical entity at a therapeutic dose. The

required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

At the November meeting, the Commission voted to remove criteria as recommended and implement quantity limits.
Quantity Limits

- Bystolic 2.5 mg, 5 mg, 10 mg – 30 tablets per 30 days
- Bystolic 20 mg – 60 tablets per 30 days

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendations will be sent to the Department for consideration.

Potassium Binders – Removal of Criteria: Due to the availability of safer, effective products, a recommendation was made to remove PA criteria (shown below) to allow access to the preferred potassium binders without requiring a trial with sodium polystyrene sulfonate (SPS).

Prior authorization (PA) is required for potassium binders subject to clinical criteria. Payment will be considered under the following conditions:

1. *Patient is 18 years of age or older; and*
2. *Patient has a diagnosis of chronic hyperkalemia; and*
3. *Patient has documentation of a recent trial and therapy failure with sodium polystyrene sulfonate.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

At the November meeting, the Commission voted to remove criteria as recommended, and to implement an age edit and quantity limits on both medications, leaving sodium polystyrene sulfonate preferred so as not to restrict access.

- Age Edit – 18 years of age and older for Lokelma and Veltassa
- Quantity Limit
    - Lokelma – 34 packets per 30 days
    - Veltassa – 30 packets per 30 days

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Select Topical Psoriasis Agents: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization is required for select topical psoriasis agents. Payment for a non-preferred agent will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following criteria are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*

2. *Patient has a diagnosis of plaque psoriasis with involvement estimated to affect ≤ 20% of the body surface area; and*
3. *Patient has documentation of an adequate trial and therapy failure of combination therapy with a preferred medium to high potency topical corticosteroid and a preferred topical vitamin D analog for a minimum of 4 consecutive weeks.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The Commission also recommended to implement a quantity limit for Vtama 1%, 60 g per 30 days. The recommendations will be sent to the Department for consideration.

Initial Days' Supply Limit Override, Benzodiazepines: The Commission reviewed the proposed prior authorization criteria as follows:

Requests for medications exceeding the initial days' supply limit require prior authorization. Payment will be considered under the following conditions:

1. *Patient has an FDA approved or compendia indication for the requested drug; and*
2. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
3. *Medical rationale for exceeding the initial days' supply limit is provided; and*
4. *Requests for opioids exceeding the 7 day initial supply limit will be considered:*
    a. *For patients with active cancer, patients experiencing acute sickle cell crises, end-of-life/palliative care, or on an individual case-by-case basis based on medical necessity documentation provided; and*
    b. *Request must meet all other opioid requirements (quantity limits, morphine milligram equivalents (MME), and the preferred drug list (PDL). If requests do not comply with these requirements, separate, additional, prior authorization is required. Please reference and use the following prior authorization (PA) forms at www.iowamedicaidpdl.com where appropriate:*
        i. *Quantity Limit Override Form (exceeds established quantity limit)*
        ii. *High Dose Opioid PA Form (exceeds established MME limit)*
        iii. *Short-Acting Opioids PA Form (non-preferred short-acting opioids)*
        iv. *Long-Acting Opioids PA Form (non-preferred long-acting opioids); or*

5. *Requests for benzodiazepines exceeding the 7 day initial supply limit will be considered:*
    a. *For patients with active cancer; end-of-life/palliative care, seizure disorder, or on an individual case-by-case basis based on medical necessity documentation provided; and*
    b. *For patients taking concurrent opioids, the prescriber must document the following:*
        i. *The risks of using an opioid and benzodiazepine concurrently have been discussed with the patient; and*
        ii. *Documentation is provided as to why concurrent use is medically necessary; and*
        iii. *A plan to taper the opioid is provided, if appropriate; and*
    c. *Request must meet all other benzodiazepine requirements (quantity limit, PDL, etc.). If requests do not comply with these requirements, separate, additional prior authorization is required. Please use the following PA forms at www.iowamedicaidpdl.com where appropriate:*
        i. *Benzodiazepines (non-preferred benzodiazepine)*
        ii. *Quantity Limit Override (as posted at www.iowamedicaidpdl.com under Billing/Quantity Limits); and*
6. *Requests for drugs or drug classes subject to the initial days' supply limit not listed above, will be considered on an individual case-by-case basis, based on medical necessity documentation provided.*

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

High Dose Opioids: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for use of high-dose opioids ≥ 90 morphine milligram equivalents (MME) per day (See CDC Clinical Practice Guideline for Prescribing Opioids for Pain – United States, 2022 at https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1.htm_w. Patients undergoing active cancer treatment or end-of-life care will not be subject to the criteria below. Payment will be considered when the following is met:

1. *Requests for non-preferred opioids meet criteria for coverage (see criteria for Long-Acting Opioids and/or Short-Acting Opioids); and*
2. *Patient has a diagnosis of severe, chronic pain with a supporting ICD-10 code. Requests for a diagnosis of fibromyalgia or migraine will not be considered; and*
3. *Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and*

4. *Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants); and*
5. *There is documentation demonstrating an appropriate upward titration or an appropriate conversion from other opioid medications; and*
6. *Pain was inadequately controlled at the maximum allowed dose without prior authorization for the requested opioid(s); and*
7. *Pain was inadequately controlled by 2 other chemically distinct preferred long-acting opioids at the maximum allowed dose without prior authorization; and*
8. *Chart notes from a recent office visit or telehealth visit for pain management are included documenting the following:*
    a. *Treatment plan – including all therapies to be used concurrently (pharmacologic and non-pharmacologic); and*
    b. *Treatment goals; and*
9. *Patient has been informed of the risks of high-dose opioid therapy; and*
10. *The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that use of high-dose opioid therapy is appropriate for this patient; and*
11. *The patient's risk for opioid addiction, abuse and misuse has been reviewed and prescriber has determined the patient is a candidate for high-dose opioid therapy; and*
12. *A signed chronic opioid therapy management plan between the prescriber and patient dated within 12 months of this request is included; and*
13. *The requested dosing interval is no more frequent than the maximum FDA-approved dosing interval; and*
14. *Patient has documentation of receipt of an opioid reversal agent (e.g. as seen in pharmacy claims or documentation from the Iowa PMP of dispensation [attach documentation]) within the prior 24 months of high dose opioid request for the emergency treatment of an opioid overdose; and*
15. *Patient has been educated on opioid overdose prevention; and*
16. *Patient's household members have been educated on the signs of opioid overdose and how to administer an opioid reversal agent; and*
17. *Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with initial and subsequent requests; and*
18. *A documented dose reduction is attempted at least annually.*

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of high-dose opioid therapy will be considered every 6 months with the following:

1. *High-dose opioid therapy continues to meet treatment goals, including sustained improvement in pain and function; and*
2. *Patient has not experienced an overdose or other serious adverse event; and*
3. *Patient is not exhibiting warning signs of opioid use disorder; and*
4. *The benefits of opioids continue to outweigh the risks; and*

5. *A documented dose reduction has been attempted at least annually, and the prescriber has determined the dose cannot be reduced at this time; and*
6. *The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that continued use of high-dose opioid therapy is appropriate for this patient; and*
7. *Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with subsequent requests.*
8. *Patient has documentation of receipt of an opioid reversal agent (e.g. as seen in pharmacy claims or documentation from the Iowa PMP of dispensation [attach documentation]) within 24 months of high dose opioid request for the emergency treatment of an opioid overdose; and*
9. *Patient has been reeducated on opioid overdose prevention; and*
10. *Patient's household members have been reeducated on the signs of opioid overdose and how to administer an opioid reversal agent.*

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Miscellaneous

DUR Digest: The Commission members conducted the second review of DUR Digest Volume 35, Number 1.

MedWatch: The Commission members received FDA announcements concerning new Black Box Warnings.

At 11:44, Jason Wilbur motioned to adjourn, and Rhea Hartley seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for May 3, 2023, location to be determined.

Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes May 3, 2023

Attendees:

Commission Members
Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; John Ellis, Pharm.D.; Jason Wilbur, M.D.; Holly Randleman, Pharm.D.; Rhea Hartley, M.D.; Susan Parker, Pharm.D.; and Emily Rogers, Pharm.D. Iowa Total Care.
Staff
Pam Smith, R.Ph.
Guests
Erin Halverson, R.Ph., IME; Gina Kuebler, R.Ph., IME; Melissa Biddle, IME; and Jeannine Murray, R.Ph., Amerigroup.

Welcome & Introductions

Chairperson Melissa Klotz called the meeting to order at 9:35 a.m. Due to the current federal state of emergency, continually fluctuating numbers of coronavirus cases in various counties, the need for stability and pre-planning for the public, and due to increased workload of our members directly related to the COVID-19 pandemic, the committee finds that it is impossible/impractical to meet in person for the May 3, 2023, meeting and that it must be held electronically. The minutes from the February 1, 2023, meeting were reviewed. Jason Wilbur motioned to accept them, and John Ellis seconded. All members were in favor. The recommendation letter sent to DHS after the last DUR meeting was also reviewed.

IME Pharmacy Update

The legislature is still in session, so no update is available yet. Jeannine Murray will be replacing Lisa Todd as the MCO representative for Amerigroup until they refill that position. Emily Rogers will take over as the non-voting MCO committee member, and the MCO representative from Molina will be at the August meeting after their company is onboarded in July.

Prevalence Report Summaries

Amerigroup*:* Jeannine Murray provided an overview for ITC's statistics from December 2022 through February 2023, including: total paid amount ($133,980,502); total prescriptions (1,127,814); and unique users (183,165). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy, 3 Walgreens locations, and 1 Hy-Vee made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Caremark Kansas Specialty Pharmacy, CVS Specialty Pharmacy, Community Walgreens Pharmacy, and Caremark Illinois Specialty Pharmacy. Similar to previous reports, the top 5 therapeutics classes by paid amount were:

Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Inflammatory; Dermatologicals, and Antiasthmatic and Bronchodilator Agents. These were the top five classes by prescription count: Antidepressants, Anticonvulsants, Antiasthmatic and Bronchodilator Agents, ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, and Antipsychotics/Antimanic Agents. Humira (CF) Pen was the most expensive medication, followed by Vyvanse, Vraylar, Trulicity, and Trikafta. Amoxicillin had the highest prescription count, followed by: sertraline, ventolin hfa, omeprazole, and trazodone.

Iowa Total Care: Emily Rogers provided an overview for ITC's statistics from December 2022 through February 2023, including: total paid amount ($98,179,999); total prescriptions (855,791); and unique users (148,185). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy, Broadlawns, and 3 Walgreens locations made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Caremark Kansas Specialty Pharmacy, Walgreens Community Pharmacy, Unity Point at Home, and Nucara Specialty. The top 5 therapeutic classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Inflammatory; Antiasthmatic and Bronchodilator Agents; and Dermatologicals. The top 5 classes by prescription count were: Antidepressants; Antiasthmatic and Bronchodilator Agents; Anticonvulsants; ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; and Antihypertensives. The most expensive drugs were Humira Pen, Trulicity, Vraylar, Vyvanse, and Biktarvy, while amoxicillin, sertraline, ventolin hfa, omeprazole, and trazodone had the top 5 prescription counts.

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from December 2022 through February 2023, including: total amount paid ($2,891,133), unique users (3,826); cost per user ($755.65), number of total prescriptions dispensed (22,068); and percent generic (88.0%). The top 5 therapeutic classes by paid amount were: Anti-Inflammatories, Non-NSAID; Antipsychotics – Atypicals; Anticonvulsants; Antineoplastics – Protein-Tyrosine Kinase Inhibitors; and Antidepressants – Selected SSRIs. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Antihypertensives - Central; and Antiasthmatic – Beta - Adrenergics. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Humira Pen, Verzenio, Vijoice, Evrysdi, and Biktarvy. The five drugs with the highest prescription counts were: clonidine hcl, trazodone hcl, ventolin hfa, sertraline hcl, and escitalopram.

Comparative Prevalence Report Summary

Pam Smith also created a report that compared the FFS stats with those from each MCO. Its side-by-side statistics showed that $ 235,051,634 was spent in total for 335,176 unique users who had 2,005,673 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Humira Pen was the most expensive drug for FFS and both MCO plans. The top 25 drugs by prescription count were also similar across FFS and both MCO plans, with amoxicillin

in the top spot for both MCOs. When all three plans were combined, Jeffrey Wilharm had the overall highest prescription count at 4,644. All three complete prevalence reports and the comparative summary can be found in the finalized meeting packet posted on https://iadur.org on the Meeting Materials page.

Public Comment

In addition to the written public comments provided to Commission members, posted in the finalized meeting packet on https://iadur.org on the Meeting Materials page and summarized below, they heard oral public comment from the speakers shown below.

Name	Representing	Drug/Topic
Cassandra Lickert	Myovant	Myfembree
John Flatt	Marinus	Ztalmy
Shani Patel	Sanofi	Dupixent
Heather Freml	Abbvie	Rinvoq

Written Provider Comments Received: Dupixent

Written Manufacturer Comments Received: Myfembree, Ztalmy, Rinvoq

Retrospective DUR Data Presentations

Contraindications to Metformin: Metformin use is contraindicated in patients with the following:

- Acute or chronic metabolic acidosis including diabetic ketoacidosis with or without coma
- Severe renal impairment (eGFR below 30 mL/min/1.73 m^2)
- Hypersensitivity to metformin

After re-running the data to catch more current member claim information, the Commission would like to send letters to the presribers of members with a contraindication to metformin and a current pharmacy claim, alerting them to the potential contraindication(s) and asking if metformin could be switched to a different drug.

Underutilization of SGLT2i in Type 2 Diabetes, Chronic Kidney Disease, and/or Heart Failure: Patients with T2D in addition to CKD and/or HF are at increased risk of cardiovascular events and progression to kidney failure and/or worsening of HF. Preventative treatment strategies that reduce the risk of both kidney and cardiovascular outcomes are vital. After reviewing results, the Commission wants to provide informational outreach to providers to let them know these medications are preferred and available.

Retrospective DUR Proposals

Antidepressants in Children: The annual federal Drug Utilization Review (DUR) report (Sec. 1927. [42 U.S.C. 1396r–8]) issued by the Centers for Medicare and Medicaid Services (CMS) contains various survey questions relative to drug utilization and practice topics. The most recent survey includes the following questions:

- Does your state have a documented program in place to either manage or monitor the appropriate use of antidepressant drugs in children? If “yes”, does your state either manage or monitor only children in foster care, all children, or other.
- Does your state have edits in place to monitor child’s age, dosage, indication, polypharmacy, other.

The Commission would like to identify members with a claim for an antidepressant where the age is below the FDA approved minimum age for potential educational letters and/or ProDUR age edits. Pam Smith will bring the findings back to the next meeting.

Metabolic Monitoring in Children and Adolescents on Antipsychotics: Use of antipsychotic medications in children and adolescents increases the risk of developing diabetes and high cholesterol that can extend into adulthood. Metabolic monitoring can help ensure early detection and management of these potential complications. This is a current Healthcare Effectiveness Data and Information Set (HEDIS) measure for health care plans. Data will be gathered to help determine if metabolic testing occurred for members ages 0 to 17 who were dispensed an antipsychotic medication in the Iowa Medicaid population. Findings will be brought back to the next meeting.

Commission Recommendations for Retrospective DUR Agenda Topics

There were no additional recommendations.

Prospective DUR

90 Day Supply Limit: The DUR Commisison had the second review of a recommended 90-day drug supply allowance of select, cost-effective generic maintenance medications. Details of the proposed policy are as follows:

- Dispensing fee - pharmacy gets one dispensing fee per 90-day supply billed.
- Copayment - member gets charged one copay (if applicable) per 90-day supply billed.
- Member exclusions - none
- Initial fill – quantity would be at the discretion of prescriber, but consideration should be given to dispensing less than a 90-day supply with the initial fill when starting members on new medications or with dose adustments to minimize waste.
- 90-day drug selection process – will include select generic products from MediSpan maintenance drug categories.
- Exclusion criteria -
    - Safety – e.g., risks associated with a particular class
    - Controlled substances
    - Narrow therapeutic index (NTI) drugs
    - Drugs subject to frequent dose adjustments
    - OTC drugs
    - Brand drugs
    - PA drug categories (Clinical PA)
    - Nopreferred or nonrecommended drugs
    - Other therapeutic categories – antibiotics, ophthalmic, otic, and topical products

- Initial categories (select, generic drugs) – blood pressure; cholesterol lowering agents; antidepressants; diabetes mellitus
- Review list annually
- No change to the existing lost/stolen/destroyed medication policy
- No change to the existing vacation medication supply policy

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

The Commission took a short break and open session resumed at 10:45 a.m.

Prior Authorization

Palivizumab (Synagis): The Commission reviewed the proposed prior authorization criteria as follows:

Respiratory Syncytial Virus (RSV) surveillance is tracked by the national respiratory and enteric virus surveillance system (NREVSS) on the centers for disease control and prevention of the United States department of health and human services website.

1. *Medicaid will use Iowa virology data reported to the NREVSS, as documented under RSV state trends.*
2. *Medicaid will provide coverage of prescription drugs that protect against RSV consistent with the current American Academy of Pediatrics (AAP) Guidelines for Infants and Children at Risk for Severe Illness due to RSV Infection.*
3. *The RSV season in Iowa is predefined as November 1st through March 31st of each RSV season. Prescribers and dispensing pharmacies should monitor state specific virology data and hold administration of palivizumab if data indicates RSV is not prevalent at the beginning of the predefined Iowa RSV season. Consideration of use of palivizumab during interseasonal spread of RSV may be considered by Medicaid with widespread RSV circulation.*

Prior authorization (PA) is required for therapy with palivizumab. PAs will be approved for administration during the RSV season for a maximum of five doses per patient. No allowances will be made for a sixth dose. Patients, who experience a breakthrough RSV hospitalization, in the prior 5 months, should have their monthly prophylaxis discontinued, as there is an extremely low likelihood of a second RSV hospitalization in the same season. Payment for palivizumab will be considered for patients who meet one of the following criteria:

Chronic Lung Disease (CLD) of Prematurity

1. *Patient is less than 12 months of age at start of therapy and has CLD of prematurity (defined as gestational age less than 32 weeks and required greater than 21% oxygen for at least the first 28 days after birth).*
2. *Requests for patients during their second year of life (12 months to < 24 months) will be considered for patients meeting the CLD of prematurity definition above and continue to require medical support (chronic*

corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season.

Prematurity (without CLD of Prematurity or Congenital Heart Disease)

1. *Patient is less than 12 months of age at start of therapy with a gestational age of less than 29 weeks.*

Neuromuscular Disorders or Anatomic Pulmonary Abnormalities

1. *Patient is 12 months of age or younger at the start of therapy and has either severe neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway due to an ineffective cough.*

Hemodynamically Significant Congenital Heart Disease (CHD)

1. *Patient is less than 12 months of age at start of therapy and has hemodynamically significant CHD further defined by any of the following: Acyanotic heart disease receiving medication to control congestive heart failure and will require cardiac surgical procedures, moderate to severe pulmonary hypertension, or cyanotic heart defects with documentation of consultation with a pediatric cardiologist that recommends palivizumab prophylaxis.*

Immunocompromised Children

1. *Patient is less than 24 months of age at start of therapy and is profoundly immunocompromised during the RSV season (e.g., severe combined immunodeficiency, advanced acquired immunodeficiency syndrome, receiving chemotherapy).*

Jason Kruse motioned to accept the criteria as amended, and Jason Wilbur seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy groups for comment and brought back to the next meeting for further discussion.

Naloxone Nasal Spray: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for a patient requiring more than 2 doses of naloxone nasal spray per 365 days. Requests for quantities greater than 2 doses per 365 days will be considered under the following conditions:

1. *Documentation is provided indicating why patient needs additional doses of naloxone nasal spray (accidental overdose, intentional overdose, other reason); and*
2. *Naloxone nasal spray is to be used solely for the patient it is prescribed for; and*
3. *The patient is receiving an opioid as verified in pharmacy claims; and*
4. *Patient has been reeducated on opioid overdose prevention; and*
5. *Documentation is provided on the steps taken to decrease the chance of opioid overdose again; and*
6. *A treatment plan is included documenting a plan to lower the opioid dose.*

Jason Kruse motioned to remove current PA criteria and the current quantity limit to reduce barriers to naloxone. Rhea Hartley seconded, and all members were in favor.

The recommendation will be sent to the medical/pharmacy groups for comment and brought back to the next meeting for further discussion.

IL-5 Antagonists: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization is required for IL-5 antagonists. Requests will not be considered with concurrent use with another monoclonal antibody. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of severe asthma with an eosinophilic phenotype, and*
    a. *Patient has a pretreatment blood eosinophil count of ≥ 150 cells/mcL within the previous 6 weeks or blood eosinophils ≥ 300 cells/ mcL within 12 months prior to initiation of therapy; and*
    b. *Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (long-acting beta2-agonist [LABA] and leukotriene receptor antagonist [LTRA]) for a minimum of 3 consecutive months, with or without oral corticosteroids. Patient must be compliant with therapy, based on pharmacy claims; and*
    c. *Patient has a history of two (2) or more exacerbations in the previous year despite regular use of high-dose ICS plus a LABA and LTRA; and*
    d. *A pretreatment forced expiratory volume in 1 second (FEV_1) < 80% predicted in adults and < 90% in adolescents; or*
3. *Patient has a diagnosis of eosinophilic granulomatosis with polyangiitis, and*
    a. *Patient has documentation of an adequate trial and therapy failure with systemic glucocorticoids; and*
    b. *One of the following:*
        i. *Eosinophil count > 1000 cells/mcL; or*
        ii. *Eosinophil count > 10% of the total leukocyte count; ~~and~~ or*
4. *Patient has a diagnosis of hypereosinophilic syndrome (HES); and*
    a. *Patient has been diagnosed with HES for ≥ 6 months prior to starting treatment; and*
    b. *Documentation that non-hematologic secondary causes of HES have been ruled out; and*
    c. *Documentation patient does not have FIP1L1-PDGFRα kinase-positive HES: and*
    d. *Documentation of ≥ 2 HES flares within the previous 12 months while on stable HES therapy (e.g., chronic or episodic oral corticosteroids, immunosuppressive, or cytotoxic therapy); and*
    e. *Patient has a blood eosinophil count ≥ 1,000 cells/mcL; and*

    f. *Medication will be used in combination with stable doses of at least one other HES therapy; ~~and~~ or*
5. *Patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP); and*
    a. *Documentation mepolizumab will be used as an add-on maintenance treatment with a nasal corticosteroid spray; and*
    b. *Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:*
        i. *Nasal corticosteroid spray; and*
        ii. *Oral corticosteroid; and*
6. *Prescribed by or in consultation with an allergist, hematologist, immunologist, otolaryngologist, pulmonologist, or rheumatologist.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

If criteria for coverage are met, an initial authorization will be given for 3 months for a diagnosis of severe asthma with an eosinophilic phenotype and eosinophilic granulomatosis with polyangiitis or 6 months for a diagnosis of hypereosinophilic syndrome or CRSwNP to assess the need for continued therapy. Requests for continuation of therapy will be based on continued medical necessity and will be considered if one or more of the following criteria are met:
Severe Asthma with an Eosinophilic Phenotype:
1. *Patient continues to receive therapy with an ICS, LABA and LTRA; and*
2. *Patient has experienced a reduction in asthma signs and symptoms including wheezing, chest tightness, coughing, shortness of breath; or*
3. *Patient has experienced a decrease in administration of rescue medication (albuterol); or*
4. *Patient has experienced a decrease in exacerbation frequency; or*
5. *Patient has experienced an increase in predicted FEV_1 from the pretreatment baseline.*

Eosinophilic Granulomatosis with Polyangiitis
1. *Patient has demonstrated a positive clinical response to therapy (increase in remission time).*

Hypereosinophilic Syndrome:
1. *Patient has demonstrated positive clinical response to therapy (improvement of symptoms and/or reduction in the number of flares); and*
2. *Medication continues to be used in combination with stable doses or at least one other HES therapy.*

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
1. *Patient has demonstrated positive clinical response to therapy (improvement in symptoms.); and*
2. *Continues to receive medication as add-on maintenance therapy with a nasal corticosteroid spray.*

Jason Wilbur motioned to accept the criteria as amended, and Rhea Hartley seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy groups for comment and brought back to the next meeting for further discussion.

Select Anticonvulsants: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for select anticonvulsants. Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has an FDA approved or compendia indicated diagnosis, for requested drug, of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, tuberous sclerosis complex, or cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder with documentation of an adequate trial and inadequate response with at least two preferred concomitant antiepileptic drugs (AEDs), if available; and*
3. *Is prescribed by or in consultation with a neurologist; and*
4. *Patient's current weight is provided; and*
5. *The total daily dose does not exceed the following:*
    a. *Cannabidiol*
        i. *Lennox-Gastaut syndrome or Dravet syndrome: 20 mg/kg/day: or*
        ii. *Tuberous sclerosis complex: 25 mg/kg/day; or*
    b. *Fenfluramine*
        i. *With concomitant stiripentol (plus clobazam): 0.4 mg/kg/day with a maximum of 17 mg per day; or*
        ii. *Without concomitant stiripentol: 0.7 mg/kg/day with a maximum of 26 mg per day; or*
    c. *Stiripentol*
        i. *Prescribed concomitantly with clobazam; and*
        ii. *50 mg/kg/day with a maximum of 3,000 mg/day; or*
    d. *Ganaxolone*
        i. *Weight ≤ 28 kg: 63 mg/kg/day; or*
        ii. *Weight > 28 kg: 1800 mg/day.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Rhea Hartley motioned to accept the criteria as amended, and Jason Wilbur seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy groups for comment and brought back to the next meeting for further discussion.

Cyclosporine Ophthalmic Emulsion (Verkazia): The Commission reviewed the newly proposed prior authorization criteria as follows:

Prior authorization (PA) is required for cyclosporine 0.1% ophthalmic emulsion (Verkazia). Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of moderate to severe vernal keratoconjunctivitis (VKC); and*
3. *Documentation of an adequate trial (2 to 3 weeks) and therapy failure with a preferred topical dual-acting mast cell stabilizer/topical antihistamine (e.g., olopatadine, azelastine); and*
4. *Documentation of an adequate trial (2 to 3 weeks) and therapy failure with a preferred topical ophthalmic corticosteroid (e.g., dexamethasone, prednisolone, fluorometholone, loteprednol); and*
5. *Is prescribed by or in consultation with an ophthalmologist or optometrist; and*
6. *Is not prescribed in combination with other ophthalmic cyclosporine products.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Initial requests will be approved for 6 months. Additional authorizations will be considered upon documentation of clinical response to therapy.

The Commission also recommended a quantity limit of 120 single-dose vials (1 box) per 30 days.

Rhea Hartley motioned to accept the criteria and Jason Kruse seconded. All members were in favor.

Topical Acne and Rosacea Products: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is not required for preferred topical acne agents (topical antibiotics and topical retinoids) for members under 21 years of age. PA is required for preferred topical acne agents for members 21 years or older, non-preferred topical acne agents and all topical rosacea agents. Payment will be considered when member has an FDA approved or compendia indication for the requested drug, except for any drug or indication excluded from coverage, as defined in Section 1927 (2)(d) of the Social Security Act, Iowa's CMS approved State Plan, and the Iowa Administrative Code (IAC) when the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Documentation of diagnosis; and*
3. *For the treatment of acne vulgaris, benzoyl peroxide is required for use with a topical antibiotic or topical retinoid; and*

4. *Payment for non-preferred topical antibiotic or topical retinoid acne products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred topical agents of a different chemical entity from the requested topical class (topical antibiotic or topical retinoid); and*
5. *Payment for non-preferred topical acne products outside of the antibiotic or retinoid class (e.g., Winlevi) will be authorized only for cases in which there is documentation of previous trials and therapy failures with a preferred topical retinoid and at least two other topical acne agents. If criteria for coverage are met, initial requests will be approved for six months; and*
6. *Payment for non-preferred topical rosacea products will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred topical agent; and*
7. *Requests for non-preferred combination products may only be considered after documented trials and therapy failures with two preferred combination products; and*
8. *Requests for topical retinoid products for skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive approval with documentation of submitted diagnosis; and*
9. *Duplicate therapy with agents in the same topical class (topical antibiotic or topical retinoid) will not be considered.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Jason Wilbur motioned to accept the criteria as amended, along with a quantity limit of one 60 gram tube per 30 days, and Rhea Hartley seconded. All members were in favor.

Viloxazine (Qelbree): The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization is required for viloxazine (Qelbree). Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV); and*
3. *Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more current environments (social, academic, or occupational) and*
4. *Documentation of a previous trial and therapy failure at a therapeutic dose with atomoxetine or a preferred stimulant; and*
5. *Dose does not exceed 400 mg per day for pediatric patients (< 18 years of age) and 600 mg per day for adult patients; and*

6. *Documentation of a recent clinical visit that confirms improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Dupilumab (Dupixent): The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization is required for Dupixent (dupilumab). Payment for non-preferred agents will be considered when there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient's current weight in kilograms (kg) is provided; and*
3. *Patient has a diagnosis of moderate-to-severe atopic dermatitis; and*
    a. *Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and*
    b. *Patient has failed to respond to good skin care and regular use of emollients; and*
    c. *Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*
    d. *Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
    e. *Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and*
    f. *Patient will continue with skin care regimen and regular use of emollients; or*
4. *Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) OR with oral corticosteroid dependent asthma; and*
    a. *Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and*
    b. *Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted; and*
    c. *Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g., long acting $beta_2$*

agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and

   d. *Patient must have one of the following, in addition to the regular maintenance medications defined above:*
      i. *Two (2) or more exacerbations in the previous year or*
      ii. *Require daily oral corticosteroids for at least 3 days; or*

5. *Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and*
   a. *Documentation dupilumab will be used as an add-on maintenance treatment; and*
   b. *Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:*
      i. *Nasal corticosteroid spray; and*
      ii. *Oral corticosteroid; or*
6. *Patient has a diagnosis of eosinophilic esophagitis (EoE); and*
   a. *Is prescribed by, or in consultation with, an allergist, gastroenterologist, or immunologist; and*
   b. *Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and*
   c. *Patient has signs and symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, food refusal, abdominal pain, heartburn regurgitation, chest pain and/or, odynophagia); and*
   d. *Documentation of previous trials and therapy failures with all of the following:*
      i. *High dose proton pump inhibitor (PPI) for at least 8 weeks; and*
      ii. *Swallowed topical corticosteroid (e.g., fluticasone propionate, oral budesonide suspension); and*
      iii. *Dietary therapy; or*
7. *Patient has a diagnosis of moderate to severe prurigo nodularis (PN); and*
   a. *Is prescribed by, or in consultation with an allergist, immunologist, or dermatologist; and*
   b. *Patient has experienced severe to very severe pruritus, as demonstrated by a current Worst Itch-Numeric Rating Scale (WI-NRS) ≥ 7; and*
   c. *Patient has ≥ 20 nodular lesions (attach documentation); and*
   d. *Documentation of a previous trial and therapy failure with a high or super high potency topical corticosteroid for at least 14 consecutive days; and*
8. *Dose does not exceed the FDA approved dosing for indication.*

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist, Oral: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for oral gonadotropin-releasing hormone (GnRH) antagonists. Payment for non-preferred oral GnRH antagonists may be considered only for cases in which there is documentation of a previous trial and therapy failure with the preferred agent. Payment will be considered for patients when the following is met:

1. *Pregnancy has been ruled out; and*
2. *Patient does not have osteoporosis; and*
3. *Request adheres to all FDA approved labeling for requested drug, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
4. *Requests for elagolix (Orilissa) or relugolix, estradiol, norethindrone acetate (Myfembree) will be considered under the following conditions:*
    a. *Patient has a diagnosis of moderate to severe pain associated with endometriosis; and*
    b. *Patient has documentation of a previous trial and therapy failure with at least one preferred oral NSAID and at least one preferred 3-month course of a continuous hormonal contraceptive taken concurrently; and*
    c. *Patient has documentation of a previous trial and therapy failure with a preferred GnRH agonist.*
    d. *Initial requests will be considered for 3 months. Additional requests will be considered upon documentation of improvement of symptoms; and*
    e. *Requests will be considered based on drug, dose, and length of therapy:*
        i. *Orilissa - maximum duration of therapy of 24 months for the 150mg dose and six (6) months for the 200mg dose; or*
        ii. *Myfembree - maximum duration of therapy of 24 months; or*
5. *Requests for elagolix, estradiol, and norethindrone acetate; elagolix (Oriahnn) or relugolix, estradiol, norethindrone acetate (Myfembree) will be considered under the following conditions:*
    a. *Patient is premenopausal; and*
    b. *Patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); and*
    c. *Patient has documentation of a previous trial and therapy failure with at least one preferred 3-month course of a continuous hormonal contraceptive; and*
    d. *Patient has documentation of a previous trial and therapy failure with tranexamic acid.*

e. *Initial requests will be considered for 6 months. Additional requests will be considered upon documentation of improvement of symptoms.*
f. *Requests will be considered for a maximum duration of therapy of 24 months.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Janus Kinase Inhibitors: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for Janus kinase (JAK) inhibitors. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug, excluding requests for the FDA approved indication of alopecia areata, vitiligo, or other excluded medical use(s), as defined in Section 1927(d)(2) of the Social Security Act, State Plan, and Rules when the following conditions are met:

1. *Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, biological therapies, or potent immunosuppressants (azathioprine or cyclosporine); and*
2. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
3. *Patient has a diagnosis of:*
    a. *Moderate to severe rheumatoid arthritis (baricitinib, tofacitinib, upadacitinib); with*
        i. *A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate; and*
        ii. *A documented trial and inadequate response to one preferred TNF inhibitor; OR*
    b. *Psoriatic arthritis (tofacitinib, upadacitinib); with*
        i. *A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*
        ii. *Documented trial and therapy failure with one preferred TNF inhibitor used for psoriatic arthritis; OR*
    c. *Moderately to severely active ulcerative colitis (tofacitinib, upadacitinib); with*
        i. *A documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and*
        ii. *A documented trial and inadequate response with a preferred TNF inhibitor; and*

iii. *If requested dose is for tofacitinib 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit; OR*

d. *Polyarticular Course Juvenile Idiopathic Arthritis (tofacitinib); with*
   i. *A documented trial and inadequate response to intraarticular glucocorticoid injections; and*
   ii. *A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*
   iii. *A documented trial and inadequate response with a preferred TNF inhibitor; OR*
e. *Axial spondyloarthritis conditions (e.g., ankylosing spondylitis or nonradiographic axial spondyloarthritis) (tofacitinib, upadacitinib); with*
   i. *A documented trial and inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at a maximally tolerated dose for a minimum of at least one month; and*
   ii. *A documented trial and inadequate response with at least one preferred TNF inhibitor; OR*
f. *Atopic dermatitis; with*
   i. *Documentation patient has failed to respond to good skin care and regular use of emollients; and*
   ii. *A documented adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*
   iii. *A documented trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
   iv. *For mild to moderate atopic dermatitis (ruxolitinib)*
      a. *A documented trial and therapy failure with crisaborole; and*
      b. *Affected area is less than 20% of body surface area (BSA); and*
      c. *Patient has been instructed to use no more than 60 grams of topical ruxolitinib per week; or*
   v. *For moderate to severe atopic dermatitis (abrocitinib, upadacitinib):*
      a. *A documented trial and therapy failure with cyclosporine or azathioprine; and*
      b. *Requests for upadacitinib for pediatric patients 12 to less than 18 years of age must include the patient's weight in kg.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Miscellaneous

DUR Digest: The Commission members conducted the first review of DUR Digest Volume 35, Number 2.

MedWatch: The Commission members received FDA announcements concerning new Black Box Warnings.

At 11:47, Rhea Hartley motioned to adjourn, and Jason Wilbur seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for August 2, 2023, location to be determined.

Appendix J
Recommendations to the P&T

P & T Recommendations
SFY23

The DUR Commission makes recommendations to the Iowa Medicaid Pharmaceutical & Therapeutics (P&T) Committee regarding the status of a medication on the Preferred Drug List (PDL) as issues arise. During the time period for this report there were no recommendations made to the P&T Committee.

Appendix K
Useful Links

Iowa Drug Utilization Review (DUR) Commission
Useful Links

DUR Website
http://iadur.org/

DUR Newsletters
http://iadur.org/newsletters

Prevalence Reports
To view prevalence reports, visit the link below under Packets. Each packet includes the bi-monthly prevalence report reviewed by the DUR Commission.
http://iadur.org/agendas