Department of
HUMAN SERVICES

Iowa Medicaid Drug Utilization Review Commission Annual Report of Activities Fee-for-Service Program SFY21

September 2021

TABLE OF CONTENTS

The Iowa Medicaid Drug Utilization Review Commission

Change Healthcare has developed the following report for the Iowa Department of 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 2020 through June 2021.

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 DHS 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 than10 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 were well underway this past state fiscal year. 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 review of the monthly paid claims report, from review of the quarterly prevalence report, from reviews of medical literature, or 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 Human Services (DHS) 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 DHS or at the Commission's discretion. All authority to accept or reject DUR Commission recommendations lies with the DHS. 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 SFY21 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 $6,289.35*. 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	$6,289.35*

Patient-focused reviews resulted in $5,733.75* in direct cost savings, or $229.35* per patient evaluated. This estimate is based on the 28 suggestions made by the DUR Commission identified from the review of the medication therapy of 25 patient profiles selected for intervention. Of these 28 suggestions, 11 suggestions were implemented by the providers, resulting in a 39 percent impact rate.

Patient-Focused Profile Review

Suggestions Made	28
Therapy Changed	11
IMPACT RATE	39%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated	$229.35*
Dollars Saved on Medication	$5,733.75*

*Savings reported are pre-rebate, total dollars

Problem-focused reviews resulted in an estimated cost savings of $555.60* or $50.51 saved per patient evaluated. This estimate is based on the review of profiles with 11 patients selected for interventions. Therapy was changed for 4 patients, resulting in an impact rate of 36 percent. These interventions are informative in nature.

Problem-Focused Profile Review	
Patients Evaluated	11
Therapy Changed	4
IMPACT RATE	36%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated	$50.51*
Dollars Saved on Medication	$555.60*

Comparison to Previous SFY Report

Cost savings estimates for SFY21 ($*6,289.35) are slightly lower than last year ($9,939.36*). 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 SFY21 patient-focused reviews ($5,733.75*) were lower than SFY20 ($9,939.36*). The number of suggestions made (28) vs. (19) increased while the number of suggestions that were accepted (11) vs. (8) from SFY20 also increased. 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. One theory could be, due to the voluntary participation of the prescriber and lack of the ability to enforce the educational recommendations made by the DUR Commission, 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 SFY21 ($555.60*) were higher than SFY20 ($0*). This was due to the collaboration between FFS and MCOs to conduct multiple problem-focused review interventions related to drug therapy issues whereas last year there was a single problem-focused review intervention.

*Savings reported are pre-rebate, total dollars

Results by Review Type

Patient-Focused Review

During this evaluation period, 61 educational intervention letters were mailed to prescribers and pharmacies regarding medication therapy. Of this total, 32 letters (52 percent) were mailed to prescribers, and 29 letters (48 percent) were mailed to pharmacies. Providers are invited to voluntarily respond to DUR Commission letters. Providers returned 26 responses to these letters, resulting in an overall response rate by the providers of 43 percent. Of the 26 responses, 10 (38 percent) were from prescribers and 16 (62 percent) were from pharmacies. The overall response rate differed between physicians and pharmacies; 31 percent for physicians and 55 percent for pharmacies.

In these 61 educational letters, the DUR Commission made 28 suggestions. Of these suggestions, 27 (96 percent) were therapeutic in nature while 1 (4 percent) was cost-saving in nature. The suggested change was implemented in 11 cases, resulting in an overall impact rate of 39 percent.

Of the 28 suggestions, three types of suggestions accounted for 100 percent of the total. Those three suggestions were Not Optimal Dosage Form (4 percent), Unnecessary Drug Therapy (4 percent) and Therapeutic Duplication (93 percent). Of the 11 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 (42 percent).

Implementation of therapeutic suggestions resulted in direct drug cost savings of $5,733.75*. Zero cost-savings suggestions were implemented based on the one cost-savings suggestion, resulting in zero direct drug cost savings*. The total amount saved on medication utilization was calculated to be $5,733.75* for the 25 patients evaluated, or $229.35* per patient.

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

Problem-Focused Reviews

Five problem-focused reviews were evaluated during SFY21. In conducting these reviews, 11 patients were selected for intervention. Of these patients, 4 cases showed evidence of a positive outcome, resulting in an impact rate of 36 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 SFY21, 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.

Jason Kruse, D.O. completed his first term on the DUR in June 2021 and was reappointed for a second term, expiring in June 2025.

Melissa Klotz, Pharm.D. completed her first term on the DUR in June 2021 and was reappointed for a second term, expiring in June 2025.

Emily Rogers, Pharm.D. completed her two year term on the Commission as the MCO representative, in June 2021.

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.

*Savings reported are pre-rebate, total dollars

The Iowa Medicaid Drug Utilization Review Mental Health Advisory Group (MHAG) was established in SFY 2008. Descriptions of the program, as well as meeting minutes are found in Appendix J.

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 K.

Links to useful items regarding the DUR Commission can be found in Appendix L, 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
2020-2021

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; his first term will expire in June 2023.

Brett Faine, Pharm.D.
Dr. Faine is a Clinical Pharmacy Specialist in Emergency Medicine at the University of Iowa Hospital. He serves as a preceptor to residents and Pharm.D. students in the Emergency Treatment Center. Dr. Faine received his Pharm.D. degree from the University of Iowa and completed an ASHP-accredited PGY1 Pharmacy Residency at the University of Iowa Hospitals and Clinics. Dr. Faine was reappointed for a third term in 2018, which will expire in June 2022.

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.

Kellen Ludvigson, Pharm.D.
Dr. Ludvigson graduated with distinction from the University of Iowa College of Pharmacy in 2007. He is currently employed as a retail pharmacist at Cherokee Main Street Pharmacy and does relief work for the Cherokee Mental Health Institute in Cherokee. Dr. Ludvigson also serves on the Iowa Medicaid P&T Committee. Dr. Ludvigson was reappointed to the DUR for a third term in 2020, which will expire in June 2024.

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.

Emily Rogers, Pharm.D.
Dr. Rogers has been the Director of Pharmacy for Iowa Total Care since October 2019. Prior to her role at Iowa Total Care, Dr. Rogers served in many roles as a pharmacist. She was the Director of Pharmacy for Mahaska Health Partnership, the Outpatient Pharmacy Supervisor for Broadlawns Medical Center, and a Pharmacy Manager for Hy-Vee. Dr. Rogers is a graduate of Drake University, earning a Doctor of Pharmacy and a Master's in Business Administration. Dr. Rogers serves on the DUR Commission as the MCO Pharmacy Director representative, which rotates among the MCOs every 2 years. Dr. Rogers two year term ended in June 2021.

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. He was appointed to the DUR Commission in 2018; his first term will expire in June 2022.

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
SFY21

Patient Focused Profile Review

Suggestions Made	28
Therapy Changed	11
Impact Rate	39.29%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated*	$229.35
Dollars Saved on Medication*	$5,733.75

Problem-Focused Profile Review

Suggestions Made	11
Therapy Changed	4
Impact Rate	36.36%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated*	$50.51
Dollars Saved on Medication*	$555.60

Cost Savings Estimate*	**$6,289.35**

*Savings reported are pre-rebate, total dollars

Appendix D
Results Patient-Focused

FFS Patient - Focused Reviews
SFY21

Initial Review Date	**October 2019 - September 2020**			
Re-review Date	**July 2020 - June 2021**			
Patient Profiles Reviewed	243			
Patient Profiles Selected for Intervention	25			
Intervention Letters Sent				
Prescribers	32	52.46%		
Pharmacists	29	47.54%		
Total	**61**	100%		
Responses Received				
Prescribers	10	38.46%	**Overall Response Rate**	**42.62%**
Pharmacists	16	61.54%	Prescriber Response Rate	31.25%
Total	**26**	100.00%	Pharmacy Response Rate	55.17%
Total Number of Suggestions				
Therapeutic	27	96.43%		
Cost-Saving	1	3.57%		
Total	**28**	100%		
Total Number of Changes				
Therapeutic	11	100.00%	**Impact Rate**	**39.29%**
Cost-Saving	0	0.00%		
Positive Impact Only	0	0.00%		
Total	**11**	100%		

FFS Patient - Focused Review
Month by Month Breakdown
SFY21

Initial Review Date Evaluation Date	Nov-19 Aug-20	Feb-20 Nov-20	May-20 Feb-21	Aug-20 May-21	Total
Profiles Reviewed	60	67	61	55	**243**
Patient Profiles Available for Evaluation	3	9	8	5	**25**
Total Number of Suggstions Made	3	11	9	5	**28**
Therapeutic	3	11	9	4	**27**
Cost Saving	0	0	0	1	**1**
Total Number of Changes Made	2	3	5	1	**11**
Therapeutic	2	3	5	1	**11**
Cost Saving	0	0	0	0	**0**
Positive Impact Only	0	0	0	0	**0**
Total Dollars Saved - Therapeutic Changes	$234.12	$276.03	$5,029.92	$193.68	**$5,733.75**
Total Dollars Saved - Cost Saving	$0.00	$0.00	$0.00	$0.00	**$0.00**
Total Dollars Saved on Medication*	$234.12	$276.03	$5,029.92	$193.68	**$5,733.75**
Total Dollars Saved per Profile Evaluated	$78.04	$30.67	$628.74	$38.74	$229.35

*Savings reported are pre-rebate total dollars.

FFS Medicaid DUR Impact Assessment
Report Patient-Focused Reviews SFY21

Initial Review Date Evaluation Date	Nov-19 Aug-20	Feb-20 Nov-20	May-20 Feb-21	Aug-20 May-21	**Total**	
Profiles Reviewed	60	67	61	55	**243**	
Profiles Evaluated	3	9	8	5	**25**	
Letters Sent	7	22	20	12	**61**	100.00%
Prescribers	4	11	10	7	32	52.46%
Pharmacy	3	11	10	5	29	47.54%
Responses Received	0	12	11	3	**26**	100.00%
Prescribers	0	5	4	1	10	38.46%
Pharmacy	0	7	7	2	16	61.54%
Total Number of Templates Mentioned	3	11	9	5	**28**	100.00%
Therapeutic	3	11	9	4	27	96.43%
Cost-Saving	0	0	0	1	1	3.57%
Total Number of Changes Made	2	3	5	1	**11**	100.00%
Therapeutic	2	3	5	1	11	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	$234.12	$276.03	$5,029.92	$193.68	**$5,733.75**	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*	$234.12	$276.03	$5,029.92	$193.68	**$5,733.75**	100.00%
Total Dollars Saved Per Profile Evaluated	$78.04	$30.67	$628.74	$38.74	**$229.35**	

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

Comment Type
FFS Patient Focused Reviews
SFY21

Initial Review Date	**Nov-19**		**Feb-20**		**May-20**		**Aug-20**			
Evaluation Date	**Aug-20**		**Nov-20**		**Feb-21**		**May-21**		**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	1	0	1	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	3	2	11	3	8	5	4	1	26	11
Unnecessary Drug Therapy	0	0	0	0	1	0	0	0	1	0
Total	**3**	**2**	**11**	**3**	**9**	**5**	**5**	**1**	**28**	**11**

FFS Patient Focused Reviews
SFY21

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	1	0	3.57%	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%	#DIV/0!	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	26	11	92.86%	100.00%	42.31%	100.00%
Unnecessary Drug Therapy	1	0	3.57%	0.00%	0.00%	0.00%
Total	**28**	**11**	100.00%	100.00%	**39.29%**	100.00%

FFS Savings By Template Class

SFY21

Initial Review Date Evaluation Date	Nov-19 Aug-20	Feb-20 Nov-20	May-20 Feb-21	Aug-20 May-21	**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	$234.12	$276.03	$5,029.92	$193.68	$5,733.75
Unnecessary Drug Therapy	$0.00	$0.00	$0.00	$0.00	$0.00
Total	**$234.12**	**$276.03**	**$5,029.92**	**$193.68**	**$5,733.75**

*additional cost but positive impact assumed

Appendix E
Results Problem-Focused

FFS Problem-Focused Studies Impact Rate
SFY 2021

Focus	Review Period	Evaluation Period	Patients Evaluated	Positive Impact	Impact Rate
Duplicate SSRIs	01/01/2020 - 02/29/2020	01/01/2021 - 02/28/2021	3	3	100.00%
Duplicate SNRIs	06/01/2020 - 07/31/2020	06/01/2021 - 07/31/2021	1	1	100.00%
Concurrent Use of Baclofen and Opioid	06/01/2020 - 07/31/2020	06/01/2021 - 07/31/2021	5	0	0.00%
Baclofen Dose > 80 mg per Day	07/01/2020 - 07/31/2020	07/01/2021 - 07/31/2021	2	0	0.00%
High Dose Gabapentin	07/01/2020 - 07/31/2020	07/01/2021 - 07/31/2021	0	0	0.00%
TOTAL			**11**	**4**	**36.36%**

FFS Problem-Focused Studies
SFY 2021

Focus	Review Period	Evaluation Period	Patients Reviewed	Patients Selected	Cost Savings Calculated
Duplicate SSRIs	01/01/2020 - 02/29/2020	01/01/2021 - 02/28/2021	3	3	$238.56
Duplicate SNRIs	06/01/2020 - 07/31/2020	06/01/2021 - 07/31/2021	1	1	$317.04
Concurrent Use of Baclofen and Opioid	06/01/2020 - 07/31/2020	06/01/2021 - 07/31/2021	5	5	$0.00
Baclofen Dose > 80 mg per Day	07/01/2020 - 07/31/2020	07/01/2021 - 07/31/2021	2	2	$0.00
High Dose Gabapentin	07/01/2020 - 07/31/2020	07/01/2021 - 07/31/2021	0	0	$0.00
TOTAL			**11**	**11**	**$555.60** *

*Savings reported are pre-rebate, total dollars.

Appendix F
Descriptions Problem-Focused

Description of Problem Focused Studies
SFY21

Duplicate SSRIs

- Identify members with concurrent use of two or more chemically distinct SSRIs.

Duplicate SNRIs

- Identify members with concurrent use of two or more chemically distinct SNRIs.

Concurrent Use of Baclofen and Opioid

- Identify members with concurrent use of baclofen and an opioid(s).

Baclofen Dose Greater than 80 mg per day

- Identify members exceeding the maximum recommended daily dose of 80 mg baclofen.

High Dose Gabapentin

- Identify members exceeding the maximum recommended daily dose of 3,600 mg gabapentin.

Appendix G
Prior Authorization Recommendations

Prior Authorization Criteria Review
SFY21

During the fiscal year ending 2021, 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
08/05/2020	• Cystic Fibrosis Agents, Oral • Voxelotor (Oxbryta)	• Valsartan/Sacubitril (Entresto) • Direct Oral Anticoagulants • IL-5 Antagonists	• Insulin, Pre-Filled Pens
11/04/2020	• Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors • Peanut Allergen Powder-dnfp (Palforzia)	• Acute Migraine Treatments • Pirfenidone (Esbriet)/Nintedanib (Ofev)	
03/03/2021	• Select Anticonvulsants • Satralizumab (Enspryng)	• Elagolix Products	
05/05/2021	• Risdiplam (Evrysdi)	• Binge Eating Disorder • IL-5 Antagonists • Isotretinoin (Oral) • Multiple Sclerosis Agents, Oral • Nonsteroidal Anti-Inflammatory Drugs	• Alpha$_2$ Agonists, Extended Release

IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

611 5th Avenue – Des Moines, IA 50309 □ (515) 974-3131 □ Fax 1-866-626-0216

Brett Faine, Pharm.D.
Melissa Klotz, Pharm.D.
Jason Kruse, D.O
Kellen Ludvigson, Pharm.D.
Susan Parker, R.Ph., Pharm.D.
Jason Wilbur, M. D.
Charles Wadle, D.O.
John Ellis, Pharm.D.

Professional Staff: Pam Smith, R.Ph.
DUR Project Coordinator

August 6, 2020

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
611 5th Avenue
Des Moines, Iowa 50309

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, August 5, 2020. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Cystic Fibrosis Agents, Oral; Valsartan/Sacubitril (Entresto); Direct Oral Anticoagulants; Voxelotor (Oxbryta); IL-5 Antagonists; and removal of PA criteria for Insulin, Pre-Filled Insulin Pens. Additionally, the DUR Commission members recommended changes to the DUR Public Comment Policy that will be reflected on the DUR website, www.iadur.org, and in the DUR Policy and Procedures. The following recommendations have been made by the DUR Commission:

Comments were received and reviewed from the medical/pharmacy associations in response to a March 17, 2020 letter that was sent to them detailing the proposed criteria for Cystic Fibrosis Agents, Oral; Valsartan/Sacubitril (Entresto); Direct Oral Anticoagulants; Voxelotor (Oxbryta); IL-5 Antagonists; and removal of PA criteria for Insulin, Pre-Filled Insulin Pens.

Cystic Fibrosis Agents, Oral (Applies to Kalydeco, Orkambi, Symdeko, and Trikafta)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for oral cystic fibrosis agents. Payment will be considered for patients when the following criteria are met:

1. Patient meets the FDA approved age; and
2. Patient has a diagnosis of cystic fibrosis (CF); and
3. Patient has a mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene confirmed by an FDA-cleared CF mutation test (attach test results) for which the requested drug is indicated; and
4. Prescriber is a CF specialist or pulmonologist; and
5. Baseline liver function tests (AST, ALT, and bilirubin) are provided; and

6. Requests for Trikafta will not be considered for patients with severe hepatic impairment (Child-Pugh Class C); and
7. Will not be used with other CFTR modulator therapies.

If the criteria for coverage are met, an initial authorization will be given for 6 months. Additional approvals will be granted if the following criteria are met:

1. Adherence to oral cystic fibrosis therapy is confirmed; and
2. Liver function tests (AST, ALT, and bilirubin) are assessed every 3 months during the first year of treatment and annually thereafter.

Valsartan/Sacubitril (Entresto)

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization (PA) is required for valsartan/sacubitril (Entresto). Requests above the manufacturer recommended dose will not be considered. Payment will be considered for patients when the following criteria are met:

1. *Patient is within the FDA labeled age for indication; and*
2. Patient has a diagnosis of NYHA Functional Class II, III, or IV heart failure; and
   ~~a. Patient is 18 years of age or older; and~~
   b. Patient has a left ventricular ejection fraction (LVEF) ≤40%; and
   c. Patient is currently tolerating treatment with an ACE inhibitor or angiotensin ll receptor blocker (ARB) at a therapeutic dose, where replacement with valsartan/sacubitril is recommended to further reduce morbidity and mortality; and
   d. Is to be administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB (list medications patient is currently taking for the treatment of heart failure); *or* ~~and~~
3. *Pediatric patient has a diagnosis of symptomatic heart failure (NYHA/Ross Class II to IV) due to systemic left ventricular systolic dysfunction with documentation of a left ventricular ejection fraction ≤ 40%; and*
4. Will not be used in combination with an ACE inhibitor or ARB; and
5. Will not be used in combination with aliskiren (Tekturna) in diabetic patients; and
6. Patient does not have a history of angioedema associated with the use of ACE inhibitor or ARB therapy; and
7. Patient is not pregnant; and
8. Patient does not have severe hepatic impairment (Child Pugh Class C)*.*~~; and~~
~~9. Prescriber is a cardiologist or has consulted with a cardiologist (telephone consultation is acceptable).~~

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

Direct Oral Anticoagulants (formerly Novel Oral Anticoagulants)

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization (PA) is not required for preferred ~~novel~~ *direct* oral anticoagulants (~~N~~*DOACs*). PA is required for non-preferred ~~N~~*D*OACs. *Requests will be considered for FDA approved dosing and length of therapy for submitted diagnosis* Requests for doses outside of the manufacturer recommended dose will not be considered. Payment will be considered for FDA approved or compendia indications *for the requested drug* under the following conditions:

1. *Patient is within the FDA labeled age for indication; and*
2. Patient does not have a mechanical heart valve; and
3. Patient does not have active bleeding; and
4. For a diagnosis of atrial fibrillation or stroke prevention, patient has the presence of at least one additional risk factor for stroke, with a CHA_2DS_2-VASc score ≥1; and
5. A recent creatinine clearance (CrCl) is provided; and
6. A recent Child-Pugh score is provided; and
7. Patient's current body weight is provided; and
8. Patient has documentation of a trial and therapy failure at a therapeutic dose with at least two preferred ~~N~~*NDOACs; and*~~.~~
9. For requests for edoxaban, *when prescribed for the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE),* documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin) *is provided*.

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

Voxelotor (Oxbryta)

Newly Proposed Clinical Prior Authorization Criteria
Prior authorization is required for Oxbryta (voxelotor). Payment will be considered for patients when the following criteria are met:

1. Patient meets the FDA approved age; and
2. Patient has a diagnosis of sickle cell disease (SCD); and
3. Requested dose is within the FDA approved dosing; and
4. Patient has experienced at least two sickle cell-related vasoocclusive crises within the past 12 months (documentation required); and
5. Patient has documentation of an adequate trial and therapy failure with hydroxyurea; and
6. Baseline hemoglobin (Hb) range is ≥5.5 to ≤10.5 g/dL; and
7. Is prescribed by or in consultation with a hematologist; and
8. Patient is not receiving concomitant blood transfusion therapy.

If the criteria for coverage are met, an initial authorization will be given for 6 months. Additional approvals will be granted if the following criteria are met:

1. Documentation of an increase in hemoglobin by ≥1 g/dL from baseline; and
2. Documentation of a decrease in the number of sickle cell-related vasoocclusive crises.

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

IL-5 Antagonists

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

Prior authorization is required for *IL-5 antagonists* ~~mepolizumab (Nucala)~~. Requests will not be considered with concurrent use *with another monoclonal antibody* ~~of omalizumab~~. Payment will be considered under the following conditions:

1. Patient meets the FDA approved age *for submitted diagnosis*; and
2. *Is dosed within FDA approved dosing for submitted diagnosis and age; and*
3. Patient has a diagnosis of severe asthma with an eosinophilic phenotype, and
    a. Patient has a pretreatment blood eosinophil count of ≥ 150 cells per mcL within the previous 6 weeks or blood eosinophils ≥ 300 cells per 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* ~~and~~
4. *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 greater than 1000 cells/mcL; or*
        ii. *Eosinophil count greater than 10% of the total leukocyte count; and*
5. *Prescribed~~r~~ by or in consultation with* ~~is~~ an allergist, immunologist, ~~or~~ pulmonologist*, or rheumatologist.*~~; and~~

If criteria for coverage are met, an initial authorization will be given for 3 months 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~~ *when* 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).*

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

Insulin, Pre-Filled Pens
Recommendation to remove clinical prior authorization criteria

Current Clinical Prior Authorization Criteria
Prior authorization (PA) is required for pre-filled insulin pens as designated on the Preferred Drug List (PDL). For pre-filled insulin pens requiring PA where the requested insulin is available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:

1. The patient's visual or motor skills are impaired to such that they cannot accurately draw up their own insulin (not applicable for pediatric patients), and
2. There is no caregiver available to provide assistance, and
3. Patient does not reside in a long-term care facility, and
4. For requests for non-preferred pre-filled insulin pens, patient has documentation of a previous trial and therapy failure with a preferred pre-filled insulin pen within the same class (i.e. rapid, regular or basal).

For pre-filled insulin pens requiring PA where the requested insulin is not available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:

1. Preferred pre-filled insulin pens- Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal) or clinical rationale as to why the patient cannot use a preferred insulin agent, and
2. Non-preferred pre-filled insulin pens- Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal).

Requests for Toujeo will require clinical rationale as to why the patient cannot use Lantus and patient must be using a minimum of 100 units of Lantus per day.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Cystic Fibrosis Agents, Oral; Valsartan/Sacubitril (Entresto); Direct Oral Anticoagulants; Voxelotor (Oxbryta); IL-5 Antagonists; and removal of PA criteria for Insulin, Pre-Filled Insulin Pens.

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

IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
1305 East Walnut – Des Moines, IA 50309 □ (515) 974-3131 □ Fax 1-866-626-0216

Brett Faine, Pharm.D.
Melissa Klotz, Pharm.D.
Jason Kruse, D.O
Kellen Ludvigson, Pharm.D.
Susan Parker, R.Ph., Pharm.D.
Jason Wilbur, M. D.
Charles Wadle, D.O.
John Ellis, Pharm.D.

Professional Staff: Pam Smith, R.Ph.
DUR Project Coordinator

November 6, 2020

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

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, November 4, 2020. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Acute Migraine Treatments; Pirfenidone (Esbriet)/Nintedanib (Ofev); Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors; and Peanut Allergen Powder (Palforzia). Additionally, the DUR Commission members recommended several ProDUR quantity limits. The following recommendations have been made by the DUR Commission:

Comments were received and reviewed from the medical/pharmacy associations in response to an August 7, 2020 letter that was sent to them detailing the proposed criteria for Acute Migraine Treatments; Pirfenidone (Esbriet)/Nintedanib (Ofev); Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors; and Peanut Allergen Powder (Palforzia); in addition to the proposed ProDUR quantity limits.

Acute Migraine Treatments (formerly Serotonin 5-HT-1-Receptor Agonists)

Current Clinical Prior Authorization Criteria
Prior authorization (PA) is required for preferred serotonin 5-HT1-receptor agonists for quantities exceeding 12 unit doses of tablets, syringes or sprays per 30 days. Payment for serotonin 5-HT1-receptor agonists beyond this limit will be considered on an individual basis after review of submitted documentation. PA will be required for all non-preferred serotonin 5-HT1-receptor agonists as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. Payment for non-preferred serotonin 5-HT1-receptor agonists will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred agents. Requests for non-preferred combination products may only be considered after documented separate trials and therapy failures with the individual ingredients. For consideration, the following information must be supplied:

1. The diagnosis requiring therapy.

2. Documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications.

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

*No ~~P~~p*rior authorization (PA) *is required for preferred acute migraine treatments, as indicated on the Preferred Drug List (PDL). PA* is required for ~~preferred~~ *acute migraine treatments* ~~serotonin 5-HT1-receptor agonists~~ *under the following conditions:*

1. *A diagnosis of acute migraine; and*
2. *Patient meets the FDA approved age for requested agent; and*
3. *For preferred acute migraine treatments where PA is required, as indicated on the PDL, documentation of previous trials and therapy failures with two preferred agents that do not require PA; and/or*
4. ~~Payment f~~*F*or *non*-preferred *acute migraine treatments,* ~~serotonin 5-HT1-receptor agonists will be authorized only for cases in which there is~~ documentation of previous trials and therapy failures with two preferred agents *that do not require PA. Requests for non-preferred CGRP inhibitors will also require documentation of a trial and therapy failure with a preferred CGRP inhibitor; and/or*
5. *~~f~~F*or quantities exceeding *the established quantity limit for each agent,* ~~12 unit doses of tablets, syringes or sprays per 30 days. Payment for serotonin 5-HT1-receptor agonists beyond *this* limit will be considered on an individual basis after review of submitted~~ documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications*; and/or*
6. ~~Requests *f~~F*or *non*-preferred combination products*,* ~~may only be considered after~~ document*ation~~ed~~ of* separate trials and therapy failures with the individual ingredients*, in addition to the above criteria for preferred or non-preferred acute migraine treatments requiring PA*.

~~PA will be required for all non-preferred serotonin 5-HT1-receptor agonists as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. For consideration, the following information must be supplied:~~

1. ~~The diagnosis requiring therapy.~~
2. ~~Documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications.~~

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

Pirfenidone (Esbriet)/Nintedanib (Ofev) (formerly Idiopathic Pulmonary Fibrosis)

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for pirfenidone (Esbriet) and nintedanib (Ofev). Dosing outside of the FDA approved dosing will not be considered. Concomitant use of pirfenidone and nintedanib will not be considered. Payment will be considered for patients when the following criteria are met:

1. Patient is 40 years of age or older; and
2. Is prescribed by a pulmonologist; and
3. Patient has a diagnosis of idiopathic pulmonary fibrosis as confirmed by one of the following (attach documentation):
    a. Findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP); or
    b. A surgical lung biopsy demonstrating usual interstitial pneumonia (UIP); and

4. Prescriber has excluded other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity; and
5. Patient has documentation of pulmonary function tests within the prior 60 days with a forced vital capacity (FVC) ≥50% predicted; and
6. Patient has a carbon monoxide diffusion capacity (%DLco) of ≥30% predicted; and
7. Patient does not have hepatic impairment as defined below:
    a. Nintedanib - Patient does not have moderate or severe hepatic impairment (Child Pugh B or C) or
    b. Pirfenidone - Patient does not have severe hepatic impairment (Child Pugh C); and
8. Patient does not have renal impairment as defined below:
    a. Nintedanib - Patient does not have severe renal impairment (CrCl <30ml/min) or end-stage renal disease or
    b. Pirfenidone – Patient does not have end-stage renal disease requiring dialysis; and
9. Patient is a nonsmoker or has been abstinent from smoking for at least six weeks.

If the criteria for coverage are met, initial requests will be given for 6 months. Additional authorizations will be considered at 6 month intervals when the following criteria are met:

1. Adherence to pirfenidone (Esbriet) and nintedanib (Ofev) is confirmed; and
2. Patient is tolerating treatment defined as improvement or maintenance of disease (<10% decline in percent predicted FVC or < 200 mL decrease in FVC); and
3. Documentation is provided that the patient has remained tobacco-free; and
4. ALT, AST, and bilirubin are assessed periodically during therapy

<u>Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)</u>
Prior authorization (PA) is required for pirfenidone (Esbriet) and nintedanib (Ofev). Dosing outside of the FDA approved dosing will not be considered. Concomitant use of pirfenidone and nintedanib will not be considered. Payment will be considered for patients when the following criteria are met:

1. Patient *meets the FDA approved age* ~~is 40 years of age or older~~; and
2. Is prescribed by a pulmonologist; and
3. Patient does not have hepatic impairment as defined below:
    a. Nintedanib - Patient does not have moderate or severe hepatic impairment (Child Pugh B or C) or
    b. Pirfenidone - Patient does not have severe hepatic impairment (Child Pugh C); and
4. Patient does not have renal impairment as defined below:
    a. Nintedanib - Patient does not have severe renal impairment (CrCl <30ml/min) or end-stage renal disease or
    b. Pirfenidone – Patient does not have end-stage renal disease requiring dialysis; and
5. Patient ~~is~~ *does not utilize non-prescribed inhalants, such as vaping or other inhaled tobacco products, prior to initiating therapy and has been instructed to avoid tobacco products while using pirfenidone or nintedanib* ~~a nonsmoker or has been abstinent from smoking for at least six weeks~~*, and*~~.~~
6. Patient has a diagnosis of idiopathic pulmonary fibrosis *(nintedanib or pirfenidone)* as confirmed by one of the following (attach documentation):
    a. Findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP); or

b. A surgical lung biopsy demonstrating usual interstitial pneumonia (UIP); and
c. Prescriber has excluded other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity; and
d. Patient has documentation of pulmonary function tests within the prior 60 days with a forced vital capacity (FVC) ≥50% predicted; and
e. Patient has a carbon monoxide diffusion capacity (%DLco) of ≥30% predicted; ~~and~~ *or*

7. *Patient has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (nintedanib)as confirmed by the following (attach documentation:*
   a. *Documentation of a chest high resolution computed tomography (HRCT) scan showing fibrosis affecting ≥ 10% of the lungs; and*
   b. *Patient has documented pulmonary function tests within the prior 60 days showing FVC ≥ 40% predicted; and*
   c. *Patient has a carbon monoxide diffusion capacity (%DLco) of ≥ 30-89% predicted; or*
8. *Patient has a diagnosis of chronic fibrosing interstitial lung disease with a progressive phenotype (nintedanib) as confirmed by the following (attach documentation):*
   a. *Documentation of a chest high resolution computed tomography (HRCT) scan showing fibrosis affecting ≥ 10% of the lungs; and*
   b. *Patient has documented pulmonary function tests within the prior 60 days showing FVC ≥ 45% predicted; and*
   c. *Patient has a carbon monoxide diffusion capacity (%DLco) of ≥ 30-79% predicted; and*
   d. *Patient has at least one sign of clinical progression for interstitial lung disease within the last 24 months despite standard treatment with an agent other than nintedanib or pirfenidone:*
      i. *A relative decline in the FVC of at least 10% predicted; or*
      ii. *A relative decline in the FVC of 5-9% predicted combined with at least one of the following:*
         1. *Worsening respiratory symptoms; or*
         2. *Increased extent of fibrosis on HRCT; or*
      iii. *Worsening of respiratory symptoms and an increased extent of fibrotic changes on HRCT only.*

If the criteria for coverage are met, initial requests will be given for 6 months. Additional authorizations will be considered at 6 month intervals when the following criteria are met:

1. Adherence to pirfenidone (Esbriet) ~~and~~ *or* nintedanib (Ofev) is confirmed; and
2. *Documentation of a positive response to therapy, defined as meeting at least one of the following:* ~~Patient is tolerating treatment defined as improvement or maintenance of disease (<10% decline in percent predicted FVC or < 200 mL decrease in FVC)~~;
   a. *Rate of lung function decline slowed; or*
   b. *Improved or no worsening of symptoms of cough or shortness of breath;* and
3. Documentation is provided that the patient has remained tobacco-free; and
4. ALT, AST, and bilirubin are assessed periodically during therapy.

Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for adenosine triphosphate-citrate lyase (ACL) inhibitors. Payment will be considered under the following conditions:

1. Patient meets the FDA approved age; and
2. Documentation of adherence to prescribed lipid lowering medications (including a maximally tolerated statin), prior to ACL inhibitor therapy, for the previous 90 days is provided (further defined below, by diagnosis); and
3. Documentation is provided that medication will be used in combination with a maximally tolerated statin; and
4. A baseline and current lipid profile is provided. Baseline lipid profile is defined as a lipid profile obtained prior to pharmacologic therapy; and
5. Patient will continue to follow an appropriate low fat diet; and
6. Is prescribed by or in consultation with a lipidologist, cardiologist, or endocrinologist; and
7. If patient is taking in combination with:
    a. Simvastatin, dose does not exceed 20mg per day; or
    b. Pravastatin, dose does not exceed 40 mg per day; and
8. Concurrent use with a PCSK9 inhibitor will not be considered; and
9. Goal is defined as a 50% reduction in untreated baseline LDL-C; and
10. Is prescribed for one of the following diagnoses:
    a. Heterozygous Familial Hypercholesterolemia (HeFH):
        i. Documentation is provided verifying diagnosis (attach documentation/results), as evidenced by:
            1. Clinical manifestations of HeFH (e.g. tendon xanthomas, cutaneous xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma); or
            2. Confirmation of diagnosis by gene or receptor testing; and
        ii. Documentation of untreated LDL-C ≥ 190 mg-dL; and
        iii. Patient is unable to reach LDL-C goal with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (must include atorvastatin and rosuvastatin), PLUS ezetimibe 10mg daily; or
    b. Clinical Atherosclerotic Cardiovascular Disease (ASCVD):
        i. History of MI, angina, coronary or other arterial revascularization, stroke, TIA, or PVD of atherosclerotic origin; and
        ii. Patient is unable to reach LDL-C goal with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (must include atorvastatin and rosuvastatin), PLUS ezetimibe 10mg daily.

If criteria for coverage are met, requests will be approved for 3 months. Additional authorizations will be considered at yearly intervals under the following conditions:

a. Patient continues therapy with a maximally tolerated statin dose and remains at goal; and
b. Patient continues to follow an appropriate low fat diet; and
c. Documentation of LDL reduction is provided.

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

Peanut Allergen Powder-dnfp (Palforzia)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for Peanut (*Arachis hypogaea*) Allergen Powder-dnfp (Palforzia). Payment will be considered under the following conditions:

1. Patient has a confirmed diagnosis of peanut allergy, as documented by a skin prick test to peanut ≥ 3 mm compared to control or a peanut-specific serum IgE ≥ 0.35 kUA/L (kilos of allergen-specific units per liter); and
2. Patient is 4 to 17 years of age at initiation of therapy or 4 years of age and older for continued up-dosing and maintenance therapy; and
3. Prescribed by or in consultation with an allergist or immunologist; and
4. Patient has access to injectable epinephrine; and
5. Will be used in conjunction with a peanut-avoidant diet; and
6. Patient does not have any of the following:
    a. Uncontrolled asthma; and/or
    b. A history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease; and
7. Patient will adhere to the complex up-dosing schedule that requires frequent visits to the administering healthcare facility; and
8. The initial dose escalation and the first dose of each new up-dosing level is administered under the supervision of a health care professional in a health care setting with the ability to manage potentially severe allergic reactions, including anaphylaxis. Initial dose escalation and the first dose of all up-dosing levels is not to be billed to the Iowa Medicaid outpatient pharmacy program as the initial dose escalation is administered in the provider office and should be billed via the medical benefit and the first dose of all up-dosing levels is provided via the Office Dose Kit; and
9. Follows FDA approved dosing; and
10. PA is required for all up-dosing dose levels (dose level 1 through 11); and
11. Maintenance dosing will be considered with documentation patient has successfully completed all dose levels of up-dosing.

ProDUR Edits

The DUR Commission recommends the following ProDUR quantity limits:

Drug Product	Quantity	Days Supply
Baclofen 5mg tablet	120	30
Baclofen 10mg tablet	120	30
Baclofen 20mg tablet	120	30
Nurtec ODT	15	30
Reyvow 50mg tablet	8	30
Reyvow 100mg tablet	8	30
Ubrelvy 50mg tablet	16	30
Ubrelvy 100mg tablet	16	30

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Acute Migraine Treatments; Pirfenidone (Esbriet)/Nintedanib (Ofev); Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors; and Peanut Allergen Powder (Palforzia); in addition to the proposed ProDUR quantity limits.

Sincerely,

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

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

IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
1305 East Walnut – Des Moines, IA 50309 □ (515) 974-3131 □ Fax 1-866-626-0216

Brett Faine, Pharm.D.
Melissa Klotz, Pharm.D.
Jason Kruse, D.O
Kellen Ludvigson, Pharm.D.
Susan Parker, R.Ph., Pharm.D.
Jason Wilbur, M. D.
Charles Wadle, D.O.
John Ellis, Pharm.D.

Professional Staff: Pam Smith, R.Ph.
DUR Project Coordinator

March 4, 2021

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

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, March 3, 2021. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Elagolix Products; Select Anticonvulsants; and Satralizumab (Enspryng). The following recommendations have been made by the DUR Commission:

Comments were received and reviewed from the medical/pharmacy associations in response to a November 11, 2020 letter that was sent to them detailing the proposed criteria for Elagolix Products; Select Anticonvulsants; and Satralizumab (Enspryng).

Elagolix Products

Current Clinical Prior Authorization Criteria [Elagolix (Orilissa)]
Prior authorization (PA) is required for gonadotropin-releasing hormone (GnRH) antagonists. Payment will be considered for patients when the following is met:

1. Patient has a diagnosis of moderate to severe pain associated with endometriosis; and
2. Pregnancy has been ruled out; and
3. Patient does not have osteoporosis; and
4. Patient does not have severe hepatic impairment; and
5. Patient is not taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g. cyclosporine and gemfibrozil); and
6. 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
7. Patient has documentation of a previous trial and therapy failure with a preferred GnRH agonist.
8. Requests will be considered for a maximum of 24 months for the 150mg dose and six (6) months for the 200mg dose.

Initial requests will be considered for 3 months. Additional requests will be considered upon documentation of improvement of symptoms.

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

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

Prior authorization (PA) is required for *elagolix containing drugs* ~~gonadotropin-releasing hormone (GnRH) antagonists~~. 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. Patient does not have severe hepatic impairment; and
4. Patient is not taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g. cyclosporine and gemfibrozil); and
5. *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*
6. *Requests for elagolix, estradiol, and norethindrone acetate; elagolix (Oriahnn) 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.*

Select Anticonvulsants

Current Clinical Prior Authorization Criteria [Cannabidiol (Epidiolex)]

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

1. Patient meets the FDA approved age; and
2. Baseline serum transaminases (ALT and AST) and total bilirubin levels have been obtained prior to initiating therapy (attach results); and

3. A diagnosis of Lennox-Gastaut syndrome with documentation of an adequate trial and inadequate response with at least two concomitant antiepileptic drugs (AEDs) from the following:
    a. Valproic acid,
    b. Lamotrigine,
    c. Topiramate,
    d. Felbamate,
    e. Rufinamide,
    f. Clobazam, or
4. A diagnosis of Dravet syndrome with documentation of an adequate trial and inadequate response with at least two concomitant AEDs from the following:
    a. Clobazam,
    b. Valproic Acid,
    c. Levetiracetam,
    d. Topiramate, and
5. Is prescribed by or in consultation with a neurologist; and
6. The total daily dose does not exceed 20 mg/kg/day.

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

<u>Newly Proposed Clinical Prior Authorization Criteria</u>

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

1. Patient meets the FDA approved age for submitted diagnosis and drug; and
2. Patient has an FDA approved or compendia indicated diagnosis, for requested drug, of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex, 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. Follows FDA approved dosing for indication and drug. 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/d 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.

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

Satralizumab (Enspryng)

Newly Proposed Clinical Prior Authorization Criteria

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

1. Patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD); and
2. Patient is anti-aquaporin 4 (AQP4) seropositive (attach documentation); and
3. Patient meets the FDA approved age and dosing; and
4. Patient has a history of at least 1 relapse in the previous 12 months prior to initiation of therapy; and
5. Patient has been tested for tuberculosis prior to the initiation of therapy and does not have active or untreated latent tuberculosis; and
6. Patient has been tested for hepatitis B virus (HBV) prior to the initiation of therapy and confirmed negative for active HBV; and
7. Prescribed by a neurologist.

If criteria for coverage are met, initial requests will be given for 1 year. Additional authorizations will be considered upon documentation of clinical response to therapy (i.e. a reduction in the frequency of relapse).

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Elagolix Products; Select Anticonvulsants; and Satralizumab (Enspryng).

Sincerely,

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

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

IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
1305 East Walnut – Des Moines, IA 50309 □ (515) 974-3131 □ Fax 1-866-626-0216

Brett Faine, Pharm.D.
Melissa Klotz, Pharm.D.
Jason Kruse, D.O
Kellen Ludvigson, Pharm.D.
Susan Parker, R.Ph., Pharm.D.
Jason Wilbur, M. D.
Charles Wadle, D.O.
John Ellis, Pharm.D.

Professional Staff: Pam Smith, R.Ph.
DUR Project Coordinator

May 7, 2021

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

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, May 5, 2021. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Risdiplam (Evrysdi); Binge Eating Disorder; IL-5 Antagonists; Isotretinoin (Oral); Multiple Sclerosis Agents - Oral; Nonsteroidal Anti-Inflammatory Drugs (NSAIDs); and removal of PA criteria for Alpha$_2$ Agonists, Extended Release. In addition, the DUR Commission discussed a ProDUR age edit for the extended release Alpha$_2$ Agonists. The following recommendations have been made by the DUR Commission:

Comments were received and reviewed from the medical/pharmacy associations in response to a March 9, 2021 letter that was sent to them detailing the proposed criteria for Risdiplam (Evrysdi); Binge Eating Disorder; IL-5 Antagonists; Isotretinoin (Oral); Multiple Sclerosis Agents - Oral; Nonsteroidal Anti-Inflammatory Drugs (NSAIDs); removal of PA criteria for Alpha$_2$ Agonists, Extended Release; and the ProDUR age edit on extended release Alpha$_2$ Agonists.

Risdiplam (Evrysdi)

Newly Proposed Clinical Prior Authorization Criteria

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

1. Patient has a diagnosis of spinal muscular atrophy (SMA); and
2. Patient meets the FDA approved age for diagnosis; and
3. Dosing follows FDA approved dose for age and weight; and
4. A negative pregnancy test for females of reproductive potential prior to initiating treatment; and
5. Female patients of reproductive potential have been advised to use effective contraception during treatment and for at least 1 month after last dose and male

patients of reproductive potential have been counseled on the potential effects on fertility; and
6. Patient does not have impaired liver function; and
7. Will not be prescribed concomitantly with other SMA treatments, such as Spinraza (nusinersen), Zolgensma (onasemnogene abeparvovec), or any other new products that are approved by the FDA and released; and
8. Documentation of previous SMA therapies and response to therapy is provided; and
    a. For patients currently on Spinraza, documentation Spinraza will be discontinued is provided, including date of last dose, and the appropriate interval based on the dosing frequency of the other drug has been met (i.e. 4 months from the last dose when on maintenance therapy); or
    b. For patients treated with Zolgensma, requests will not be considered; and
9. Is prescribed by or in consultation with a neurologist; and
10. Pharmacy will educate the member, or member's caregiver, on the storage and administration of Evrysdi, as replacements for improper storage or use will not be authorized.

If the criteria for coverage are met, requests will be approved for 1 year. Requests for continuation of therapy will require documentation of a positive response to therapy including stabilization or improved function unless intercurrent event (fracture, illness, other) affects functional testing.

Binge Eating Disorder

Current Clinical Prior Authorization Criteria
Binge Eating Disorder (Vyvanse only)
a. Patient is 18 to 55 years of age; and
b. Patient meets DSM-5 criteria for Binge Eating Disorder (BED); and
c. Patient has documentation of moderate to severe BED, as defined by the number of binge eating episodes per week (number of episodes must be reported); and
d. Patient has documentation of non-pharmacologic therapies tried, such as cognitive-behavioral therapy or interpersonal therapy, for a recent 3 month period, that did not significantly reduce the number of binge eating episodes; and
e. Prescription is written by a psychiatrist or psychiatric nurse practitioner; and
f. Patient has a BMI of 25 to 45; and
g. Patient does not have a history of cardiovascular disease; and
h. Patient has no history of substance abuse; and
i. Is not being prescribed for the treatment of obesity or weight loss; and
j. Doses above 70mg per day will not be considered.
k. Initial requests will be approved for 12 weeks.

Requests for renewal must include documentation of a change from baseline at week 12 in the number of binge days per week.

DSM-5 Criteria
i. Recurrent episodes of binge eating, including eating an abnormally large amount of food in a discrete period of time and has a feeling of lack of control over eating; and

ii. The binge eating episodes are marked by at least three of the following:
    1. Eating more rapidly than normal
    2. Eating until feeling uncomfortably full
    3. Eating large amounts of food when not feeling physically hungry
    4. Eating alone because of embarrassment by the amount of food consumed
    5. Feeling disgusted with oneself, depressed, or guilty after overeating; and
iii. Episodes occur at least 1 day a week for at least 3 months; and
iv. No regular use of inappropriate compensatory behaviors (e.g. purging, fasting, or excessive exercise) as are seen in bulimia nervosa; and
v. Does not occur solely during the course of bulimia nervosa or anorexia nervosa.

Moderate to Severe BED

Based on the number of binge eating episodes per week:

Moderate - 4 to 7
Severe – 8 to 13
Extreme – 14 or more

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

Binge Eating Disorder (Vyvanse only)

a. Patient is 18 to 55 years of age; and
b. Patient meets DSM-5 criteria for Binge Eating Disorder (BED); and
c. Patient has documentation of moderate to severe BED, as defined by the number of binge eating episodes per week (number of episodes must be reported); and
d. Patient has documentation of non-pharmacologic therapies tried, such as cognitive-behavioral therapy or interpersonal therapy, for a recent 3 month period, that did not significantly reduce the number of binge eating episodes; and
e. Prescription is written by a psychiatrist*,* ~~or~~ psychiatric nurse practitioner*, or psychiatric physician assistant*; and
f. Patient has a BMI of 25 to 45; and
g. Patient does not have a history of cardiovascular disease; and
h. Patient has no history of substance abuse; and
i. Is not being prescribed for the treatment of obesity or weight loss; and
j. Doses above 70mg per day will not be considered.
k. Initial requests will be approved for 12 weeks.

Requests for renewal must include documentation of a change from baseline at week 12 in the number of binge days per week.

DSM-5 Criteria

i. Recurrent episodes of binge eating, including eating an abnormally large amount of food in a discrete period of time and has a feeling of lack of control over eating; and
ii. The binge eating episodes are marked by at least three of the following:
    1. Eating more rapidly than normal
    2. Eating until feeling uncomfortably full
    3. Eating large amounts of food when not feeling physically hungry
    4. Eating alone because of embarrassment by the amount of food consumed

5. Feeling disgusted with oneself, depressed, or guilty after overeating; and

iii. Episodes occur at least 1 day a week for at least 3 months; and
iv. No regular use of inappropriate compensatory behaviors (e.g. purging, fasting, or excessive exercise) as are seen in bulimia nervosa; and
v. Does not occur solely during the course of bulimia nervosa or anorexia nervosa.

Moderate to Severe BED

Based on the number of binge eating episodes per week:
Moderate - 4 to 7
Severe – 8 to 13
Extreme – 14 or more

IL-5 Antagonists

Current Clinical Prior Authorization Criteria

Prior authorization is required for IL-5 antagonists. Requests will not be considered with concurrent use with another monoclonal antibody. Payment will be considered under the following conditions:

1. Patient meets the FDA approved age for submitted diagnosis; and
2. Is dosed within FDA approved dosing for submitted diagnosis and age; and
3. Patient has a diagnosis of severe asthma with an eosinophilic phenotype, and
    a. Patient has a pretreatment blood eosinophil count of ≥ 150 cells per mcL within the previous 6 weeks or blood eosinophils ≥ 300 cells per 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
4. 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 greater than 1000 cells/mcL; or
        ii. Eosinophil count greater than 10% of the total leukocyte count; and
5. Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist.

If criteria for coverage are met, an initial authorization will be given for 3 months to assess the need for continued therapy. Requests for continuation of therapy will be based on continued medical necessity and will be considered when 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).

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 or stricken)
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 under the following conditions:

1. *Is requested for an FDA approved or compendia indicated diagnosis; and*
2. Patient meets the FDA approved *or compendia indicated* age *and dose* for submitted diagnosis; and
3. ~~Is dosed within FDA approved dosing for submitted diagnosis and age; and~~
4. Patient has a diagnosis of severe asthma with an eosinophilic phenotype, and
    a. Patient has a pretreatment blood eosinophil count of ≥ 150 cells*/mcL* ~~per mcL~~ within the previous 6 weeks or blood eosinophils ≥ 300 cells*/mcL* ~~per 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
5. 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 ~~greater than~~ >1000 cells/mcL; or
        ii. Eosinophil count ~~greater than~~ > 10% of the total leukocyte count; *or* ~~and~~
6. *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

7. Prescribed by or in consultation with an allergist, *hematologist,* immunologist, pulmonologist, or rheumatologist.

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* to assess the need for continued therapy. Requests for continuation of therapy will be based on continued medical necessity and will be considered when 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 a 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 of at least one other HES therapy.

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

Isotretinoin (Oral)

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for oral isotretinoin therapy. Payment will be approved for preferred oral isotretinoin products for acne under the following conditions:

1. There are documented trials and therapy failures of systemic antibiotic therapy and topical tretinoin therapy. Documented trials and therapy failures of systemic antibiotic therapy and topical tretinoin therapy are not required for approval for treatment of acne conglobata.
2. Patients and providers must be registered in, and meet all requirements of, the iPLEDGE (www.ipledgeprogram.com) risk management program.

Payment for non-preferred oral isotretinoin products will be authorized only for cases in which there is documentation of trial(s) and therapy failure with a preferred agent(s). Initial authorization will be granted for up to 20 weeks. A minimum of two months without therapy is required to consider subsequent authorizations.

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization (PA) is required for oral isotretinoin therapy. Payment for non-preferred oral isotretinoin products will be authorized only for cases in which there is documentation of trial(s) and therapy failure with a preferred agent(s). Payment will be ~~approved~~ *considered* for preferred oral isotretinoin products for *moderate to severe* acne under the following conditions:

1. There are documented trials and therapy failures of systemic antibiotic therapy and topical *vitamin A derivative (*tretinoin *or adapalene)* therapy. Documented trials and therapy failures of systemic antibiotic therapy and topical *vitamin A derivative* ~~tretinoin~~ therapy are not required for approval for treatment of acne *conglobata; and*~~.~~
2. *Prescriber attests patient has enrolled in and meets all requirements of the iPLEDGE program.* ~~Patients and providers must be registered in, and meet all requirements of, the iPLEDGE (www.ipledgeprogram.com) risk management program.~~

Initial authorization will be granted for up to ~~20~~ *24* weeks. A minimum of *8 weeks* ~~two months~~ without therapy is required to consider subsequent authorizations.

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

Multiple Sclerosis Agents – Oral

Current Clinical Prior Authorization Criteria
For patients initiating therapy with a preferred oral medication, a manual prior authorization (PA) is not required if a preferred injectable interferon or non-interferon agent is found in the member's pharmacy claims history in the previous 12 months. If a preferred injectable agent is not found in the member's pharmacy claims, documentation of the following must be provided:

1. A diagnosis of relapsing forms of multiple sclerosis; and
2. Patient meets the FDA approved age; and
3. Request is for FDA approved dosing; and
4. A previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis.
5. Requests for a non-preferred oral multiple sclerosis agent must document a previous trial and therapy failure with a preferred oral multiple sclerosis agent.

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

For patients initiating therapy with fingolimod (Gilenya):

1. Patient does not have a recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization or Class lll/IV heart failure; and
2. Patient does not have a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a pacemaker; and
3. Patient does not have a baseline QTc interval ≥ 500ms; and

4. Patient is not being treated with Class Ia or Class III anti-arrhythmic drugs.

For patients initiating therapy with teriflunomide (Aubagio):
1. Patient does not have severe hepatic impairment; and
2. A negative pregnancy test for females of childbearing age; and
3. Use of a reliable form of contraception for females of childbearing age; and
4. Patient is not taking leflunomide.

For patients initiating therapy with dimethyl fumarate (Tecfidera & Vumerity):
1. Patient does not have a low lymphocyte count as documented by a recent (within 6 months) CBC prior to initiating therapy; and
2. Upon renewal, documentation of an updated CBC.

For patients initiating therapy with cladribine (Mavenclad):
1. Patient's current weight is provided; and
2. Patient does not have a current malignancy and patient is up to date on all age appropriate malignancy screening; and
3. Pregnancy has been excluded in females of reproductive potential; and
4. Women and men of reproductive potential must use effective contraception during treatment and for 6 months after the last dose in each treatment course; and
5. Women must not intend to breastfeed while being treated and for 10 days after the last dose; and
6. Patient does not have HIV infection; and
7. Patient does not have active chronic infection (e.g. hepatitis or tuberculosis); and
8. No more than two yearly treatment courses (i.e. two treatment courses consisting of two treatment cycles) will be considered.

For patients initiating therapy with siponimod (Mayzent):
1. Patient does not have a CYP2C9*3/*3 genotype; and
2. Patient does not have a recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure; and
3. Patient does not have a presence of Mobitz Type II 2nd degree, 3rd degree AV block or sick sinus syndrome, unless the patient has a functioning pacemaker.

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
For patients initiating therapy with a preferred oral *multiple sclerosis agent* ~~medication~~, a manual prior authorization (PA) is not required if a preferred injectable interferon or non-interferon agent is found in the member's pharmacy claims history in the previous 12 months. If a preferred injectable agent is not found in the member's pharmacy claims, documentation of the following must be provided:
1. A diagnosis of relapsing forms of multiple sclerosis; and
2. *Request must adhere to all FDA approved labeling, including indication, age, dosing, contraindications, and warnings and precautions* ~~Patient meets the FDA approved age~~; and
3. ~~Request is for FDA approved dosing; and~~
4. *Documentation of a* previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis.

Requests for a non-preferred oral multiple sclerosis agent must document a previous trial and therapy failure with a preferred oral multiple sclerosis agent.

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

~~For patients initiating therapy with fingolimod (Gilenya):~~

1. ~~Patient does not have a recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization or Class III/IV heart failure; and~~
2. ~~Patient does not have a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a pacemaker; and~~
3. ~~Patient does not have a baseline QTc interval ≥ 500ms; and~~
4. ~~Patient is not being treated with Class Ia or Class III anti-arrhythmic drugs.~~

~~For patients initiating therapy with teriflunomide (Aubagio):~~

1. ~~Patient does not have severe hepatic impairment; and~~
2. ~~A negative pregnancy test for females of childbearing age; and~~
3. ~~Use of a reliable form of contraception for females of childbearing age; and~~
4. ~~Patient is not taking leflunomide.~~

~~For patients initiating therapy with dimethyl fumarate (Tecfidera & Vumerity):~~

1. ~~Patient does not have a low lymphocyte count as documented by a recent (within6 months) CBC prior to initiating therapy; and~~
2. ~~Upon renewal, documentation of an updated CBC.~~

~~For patients initiating therapy with cladribine (Mavenclad):~~

1. ~~Patient's current weight is provided; and~~
2. ~~Patient does not have a current malignancy and patient is up to date on all age appropriate malignancy screening; and~~
3. ~~Pregnancy has been excluded in females of reproductive potential; and~~
4. ~~Women and men of reproductive potential must use effective contraception during treatment and for 6 months after the last dose in each treatment course; and~~
5. ~~Women must not intend to breastfeed while being treated and for 10 days after the last dose; and~~
6. ~~Patient does not have HIV infection; and~~
7. ~~Patient does not have active chronic infection (e.g. hepatitis or tuberculosis); and~~
8. ~~No more than two yearly treatment courses (i.e. two treatment courses consisting of two treatment cycles) will be considered.~~

~~For patients initiating therapy with siponimod (Mayzent):~~

1. ~~Patient does not have a CYP2C9*3/*3 genotype; and~~
2. ~~Patient does not have a recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure; and~~
3. ~~Patient does not have a presence of Mobitz Type II 2nd degree, 3rd degree AV block or sick sinus syndrome, unless the patient has a functioning pacemaker.~~

Nonsteroidal Anti-Inflammatory Drugs

Current Clinical Prior Authorization

Prior authorization (PA) is required for all non-preferred nonsteroidal anti-inflammatory drugs

(nsaids) and COX-2 inhibitors. PA is not required for preferred nonsteroidal anti-inflammatory drugs or COX-2 inhibitors.

1. Requests for a non-preferred nsaid must document previous trials and therapy failures with at least three preferred nsaids.
2. Requests for a non-preferred COX-2 inhibitor must document previous trials and therapy failures with three preferred nsaids, two of which must be a preferred COX-2 preferentially selective nsaid.
3. Requests for a non-preferred extended release nsaid must document previous trials and therapy failures with three preferred nsaids, one of which must be the preferred immediate release nsaid of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance.

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 or stricken)
Prior authorization (PA) is required for all non-preferred nonsteroidal anti-inflammatory drugs (*NSAID*s) ~~and COX-2 inhibitors~~. ~~PA is not required for preferred nonsteroidal anti-inflammatory drugs or COX-2 inhibitors.~~ *Payment for a non-preferred NSAID will be considered under the following conditions:*

1. ~~Requests for a non-preferred nsaid must document~~ *Documentation of* previous trials and therapy failures with at least three preferred *NSAID*s*; and*~~.~~
2. ~~Requests for a non-preferred COX-2 inhibitor must document previous trials and therapy failures with three preferred nsaids, two of which must be a preferred COX-2 preferentially selective nsaid.~~
3. Requests for a non-preferred extended release *NSAID* must document previous trials and therapy failures with three preferred *NSAID*s, one of which must be the preferred immediate release *NSAID* of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance.

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

Alpha$_2$ Agonists, Extended Release

Current Clinical Prior Authorization – ***Recommendation to Remove Criteria***
Prior authorization (PA) is required for extended-release alpha$_2$ agonists. Payment will be considered for patients when the following is met:

1. The patient has a diagnosis of ADHD and is between 6 and 17 years of age; and
2. Previous trial 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 one preferred amphetamine and one preferred non-amphetamine stimulant.

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

ProDUR Edit(s)

The DUR Commission recommends implementing a ProDUR age edit on Alpha$_2$ Agonists for ADHD, allowing claims for members 6 through 17 years of age, with the removal of PA criteria.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Risdiplam (Evrysdi); Binge Eating Disorder; IL-5 Antagonists; Isotretinoin (Oral); Multiple Sclerosis Agents (Oral); Nonsteroidal Anti-Inflammatory Drugs (NSAIDs); removal of PA criteria for Alpha$_2$ Agonists, Extended Release; and the ProDUR age edit for extended release Alpha$_2$ Agonists.

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

Appendix H
Prospective DUR Recommendations

Prospective DUR
SFY21

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

Quantity Limits

Drug Product	Quantity per 30 Days
Baclofen 5 mg, 10 mg, 20 mg tablet	120
Nurtec ODT	15
Reyvow 50 mg, 100 mg tablet	8
Ubrelvy 50 mg, 100 mg tablet	16

ProDUR Age Edit(s)

- Alpha$_2$ Agonists for ADHD - allow claims for members 6 through 17 years of age

Appendix I
Meeting Minutes

Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes August 5, 2020

Attendees:

Commission Members
Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; Chuck Wadle, D.O.; John Ellis, Pharm.D.; Jason Wilbur, M.D.; Susan Parker, Pharm.D.; and Emily Rogers, Iowa Total Care.
Staff
Pam Smith, R.Ph.
Guests
Erin Halverson, R.Ph., IME; Melissa Biddle, IME; and Lisa Todd, Amerigroup.

Welcome & Introductions

Pam Smith called the meeting to order at 9:35 a.m. She performed the usual chairperson duties as this meeting was purely virtual and done through WebEx teleconference due to COVID-19. The minutes from the March 4, 2020 meeting were reviewed. Kellen Ludvigson motioned to accept them, and Jason Kruse seconded. All members were in favor. The recommendation letter sent to DHS after the last meeting was also reviewed.

Commission Recommendations for Retrospective DUR Agenda Topics

The Commission did not have any new recommendations.

Public Comment Policy – Virtual Meetings

Pam Smith read through the proposed public comment policy. The Commission would like to allow both written and verbal public comment, but requested that those submitting written comment also fill out a conflict of interest form in advance of the meeting. They also felt use of video when providing verbal comment would be helpful, and wanted to add an amendment to the policy to encourage video usage if possible, though it would not be mandatory. Pam Smith suggested that those asking to provide verbal comment be required to sign up prior to the meeting, rather than the morning of the meeting. Jason Wilbur motioned to accept the policy as amended, and Kellen Ludvigson seconded. The decision was unanimous.

IME Pharmacy Update

Medicaid Director Mike Randol has resigned, and Julie Lovelady will be Interim Director. A set of rules relating to pharmacists enrolling as providers have been delayed due to COVID-19. Informational Letter 2153 notified providers that the effective date for these rules was changed to June 1, 2021. The legislature also extended the related Iowa Code changes. Providers received Informational Letter 2119-MC-FFS-CVD and Informational Letter 2123-MC-FFS-CVD in response to COVID-19 regarding PA extensions, copayment issues, early refills, signature guidelines, and audit suspension. CMS has provided an update to a provision on the SUPPORT Act, requiring state Medicaid

programs to cover Medication Assisted Treatment (MAT) for opioid use disorder, including the behavioral therapy component as well as the medication component, effective October 1, 2020 for a five-year period. As a result, these drugs, when used as a component of MAT, will no longer be eligible for the national Medicaid drug rebate, because that rebate applies only to drugs covered under an optional prescription drug benefit. This will also remove their eligibility for 340B and supplemental rebate programs. The impact in Iowa will not be as substantial as in many states, due to Iowa preferring buprenorphine-naloxone tablets on the PDL.

There is still an opening for a doctor on the DUR Commission, as Mark Graber has reached the end of his 3 allowable terms, and was unfortunately not able to attend his last meeting that was cancelled due to COVID-19.

The updated DUR Meeting schedule has been posted on the https://iadur.org/ site, with the next one being in November 2020, then March and May 2021.

Prevalence Report Summaries

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from March 2020 through June 2020, including: eligible users (38,120); total amount paid ($2,025,281), unique users (4,003); cost per user ($505.94), number of total prescriptions dispensed (24,362); and percent generic (87.8%). The top 100 pharmacies by paid amount report was largely influenced by specialty drugs. Meskwaki, which was #1 on the list, gets an encounter rate of the same flat rate for each drug; encounter claims do not qualify for dispensing fees. The top 5 prescribing providers by prescription count were: Michael Ciliberto, Joada Jean Best, Leighton Frost, Molly Earleywine, and Melissa Konken. The top 5 therapeutic classes by paid amount were: Anticonvulsants; Anti-Inflammatories, Antipsychotics – Atypicals; Antineoplastics – Protein-Tyrosine Kinase Inhibitors; and Diabetic – Insulin Penfills. 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, Vyvanse, Invega Systenna, Sutent, and Enbrel Sureclick. The five drugs with the highest prescription counts were: trazodone hcl, montekulast sodium, gabapentin, omeprazole, and clonidine hcl.

Iowa Total Care: Emily Rogers spoke and provided written summaries that included ITC's statistics from March through June 2020, including: eligible users (approximately 274,000); total paid amount ($61,817,075.08); total prescriptions (730,717); and unique users (98,907). 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, Broadlawns Outpatient Pharmacy, 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, Nucara Specialty, Hy-Vee Pharmacy Solutions, Unity Point at Home, and CVS

Caremark. The top 5 therapeutic classes by paid amount were: Insulin; Sympathomimetics; Antiretrovirals; Anti-TNF-alpha-Monoclonal Antibodies; and Antipsychotics - Misc. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Sympathomimetics; Proton-Pump Inhibitors; and HMG CoA Reductase Inhibitors. The most expensive drugs were Humira Pen, Vyvanse, Trikafta, Invega Sustenna, and Novolog, while omeprazole, atorvastatin, lisinopril, sertraline, and levothyroxine sodium had the top 5 prescription counts.

Amerigroup *(provided at the end of the meeting as Lisa Todd was not yet present at this point in the agenda):* Lisa Todd provided an overview for Amerigroup's statistics from March 2020 through June 2020, including: eligible users (approximately 385,000); total paid amount ($100,195,886); unique users (143,428); total prescriptions (1,145,753); generic prescriptions (1,024,019 totaling $21,440,670); brand prescriptions (121,734 totaling $78,755,216). The breakdown of utilization by age shows that ages 19-64 continue to have the highest utilization. The top 100 pharmacies by prescription count had 4 Walgreens locations and the University of Iowa Ambulatory Care Pharmacy making 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, CVS Specialty, Caremark Kansas Specialty, Hy-Vee Pharmacy Solutions, and Caremark Illinois Specialty. On the top 100 prescribing providers by prescription count report, Jeffrey Wilham took the top spot, followed by: Thomas Earwood, Charles Tilley, Mark Mittauer, and Jennifer Zalaznik. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Antiasthmatic and Bronchodilator Agents; ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; and Analgesics – Anti-Inflammatory. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Antihypertensives, and Ulcer Drugs/Antispasmodics/ Anticholinergics. Vyvanse was the most expensive medication, followed by Humira (CF) Pen, Latuda, Invega Sustenna, and Vraylar. Omeprazole had the highest prescription count, followed by: atorvastatin calcium, sertraline hcl, lisinopril, and trazodone hcl.

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 $164,038,242 was spent in total for 246,338 unique users who had 1,900,832 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Humira and Vyvanse were the two most expensive drugs for all 3 plans. The top 25 drugs by prescription count were also similar across FFS and both MCO plans. When all three plans were combined, Jeffrey Wilharm had the overall highest prescription count at 4,706. All three complete prevalence reports and the comparative summary can be found in the finalized meeting packet posted at https://iadur.org/sites/default/files/ghs-files//08-06-20-dur-packet-updated-3.pdf.

Public Comment

As this meeting was purely virtual, only written public comment was accepted. The committee members reviewed the received comments, which have been posted in the finalized meeting packet at: https://iadur.org/sites/default/files/ghs-files//08-06-20-dur-packet-updated-3.pdf.

Retrospective DUR Data Presentations

Duplicate SNRIs: Educational letters will be sent to the the providers regarding members identified as having had fills of 2 or more concurrent SNRIs within 60 days. The letters will be educational in nature, pointing out the combined use of two or more chemically distinct SNRIs asking if one of the agents could be discontinued, while also warning that a ProDUR edit may be implemented in the future. The Commission will follow-up on this issue in 12 months.

Gabapentin and Baclofen: Educational letters will be sent to providers regarding members exceeding 80mg baclofen per day, alerting the provider the dose exceeds the maximum daily dose and asking if the dose could be decreased. Educational letters will also be sent to providers regarding members with concurrent baclofen and opioid use, warning them of the increased risk of respiratory and CNS depression and asking if one or both agents could be discontinued or if the dose of either agent could be decreased. In addition, Kellen Ludvigson motioned to implement a quantity limit of 4 tablets daily (120/30 days) across all strengths of baclofen as recommended. Jason Kruse seconded, and all members were in favor.

Retrospective DUR Proposals

Concurrent Use of Gabapentin and Pregabalin: Claims will be queried to identify members with multiple claims for both gabapentin and pregabalin over a 3-month period and bring the results back to the next meeting for further discussion.

Concurrent Use of a SSRI and SNRI: Claims will be queried to identify members with multiple claims for both an SNRI and SSRI over a 3-month period to see how many members and prescribers would be involved. The data will be brought back to the next meeting for further discussion.

The Commission took a short break and open session resumed at 11:02.

Prior Authorization

Acute Migraine Treatments: The Commission reviewed the prior authorization criteria as follows:

No prior authorization (PA) is required for preferred acute migraine treatments, as

indicated on the Preferred Drug List (PDL). PA is required for acute migraine treatments under the following conditions:

1. *A diagnosis of acute migraine; and*
2. *Patient meets the FDA approved age for requested agent; and*
3. *For preferred acute migraine treatments where PA is required, as indicated on the PDL, documentation of previous trials and therapy failures with two preferred agents that do not require PA; and/or*
4. *For non-preferred acute migraine treatments, documentation of previous trials and therapy failures with two preferred agents that do not require PA. Requests for non-preferred CGRP inhibitors will also require documentation of a trial and therapy failure with a preferred CGRP inhibitor; and/or*
5. *For quantities exceeding the established quantity limit for each agent, documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications; and/or*
6. *For non-preferred combination products, documentation of separate trials and therapy failures with the individual ingredients, in addition to the above criteria for preferred or non-preferred acute migraine treatments requiring PA.*

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. Melissa Klotz then motioned to implement the suggested quantity limits shown below, changing lasmiditan 50mg to 8 per 30 days, and Jason Kruse seconded. This was also unanimous.

- Triptans – keep current limit of 12 unit doses of tablets, syringes or sprays per 30 days.
- Other acute migraine treatments – based on label dosing and safety of treating more than the specified number of migraines in a 30-day period.
    - Ubrogepant – 16 tablets per 30 days for each strength
    - Rimegepant – 15 tablets per 30 days
    - Lasmiditan – 50mg tablet – 8 tablets per 30 days; 100 mg tablet - 8 tablets per 30 days

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

Perfenidone (Esbriet)/Nintedanib (Ofev): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for pirfenidone (Esbriet) and nintedanib (Ofev). Dosing outside of the FDA approved dosing will not be considered. Concomitant use of pirfenidone and nintedanib will not be considered. Payment will be considered for patients when the following criteria are met:

1. *Patient meets the FDA approved age; and*
2. *Is prescribed by a pulmonologist; and*

3. *Patient does not have hepatic impairment as defined below:*
    a. *Nintedanib - Patient does not have moderate or severe hepatic impairment (Child Pugh B or C) or*
    b. *Pirfenidone - Patient does not have severe hepatic impairment (Child Pugh C); and*
4. *Patient does not have renal impairment as defined below:*
    a. *Nintedanib - Patient does not have severe renal impairment (CrCl <30ml/min) or end-stage renal disease or*
    b. *Pirfenidone – Patient does not have end-stage renal disease requiring dialysis; and*
5. *Patient does not utilize non-prescribed inhalants, such as vaping or other inhaled tobacco products, prior to initiating therapy and has been instructed to avoid tobacco products while using pirfenidone or nintedanib, and*
6. *Patient has a diagnosis of idiopathic pulmonary fibrosis (nintedanib or pirfenidone) as confirmed by one of the following (attach documentation):*
    a. *Findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP); or*
    b. *A surgical lung biopsy demonstrating usual interstitial pneumonia (UIP); and*
    c. *Prescriber has excluded other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity;): and*
    d. *Patient has documentation of pulmonary function tests within the prior 60 days with a forced vital capacity (FVC) ≥50% predicted; and*
    e. *Patient has a carbon monoxide diffusion capacity (%DLco) of ≥30% predicted; or*
7. *Patient has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (nintedanib)as confirmed by the following (attach documentation); and*
    a. *Documentation of a chest high resolution computed tomography (HRCT) scan showing fibrosis affecting ≥ 10% of the lungs; and*
    b. *Patient has documented pulmonary function tests within the prior 60 days showing FVC ≥ 40% predicted; and*
    c. *Patient has a carbon monoxide diffusion capacity (%DLco) of ≥ 30-89% predicted; or*
8. *Patient has a diagnosis of chronic fibrosing interstitial lung disease with a progressive phenotype (nintedanib) as confirmed by the following (attach documentation); and*
    a. *Documentation of a chest high resolution computed tomography (HRCT) scan showing fibrosis affecting ≥ 10% of the lungs; and*
    b. *Patient has documented pulmonary function tests within the prior 60 days showing FVC ≥ 45% predicted; and*
    c. *Patient has a carbon monoxide diffusion capacity (%DLco) of ≥ 30-79% predicted; and*

d. *Patient has at least one sign of clinical progression for interstitial lung disease within the last 24 months despite standard treatment with an agent other than nintedanib or pirfenidone:*
    i. *A relative decline in the FVC of at least 10% predicted; or*
    ii. *A relative decline in the FVC of 5-9% predicted combined with at least one of the following:*
        1. *Worsening respiratory symptoms; or*
        2. *Increased extent of fibrosis on HRCT; or*
    iii. *Worsening of respiratory symptoms and an increased extent of fibrotic changes on HRCT only.*

If the criteria for coverage are met, initial requests will be given for 6 months. Additional authorizations will be considered at 6 month intervals when the following criteria are met:

1. *Adherence to pirfenidone (Esbriet) or nintedanib (Ofev) is confirmed; and*
2. *Documentation of a positive response to therapy, defined as meeting at least one of the following:*
    a. *Rate of lung function decline slowed; or*
    b. *Improved or no worsening of symptoms of cough or shortness of breath; and*
3. *Documentation is provided that the patient has remained tobacco-free; and*
4. *ALT, AST, and bilirubin are assessed periodically during therapy.*

Jason Kruse motioned to accept the criteria as modified, and Melissa Klotz 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.

Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for adenosine triphosphate-citrate lyase (ACL) inhibitors. Payment will be considered under the following conditions:

1. *Patient meets the FDA approved age; and*
2. *Documentation of adherence to prescribed lipid lowering medications (including a maximally tolerated statin), prior to ACL inhibitor therapy, for the previous 90 days is provided (further defined below, by diagnosis); and*
3. *Documentation is provided that medication will be used in combination with a maximally tolerated statin; and*
4. *A baseline and current lipid profile is provided. Baseline lipid profile is defined as a lipid profile obtained prior to pharmacologic therapy; and*
5. *Patient will continue to follow an appropriate low fat diet; and*
6. *Is prescribed by or in consultation with a lipidologist, cardiologist, or endocrinologist; and*
7. *If patient is taking in combination with:*
    a. *Simvastatin, dose does not exceed 20mg per day; or*
    b. *Pravastatin, dose does not exceed 40 mg per day; and*

8. *Concurrent use with a PCSK9 inhibitor will not be considered; and*
9. *Goal is defined as a 50% reduction in untreated baseline LDL-C; and*
10. *Is prescribed for one of the following diagnoses:*
    a. *Heterozygous Familial Hypercholesterolemia (HeFH):*
        i. *Documentation is provided verifying diagnosis (attach documentation/results), as evidenced by:*
            1. *Clinical manifestations of HeFH (e.g. tendon xanthomas, cutaneous xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma); or*
            2. *Confirmation of diagnosis by gene or receptor testing; and*
        ii. *Documentation of untreated LDL-C ≥ 190 mg-dL; and*
        iii. *Patient is unable to reach LDL-C goal with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (must include atorvastatin and rosuvastatin), PLUS ezetimibe 10mg daily; or*
    b. *Clinical Atherosclerotic Cardiovascular Disease (ASCVD):*
        i. *History of MI, angina, coronary or other arterial revascularization, stroke, TIA, or PVD of atherosclerotic origin; and*
        ii. *Patient is unable to reach LDL-C goal with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (must include atorvastatin and rosuvastatin), PLUS ezetimibe 10mg daily.*

If criteria for coverage are met, requests will be approved for 3 months. Additional authorizations will be considered at yearly intervals under the following conditions:

a. *Patient continues therapy with a maximally tolerated statin dose and remains at goal; and*
b. *Patient continues to follow an appropriate low fat diet; and*
c. *Documentation of LDL reduction is provided.*

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

Brett Faine motioned to accept the criteria as recommended, and Jason Kruse 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.

Peanut Allergen Powder-dnfp: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for Peanut (Arachis hypogaea) Allergen Powder-dnfp (Palforzia). Payment will be considered under the following conditions:

1. *Patient has a confirmed diagnosis of peanut allergy, as documented by a skin prick test to peanut ≥ 3 mm compared to control or a peanut-specific serum IgE ≥ 0.35 kUA/L (kilos of allergen-specific units per liter); and*
2. *Patient is 4 to 17 years of age at initiation of therapy or 4 years of age and older for continued up-dosing and maintenance therapy; and*
3. *Prescribed by or in consultation with an allergist or immunologist; and*
4. *Patient has access to injectable epinephrine; and*
5. *Will be used in conjunction with a peanut-avoidant diet; and*
6. *Patient does not have any of the following:*
    a. *Uncontrolled asthma; and/or*
    b. *A history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease; and*
7. *Patient will adhere to the complex up-dosing schedule that requires frequent visits to the administering healthcare facility; and*
8. *The initial dose escalation and the first dose of each new up-dosing level is administered under the supervision of a health care professional in a health care setting with the ability to manage potentially severe allergic reactions, including anaphylaxis. Initial dose escalation and the first dose of all up-dosing levels is not to be billed to the Iowa Medicaid outpatient pharmacy program as the dose is provided via the Office Dose Kit; and*
9. *Follows FDA approved dosing; and*
10. *PA is required for all up-dosing dose levels (dose level 1 through 11); and*

Maintenance dosing will be considered with documentation patient has successfully completed all dose levels of up-dosing.

Jason Kruse motioned to accept the criteria as recommended, 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.

Cystic Fibrosis Agents, Oral: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for oral cystic fibrosis agents. Payment will be considered for patients when the following criteria are met:

1. *Patient meets the FDA approved age; and*
2. *Patient has a diagnosis of cystic fibrosis (CF); and*
3. *Patient has a mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene confirmed by an FDA-cleared CF mutation test (attach test results) for which the requested drug is indicated; and*

4. *Prescriber is a CF specialist or pulmonologist; and*
5. *Baseline liver function tests (AST, ALT, and bilirubin) are provided; and*
6. *Requests for Trikafta will not be considered for patients with severe hepatic impairment (Child-Pugh Class C); and*
7. *Will not be used with other CFTR modulator therapies.*

If the criteria for coverage are met, an initial authorization will be given for 6 months. Additional approvals will be granted if the following criteria are met:

1. *Adherence to oral cystic fibrosis therapy is confirmed; and*
2. *Liver function tests (AST, ALT, and bilirubin) are assessed every 3 months during the first year of treatment and annually thereafter.*

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.

Valsartan/Sacubitril (Entresto): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for valsartan/sacubitril (Entresto). Requests above the manufacturer recommended dose will not be considered. Payment will be considered for patients when the following criteria are met:

1. *Patient is within the FDA labeled age for indication; and*
2. *Patient has a diagnosis of NYHA Functional Class II, III, or IV heart failure; and*
    a. *Patient has a left ventricular ejection fraction (LVEF) ≤40%; and*
    b. *Patient is currently tolerating treatment with an ACE inhibitor or angiotensin II receptor blocker (ARB) at a therapeutic dose, where replacement with valsartan/sacubitril is recommended to further reduce morbidity and mortality; and*
    c. *Is to be administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB (list medications patient is currently taking for the treatment of heart failure); or*
3. *Pediatric patient has a diagnosis of symptomatic heart failure (NYHA/Ross Class II to IV) due to systemic left ventricular systolic dysfunction with documentation of a left ventricular ejection fraction ≤ 40%; and*
4. *Will not be used in combination with an ACE inhibitor or ARB; and*
5. *Will not be used in combination with aliskiren (Tekturna) in diabetic patients; and*
6. *Patient does not have a history of angioedema associated with the use of ACE inhibitor or ARB therapy; and*
7. *Patient is not pregnant; and*
8. *Patient does not have severe hepatic impairment (Child Pugh Class C).*

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.

Novel Oral Anticoagulants: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is not required for preferred novel oral anticoagulants (NOACs). PA is required for non-preferred NOACs. Requests will be considered for FDA approved dosing and length of therapy for submitted diagnosis. Requests for doses outside of the manufacturer recommended dose will not be considered. Payment will be considered for FDA approved or compendia indications for the requested drug under the following conditions:

1. *Patient is within the FDA labeled age for indication; and*
2. *Patient does not have a mechanical heart valve; and*
3. *Patient does not have active bleeding; and*
4. *For a diagnosis of atrial fibrillation or stroke prevention, patient has the presence of at least one additional risk factor for stroke, with a CHA_2DS_2-VASc score ≥1; and*
5. *A recent creatinine clearance (CrCl) is provided; and*
6. *A recent Child-Pugh score is provided; and*
7. *Patient's current body weight is provided; and*
8. *Patient has documentation of a trial and therapy failure at a therapeutic dose with at least two preferred NOACs; and*
9. *For requests for edoxaban, when prescribed for the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE), documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin) is provided.*

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.

Voxelotor (Oxbryta): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Oxbryta (voxelotor). Payment will be considered for patients when the following criteria are met:

1. *Patient meets the FDA approved age; and*
2. *Patient has a diagnosis of sickle cell disease (SCD); and*
3. *Requested dose is within the FDA approved dosing; and*
4. *Patient has experienced at least two sickle cell-related vasoocclusive crises within the past 12 months (documentation required); and*

5. *Patient has documentation of an adequate trial and therapy failure with hydroxyurea; and*
6. *Baseline hemoglobin (Hb) range is ≥5.5 to ≤10.5 g/dL; and*
7. *Is prescribed by or in consultation with a hematologist; and*
8. *Patient is not receiving concomitant blood transfusion therapy.*

If the criteria for coverage are met, an initial authorization will be given for 6 months. Additional approvals will be granted if the following criteria are met:

1. *Documentation of an increase in hemoglobin by ≥1 g/dL from baseline; and*
2. *Documentation of a decrease in the number of sickle cell-related vasoocclusive crises.*

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.

IL-5 Antagonists: The Commission reviewed the 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 will be considered under the following conditions:

1. *Patient meets the FDA approved age for submitted diagnosis; and*
2. *Is dosed within FDA approved dosing for submitted diagnosis and age; and*
3. *Patient has a diagnosis of severe asthma with an eosinophilic phenotype, and*
    a. *Patient has a pretreatment blood eosinophil count of ≥ 150 cells per mcL within the previous 6 weeks or blood eosinophils ≥ 300 cells per 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*
4. *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 greater than 1000 cells/mcL; or*
    ii. *Eosinophil count greater than 10% of the total leukocyte count; and*

5. *Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist.*

If criteria for coverage are met, an initial authorization will be given for 3 months to assess the need for continued therapy. Requests for continuation of therapy will be based on continued medical necessity and will be considered when 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).*

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.

Insulin, Pre-Filled Pens: The Commission reviewed the prior authorization criteria recommended to be removed as follows:

Prior authorization (PA) is required for pre-filled insulin pens as designated on the Preferred Drug List (PDL). For pre-filled insulin pens requiring PA where the requested insulin is available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:

1. *The patient's visual or motor skills are impaired to such that they cannot accurately draw up their own insulin (not applicable for pediatric patients), and*
2. *There is no caregiver available to provide assistance, and*
3. *Patient does not reside in a long-term care facility, and*

4. *For requests for non-preferred pre-filled insulin pens, patient has documentation of a previous trial and therapy failure with a preferred pre-filled insulin pen within the same class (i.e. rapid, regular or basal).*

For pre-filled insulin pens requiring PA where the requested insulin is not available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:

1. *Preferred pre-filled insulin pens- Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal) or clinical rationale as to why the patient cannot use a preferred insulin agent, and*
2. *Non-preferred pre-filled insulin pens- Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal).*

Requests for Toujeo will require clinical rationale as to why the patient cannot use Lantus and patient must be using a minimum of 100 units of Lantus per day.

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 the draft DUR Digest Volume 32, Number 2.

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

At 12:14, Jason Kruse motioned to adjourn, and Chuck Wadle seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for November 4, 2020, with location or virtual status to be determined.

Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes November 4, 2020

Attendees:

Commission Members
Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Jason Kruse, D.O.; Chuck Wadle, D.O.; John Ellis, Pharm.D.; Jason Wilbur, M.D.; and Susan Parker, Pharm.D.
Staff
Pam Smith, R.Ph.
Guests
Erin Halverson, R.Ph., IME; Melissa Biddle, IME; Emily Rogers, Iowa Total Care; and Lisa Todd, Amerigroup.

Welcome & Introductions

Pam Smith called the meeting to order at 9:31 a.m. She performed most of the usual chairperson duties as this meeting was purely virtual and done through WebEx teleconference due to COVID-19. The minutes from the August 5, 2020 meeting were reviewed. Kellen Ludvigson 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 recommendation letter from the P&T Committee to the DUR Commission requesting development of prior authorization (PA) criteria for Nexletol, Nurtec ODT, Oxbryta, Palforzia, Reyvow, and Ubrelvy. Kellen Ludvigson motioned to retain Brett Faine as chairperson, and Jason Wilbur seconded. Jason Kruse then motioned to retain Kellen Ludvigson as vice-chairperson, and Brett Faine seconded. All members in attendance were in favor of both motions. Members were also asked to complete their annual conflict of interest disclosures. The revised public comment policy as discussed at the August meeting is now posted online at www.iadur.org. Conflict of interest forms are now required for both written and verbal comments, and those wanting to speak during the meeting will need to register in advance, as long as meetings continue to be held virtually.

Commission Recommendations for Retrospective DUR Agenda Topics

Fraud, Waste, and Abuse: The commission did not have any new recommendations. Pam Smith said that IME and MCO staff had discussed some ideas and will bring those back to future meetings. Jason Wilbur asked if the IME had access to PMP reports. Pam Smith said that IME had limited access to PMP information, likely not down to prescriber level. Susan Parker added that there were provisions in the SUPPORT Act, she believed effective in 2023, that do require obtaining some information from the PMP programs relative to Medicaid provider prescribing. The IME is still figuring out how to comply with those provisions given the current level of PMP access. CMS has not provided much guidance as of yet, but more will hopefully be coming in the future.

IME Pharmacy Update

The potential loss of rebates on Medication Assisted Treatment (MAT) medications due to a provision of the SUPPORT Act passed by Congress was discussed at the last meeting. However, since then, Congress has fixed the language in the SUPPORT Act, so states and the federal government can continue to receive the applicable rebates. The IME has moved into the Hoover Building in the Capitol Complex, 1305 East Walnut Street, though most employees continue to work remotely. The cost of dispensing study report, final in June 2020, has been posted on the reimbursement website. $10.38 per prescription was the mean cost reflected from that study, for all pharmacies including specialty. $9.71 was the mean without specialty pharmacies included. The current dispensing fee of $10.07 will remain in place until additional state funding is appropriated by the legislature, and a state plan amended has been completed thereafter.

Prevalence Report Summaries

Iowa Total Care: Emily Rogers spoke and provided written summaries that included ITC's statistics from June through August 2020, including: total paid amount ($58,155,843.50); total prescriptions (700,820); and unique users (100,698). 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 Outpatient Pharmacy, 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, Nucara Specialty, Hy-Vee Pharmacy Solutions, CVS, and Unity Point at Home. The top 5 therapeutic classes by paid amount were: Insulin; Sympathomimetics; Antiretrovirals; Anti-TNF-Alpha-Monoclonal Antibodies; and Antipsychotics - Misc. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Sympathomimetics; Proton-Pump Inhibitors; and HMG CoA Reductase Inhibitors. The most expensive drugs were Humira Pen, Vyvanse, Invega Sustenna, Trikafta, and Novolog, while omeprazole, atorvastatin, sertraline, lisinopril, and trazodone had the top 5 prescription counts.

Amerigroup*:* Lisa Todd provided an overview for Amerigroup's statistics from June 2020 through August 2020, including: total paid amount ($97,831,718); unique users (145,254); total prescriptions (1,091,035); generic prescriptions (979,720 totaling $20,006,784); brand prescriptions (111,315 totaling $77,824,934). The breakdown of utilization by age shows that ages 19-64 continue to have the highest utilization. The top 100 pharmacies by prescription count had 4 Walgreens locations and the University of Iowa Ambulatory Care Pharmacy making 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, CVS Specialty, Hy-Vee Pharmacy Solutions, and Nucara Specialty. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Antiasthmatic and Bronchodilator Agents; Analgesics – Anti-Inflammatory; and ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Antihypertensives, and Antipsychotics/Antimanic Agents. Humira (CF) Pen was the most expensive medication, followed by Vyvanse, Latuda, Invega Sustenna,

and Vraylar. Omeprazole had the highest prescription count, followed by: sertraline hcl, atorvastatin calcium, trazodone hcl, and lisinopril.

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from June 2020 through August 2020, including: total amount paid ($1,891,467), unique users (3,679); cost per user ($514.13), number of total prescriptions dispensed (22,615); and percent generic (89.0%). The top 5 therapeutic classes by paid amount were: Anti-Inflammatories, Non-NSAID; Antipsychotics – Atypicals; Anticonvulsants; Diabetic – Insulin Penfills; and Stimulants – Amphetamines – Long Acting. 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 Inhibitors. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Humira Pen, Vyvanse, Latuda, Invega Systenna, and Enbrel Sureclick. The five drugs with the highest prescription counts were: clonidine hcl, omeprazole, trazodone hcl, sertraline hcl, and lisinopril.

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 $157,879,029 was spent in total for 249,631 unique users who had 1,814,470 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Humira and Vyvanse were the two most expensive drugs for all 3 plans. The top 25 drugs by prescription count were also similar across FFS and both MCO plans. When all three plans were combined, Jeffrey Wilharm had the overall highest prescription count at 4,428. All three complete prevalence reports and the comparative summary can be found in the finalized meeting packet posted at https://iadur.org/sites/default/files/ghs-files//november42020dur-packet.pdf. Kellen Ludvigson asked how long COVID-19 POS overrides would be an option, and Susan Parker replied that was not yet decided, but that providers and pharmacies would be notified in advance of any changes. Pam Smith will pull additional information on providers with 40-50+ prescriptions per day, and bring that to the next meeting.

Public Comment

In addition to the written public comments provided to Commission members, posted in the finalized meeting packet at: https://iadur.org/sites/default/files/ghs-files//november42020dur-packet.pdf, they heard oral public comment from the speakers listed below. Kellen Ludvigson suggested adding a check box to the conflict of interest form for those wishing to provide comment, specifying whether it would be written or oral, to make administrative planning easier while meetings are being held remotely.

Name	Representing	Drug/Topic
Stephanie Kennedy	Greenwich Biosciences	Epidiolex
Brett McCabe	Aimmune Therapeutics	Palforzia
Jim Baumann	Pfizer	Eucrisa & Xeljanz/XR
Jenna Gianninoto	AbbVie	Oriahnn
Craig Biggs	Genentech	Evrysdi & Enspryng

ProDUR Edits

Baclofen Quantity Limits: At the August meeting, the DUR voted to make a recommendation to implement a quantity limit of 120 tablets per 30 days on all strengths of baclofen tablets. As this was the second review, with no further changes, the recommendation will be sent to the Department for consideration.

Retrospective DUR Data Presentations

Concurrent Use of Gabapentin and Pregabalin: Educational letters will be sent to providers regarding members identified as having concurrent claims of gabapentin and pregabalin, alerting the provider to the therapeutic duplication, the lack of evidence of an increased therapeutic benefit with the use of these medications concurrently, and asking if one agent could be discontinued. Given the small number of members meeting the criteria, Kellen Ludvigson also suggested phone calls to providers instead.

Concurrent Use of an SSRI and SNRI: The Commission questioned how the MCOs had found such varying member counts in their results. The data will be re-run, confirming specific drugs that are included, and brought to the next meeting.

Duplicate Therapy – Opioids: Educational letters will be sent to providers regarding members identified as using 3 or 4 unique opioids, alerting the provider to the therapeutic duplication and asking if one or more opioids could be discontinued. More information will be gathered for those members on 2 unique opioids, and brought back to the next meeting.

Retrospective DUR Proposals

Duplicate Therapy – Skeletal Muscle Relaxants: There is no evidence that concurrent use of two or more skeletal muscle relaxants offers any additional therapeutic benefit and puts patients at an increased risk of adverse effects. The Commission would like to proceed with this study proposal, identifying members with two more chemically distinct skeletal muscle relaxants, with at least 45 days overlap, over a 3 month period. Data results will be brought back to the next meeting.

Concurrent Gabapentinoid and Opioid: Data will be run to identify members with claims for a gabapentinoid and opioid, with at least 60 days overlap, over a 3 month period. The Commission will review the findings at the next meeting before deciding on any potential course of action.

The Commission took a short break and open session resumed at 11:32.

Prior Authorization

Annual Review of Prior Authorization Criteria: Changes were suggested for the following categories, to be discussed at upcoming meetings.

PA Category	Recommended Changes
Alpha2 Agonists, Extended-Release	Possibly remove criteria, check utilization first.
Anti-Diabetics, Non-Insulin Agents	Add criteria for SGLT2 use for heart failure, if agent is not already preferred on the PDL.
Crisaborole (Eucrisa)	Modify to account for member age and appropriate use of high-potency corticosteroids.
Hepatitis C Treatments	Look at ways Medicaid might help get people referred to specialists.
Isotretinoin (Oral)	Re-evaluate iPLEDGE enrollment and allow 24 week therapy needs.
Janus Kinase Inhibitors	Request P&T evaluate requirement for two preferred biological DMARDs as patients often do not want to try the injectables.
Multiple Sclerosis Agents-Oral	Try to simplify and shorten as criteria is getting long with so many oral options now available.
Nonsteroidal Anti-inflammatory Drugs	Possibly simplify now that there are so many preferred agents.
PCSK9 Inhibitors	On #6 allow consultation with a specialist.
Proton Pump Inhibitors	Consider revising #5 with regards to once daily dosing.
Topical Acne and Rosacea Products	Review due to reported prior authorization denial rate.
Vesicular Monoamine Transporter (VMAT) 2 Inhibitors	For 7a, that criteria is actually only intended for patients with Huntington's Disease.

Elagolix/Estradiol/Norethindrone Acetate (Oriahnn): The Commission reviewed the update prior authorization criteria as follows:

Prior authorization (PA) is required for elagolix containing drugs. 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. *Patient does not have severe hepatic impairment; and*
4. *Patient is not taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g. cyclosporine and gemfibrozil); and*
5. *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*

6. *Requests for elagolix, estradiol, and norethindrone acetate; elagolix (Oriahnn) 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 treatment.*

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

Brett Faine motioned to accept the criteria as recommended, and Jason Kruse 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.

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

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

1. *Patient meets the FDA approved age for submitted diagnosis and drug; and*
2. *Patient has an FDA approved or compendia indicated diagnosis, for requested drug, of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex, 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. *Follows FDA approved dosing for indication and drug. 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/d 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.

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

Kellen Ludvigson motioned to accept the criteria as recommended, and Jason Kruse 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.

Risdiplam (Evrysdi): The Commission reviewed the newly proposed prior authorization criteria as follows:

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

1. *Patient has a diagnosis of spinal muscular atrophy (SMA); and*
2. *Patient meets the FDA approved age for diagnosis; and*
3. *Dosing follows FDA approved dose for age and weight; and*
4. *A negative pregnancy test for females of reproductive potential prior to initiating treatment; and*
5. *Female patients of reproductive potential have been advised to use effective contraception during treatment and for at least 1 month after last dose; and*
6. *Patient does not have impaired liver function; and*
7. *Will not be prescribed concomitantly with other SMA treatments, such as Spinraza (nusinersen), Zolgensma (onasemnogene abeparvovec), or any other new products that are approved by the FDA and released; and*
8. *Documentation of previous SMA therapies and response to therapy is provided; and*
    a. *For patients currently on Spinraza, documentation Spinraza will be discontinued is provided, including date of last dose, and the appropriate interval based on the dosing frequency of the other drug has been met (i.e. 4 months from the last dose when on maintenance therapy); or*
    b. *For patients treated with Zolgensma, requests will not be considered; and*
9. *Is prescribed by or in consultation with a neurologist; and*
10. *Pharmacy will educate the member, or member's caregiver, on the storage and administration of Evrysdi, as replacements for improper storage or use will not be authorized.*

If the criteria for coverage are met, requests will be approved for 1 year. Requests for continuation of therapy will require documentation of a positive response to therapy.

Jason Kruse motioned to accept the criteria as recommended, and Kellen Ludvigson 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.

Satralizumab-mwge (Enspryng): The Commission reviewed the newly proposed prior authorization criteria as follows:

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

1. *Patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD); and*
2. *Patient is anti-aquaporin 4 (AQP4) seropositive (attach documentation); and*
3. *Patient meets the FDA approved age and dosing; and*
4. *Patient has a history of at least 1 relapse in the previous 12 months prior to initiation of therapy; and*
5. *Patient has been tested for tuberculosis prior to the initiation of therapy and does not have active or untreated latent tuberculosis; and*
6. *Patient has been tested for hepatitis B virus (HBV) prior to the initiation of therapy and confirmed negative for active HBV; and*
7. *Prescribed by a neurologist.*

If criteria for coverage are met, initial requests will be given for 1 year. Additional authorizations will be considered upon documentation of clinical response to therapy (i.e. a reduction in the frequency of relapse).

Jason Wilbur motioned to accept the criteria as recommended, and Jason Kruse 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.

Acute Migraine Treatments: The Commission reviewed the updated prior authorization criteria as follows:

No prior authorization (PA) is required for preferred acute migraine treatments, as indicated on the Preferred Drug List (PDL). PA is required for acute migraine treatments under the following conditions:

1. *A diagnosis of acute migraine; and*
2. *Patient meets the FDA approved age for requested agent; and*
3. *For preferred acute migraine treatments where PA is required, as indicated on the PDL, documentation of previous trials and therapy failures with two preferred agents that do not require PA; and/or*

4. *For non-preferred acute migraine treatments, documentation of previous trials and therapy failures with two preferred agents that do not require PA. Requests for non-preferred CGRP inhibitors will also require documentation of a trial and therapy failure with a preferred CGRP inhibitor; and/or*
5. *For quantities exceeding the established quantity limit for each agent, documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications; and/or*
6. *For non-preferred combination products, documentation of separate trials and therapy failures with the individual ingredients, in addition to the above criteria for preferred or non-preferred acute migraine treatments requiring PA.*

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, including the quantity limits below, no motion was necessary. The recommendation will be sent to the Department for consideration.

- Triptans – keep current limit of 12 unit doses of tablets, syringes or sprays per 30 days.
- Other acute migraine treatments – based on label dosing and safety of treating more than the specified number of migraines in a 30-day period.
    - Ubrogepant – 16 tablets per 30 days for each strength
    - Rimegepant – 15 tablets per 30 days
    - Lasmiditan – 50mg tablet – 8 tablets per 30 days; 100 mg tablet - 8 tablets per 30 days

Pirfenidone (Esbriet)/Nintedanib (Ofev): The Commission reviewed the updated prior authorization criteria as follows:

Prior authorization (PA) is required for pirfenidone (Esbriet) and nintedanib (Ofev). Dosing outside of the FDA approved dosing will not be considered. Concomitant use of pirfenidone and nintedanib will not be considered. Payment will be considered for patients when the following criteria are met:

1. *Patient meets the FDA approved age; and*
2. *Is prescribed by a pulmonologist; and*
3. *Patient does not have hepatic impairment as defined below:*
    a. *Nintedanib - Patient does not have moderate or severe hepatic impairment (Child Pugh B or C) or*
    b. *Pirfenidone - Patient does not have severe hepatic impairment (Child Pugh C); and*
4. *Patient does not have renal impairment as defined below:*
    a. *Nintedanib - Patient does not have severe renal impairment (CrCl <30ml/min) or end-stage renal disease or*
    b. *Pirfenidone – Patient does not have end-stage renal disease requiring dialysis; and*

5. *Patient does not utilize non-prescribed inhalants, such as vaping or other inhaled tobacco products, prior to initiating therapy and has been instructed to avoid tobacco products while using pirfenidone or nintedanib, and*
6. *Patient has a diagnosis of idiopathic pulmonary fibrosis (nintedanib or pirfenidone) as confirmed by one of the following (attach documentation):*
    a. *Findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP); or*
    b. *A surgical lung biopsy demonstrating usual interstitial pneumonia (UIP); and*
    c. *Prescriber has excluded other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity;): and*
    d. *Patient has documentation of pulmonary function tests within the prior 60 days with a forced vital capacity (FVC) ≥50% predicted; and*
    e. *Patient has a carbon monoxide diffusion capacity (%DLco) of ≥30% predicted; or*
7. *Patient has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (nintedanib)as confirmed by the following (attach documentation); and*
    a. *Documentation of a chest high resolution computed tomography (HRCT) scan showing fibrosis affecting ≥ 10% of the lungs; and*
    b. *Patient has documented pulmonary function tests within the prior 60 days showing FVC ≥ 40% predicted; and*
    c. *Patient has a carbon monoxide diffusion capacity (%DLco) of ≥ 30-89% predicted; or*
8. *Patient has a diagnosis of chronic fibrosing interstitial lung disease with a progressive phenotype (nintedanib) as confirmed by the following (attach documentation); and*
    a. *Documentation of a chest high resolution computed tomography (HRCT) scan showing fibrosis affecting ≥ 10% of the lungs; and*
    b. *Patient has documented pulmonary function tests within the prior 60 days showing FVC ≥ 45% predicted; and*
    c. *Patient has a carbon monoxide diffusion capacity (%DLco) of ≥ 30-79% predicted; and*
    d. *Patient has at least one sign of clinical progression for interstitial lung disease within the last 24 months despite standard treatment with an agent other than nintedanib or pirfenidone:*
        i. *A relative decline in the FVC of at least 10% predicted; or*
        ii. *A relative decline in the FVC of 5-9% predicted combined with at least one of the following:*
            1. *Worsening respiratory symptoms; or*
            2. *Increased extent of fibrosis on HRCT; or*
        iii. *Worsening of respiratory symptoms and an increased extent of fibrotic changes on HRCT only.*

If the criteria for coverage are met, initial requests will be given for 6 months. Additional authorizations will be considered at 6 month intervals when the following criteria are met:

1. *Adherence to pirfenidone (Esbriet) or nintedanib (Ofev) is confirmed; and*
2. *Documentation of a positive response to therapy, defined as meeting at least one of the following:*
    a. *Rate of lung function decline slowed; or*
    b. *Improved or no worsening of symptoms of cough or shortness of breath; and*
3. *Documentation is provided that the patient has remained tobacco-free; and*
4. *ALT, AST, and bilirubin are assessed periodically during therapy.*

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.

Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors: The Commission reviewed the newly proposed prior authorization criteria as follows:

Prior authorization (PA) is required for adenosine triphosphate-citrate lyase (ACL) inhibitors. Payment will be considered under the following conditions:

1. *Patient meets the FDA approved age; and*
2. *Documentation of adherence to prescribed lipid lowering medications (including a maximally tolerated statin), prior to ACL inhibitor therapy, for the previous 90 days is provided (further defined below, by diagnosis); and*
3. *Documentation is provided that medication will be used in combination with a maximally tolerated statin; and*
4. *A baseline and current lipid profile is provided. Baseline lipid profile is defined as a lipid profile obtained prior to pharmacologic therapy; and*
5. *Patient will continue to follow an appropriate low fat diet; and*
6. *Is prescribed by or in consultation with a lipidologist, cardiologist, or endocrinologist; and*
7. *If patient is taking in combination with:*
    a. *Simvastatin, dose does not exceed 20mg per day; or*
    b. *Pravastatin, dose does not exceed 40 mg per day; and*
8. *Concurrent use with a PCSK9 inhibitor will not be considered; and*
9. *Goal is defined as a 50% reduction in untreated baseline LDL-C; and*
10. *Is prescribed for one of the following diagnoses:*
    a. *Heterozygous Familial Hypercholesterolemia (HeFH):*
        i. *Documentation is provided verifying diagnosis (attach documentation/results), as evidenced by:*
            1. *Clinical manifestations of HeFH (e.g. tendon xanthomas, cutaneous xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma); or*
            2. *Confirmation of diagnosis by gene or receptor testing; and*

ii. *Documentation of untreated LDL-C ≥ 190 mg/dL; and*
iii. *Patient is unable to reach LDL-C goal with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (must include atorvastatin and rosuvastatin), PLUS ezetimibe 10mg daily; or*

b. *Clinical Atherosclerotic Cardiovascular Disease (ASCVD):*
   i. *History of MI, angina, coronary or other arterial revascularization, stroke, TIA, or PVD of atherosclerotic origin; and*
   ii. *Patient is unable to reach LDL-C goal with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (must include atorvastatin and rosuvastatin), PLUS ezetimibe 10mg daily.*

If criteria for coverage are met, requests will be approved for 3 months. Additional authorizations will be considered at yearly intervals under the following conditions:

a. *Patient continues therapy with a maximally tolerated statin dose and remains at goal; and*
b. *Patient continues to follow an appropriate low fat diet; and*
c. *Documentation of LDL reduction is provided.*

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.

Peanut Allergen Powder-dnfp: The Commission reviewed the newly proposed prior authorization criteria as follows:

Prior authorization (PA) is required for Peanut (Arachis hypogaea) Allergen Powder-dnfp (Palforzia). Payment will be considered under the following conditions:

1. *Patient has a confirmed diagnosis of peanut allergy, as documented by a skin prick test to peanut ≥ 3 mm compared to control or a peanut-specific serum IgE ≥ 0.35 kUA/L (kilos of allergen-specific units per liter); and*
2. *Patient is 4 to 17 years of age at initiation of therapy or 4 years of age and older for continued up-dosing and maintenance therapy; and*
3. *Prescribed by or in consultation with an allergist or immunologist; and*

4. *Patient has access to injectable epinephrine; and*
5. *Will be used in conjunction with a peanut-avoidant diet; and*
6. *Patient does not have any of the following:*
    a. *Uncontrolled asthma; and/or*
    b. *A history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease; and*
7. *Patient will adhere to the complex up-dosing schedule that requires frequent visits to the administering healthcare facility; and*
8. *The initial dose escalation and the first dose of each new up-dosing level is administered under the supervision of a health care professional in a health care setting with the ability to manage potentially severe allergic reactions, including anaphylaxis. Initial dose escalation and the first dose of all up-dosing levels is not to be billed to the Iowa Medicaid outpatient pharmacy program as the initial dose escalation is administered in the provider office and should be billed via the medical benefit and the first dose of all up-dosing levels is provided via the Office Dose Kit; and*
9. *Follows FDA approved dosing; and*
10. *PA is required for all up-dosing dose levels (dose level 1 through 11); and*

Maintenance dosing will be considered with documentation patient has successfully completed all dose levels of up-dosing.

Clarification was provided for #8. Kellen Ludvigson motioned to accept the criteria as amended, and Jason Kruse seconded. As this was the second review of these criteria, the recommendation will be sent to the Department for consideration.

Miscellaneous

DUR Digest: The Commission members conducted the first review of the draft DUR Digest Volume 33, Number 1.

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

At 12:59, Kellen Ludvigson motioned to adjourn, and Jason Wilbur seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for March 3, 2021, with location or virtual status to be determined.

Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes March 3, 2021

Attendees:

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

Welcome & Introductions

In Brett Faine's absence, vice-chairperson Kellen Ludvigson called the meeting to order at 9:31 a.m. This meeting was purely virtual and done through WebEx teleconference due to COVID-19. The minutes from the November 19, 2020 meeting were reviewed. Jason Kruse motioned to accept them, and Melissa Klotz seconded. All members were in favor. The recommendation letter sent to DHS after the last DUR meeting was also reviewed, along with a recommendation letter from the P&T Committee to the DUR Commission requesting development of prior authorization (PA) criteria for Evrysdi and Fintepla. Pam Smith provided an overview of additions to the SUPPORT Act Final Rule related to opioid standards, which will be discussed at future meetings.

IME Pharmacy Update

There is still an opening for a doctor on the DUR Commission, as Mark Graber reached the end of his 3 allowable terms, but the search has been on hold due to COVID-19.

Prevalence Report Summaries

***Amerigroup**:* Lisa Todd provided an overview for Amerigroup's statistics from September 2020 through November 2020, including: total paid amount ($99,126,320); unique users (152,661); total prescriptions (1,102,276); generic prescriptions (982,700 totaling $19,719,158); brand prescriptions (119,576 totaling $79,407,162). The breakdown of utilization by age shows that ages 19-64 continue to have the highest utilization. The top 100 pharmacies by prescription count had 4 Walgreens locations and the University of Iowa Ambulatory Care Pharmacy making 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, CVS Specialty, Hy-Vee Pharmacy Solutions, and Nucara Specialty. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Antiasthmatic and Bronchodilator Agents; Analgesics – Anti-Imflammatory; and ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents,

Anticonvulsants, Antihypertensives, and ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants. Humira (CF) Pen was the most expensive medication, followed by Vyvanse, Latuda, Vraylar, and Ozempic. Omeprazole had the highest prescription count, followed by: sertraline hcl, trazodone hcl, atorvastatin calcium, and gabapentin.

Iowa Total Care: Emily Rogers spoke and provided written summaries that included ITC's statistics from September through November 2020, including: total paid amount ($63,672,027.61); total prescriptions (761,226); and unique users (109,718). 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 Outpatient Pharmacy, 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, Nucara Specialty, Unity Point at Home, Hy-Vee Pharmacy Solutions, and CVS. The top 5 therapeutic classes by paid amount were: Insulin; Sympathomimetics; Antiretrovirals; Anti-TNF-alpha-Monoclonal Antibodies; and Antipsychotics - Misc. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Sympathomimetics; Proton-Pump Inhibitors; and HMG CoA Reductase Inhibitors. The most expensive drugs were Humira Pen, Vyvanse, Vraylar, Trikafta, and Invega Sustenna, while omeprazole, albuterol, sertraline, atorvastatin, and Lisinopril had the top 5 prescription counts.

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from September 2020 through November 2020, including: total amount paid ($2,240,412), unique users (3,710); cost per user ($603.88), number of total prescriptions dispensed (21,985); and percent generic (88.7%). The top 5 therapeutic classes by paid amount were: Anticonvulsants; Antipsychotics – Atypicals; Anti-Inflammatories, Non-NSAID; Muscular Dystrophy Agents; 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 Inhibitors. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Fintepla, Evrysdi, Humira Pen, Vyvanse, and Biktarvy. The five drugs with the highest prescription counts were: trazodone hcl, clonidine hcl, omeprazole, sertraline hcl, and albuterol.

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 $165,038,760 was spent in total for 264,089 unique users who had 1,885,487 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Humira and Vyvanse were the two most expensive drugs for the MCO plans. Humira was in third place for FFS, but Fintepla and Evrysdi had the top 2 spots. The top 25 drugs by prescription count were also similar across FFS and both MCO plans. When all three plans were combined, Scott Murray had the overall highest prescription count at 5,873. All three complete prevalence reports and the comparative summary can be found in the finalized meeting packet posted at https://iadur.org/sites/default/files/ghs-files//03-03-21-dur-meeting-packet-final.pdf.

Public Comment

In addition to the written public comments provided to Commission members, posted in the finalized meeting packet at: https://iadur.org/sites/default/files/ghs-files//03-03-21-dur-meeting-packet-final.pdf, they heard oral public comment from the speakers listed below.

Name	Representing	Drug/Topic
Jeremy Whalen	Genentech	Evrysdi & Enspryng
Holly Budlong	AbbVie	Elagolix
Tami Sova	Biogen	Vumerity
Kevin Duhrkopf	Sanofi Genzyme	Aubagio
Joseph Dang	Novartis	Kesimpta

Retrospective DUR Data Presentations

Concurrent Use of an SSRI and SNRI: Educational letters will be sent to providers regarding members identified as having concurrent claims for an SNRI and SSRI, alerting providers to the therapeutic duplication and increased risk of serious adverse effects, the lack of evidence of an increased therapeutic benefit with the use of these medications concurrently, and asking if one agent could be discontinued. The presented data will appear appear in a future DUR Digest.

Duplicate Therapy – Two Unique Opioids: Educational letters will be sent to providers regarding members identified as having 2 long-acting opioids, alerting providers to the therapeutic duplication and asking if one could be discontinued. Educational letters will also be sent to providers regarding members identified as having 2 short-acting opioids, alerting providers to the therapeutic duplication and asking if one could be discontinued and/or asking if the patient's chronic pain would be better controlled with a preferred long-acting opioid. Letters will be held until data from January through March 2021 is available.

Duplicate Therapy – Skeletal Muscle Relaxants: Educational letters will be sent to providers regarding members identified as having two or more chemically distinct muscle relaxants, with at least a 45 day overlap, in their pharmacy claims, alerting the provider(s) to the therapeutic duplication and increased risk of adverse effects, and asking if one agent could be discontinued. The DUR Commission will then re-evaluate the data trends to decide if additional steps, such as a ProDUR duplicate therapy edit, need to be implemented. This will also appear as a DUR Digest article.

Concurrent Use of Gabapentinoid and Opioid: Educational letters will be sent to providers regarding members identified as having concurrent therapy with an opioid and gabapentinoid in their pharmacy claims, alerting the provider(s) to the increased risk of adverse effects and asking if one agent could be discontinued.

Concurrent Opioids and Benzodiazepines: Data will be re-run, for a 90 day period with a 45 day overlap showing concurrent use of an opioid and benzodiazepine. Updated results will be brought back to the next meeting. Members with claims for naloxone within that group will also be reported.

Retrospective DUR Proposals

Duplicate Therapy – Benzodiazepines: The Commission would like to move forward with the recommendation to review data for members with two or more chemically distinct benzodiazepines, with at least 60 days overlap, over a 3 month period. Dr. Wilbur suggested also looking at non-sedative hypnotic benzodiazepines, like zolpidem and eszopiclone.

Single Ingredient Buprenorphine: Data will be run to look at members with a claim for single ingredient buprenorphine tablets, broken out by gender, then looking further at female patients and reviewing medical claims for a pregnancy diagnosis.

Commission Recommendations for Retrospective DUR Agenda Topics

There were no additional topic suggestions.

The Commission took a short break and open session resumed at 11:36. A roll call was conducted to ensure a quorum.

Prior Authorization

Binge Eating Disorder: The Commission reviewed the prior authorization criteria as follows:

Binge Eating Disorder (Vyvanse only)

a. *Patient is 18 to 55 years of age; and*
b. *Patient meets DSM-5 criteria for Binge Eating Disorder (BED); and*
c. *Patient has documentation of moderate to severe BED, as defined by the number of binge eating episodes per week (number of episodes must be reported); and*
d. *Patient has documentation of non-pharmacologic therapies tried, such as cognitive-behavioral therapy or interpersonal therapy, for a recent 3 month period, that did not significantly reduce the number of binge eating episodes; and*
e. *Prescription is written by a psychiatrist, psychiatric nurse practitioner, or psychiatric physician assistant; and*
f. *Patient has a BMI of 25 to 45; and*
g. *Patient does not have a history of cardiovascular disease; and*
h. *Patient has no history of substance abuse; and*
i. *Is not being prescribed for the treatment of obesity or weight loss; and*
j. *Doses above 70mg per day will not be considered.*
k. *Initial requests will be approved for 12 weeks.*

Requests for renewal must include documentation of a change from baseline at week 12 in the number of binge days per week.

DSM-5 Criteria

i. *Recurrent episodes of binge eating, including eating an abnormally large amount of food in a discrete period of time and has a feeling of lack of control over eating; and*
ii. *The binge eating episodes are marked by at least three of the following:*
    1. *Eating more rapidly than normal*
    2. *Eating until feeling uncomfortably full*
    3. *Eating large amounts of food when not feeling physically hungry*
    4. *Eating alone because of embarrassment by the amount of food consumed*
    5. *Feeling disgusted with oneself, depressed, or guilty after overeating; and*
iii. *Episodes occur at least 1 day a week for at least 3 months; and*
iv. *No regular use of inappropriate compensatory behaviors (e.g. purging, fasting, or excessive exercise) as are seen in bulimia nervosa; and*
v. *Does not occur solely during the course of bulimia nervosa or anorexia nervosa.*

Moderate to Severe BED

Based on the number of binge eating episodes per week:
Moderate - 4 to 7
Severe – 8 to 13
Extreme – 14 or more

Chuck Wadle motioned to accept the criteria as recommended, 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.

IL-5 Antagonists: The Commission reviewed the 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 under the following conditions:

1. *Is requested for an FDA approved or compendia indicated diagnosis; and*
2. *Patient meets the FDA approved or compendia indicated age and dose for submitted diagnosis; and*
3. *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*

4. *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; or*
5. *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-PDGFR□ 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*
6. *Prescribed by or in consultation with an allergist, hematologist, immunologist, pulmonologist, or rheumatologist.*

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 to assess the need for continued therapy. Requests for continuation of therapy will be based on continued medical necessity and will be considered when 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 a 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 of at least one other HES 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 recommended, 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.

Isotretinoin (Oral): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for oral isotretinoin therapy. Payment for non-preferred oral isotretinoin products will be authorized only for cases in which there is documentation of trial(s) and therapy failure with a preferred agent(s). Payment will be considered for preferred oral isotretinoin products for moderate to severe acne under the following conditions:

1. *There are documented trials and therapy failures of systemic antibiotic therapy and topical vitamin A derivative (tretinoin or adapalene) therapy. Documented trials and therapy failures of systemic antibiotic therapy and topical vitamin A derivative therapy are not required for approval for treatment of acne conglobata; and*
2. *Prescriber attests patient has enrolled in and meets all requirements of the iPLEDGE program.*

Initial authorization will be granted for up to 24 weeks. A minimum of 8 weeks without therapy is required to consider subsequent authorizations.

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.

Multiple Sclerosis Agents, Oral: The Commission reviewed the prior authorization criteria as follows:

For patients initiating therapy with a preferred oral multiple sclerosis agent, a manual prior authorization (PA) is not required if a preferred injectable interferon or non-

interferon agent is found in the member's pharmacy claims history in the previous 12 months. If a preferred injectable agent is not found in the member's pharmacy claims, documentation of the following must be provided:

1. *A diagnosis of relapsing forms of multiple sclerosis; and*
2. *Request must adhere to all FDA approved labeling, including indication, age, dosing, contraindications, and warnings and precautions; and*
3. *Documentation of a previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis.*

Requests for a non-preferred oral multiple sclerosis agent must document a previous trial and therapy failure with a preferred oral multiple sclerosis agent.

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 recommended, and Melissa Klotz 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.

Nonsteroidal Anti-Inflammatory Drugs: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for all non-preferred nonsteroidal anti-inflammatory drugs (NSAIDs). Payment for a non-preferred NSAID will be considered under the following conditions:

1. *Documentation of previous trials and therapy failures with at least three preferred NSAIDs; and*
2. *Requests for a non-preferred extended release NSAID must document previous trials and therapy failures with three preferred NSAIDs, one of which must be the preferred immediate release NSAID of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance.*

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 recommended, 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.

Proton Pump Inhibitors: The Commission discussed prior authorization criteria as follows and discussed next steps:

Prior authorization (PA) is not required for preferred proton pump inhibitors (PPI) for doses within the established quantity limits of one unit per day.

Requests for PPIs exceeding one unit per day will be considered for the following

diagnoses with additional documentation regarding the medical necessity:

1. *Barrett's esophagus (Please fax a copy of the scope results with the initial request)*
2. *Erosive esophagitis (Please fax a copy of the scope results with the initial request)*
3. *Hypersecretory conditions (Zollinger-Ellison syndrome, systemic mastocytosis, and multiple endocrine adenomas).*
4. *Recurrent peptic ulcer disease*
5. *Gastroesophageal reflux disease will be considered after documentation of a therapeutic trial and therapy failure with concomitant use of once daily PPI dosing and a bedtime dose of a histamine H2-receptor antagonist. Upon failure of the combination therapy, subsequent requests for PPIs exceeding one unit per day will be considered on a short term basis (up to 3 months). After the three month period, a retrial of the recommended once daily dosing will be required. A trial of the recommended once daily dosing will be required on an annual basis for those patients continuing to need doses beyond one unit per day.*
6. *Helicobacter pylori will be considered for up to 14 days of treatment with documentation of active infection.*

Payment for a non-preferred proton pump inhibitor will be authorized only for cases in which there is documentation of previous trials and therapy failures with three preferred products.

Criteria under #5 will be simplified, possibly to allow for failure on once-daily dosing at maximum daily dose, and potentially requiring higher once-a-day dosing prior to letting them go to twice daily. Pam Smith will look at current guidelines, and bring adjusted proposed criteria back to the next meeting.

Alpha$_2$ Agonists, Extended Release: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for extended-release alpha$_2$ agonists. Payment will be considered for patients when the following is met:

1. *The patient has a diagnosis of ADHD and is between 6 and 17 years of age; and*
2. *Previous trial 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 one preferred amphetamine and one preferred non-amphetamine stimulant.*

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 the criteria as recommended, but keep the ProDUR age edit, and Chuck Wadle seconded. All members were in favor. A claim for a preferred alpha$_2$ agonist, extended release, will adjudicate when the member is between 6 and 17 years of age (and meets already established quantity limits); requests for a non-preferred

agent will require prior authorization. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Elagolix/Estradiol/Norethindrone Acetate (Oriahnn): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for elagolix containing drugs. 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. *Patient does not have severe hepatic impairment; and*
4. *Patient is not taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g. cyclosporine and gemfibrozil); and*
5. *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*
6. *Requests for elagolix, estradiol, and norethindrone acetate; elagolix (Oriahnn) 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 treatment.*

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.

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

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

1. *Patient meets the FDA approved age for submitted diagnosis and drug; and*
2. *Patient has an FDA approved or compendia indicated diagnosis, for requested drug, of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex, 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. *Follows FDA approved dosing for indication and drug. 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/d 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.*

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.

Risdiplam (Evrysdi): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient has a diagnosis of spinal muscular atrophy (SMA); and*
2. *Patient meets the FDA approved age for diagnosis; and*
3. *Dosing follows FDA approved dose for age and weight; and*
4. *A negative pregnancy test for females of reproductive potential prior to initiating treatment; and*

5. *Female patients of reproductive potential have been advised to use effective contraception during treatment and for at least 1 month after last dose and male patients of reproductive potential have been counseled on the potential effects on fertility; and*
6. *Patient does not have impaired liver function; and*
7. *Will not be prescribed concomitantly with other SMA treatments, such as Spinraza (nusinersen), Zolgensma (onasemnogene abeparvovec), or any other new products that are approved by the FDA and released; and*
8. *Documentation of previous SMA therapies and response to therapy is provided; and*
    a. *For patients currently on Spinraza, documentation Spinraza will be discontinued is provided, including date of last dose, and the appropriate interval based on the dosing frequency of the other drug has been met (i.e. 4 months from the last dose when on maintenance therapy); or*
    b. *For patients treated with Zolgensma, requests will not be considered; and*
9. *Is prescribed by or in consultation with a neurologist; and*
10. *Pharmacy will educate the member, or member's caregiver, on the storage and administration of Evrysdi, as replacements for improper storage or use will not be authorized.*

If the criteria for coverage are met, requests will be approved for 1 year. Requests for continuation of therapy will require documentation of a positive response to therapy including stabilization or improved function unless intercurrent event (fracture, illness, other) affects functional testing.

Jason Kruse motioned to accept the criteria as amended, and Jason Wilbur seconded. All members were in favor. As additional changes had been recommended during this second review, these criteria will be reviewed again at the next meeting prior to the recommendation being sent to the Department for consideration.

Satralizumab-mwge (Enspryng): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD); and*
2. *Patient is anti-aquaporin 4 (AQP4) seropositive (attach documentation); and*
3. *Patient meets the FDA approved age and dosing; and*
4. *Patient has a history of at least 1 relapse in the previous 12 months prior to initiation of therapy; and*
5. *Patient has been tested for tuberculosis prior to the initiation of therapy and does not have active or untreated latent tuberculosis; and*

6. *Patient has been tested for hepatitis B virus (HBV) prior to the initiation of therapy and confirmed negative for active HBV; and*
7. *Prescribed by a neurologist.*

If criteria for coverage are met, initial requests will be given for 1 year. Additional authorizations will be considered upon documentation of clinical response to therapy (i.e. a reduction in the frequency of relapse).

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 the draft DUR Digest Volume 33, Number 1. Typos showing the word serious as serous will be corrected before posting.

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

At 12:36, Jason Kruse motioned to adjourn, and Chuck Wadle seconded. All in attendance agreed.

The next scheduled meeting is set for May 5, 2021, and will be a virtual meeting.

Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes May 5, 2021

Attendees:

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

Welcome & Introductions

Chairperson Brett Faine called the meeting to order at 9:32 a.m. This meeting was purely virtual and done through WebEx teleconference due to COVID-19. The minutes from the March 3, 2021 meeting were reviewed. Kellen Ludvigson motioned to accept them, and Jason Wilbur seconded. All members were in favor. The recommendation letter sent to DHS after the last DUR meeting was also reviewed.

IME Pharmacy Update

Jason Kruse and Melissa Klotz will begin their second terms in July. Meeting dates for 2022 will be reverting back to the previous schedule, with a meeting in February rather than March, to allow more time between that meeting and the following one in May. Liz Matney has been announced as the new Medicaid Director, effective June 1, 2021. The dispensing fee change included in the appropriations bill is still pending, with the legislature still in session.

Prevalence Report Summaries

Iowa Total Care: Emily Rogers spoke and provided written summaries that included ITC's statistics from December 2020 through February 2021, including: total paid amount ($63,709,647.82); total prescriptions (761,500); and unique users (109,822). 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 Outpatient Pharmacy, 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, Hy-Vee Pharmacy Solutions, Nucara Specialty, and CVS. The top 5 therapeutic classes by paid amount were: Insulin; Sympathomimetics; Anti-TNF-alpha-Monoclonal Antibodies; Antipsychotics – Misc.; and Antiretrovirals. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Sympathomimetics; Proton-Pump Inhibitors; and

HMG CoA Reductase Inhibitors. The most expensive drugs were Humira Pen, Vyvanse, Vraylar, Synagis, and Invega Sustenna, while omeprazole, sertraline, albuterol, atorvastatin, and lisinopril had the top 5 prescription counts.

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from December 2020 through February 2021, including: total amount paid ($2,213,577), unique users (3,755); cost per user ($589.50), number of total prescriptions dispensed (22,870); and percent generic (89.1%). The top 5 therapeutic classes by paid amount were: Anticonvulsants; Antipsychotics – Atypicals; Anti-Inflammatories, Non-NSAID; Muscular Dystrophy Agents; and Stimulants – Amphetamines – Long Acting. 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 Inhibitors. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Evrysdi, Fintepla, Humira Pen, Vyvanse, and Invega Sustenna. The five drugs with the highest prescription counts were: trazodone hcl, clonidine hcl, sertraline hcl, omeprazole, and escitalopram.

Amerigroup*:* Lisa Todd provided an overview for Amerigroup's statistics from December 2020 through February 2021, including: total paid amount ($103,221,148); unique users (151,293); total prescriptions (1,079,016); generic prescriptions (967,324 totaling $19,956,404); brand prescriptions (111,692 totaling $83,264,743). The breakdown of utilization by age shows that ages 19-64 continue to have the highest utilization. The top 100 pharmacies by prescription count had 4 Walgreens locations and the University of Iowa Ambulatory Care Pharmacy making 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, CVS Specialty, Hy-Vee Pharmacy Solutions, and Unity Point at Home. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Imflammatory; Antiasthmatic and Bronchodilator Agents; and ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants. These were the top five classes by prescription count: Antidepressants, Anticonvulsants, Antiasthmatic and Bronchodilator Agents, ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, and Antihypertensives. Humira (CF) Pen was the most expensive medication, followed by Vyvanse, Latuda, Vraylar, and Ozempic. Omeprazole had the highest prescription count, followed by: sertraline hcl, trazodone hcl, atorvastatin calcium, and gabapentin.

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 $172,210.79 was spent in total for 261,123 unique users who had 1,833,413 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Humira and Vyvanse were the two most expensive drugs for the MCO plans. Humira was in third place for FFS, but Everysdi and Fintepla had the top 2 spots. The top 25 drugs by prescription count were also similar across FFS and both MCO plans. When all three plans were combined, Jeffrey Wilharm had the overall highest prescription count at

4,345. 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
Joseph Dang	Novartis	Entresto
Kevin Durkopf	Genzyme	Aubagio
Maggie Murphy	Teva	Austedo

Written Provider Comments Received:
Dermatologic disease prior authorization requirements, Risdiplam, various criteria and edit issues at the pharmacy level, Hepatitis C, Xofluza

Written Manufacturer Comments Received: Austedo

Retrospective DUR Data Presentations

Concurrent Opioids and Benzodiazepines: Pam Smith and the MCO staff will research what other payors and states are doing with regards to this issue. Melissa Klotz thought it might be helpful to look at the strengths of medications and not just overall number of members, as those on higher dosages would be at more risk. Kellen Ludvigson also suggested looking at reviewing current quantity limits on benzodiazepines to narrow some down as they are not very stringent. This topic is included in the SUPPORT Act and required for CMS reporting, optional this year, but mandatory in 2 years.

Duplicate Therapy – Benzodiazepines: Letters will be sent to prescribers for members taking 2 or more anxiolytic benzodiazepines or sedative hypnotics, pointing out the duplicative therapy and increased risk of adverse effects, including physical and psychological dependence, and asking if one agent could be slowly tapered and discontinued or if alternatives to benzodiazepines could be used (i.e. antidepressants, buspirone or cognitive behavior therapy for anxiety; sleep hygiene for insomnia). Kellen Ludvigson also motioned to implement a ProDUR duplicate therapy benzodiazepine edit, and Jason Wilbur seconded. All members were in favor.

Single Ingredient Buprenorphine: Susan Parker suggested combining data sets from both MCOs and FFS to identify any recurring providers, then target those providers rather than approaching the issue from a member perspective. Letters will then be sent to prescribers inquiring about use of single ingredient buprenorphine tablets and asking if buprenorphine/naloxone would be appropriate for the member and encouraging use of buprenorphine/naloxone for all patients.

Retrospective DUR Proposals

Montelukast for Allergic Rhinitis: Data will be re-run to exclude members with an asthma diagnosis from the results. Updated data will be brought to the next meeting.

GERD and PPI Therapy: Discussion centered around the large number of members that would most likely be identified with ≥ 90 days therapy and suggested narrowing the focus. After discussion, the Commission recommended focusing on members newly started on a PPI and members on high dose PPI. Updated data will be brought back to the next meeting.

Commission Recommendations for Retrospective DUR Agenda Topics

There were no additional topic suggestions.

The Commission took a short break and open session resumed at 11:40 a.m.

Prospective DUR

Budesonide/Formoterol Inhalation Aerosol & Mometasone/Formoterol Inhalation Aerosol: Jason Kruse motioned to accept the recommended quantity limit, allowing 2 inhalers per 30 days. Kellen Ludvigson seconded, and Jason Wilbur abstained as he felt he did not have sufficient knowledge of the topic. All other members were in favor, and the motion passed. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Prior Authorization

Proton Pump Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is not required for preferred proton pump inhibitors (PPI) for doses within the established quantity limits of one unit per day.

Requests for PPIs exceeding one unit per day will be considered for the following diagnoses with additional documentation regarding the medical necessity:

1. *Barrett's esophagus, Erosive esophagitis, or Peptic stricture (Please fax a copy of the scope results with the initial request); or*
2. *Hypersecretory conditions (Zollinger-Ellison syndrome, systemic mastocytosis, and multiple endocrine adenomas); or*
3. *Recurrent peptic ulcer disease; or*
4. *Gastroesophageal reflux disease will be considered after documentation of a therapeutic trial and therapy failure with the requested PPI at maximal dose within the established quantity limit of one unit per day. Requests for PPIs exceeding one unit per day will be considered on a short term basis (up to 3 months). After the three month period, a dose reduction to the recommended once daily dosing will be required. A trial of the recommended once daily*

dosing will be required on an annual basis for those patients continuing to need doses beyond one unit per day; or

5. *Helicobacter pylori will be considered for up to 14 days of treatment with documentation of active infection.*

Payment for a non-preferred proton pump inhibitor will be authorized only for cases in which there is documentation of previous trials and therapy failures with three preferred products.

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.

Valsartan/Sacubitril (Entresto): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for valsartan/sacubitril (Entresto). Requests above the manufacturer recommended dose will not be considered. Payment will be considered for patients when the following criteria are met:

1. *Patient is within the FDA labeled age for indication; and*
2. *Patient has a diagnosis of NYHA Functional Class II, III, or IV heart failure; and*
    a. *Patient has a left ventricular ejection fraction (LVEF) ≤40%; and*
    b. *Patient is currently tolerating treatment with an ACE inhibitor or angiotensin ll receptor blocker (ARB) at a therapeutic dose, where replacement with valsartan/sacubitril is recommended to further reduce morbidity and mortality; and*
    c. *Is to be administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB (list medications patient is currently taking for the treatment of heart failure); or*
3. *Pediatric patient has a diagnosis of symptomatic heart failure (NYHA/Ross Class ll to IV) due to systemic left ventricular systolic dysfunction with documentation of a left ventricular ejection fraction ≤40%; and*
4. *Will not be used in combination with an ACE inhibitor or ARB; and*
5. *Will not be used in combination with aliskiren (Tekturna) in diabetic patients; and*
6. *Patient does not have a history of angioedema associated with the use of ACE inhibitor or ARB therapy; and*
7. *Patient is not pregnant; and*
8. *Patient does not have severe hepatic impairment (Child Pugh Class C); and*

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 the prior authorization criteria, and Jason Wilbur seconded. All members were in favor. Kellen Ludvigson then motioned to implement a quantity limit of 60 for 30 for all strengths, which John Ellis seconded. 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.

Initial Days Supply Limit Override: The Commission reviewed the 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. *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*

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.

Jason Kruse motioned to accept the criteria as amended, and Kellen Ludvigson 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.

Mannitol Inhalation Powder (Bronchitol): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for mannitol inhalation powder (Bronchitol). Payment will be considered when the following criteria are met:

1. *Patient has a diagnosis of cystic fibrosis; and*
2. *Patient meets the FDA approved age; and*
3. *Prescriber is a cystic fibrosis specialist or pulmonologist; and*
4. *Documentation is provided that patient has successfully completed the Bronchitol tolerance test (BTT); and*
5. *Patient will pre-medicate with a short-acting bronchodilator; and*
6. *Dose does not exceed the FDA approved dose.*

If the criteria for coverage are met, an initial authorization will be given for 6 months. Additional approvals will be granted if the following criteria are met:

1. *Adherence to mannitol inhalation powder (Bronchitol) therapy is confirmed; and*
2. *Patient has demonstrated improvement or stability of disease symptoms, such as improvement in FEV_1, decrease in pulmonary exacerbations, decrease in hospitalizations, or improved quality of life.*

Kellen Ludvigson 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.

Vesicular Monoamine Transporter (VMAT) 2 Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for VMAT 2 inhibitors. Payment for non-preferred agents will be considered only for cases in which there is documentation of previous trial and therapy failure with a preferred agent (when applicable, based on diagnosis). Payment will be considered under the following conditions:

<u>Tardive Dyskinesia</u> (Ingrezza or Austedo)

1. *Patient meets the FDA approved age; and*
2. *Patient has a diagnosis of tardive dyskinesia (TD) based on the presence of ALL of the following:*
    a. *Involuntary athetoid or choreiform movements*
    b. *Documentation or claims history of current or prior chronic use (≥ 3 months or 1 month in patients ≥ 60 years old) of a dopamine receptor blocking agent (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.)*
    c. *Symptoms lasting longer than 4-8 weeks; and*
3. *Prescribed by or in consultation with a neurologist or psychiatrist; and*
4. *Prescriber has evaluated the patient's current medications for consideration of a dose reduction, withdrawal, or change of the dopamine receptor blocking agent causing the TD; and*
5. *Documentation of baseline AIMS (Abnormal Involuntary Movement Scale) Score (attach AIMS); and*
6. *For Ingrezza:*
    a. *Will not be used concurrently with MAO inhibitors (e.g., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine, etc.) or strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, phenobarbital, rifampin and related agents, St. John's wort, etc.); and*
    b. *Will not be used concurrently with other vesicular monoamine transporter 2 (VMAT2) inhibitors; and*
    c. *Is prescribed within the FDA approved dosing; or*
7. *For Austedo:*
    a. *Patient does not have hepatic impairment;*

b. *Will not be used concurrently with MAO inhibitors, reserpine, or other VMAT2 inhibitors; and*
c. *Patients that are taking a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) or are poor CYP2D6 metabolizers, the daily dose does not exceed 36mg per day (18mg twice daily); and*
d. *Is prescribed within the FDA approved dosing.*

If criteria for coverage are met, initial requests will be given for 3 months.
Continuation of therapy will be considered when the following criteria are met:

1. *Patient continues to meet the criteria for initial approval; and*
2. *Documentation of improvement in TD symptoms as evidenced by a reduction of AIMS score from baseline (attach current AIMS).*

Chorea associated with Huntington's disease (Austedo or tetrabenazine)

1. *Patient meets the FDA approved age; and*
2. *Patient has a diagnosis of Huntington's disease with chorea symptoms; and*
3. *Prescribed by or in consultation with a neurologist or psychiatrist; and*
4. *Is prescribed within the FDA approved dosing; and*
5. *Patient is not suicidal, or does not have untreated or inadequately treated depression; and*
6. *Patient does not have hepatic impairment; and*
7. *Patient does not have concurrent therapy with MAO inhibitors, reserpine, or other VMAT2 inhibitors; and*
8. *For tetrabenazine, patients requiring doses above 50mg per day have been tested and genotyped for the drug metabolizing enzyme CYP2D6 to determine if they are a poor metabolizer or extensive metabolizer; and*
9. *In patients that are taking a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) or are poor CYP2D6 metabolizers, the daily dose does not exceed the following:*
    a. *Austedo - 36mg per day (18mg single dose) or*
    b. *Tetrabenazine – 50mg per day (25mg single dose)*

If criteria for coverage are met, initial requests will be given for 3 months.
Continuation of therapy will be considered when the following criteria are met:

1. *Patient continues to meet the criteria for initial approval; and*
2. *Documentation of improvement in chorea symptoms is provided.*

Chuck Wadle motioned to accept the criteria as amended, and Jason Kruse 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.

Risdiplam (Evrysdi): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient has a diagnosis of spinal muscular atrophy (SMA); and*
2. *Patient meets the FDA approved age for diagnosis; and*
3. *Dosing follows FDA approved dose for age and weight; and*

4. *A negative pregnancy test for females of reproductive potential prior to initiating treatment; and*
5. *Female patients of reproductive potential have been advised to use effective contraception during treatment and for at least 1 month after last dose and male patients of reproductive potential have been counseled on the potential effects on fertility; and*
6. *Patient does not have impaired liver function; and*
7. *Will not be prescribed concomitantly with other SMA treatments, such as Spinraza (nusinersen), Zolgensma (onasemnogene abeparvovec), or any other new products that are approved by the FDA and released; and*
8. *Documentation of previous SMA therapies and response to therapy is provided; and*
    a. *For patients currently on Spinraza, documentation Spinraza will be discontinued is provided, including date of last dose, and the appropriate interval based on the dosing frequency of the other drug has been met (i.e. 4 months from the last dose when on maintenance therapy); or*
    b. *For patients treated with Zolgensma, requests will not be considered; and*
9. *Is prescribed by or in consultation with a neurologist; and*
10. *Pharmacy will educate the member, or member's caregiver, on the storage and administration of Evrysdi, as replacements for improper storage or use will not be authorized.*

If the criteria for coverage are met, requests will be approved for 1 year. Requests for continuation of therapy will require documentation of a positive response to therapy including stabilization or improved function unless intercurrent event (fracture, illness, other) affects functional testing.

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.

Binge Eating Disorder: The Commission reviewed the prior authorization criteria as follows:

Binge Eating Disorder (Vyvanse only)

a. *Patient is 18 to 55 years of age; and*
b. *Patient meets DSM-5 criteria for Binge Eating Disorder (BED); and*
c. *Patient has documentation of moderate to severe BED, as defined by the number of binge eating episodes per week (number of episodes must be reported); and*
d. *Patient has documentation of non-pharmacologic therapies tried, such as cognitive-behavioral therapy or interpersonal therapy, for a recent 3 month*

period, that did not significantly reduce the number of binge eating episodes; and

e. *Prescription is written by a psychiatrist, psychiatric nurse practitioner, or psychiatric physician assistant; and*
f. *Patient has a BMI of 25 to 45; and*
g. *Patient does not have a history of cardiovascular disease; and*
h. *Patient has no history of substance abuse; and*
i. *Is not being prescribed for the treatment of obesity or weight loss; and*
j. *Doses above 70mg per day will not be considered.*
k. *Initial requests will be approved for 12 weeks.*

Requests for renewal must include documentation of a change from baseline at week 12 in the number of binge days per week.

<u>DSM-5 Criteria</u>

i. *Recurrent episodes of binge eating, including eating an abnormally large amount of food in a discrete period of time and has a feeling of lack of control over eating; and*
ii. *The binge eating episodes are marked by at least three of the following:*
    1. *Eating more rapidly than normal*
    2. *Eating until feeling uncomfortably full*
    3. *Eating large amounts of food when not feeling physically hungry*
    4. *Eating alone because of embarrassment by the amount of food consumed*
    5. *Feeling disgusted with oneself, depressed, or guilty after overeating; and*
iii. *Episodes occur at least 1 day a week for at least 3 months; and*
iv. *No regular use of inappropriate compensatory behaviors (e.g. purging, fasting, or excessive exercise) as are seen in bulimia nervosa; and*
v. *Does not occur solely during the course of bulimia nervosa or anorexia nervosa.*

<u>Moderate to Severe BED</u>

Based on the number of binge eating episodes per week:
Moderate - 4 to 7
Severe – 8 to 13
Extreme – 14 or more

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.

IL-5 Antagonists: The Commission reviewed the 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 under the following conditions:

1. *Is requested for an FDA approved or compendia indicated diagnosis; and*
2. *Patient meets the FDA approved or compendia indicated age and dose for submitted diagnosis; and*
3. *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*
4. *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; or*
5. *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-PDGFR□ 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*
6. *Prescribed by or in consultation with an allergist, hematologist, immunologist, pulmonologist, or rheumatologist.*

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 to assess the need for continued therapy. Requests for continuation of

therapy will be based on continued medical necessity and will be considered when 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 a 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 of at least one other HES 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.

Isotretinoin (Oral): The Commission reviewed the prior authorization criteria as follows:
Prior authorization (PA) is required for oral isotretinoin therapy. Payment for non-preferred oral isotretinoin products will be authorized only for cases in which there is documentation of trial(s) and therapy failure with a preferred agent(s). Payment will be considered for preferred oral isotretinoin products for moderate to severe acne under the following conditions:

1. *There are documented trials and therapy failures of systemic antibiotic therapy and topical vitamin A derivative (tretinoin or adapalene) therapy. Documented trials and therapy failures of systemic antibiotic therapy and topical vitamin A derivative therapy are not required for approval for treatment of acne conglobata; and*
2. *Prescriber attests patient has enrolled in and meets all requirements of the iPLEDGE program.*

Initial authorization will be granted for up to 24 weeks. A minimum of 8 weeks without therapy is required to consider subsequent authorizations.

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.

Multiple Sclerosis Agents, Oral: The Commission reviewed the prior authorization criteria as follows:

For patients initiating therapy with a preferred oral multiple sclerosis agent, a manual prior authorization (PA) is not required if a preferred injectable interferon or non-interferon agent is found in the member's pharmacy claims history in the previous 12 months. If a preferred injectable agent is not found in the member's pharmacy claims, documentation of the following must be provided:

1. *A diagnosis of relapsing forms of multiple sclerosis; and*
2. *Request must adhere to all FDA approved labeling, including indication, age, dosing, contraindications, and warnings and precautions; and*
3. *Documentation of a previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis.*

Requests for a non-preferred oral multiple sclerosis agent must document a previous trial and therapy failure with a preferred oral multiple sclerosis agent.

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.

Nonsteroidal Anti-Inflammatory Drugs: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for all non-preferred nonsteroidal anti-inflammatory drugs (NSAIDs). Payment for a non-preferred NSAID will be considered under the following conditions:

1. *Documentation of previous trials and therapy failures with at least three preferred NSAIDs; and*
2. *Requests for a non-preferred extended release NSAID must document previous trials and therapy failures with three preferred NSAIDs, one of which must be the preferred immediate release NSAID of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance.*

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.

Alpha$_2$ Agonists, Extended Release: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for extended-release alpha$_2$ agonists. Payment will be considered for patients when the following is met:

1. *The patient has a diagnosis of ADHD and is between 6 and 17 years of age; and*
2. *Previous trial 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 one preferred amphetamine and one preferred non-amphetamine stimulant.*

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

At the March meeting, the commission voted to remove the criteria as recommended, but keep the ProDUR age edit. A claim for a preferred alpha$_2$ agonist, extended release, will adjudicate when the member is between 6 and 17 years of age (and meets already established quantity limits); requests for a non-preferred agent will require prior authorization. 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 the draft DUR Digest Volume 33, Number 2. A typo in the second paragraph will be corrected.

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

At 12:19, Kellen Ludvigson motioned to adjourn, and Jason Wilbur seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for August 4, 2021, and will be a virtual meeting.

Appendix J
Mental Health Advisory Group

Mental Health Advisory Group

The Iowa Medicaid Drug Utilization Review Mental Health Advisory Group (MHAG), formerly know as the Mental Health Work Group, was established in SFY08.

The Mental Health Advisory Group is a separate entity from the Iowa Medicaid Drug Utilization Review (DUR) Commission. All recommendations from the MHAG must be approved by the DUR Commission before they can be implemented.

The original goal of the MHAG was to address issues that developed specific to the pediatric and adolescent psychiatrists within the State of Iowa when mental health drug consolidation edits were implemented in October, 2007. Since then, the DUR Commission has made the decision to refer to the MHAG other mental health issues as issues arise for their consultation.

The MHAG did not meet in SFY21.

Appendix K
Recommendations to the P&T

P & T Recommendations
SFY21

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 L
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