Department of
HUMAN SERVICES

Iowa Medicaid Drug Utilization Review Commission Annual Report of Activities Fee-for-Service Program SFY20

September 2020

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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 2019 through June 2020.

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, roughly 90 percent of the population moved to managed care leaving 10 percent of the population in the fee-for-service (FFS) program. Due to the transition, the DUR Commission only has access to FFS claims, limiting the ability to perform patient-focused and problem-focused reviews. However, the 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, with outcomes of the retroDUR initiatives to be reported in state fiscal year 2021. 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. 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 SFY20 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 previous years. The direct cost savings from all activities of the DUR Commission are calculated to be $9,939.36*. 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	$9,939.36*

Patient-focused reviews resulted in $9,939.36* in direct cost savings, or $552.19* per patient evaluated. This estimate is based on the 19 suggestions made by the DUR Commission identified from the review of the medication therapy of 234 patient profiles selected for intervention. Of these 19 suggestions, 8 suggestions were implemented by the providers, resulting in a 42 percent impact rate.

Patient-Focused Profile Review	
Suggestions Made	19
Therapy Changed	8
IMPACT RATE	42%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated	$552.19*
Dollars Saved on Medication	$9,939.36*

Problem-focused reviews were conducted based on the review of the quarterly prevalence report. These interventions are informative in nature.

Problem-Focused Profile Review	
Patients Evaluated	1
Therapy Changed	0
IMPACT RATE	0%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated	$0*
Dollars Saved on Medication	$0*

*Savings reported are pre-rebate, total dollars

Comparison to Previous SFY Report

Cost savings estimates for SFY20 ($9,939.36*) are slightly higher than last year ($7,913.23*). 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 SFY20 patient-focused reviews ($9,939.36*) were higher than SFY19 ($1,317.31*). The number of suggestions made (19) vs. (34) decreased while the number of suggestions that were accepted (8) vs. (5) from SFY19 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 SFY20 ($0*) were lower than SFY19 ($6,595.92*). This was due to the single problem-focused review dealing with a drug therapy related issue whereas last year the interventions conducted identified multiple drug therapy related issues from review of the monthly paid claims report that had an impact.

*Savings reported are pre-rebate, total dollars

Results by Review Type

Patient-Focused Review

During this evaluation period, 45 educational intervention letters were mailed to prescribers and pharmacies regarding medication therapy. Of this total, 26 letters (58 percent) were mailed to prescribers, and 19 letters (42 percent) were mailed to pharmacies. Providers are invited to voluntarily respond to DUR Commission letters. Providers returned 18 responses to these letters, resulting in an overall response rate by the providers of 40 percent. Of the 18 responses, 11 (61 percent) were from prescribers and 7 (39 percent) were from pharmacies. The overall response rate differed between physicians and pharmacies; 42 percent for physicians and 37 percent for pharmacies.

In these 45 educational letters, the DUR Commission made 19 suggestions. Of these suggestions, 19 (100 percent) were therapeutic in nature while 0 (0 percent) were cost-saving in nature. The suggested change was implemented in 8 cases, resulting in an overall impact rate of 42 percent.

Of the 19 suggestions, two types of suggestions accounted for 100 percent of the total. Those two suggestions were Not Optimal Drug (5 percent) and Therapeutic Duplication (95 percent). Of the 8 changes, the only reason for the Commission's inquiry was Therapeutic Duplication (100 percent). No other single category accounted for any changes.

The suggestion(s) that resulted in change the highest percentage of the time was Therapeutic Duplication (44 percent).

Implementation of therapeutic suggestions resulted in direct drug cost savings of $9,939.36*. No cost-saving suggestions were suggested or implemented resulting in zero direct drug cost savings*. The total amount saved on medication utilization was calculated to be $9,939.36* for the 18 patients evaluated, or $552.19* per patient.

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

Problem-Focused Reviews

One problem-focused review was evaluated during SFY20. In conducting this review, one patient was selected for intervention. Of this one intervention, a positive outcome was not realized, resulting in an impact rate of 0 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 similar 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 SFY20, 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.

Three 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.

Mark Graber, M.D. completed his third term on the DUR in June 2020.

Emily Rogers, Pharm.D. began her two year term on the Commission as the MCO representative.

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.

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

*Savings reported are pre-rebate, total dollars

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
2019-2020

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 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.

Mark Graber, M.D., FACEP, MSHCE
Dr. Graber is a professor of clinical Emergency and Family Medicine at the University of Iowa. He has been at the University of Iowa since 1992. Before this he practiced in Wyoming and Upstate New York. He has a Master's degree in Health Care Ethics, is a Fulbright scholar and is a Fellow in the American College of Emergency Physicians. He is the author of two books and numerous articles. Dr. Graber was reappointed for a third term in 2016 which expired in June 2020.

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 appointed to the DUR Commission in 2017; her first term will expire in June 2021.

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 appointed to the DUR Commission in 2017; his first term will expire in June 2021.

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 was recently appointed to 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 Masters in Business Administration. Dr. Rogers serves on the DUR Commission as the MCO Pharmacy Director representative, which rotates among the MCOs every 2 years.

Charles Wadle, D.O.
Dr. Wadle graduated from Des Moines University of Osteopathic Medicine and then completed his residency at the University of Nebraska Medical Center in Omaha. Dr. Wadle is currently Section Chief of Outpatient Behavioral Health at Broadlawns Medical Center in Des Moines. He is a Board Certified in Psychiatry by the American Board of Psychiatry and Neurology; Addictions by American Society of Addiction Medicine and American Board of Addiction Medicine; and Quality Assurance by the American Board of Quality Assurance and Utilization Review Physicians. Dr. Wadle also serves on the Iowa Medicaid P&T Committee. Dr. Wadle was 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
SFY20

Patient Focused Profile Review

Suggestions Made	19
Therapy Changed	8
Impact Rate	42.11%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated*	$552.19
Dollars Saved on Medication*	$9,939.36

Problem-Focused Profile Review

Suggestions Made	1
Therapy Changed	0
Impact Rate	0.00%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated*	$0.00
Dollars Saved on Medication*	$0.00

Cost Savings Estimate* **$9,939.36**

*Savings reported are pre-rebate, total dollars

Appendix D
Results Patient-Focused

FFS Patient - Focused Reviews

SFY20

Initial Review Date	**October 2018 - September 2019**			
Re-review Date	**July 2019 - June 2020**			
Patient Profiles Reviewed	234			
Patient Profiles Selected for Intervention	18			
Intervention Letters Sent				
Prescribers	26	57.78%		
Pharmacists	19	42.22%		
Total	**45**	100%		
Responses Received				
Prescribers	11	61.11%	**Overall Response Rate**	**40.00%**
Pharmacists	7	38.89%	Prescriber Response Rate	42.31%
Total	**18**	100.00%	Pharmacy Response Rate	36.84%
Total Number of Suggestions				
Therapeutic	19	100.00%		
Cost-Saving	0	0.00%		
Total	**19**	100%		
Total Number of Changes				
Therapeutic	8	100.00%	**Impact Rate**	**42.11%**
Cost-Saving	0	0.00%		
Positive Impact Only	0	0.00%		
Total	**8**	100%		

FFS Patient - Focused Review
Month by Month Breakdown
SFY20

Initial Review Date **Evaluation Date**	**Nov-18** **Aug-19**	**Feb-19** **Nov-19**	**May-19** **Feb-20**	**Aug-19** **May-20**	**Total**
Profiles Reviewed	62	41	83	48	**234**
Patient Profiles Available for Evaluation	2	4	7	5	**18**
Total Number of Suggstions Made	2	4	8	5	**19**
Therapeutic	2	4	8	5	**19**
Cost Saving	0	0	0	0	**0**
Total Number of Changes Made	0	3	3	2	**8**
Therapeutic	0	3	3	2	**8**
Cost Saving	0	0	0	0	**0**
Positive Impact Only	0	0	0	0	**0**
Total Dollars Saved - Therapeutic Changes	$0.00	$8,430.12	$393.24	$1,116.00	**$9,939.36**
Total Dollars Saved - Cost Saving	$0.00	$0.00	$0.00	$0.00	**$0.00**
Total Dollars Saved on Medication*	$0.00	$8,430.12	$393.24	$1,116.00	**$9,939.36**
Total Dollars Saved per Profile Evaluated	$0.00	$2,107.53	$56.18	$223.20	$552.19

*Savings reported are pre-rebate total dollars.

FFS Medicaid DUR Impact Assessment
Report Patient-Focused Reviews SFY20

Initial Review Date Evaluation Date	Nov-18 Aug-19	Feb-19 Nov-19	May-19 Feb-20	Aug-19 May-20	**Total**	
Profiles Reviewed	62	41	83	48	**234**	
Profiles Evaluated	2	4	7	5	**18**	
Letters Sent	5	9	18	13	**45**	100.00%
Prescribers	3	5	10	8	26	57.78%
Pharmacy	2	4	8	5	19	42.22%
Responses Received	0	3	7	8	**18**	100.00%
Prescribers	0	1	5	5	11	61.11%
Pharmacy	0	2	2	3	7	38.89%
Total Number of Templates Mentioned	2	4	8	5	**19**	100.00%
Therapeutic	2	4	8	5	19	100.00%
Cost-Saving	0	0	0	0	0	0.00%
Total Number of Changes Made	0	3	3	2	**8**	100.00%
Therapeutic	0	3	3	2	8	100.00%
Cost-Saving	0	0	0	0	0	0.00%
Positive Impact Only	0	0	0	0	0	0.00%
Total Dollars Saved - Therapeutic Changes	$0.00	$8,430.12	$393.24	$1,116.00	**$9,939.36**	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*	$0.00	$8,430.12	$393.24	$1,116.00	**$9,939.36**	100.00%
Total Dollars Saved Per Profile Evaluated	$0.00	$2,107.53	$56.18	$223.20	**$552.19**	

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

Comment Type
FFS Patient Focused Reviews
SFY20

Initial Review Date	**Nov-18**		**Feb-19**		**May-19**		**Aug-19**			
Evaluation Date	**Aug-19**		**Nov-19**		**Feb-20**		**May-20**		**Total**	
Template Classification	**Suggestions**	**Changes**	**Suggestions**	**Changes**	**Suggestions**	**Changes**	**Suggestions**	**Changes**	**Total Suggestions**	**Total Changes**
Adverse Drug Reaction	0	0	0	0	0	0	0	0	0	0
Drug-Disease Interaction	0	0	0	0	0	0	0	0	0	0
Drug-Drug Interaction	0	0	0	0	0	0	0	0	0	0
High Cost Drug	0	0	0	0	0	0	0	0	0	0
Innapropriate Billing	0	0	0	0	0	0	0	0	0	0
Missing Drug Therapy	0	0	0	0	0	0	0	0	0	0
Not Optimal Dosage Form	0	0	0	0	0	0	0	0	0	0
Not Optimal Dose	0	0	0	0	0	0	0	0	0	0
Not Optimal Drug	0	0	0	0	1	0	0	0	1	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	2	0	4	3	7	3	5	2	18	8
Unnecessary Drug Therapy	0	0	0	0	0	0	0	0	0	0
Total	**2**	**0**	**4**	**3**	**8**	**3**	**5**	**2**	**19**	**8**

FFS Patient Focused Reviews
SFY20

Template Classification	Total Suggestions	Total Changes	% of Total Suggestions	% of Total Changes	% of Suggestions Changed	% Dollars Saved
Adverse Drug Reaction	0	0	0.00%	0.00%	0.00%	0.00%
Drug-Disease Interaction	0	0	0.00%	0.00%	0.00%	0.00%
Drug-Drug Interaction	0	0	0.00%	0.00%	0.00%	0.00%
High Cost Drug	0	0	0.00%	0.00%	0.00%	0.00%
Inappropriate Billing	0	0	0.00%	0.00%	0.00%	0.00%
Missing Drug Therapy	0	0	0.00%	0.00%	0.00%	0.00%
Not Optimal Dosage Form	0	0	0.00%	0.00%	0.00%	0.00%
Not Optimal Dose	0	0	0.00%	0.00%	0.00%	0.00%
Not Optimal Drug	1	0	5.26%	0.00%	0.00%	0.00%
Not Optimal Duration	0	0	0.00%	0.00%	0.00%	0.00%
Patient Overuse	0	0	0.00%	0.00%	0.00%	0.00%
Patient Underuse	0	0	0.00%	0.00%	0.00%	0.00%
Potential Generic Use	0	0	0.00%	0.00%	0.00%	0.00%
Therapeutic Alternative	0	0	0.00%	0.00%	0.00%	0.00%
Therapeutic Duplication	18	8	94.74%	100.00%	44.44%	100.00%
Unnecessary Drug Therapy	0	0	0.00%	0.00%	0.00%	0.00%
Total	**19**	**8**	100.00%	100.00%	**42.11%**	100.00%

FFS Savings By Template Class

SFY20

Initial Review Date	Nov-18	Feb-19	May-19	Aug-19	
Evaluation Date	Aug-19	Nov-19	Feb-20	May-20	
					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	$0.00	$8,430.12	$393.24	$1,116.00	$9,939.36
Unnecessary Drug Therapy	$0.00	$0.00	$0.00	$0.00	$0.00
Total	**$0.00**	**$8,430.12**	**$393.24**	**$1,116.00**	**$9,939.36**

*additional cost but positive impact assumed

Appendix E
Results Problem-Focused

FFS Problem-Focused Studies
Impact Rate
SFY 2020

Focus	Review Period	Evaluation Period	Patients Evaluated	Positive Impact	Impact Rate
Gabapentin Overutilization	09/01/2019 - 09/30/2019	05/01/2020 - 05/31/2020	1	0	0.00%
TOTAL			**1**	**0**	**0.00%**

FFS Problem-Focused Studies
SFY 2020

Focus	Review Period	Evaluation Period	Patients Reviewed	Patients Selected	Cost Savings Calculated
Gabapentin Overutilization	09/01/2019 - 09/30/2019	05/01/2020 - 05/31/2020	1	1	$0.00
TOTAL			**1**	**1**	**$0.00** *

*Savings reported are pre-rebate, total dollars.

Prepared by the Iowa Medicaid Drug Utilization Review Commission

Appendix F
Descriptions Problem-Focused

Description of Problem Focused Studies
SFY20

One problem focused study was conducted in SFY20 based on review of the quarterly prevalence report. The individual was identified while reviewing their specific medication profile for drug specific issues. Educational letters were sent to the prescribers and pharmacy. The intent of the educational letters was to be informative in nature, alerting providers to the overutilization of medication.

Appendix G
Prior Authorization Recommendations

Prior Authorization Criteria Review
SFY20

During the fiscal year ending 2020, 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
08/07/2018	• Cannabidiol (Epidiolex)	• Benzodiazepines • Lupron Depot – Adult • Dupilumab (Dupixent) • Growth Hormone	
11/06/2019	• Ospemifine (Osphena) • Aripiprazole Tablets with Sensor (Abilify MyCite)	• Multiple Sclerosis Agents - Oral • CGRP Inhibitors	
03/04/2020		• Linezolid • Dupilumab (Dupixent) • Biologicals for Axial Spondyloarthritis • Ivabradine (Corlanor) • Anti-Diabetic Non-Insulin Agents	• Chronic Pain Syndromes
05/06/2020 Cancelled (*due to COVID-19)*			

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August 8, 2019

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 7, 2019. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Benzodiazepines; Lupron Depot – Adult; Dupilumab (Dupixent); Cannabidiol (Epidiolex): and Growth Hormones. The DUR Commission members also discussed a proposed ProDUR edit limiting initial opioid prescriptions to a seven-day supply. The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments received from the medical/pharmacy associations in response to a May 7, 2019 letter that was sent to them detailing the proposed criteria for Benzodiazepines; Lupron Depot – Adult; Dupilumab (Dupixent); Cannabidiol (Epidiolex): and Growth Hormones in addition to the proposed ProDUR edit for an initial seven-day opioid supply limit.

Benzodiazepines

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization is required for non-preferred benzodiazepines. Payment for non-preferred benzodiazepines will be authorized in cases with documentation of previous trial and therapy failure with two preferred products. If a long-acting medication is requested, one of the therapeutic trials must include the immediate release form of the requested benzodiazepine. *The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determine if the use of a benzodiazepine is appropriate for this member.*

~~Requests for clobazam (ONFI) will be considered for a diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older when used as an adjunctive treatment.~~ Prior authorization will be approved for up to 12 months for documented:

1. Generalized anxiety disorder.
2. Panic attack with or without agoraphobia.
3. Seizure.
4. Non-progressive motor disorder.
5. Dystonia.

Prior authorization requests will be approved for up to a three-month period for all other diagnoses related to the use of benzodiazepines.

For patients taking concurrent opioids, the prescriber must document the following:

1. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
2. *Documentation as to why concurrent use is medically necessary is provided; and*
3. *A plan to taper the opioid or benzodiazepine is provided, if appropriate.*

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

Lupron Depot - Adult

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization is required for Lupron Depot (leuprolide acetate). Payment will be considered for patients under the following conditions:

1. Patient *meets the FDA approved* ~~is 18 years of~~ age ~~or older~~; and
2. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and
3. Patient has a diagnosis of endometriosis for ~~whom~~ *which concurrent* therapy with *a preferred* NSAID~~s~~ and at least one preferred 3 month ~~course of a~~ continuous *course of* hormonal contraceptive has failed; or
4. Patient has a diagnosis of uterine leiomyomata with anemia (hematocrit < 30 g/dL or hemoglobin < 10 g/dL) that did not respond to treatment with at least a one month trial of iron and is to be used preoperatively; or
5. Patient has a diagnosis of advanced prostate cancer.

Therapy will be limited as follows:

1. Endometriosis – initial 6 month approval. If symptoms of endometriosis recur after the first course of therapy, a second course of therapy with concomitant norethindrone acetate 5 mg daily will be considered. Retreatment is not recommended for longer than one additional 6 month course.
2. Uterine leiomyomata – 3 month approval.
3. Advanced prostate cancer – initial 6 month approval. Renewal requests must document suppression of testosterone levels towards a castrate level of < 50 ng/dL (attach lab).

Dupilumab (Dupixent)

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization is required for Dupixent (dupilumab). Payment will be considered ~~for patients when~~ *under* the following *conditions* ~~criteria are met~~:

1. Patient is within the FDA labeled age *for indication*; and
2. Patient has a diagnosis of moderate-to-severe atopic dermatitis; and
    a. Is prescribed by or in consultation with a dermatologist*, allergist, or immunologist*; and
    b. Patient has failed to respond to good skin care and regular use of emollients; and
    c. Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
    d. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
    e. Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and
    f. Patient will continue with skin care regimen and regular use of emollients; ~~and~~ *or*
    ~~g. Dose does not exceed an initial one-time dose of 600mg and maintenance dose of 300mg thereafter given every other week.~~
3. *Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) OR with oral corticosteroid dependent asthma; and*
    a. *Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and*
    b. *Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted; and*
    c. *Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g. long acting $beta_2$ agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and*
    d. *Patient must have one of the following, in addition to the regular maintenance medications defined above:*
        i. *Two (2) or more exacerbations in the previous year or*
        ii. *Require daily oral corticosteroids for at least 3 days; and*
4. *Dose does not exceed the FDA approved dosing for indication.*

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

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

Cannabidiol (Epidiolex)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization 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 Lenox-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 20mg/kg/day.

If criteria for coverage are met, initial requests will be approved for 3 months. Additional prior authorization requests will be considered when the following criteria are met:

1. Documentation of clinical response to therapy (i.e. reduction in the frequency of seizures); and
2. The total daily dose does not exceed 20mg/kg/day.

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

Growth Hormone

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization *(PA)* is required for therapy with growth hormones. *Requests will only be considered for FDA approved dosing.* Payment for non-preferred growth hormones will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. The following FDA approved indications for Growth Hormone therapy are considered not medically necessary and requests will be denied: Idiopathic Short Stature (ISS) and Small for Gestational Age (SGA). *Payment will be considered under the following conditions* ~~All of the following criteria must be met for approval for prescribing of growth hormones~~:

Children with Growth Hormone Deficiency

1. Standard deviation of 2.0 or more below mean height for chronological age*; and*~~.~~
2. No *expanding* intracranial lesion or tumor diagnosed by MRI*; and*~~.~~
3. Growth rate below five centimeters per year*; and*~~.~~
4. Failure of any two stimuli tests to raise the serum growth hormone level above ten nanograms per milliliter*; and*~~.~~ ~~Stimuli testing will not be required for the following diagnoses: Turners Syndrome, chronic renal failure, and HIV/AIDS.~~
5. Annual bone age testing is required ~~for the diagnosis of Growth Hormone Deficiency~~. A Bone age 14 to 15 years or less in females and 15 to 16 years or less in males is required*; and*~~.~~
6. Epiphyses open.

Pediatric Chronic Kidney Disease

1. *Is prescribed by or in consultation with a nephrologist; and*
2. *Standard deviation of 2.0 or more below mean height for chronological age; and*
3. *No expanding intracranial lesion or tumor diagnosed by MRI; and*
4. *Growth rate below five centimeters per year; and*
5. *Bone age of 14-15 years or less in females and 15-16 years or less in males; and*
6. *Epiphyses open.*

Turner's Syndrome

1. *Chromosomal abnormality showing Turner's syndrome; and*
2. *Prescribed by or in consultation with an endocrinologist; and*
3. *Standard deviation of 2.0 or more below mean height for chronological age; and*
4. *No expanding intracranial lesion or tumor diagnosed by MRI; and*
5. *Growth rate below five centimeters per year; and*
6. *Bone age of 14-15 years or less in females and 15-16 years or less in males; and*
7. *Epiphyses open.*

Prader Willi Syndrome

1. *Diagnosis is confirmed by appropriate genetic testing (attach results); and*
2. *Prescribed by or in consultation with an endocrinologist; and*
3. *Bone age of 14-15 years or less in females and 15-16 years or less in males; and*
4. *Epiphyses open.*

Noonan Syndrome

1. *Diagnosis is confirmed by the appropriate genetic testing (attach results); and*
2. *Prescribed by or in consultation with an endocrinologist; and*
3. *Standard deviation of 2.0 or more below mean height for chronological age; and*
4. *Bone age of 14-15 years or less in females and 15-16 years or less in males; and*
5. *Epiphyses open.*

SHOX (Short Stature Homeobox)

1. *Diagnosis is confirmed by the appropriate genetic testing (attach results); and*
2. *Prescribed by or in consultation with an endocrinologist; and*
3. *Bone age of 14-15 years or less in females and 15-16 years or less in males; and*
4. *Epiphyses open.*

Adults with Growth Hormone Deficiency

1. *Patients who were growth hormone deficient during childhood (childhood onset) and who have a continued deficiency; or*
2. *Patients who have growth hormone deficiency (adult onset) as a result of pituitary or hypothalamic disease (e.g., panhypopituitarism, pituitary adenoma, trauma, cranial irradiation, pituitary surgery); and*
3. *Failure of at least one growth hormone stimulation test as an adult with a peak growth hormone value of ≤5 mcg/L after stimulation.*

Adults with AIDS Wasting/Cachexia

1. *Greater than 10% of baseline weight loss over 12 months that cannot be explained by a concurrent illness other than HIV infection; and*
2. *Patient is currently being treated with antiviral agents; and*
3. *Patient has documentation of a previous trial and therapy failure with an appetite*

stimulant (i.e. dronabinol or megestrol).

Short Bowel Syndrome
If the request is for **Zorbtive**® [somatropin (rDNA origin) for injection] approval will be granted ~~for the treatment of Short Bowel Syndrome~~ in patients receiving specialized nutritional support. Zorbtive® therapy should be used in conjunction with optimal management of Short Bowel Syndrome. *PA will be considered for a maximum of 4 weeks.*

If the criteria for coverage is met, initial requests ~~Prior authorization~~ will be ~~granted~~ *given* for 12-month~~s periods per patient as needed~~*, unless otherwise stated above. Additional prior authorizations will be considered upon documentation of clinical response to therapy and patient continues to meet the criteria for the submitted diagnosis.*

ProDUR Edit Recommendations

The DUR Commission recommended implementing an initial seven-day opioid supply limit. The hard edit would stop claims for opioid naïve members, defined as not having an opioid in their claims history in the previous 60 days, to allow pharmacist and prescriber DUR interventions at the point of sale (POS).

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Benzodiazepines; Lupron Depot – Adult; Dupilumab (Dupixent); Cannabidiol (Epidiolex): and Growth Hormones in addition to the proposed ProDUR edit for an initial seven-day opioid supply limit.

Sincerely,

Pamela Smith R.Ph.

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

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

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November 7, 2019

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, November 6, 2019. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Multiple Sclerosis Agents, Oral; Ospemifene (Osphena); Abilify MyCite; and CGRP Inhibitors. The DUR Commission members also discussed a proposed ProDUR quantity limit and maximum milligram per day edit for gabapentinoid agents. The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments received from the medical/pharmacy associations in response to an August 19, 2019 letter that was sent to them detailing the proposed criteria for Multiple Sclerosis Agents, Oral; Ospemifene (Osphena); Abilify MyCite; and CGRP Inhibitors in addition to the proposed ProDUR quantity limit for gabapentinoid agents.

Multiple Sclerosis Agents – Oral

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized or stricken)
For patients initiating therapy with a preferred oral medication, a manual prior authorization 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 lll 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):

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 on 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.*

Ospemifene (Osphena)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for ospemifene (Osphena). Requests for a diagnosis of moderate to severe dyspareunia are considered not medically necessary and will be denied. Payment will be considered under the following conditions:

1. Patient is a post-menopausal woman with a diagnosis of moderate to severe vaginal dryness due to vulvar and vaginal atrophy; and
2. Patient has documentation of an adequate trial and therapy failure with a preferred vaginal estrogen agent; and
3. Patient does not have any contraindications to ospemifene as listed in the FDA approved label; and
4. Will not be used with estrogens, estrogen agonist/antagonists, fluconazole, or rifampin; and
5. Patient does not have severe hepatic impairment (Child-Pugh Class C); and
6. Patient will be evaluated periodically as clinically appropriate to determine if treatment is still necessary as ospemifene should be used for the shortest duration consistent with treatment goals and risks for the individual woman; and
7. Dose does not exceed the FDA approved dose.

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

Initial requests will be approved for 3 months. Additional prior authorizations will be considered upon documentation of clinical response to therapy.

Aripiprazole Tablets with Sensor (Abilify MyCite)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for aripiprazole tablets with sensor (Abilify MyCite). Payment will be considered under the following conditions:

1. Patient has a diagnosis of Schizophrenia, Bipolar I Disorder, or Major Depressive Disorder; and
2. Patient meets the FDA approved age for use of the Abilify MyCite device; and
3. Dosing follows the FDA approved dose for the submitted diagnosis; and
4. Documentation of patient adherence to generic aripiprazole tablets is less than 80% within the past 6 months (prescriber must provide documentation of the previous 6 months' worth of pharmacy claims for aripiprazole documenting non-adherence); and
5. Documentation all the following strategies to improve patient adherence have been tried without success:
    a. Utilization of a pill box
    b. Utilization of a reminder device (e.g. alarm, application, or text reminder)
    c. Involving family members or friends to assist
    d. Coordinating timing of dose with dosing of another daily medication; and
6. Documentation of a trial and intolerance to a preferred long-acting aripiprazole injectable agent; and
7. Prescriber agrees to track and document adherence of Abilify MyCite through the web-based portal for health care providers and transition member to generic

aripiprazole tablets after a maximum of 4 months use of Abilify MyCite. Initial approvals will be given for one month. Prescriber must review member adherence in the web-based portal and document adherence for additional consideration. If non-adherence continues, prescriber must document a plan to improve adherence. If adherence is improved, consideration to switch member to generic aripiprazole tablets must be considered. Note, the ability of the Abilify MyCite to improve patient compliance has not been established.

8. Requests will not be considered for patients in long-term care facilities.
9. A once per lifetime approval will be allowed.

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

CGRP Inhibitors

Proposed Clinical Prior Authorization Criteria *(changes highlighted/italicized or stricken)*
Prior authorization is required for CGRP Inhibitors. Payment will be considered for *a FDA approved or compendia indicated diagnosis under the following conditions* ~~patients when the following is met~~:

1. Patient has *one of the following* ~~a~~ *diagnosis* ~~of migraine as defined by one of the following~~:
    a. Chronic Migraine*, defined as:*
        i. ≥ 15 headache days per month for a minimum of 3 months; and
        ii. ≥ 8 migraine headaches days per month for a minimum of 3 months; or
    b. Episodic Migraine*, defined as:*
        i. 4 to 14 migraine days per month for a minimum of 3 months; ~~and~~ *or*
    c. *Episodic Cluster Headache, defined as:*
        i. *Occurring with a frequency between one attack every other day and 8 attacks per day; and*
        ii. *With at least 2 cluster periods lasting 7 days to one year (when untreated) and separated by pain-free remission periods of ≥3 months; and*
        iii. Patient does not have chronic cluster headache (attacks occurring without a remission period, or with remissions lasting <3 months, for at least 1 year); and
2. Patient meets the FDA approved age *for submitted diagnosis*; and
3. Patient has been evaluated for and does not have medication overuse headache; and
4. *For Episodic and Chronic Migraine, ~~P~~patient* has documentation of three trials and therapy failures, of at least 3 months per agent, at a maximally tolerated dose with a minimum of two different migraine prophylaxis drug classes (i.e. anticonvulsants [divalproex, valproate, topiramate], beta blockers [atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [amitriptyline, venlafaxine]); ~~and~~ *or;*
5. *For Episodic Cluster Headache, patient has documentation of*
    a. *A previous trial and therapy failure at an adequate dose with glucocorticoids (prednisone 30mg per day or dexamethasone 8mg BID) started promptly at the start of a cluster period. Failure is defined as the need to use acute/abortive*

medications (oxygen, triptans, ergotamine, lidocaine) at least once daily for at least two days per week after the first full week of adequately dosed steroid therapy; and

b. *A previous trial and therapy failure at an adequate dose of verapamil for at least 3 weeks (total daily dose of 480 mg to 960 mg). Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamines, lidocaine) at least once daily for at least two days per week after three weeks of adequately dosed verapamil therapy.*

6. The requested dose does not exceed the maximum FDA labeled dose *for the submitted diagnosis*; and
7. Lost, stolen, or destroyed medication replacement requests will not be authorized.

Initial requests will be approved for 3 months. Additional prior authorizations will be considered upon documentation of clinical response to therapy (i.e., reduced migraine frequency, reduced migraine headache days*, reduced weekly cluster headache attack frequency*).

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

ProDUR Edit Recommendations

The DUR Commission recommended implementing a ProDUR quantity limit on gabapentin (see table below). Additionally, the DUR Commission recommended implementing a maximum milligram per day edit on gabapentin (3600 mg) and pregabalin immediate release (600 mg), limiting each medication to the maximum milligram per day across all strengths.

Recommended Quantity Limits for Gabapentin

Strength	Daily Quantity Limit	Monthly Quantity Limit
100 mg	6 capsules	180 capsules
300 mg	9 capsules	270 capsules
400 mg	9 capsules/tablets	270 capsules/tablets
600 mg	6 tablets	180 capsules
800 mg	4.5 tablets	135 tablets
50 mg/mL	72 mL	2160 mL

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Multiple Sclerosis Agents, Oral; Ospemifene (Osphena); Abilify MyCite; and CGRP Inhibitors in addition to the proposed ProDUR quantity limit and maximum milligram per day edit for gabapentinoid agents.

Sincerely,

Paula Smith R.Ph.

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

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

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March 6, 2020

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

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, March 4, 2020. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Linezolid; Dupilumab (Dupixent); Biologicals for Axial Spondyloarthritis; Ivabradine (Corlanor); Anti-Diabetic Non-Insulin Agents; and removal of Chronic Pain Syndromes clinical PA criteria. The DUR Commission members also discussed ProDUR quantity limits for opioid agents. The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to a November 19, 2019 letter that was sent to them detailing the proposed criteria for Linezolid; Dupilumab (Dupixent); Biologicals for Axial Spondyloarthritis; Ivabradine (Corlanor); Anti-Diabetic Non-Insulin Agents; removal of Chronic Pain Syndromes clinical PA criteria; and the proposed ProDUR quantity limits for opioid agents.

Linezolid

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized or stricken)
Prior authorization (PA) is required for linezolid ~~(Zyvox).~~ Payment for linezolid ~~(Zyvox)~~ will be authorized when there is documentation that:

1. ~~Prescriber is an infectious disease (ID) physician or has consulted~~ *an* ~~ID physician (telephone consultation is acceptable.~~
2. *The* ~~*P*~~*patient* has ~~an active infection and meets~~ one of the following diagnostic criteria:
   a. Vancomycin-resistant Enterococcus (VRE) ~~and no alternative regimens with documented efficacy are available and VRE is not in lower urinary tract**.~~*; or*
   b. Methicillin-resistant Staph aureus (MRSA) ~~and patient is intolerant to vancomycin*~~*; or*
   c. Methicillin-resistant Staph epidermis (MRSE) ~~and patient is intolerant to vancomycin*~~*; or*

d. *Other multiply resistant gram positive infection (e.g. penicillin resistant Streptococcus spp); and*

3. *Patient meets ONE of the following criteria:*
    a. *Patient is severely intolerant to vancomycin with no alternative regimens with documented efficacy available*, or*
    b. *VRE in a part of body other than lower urinary tract**, or*
    c. *Patient discharged on linezolid and requires additional quantity (up to 10 days oral therapy will be allowed).*
4. *A current culture and sensitivity report is provided documenting sensitivity to linezolid.*

*Severe intolerance to vancomycin is defined as:

1. Severe rash, immune-complex mediated, determined to be directly related to vancomycin administration
2. Red-man's syndrome (histamine-mediated), refractory to traditional counter measures (e.g., prolonged IV infusion, premedicated with diphenhydramine)

**VRE in lower urinary tract, considered to be pathogenic, may be treated with linezolid if severe renal insufficiency exists and/or patient is receiving hemodialysis or has known hypersensitivity to nitrofurantoin.

Dupilumab (Dupixent)

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized or stricken)
Prior authorization is required for Dupixent (dupilumab). Payment will be considered under the following conditions:

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

medications defined above:
    i. Two (2) or more exacerbations in the previous year or
    ii. Require daily oral corticosteroids for at least 3 days; ~~and~~ *or*
4. *Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and*
    a. *Documentation dupilumab will be used as an add-on maintenance treatment; and*
    b. *Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:*
        i. *Nasal corticosteroid spray; and*
        ii. *Oral corticosteroid; and*
5. Dose does not exceed the FDA approved dosing for indication.

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

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

Biologicals for Axial Spondyloarthritis

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized or stricken)
Prior authorization (PA) is required for biologicals used for *axial spondyloarthritis conditions* ~~ankylosing spondylitis. Request must adhere to all FDA approved labeling. Payment for non-preferred biologicals for ankylosing spondylitis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents~~. Payment will be considered under the following conditions:

1. *Patient has a diagnosis of:*
    a. ankylosing spondylitis *(AS) or*
    b. *nonradiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; and*
2. *The requested dose does not exceed the maximum FDA labeled or compendia recommended dose for the submitted diagnosis; and*
3. Patient has been screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and
4. Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and
5. Patient has documentation of an inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at maximum therapeutic doses, unless there are documented adverse responses or contraindications to NSAID use. These trials should be at least ~~three~~ *one* month~~s~~ in duration; and
6. Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include sulfasalazine and methotrexate*; and*~~.~~
7. ~~Payment~~ *Requests* for non-preferred biologicals for *axial spondyloarthritis conditions* ~~ankylosing spondylitis~~ will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological

agents *that are FDA approved or compendia indicated for the submitted diagnosis, when applicable*.

In addition to the above:
Requests for TNF Inhibitors:

1. Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and
2. Patient does not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or lV and with an ejection fraction of 50% or less.

Requests for Interleukins:

1. Medication will not be given concurrently with live vaccines.

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

Ivabradine (Corlanor)

Proposed Clinical Prior Authorization Criteria *(changes highlighted/italicized or stricken)*
Prior authorization (PA) is required for ivabradine. Only FDA approved dosing will be considered. Payment will be considered under the following conditions:

1. Patient has a diagnosis of stable, symptomatic heart failure (NYHA Class II, III, or IV); and
   a. Patient is 18 years of age or older; and
   b. Patient has documentation of a left ventricular ejection fraction ≤35%; and
   c. Patient is in sinus rhythm with a resting heart rate of ≥70 beats per minute; and
   d. Patient has documentation of blood pressure ≥90/50 mmHg; ~~and~~ *or*
2. *Patient has a diagnosis of stable symptomatic heart failure (NYHA/Ross class II to IV) due to dilated cardiomyopathy, and*
   a. *Pediatric patient age 6 months and less than 18 years old; and*
   b. *Patient has documentation of a left ventricular ejection fraction ≤45%; and*
   c. *Patient is in sinus rhythm with a resting heart rate (HR) defined below;*
      i. 6 to 12 months - HR ≥ 105 bpm
      ii. 1 to 3 years - HR ≥ 95 bpm
      iii. 3 to 5 years - HR ≥ 75 bpm
      iv. *5 to 18 years - HR ≥ 70 bpm; and*
3. Heart failure symptoms persist with maximally tolerated doses of at least one beta-blocker with proven mortality benefit in a heart failure clinical trial (e.g. carvedilol 50mg daily, metoprolol succinate 200mg daily, or bisoprolol 10mg daily) *or weight appropriate dosing for pediatric patients*, or patient has a documented intolerance or FDA labeled contraindication to beta-blockers; and
4. Patient has documentation of a trial and continued use with a preferred *angiotensin system blocker* ~~ACE inhibitor or preferred ARB~~ at a maximally tolerated dose.

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

Anti-Diabetic Non-Insulin Agents

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization (PA) is required for preferred anti-diabetic, non-insulin agents subject to

clinical criteria. Payment will be considered under the following conditions:

1. *Patient has an FDA approved or compendia indicated diagnosis* ~~A diagnosis of Type 2 Diabetes Mellitus~~, and
2. Patient *meets the FDA approved or compendia indicated age* ~~is 18 years of age or older~~, and
3. *For the treatment of Type 2 Diabetes Mellitus,* ~~T~~*the* patient has not achieved HgbA1C goals after a minimum three month trial with metformin at maximally tolerated dose.
4. ~~Payment~~ *Requests* for ~~a~~ non-preferred anti-diabetic, non-insulin agent*s,* subject to clinical criteria*,* will be authorized only for cases in which there is documentation of previous trials and therapy failures with *a preferred drug in the same class. Requests for a non-preferred agent for the treatment of Type 2 Diabetes Mellitus must document previous trials and therapy failures with* metformin, a preferred DPP-4 Inhibitor or DPP-4 Inhibitor Combination, a preferred Incretin Mimetic, and a preferred SGLT2 Inhibitor at maximally tolerated doses.

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

Initial authorizations will be approved for six months. Additional PAs will be considered on an individual basis after review of medical necessity and documented continued improvement in *symptoms (such as* HgbA1C *for Type 2 Diabetes)*.

Chronic Pain Syndromes

Recommendation to remove clinical prior authorization criteria

Current Clinical Prior Authorization Criteria

A prior authorization (PA) is required for pregabalin (Lyrica) and milnacipran (Savella). These drugs will be considered for their FDA indications(s) and other conditions as listed in the compendia. Requests for doses above the manufacturer recommended dose will not be considered. For patients with a chronic pain diagnosis who are currently taking opioids, as seen in pharmacy claims, a plan to decrease and/or discontinue the opioid(s) must be provided with the initial request. Initial authorization will be given for three (3) months. Requests for renewal must include an updated opioid treatment plan and documentation of improvement in symptoms and quality of life. Requests for non-preferred brand name drugs, when there is a preferred A-rated bioequivalent generic product available, are also subject to the Selected Brand Name prior authorization criteria and must be included with this request. Payment will be considered under the following conditions:

1. A diagnosis of fibromyalgia (Lyrica and Savella)
   a. a trial and therapy failure at a therapeutic dose with gabapentin plus one of the following preferred generic agents: tricyclic antidepressant or SNRI **WITH**
   b. documented non-pharmacologic therapies (cognitive behavior therapies, exercise, etc.)
2. A diagnosis of post-herpetic neuralgia (Lyrica)
   A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, topical lidocaine, or valproate.
3. A diagnosis of diabetic peripheral neuropathy (duloxetine and Lyrica)
   A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant or duloxetine.
4. A diagnosis of partial onset seizures, as adjunct therapy (Lyrica)
5. A diagnosis of neuropathic pain associated with spinal cord injury (Lyrica)

ProDUR Edit Recommendations

The DUR Commission recommends the following ProDUR quantity limits on opioids:

- Remove opioids from the current Iowa Medicaid Quantity Limit list that total ≥ 90 morphine milligram eqivalents (MME) per day, leaving current quantity limits in place for liquid agents. See Current Opioid Quantity Limits table below, drug product stricken.
- Current short-acting opioid quantity limits – six (6) units per day on all solid oral dosage forms where the quantity exceeds 6 units per day on the current Iowa Medicaid Quantity Limit list. See Current Opioid Quantity Limits table below, quantities stricken and updated.
- Establish quantity limits for opioids that fall below 90 MME per day, that do not have current quantity limits, including a maximum limit of six (6) units per day on all short-acting solid oral doage forms. See Proposed New Opioid Quantity Limits table below.

Current Opioid Quantity Limits – Proposed Changes (changes stricken)

Drug Product	Quantity	Days Supply	Comments
AVINZA 30MG (morphine er)	30	30	
AVINZA 45MG (morphine er)	30	30	
AVINZA 60MG (morphine er)	30	30	
AVINZA 75MG (morphine er)	30	30	
~~AVINZA 90MG (morphine er)~~	~~30~~	~~30~~	Exceeds 90 MME/day; Remove
~~AVINZA 120MG (morphine er)~~	~~150~~	~~30~~	Exceeds 90 MME/day; Remove
CODEINE SULFATE 15MG	180	30	6 tablets per day
CODEINE SULFATE 30MG	180	30	6 tablets per day
CODEINE SULFATE 60MG	180	30	6 tablets per day
COMBUNOX (oxycodone/ibuprofen)	28	30	
DURAGESIC 25MCG (fentanyl)	10	30	
~~DURAGESIC 50MCG (fentanyl)~~	~~10~~	~~30~~	Exceeds 90 MME/day; Remove
~~DURAGESIC 75MCG (fentanyl)~~	~~10~~	~~30~~	Exceeds 90 MME/day; Remove
~~DURAGESIC 100MCG (fentanyl)~~	~~10~~	~~30~~	Exceeds 90 MME/day; Remove
~~EMBEDA 20-0.8MG (morphine/naltrexone)~~	~~60~~	~~30~~	Removed from market
~~EMBEDA 30-1.2MG (morphine/naltrexone)~~	~~60~~	~~30~~	Removed from market
~~EMBEDA 50-2MG (morphine/naltrexone)~~	~~60~~	~~30~~	Removed from market
~~EMBEDA 60-2.4MG (morphine/naltrexone)~~	~~60~~	~~30~~	Removed from market
~~EMBEDA 80-3.2MG (morphine/naltrexone)~~	~~60~~	~~30~~	Removed from market
~~EMBEDA 100-4MG (morphine/naltrexone)~~	~~60~~	~~30~~	Removed from market
FIORICET/CODEINE 50-300-40-30MG (butalbital-apap-caffeine w/ codeine)	60	30	
FIORICET/CODEINE 50-325-40-30MG (butalbital-apap-caffeine w/ codeine)	60	30	
FIORINAL/CODEINE 50-325-40-30MG(butalbital-asa-caffeine-codeine)	60	30	
HYCET SOL (hydrocodone/apap)	3600ML	30	120ML per day
KADIAN 10MG (morphine sulfate er capsule)	60	30	
KADIAN 20MG (morphine sulfate er capsule)	60	30	
KADIAN 30MG (morphine sulfate er capsule)	60	30	
KADIAN 40MG (morphine sulfate er capsule)	60	30	
~~KADIAN 50MG (morphine sulfate er capsule)~~	~~60~~	~~30~~	Exceeds 90 MME/day; Remove

~~KADIAN 60MG (morphine sulfate er capsule)~~	~~60~~	~~30~~	Exceeds 90 MME/day; Remove
~~KADIAN 80MG (morphine sulfate er capsule)~~	~~60~~	~~30~~	Exceeds 90 MME/day; Remove
~~KADIAN 100MG (morphine sulfate er capsule)~~	~~60~~	~~30~~	Exceeds 90 MME/day; Remove
MSCONTIN 15MG (morphine sulfate sa)	90	30	
~~MSCONTIN 30MG (morphine sulfate sa)~~	~~90~~	~~30~~	Exceeds 90 MME/day; Remove
~~MSCONTIN 60MG (morphine sulfate sa)~~	~~90~~	~~30~~	Exceeds 90 MME/day; Remove
~~MSCONTIN 100MG (morphine sulfate sa)~~	~~300~~	~~30~~	Exceeds 90 MME/day; Remove
NORCO 5-325MG (hydrocodone/apap)	180 (~~360~~)	30	6 tablets per day
NORCO 7.5-325MG (hydrocodone/apap)	180 (~~240~~)	30	6 tablets per day
NORCO 10-325MG (hydrocodone/apap)	180	30	6 tablets per day
~~NUCYNTA 50MG (tapentadol)~~	~~180~~	~~30~~	Exceeds 90 MME/day; Remove
~~NUCYNTA 75MG (tapentadol)~~	~~180~~	~~30~~	Exceeds 90 MME/day; Remove
~~NUCYNTA 100MG (tapentadol)~~	~~180~~	~~30~~	Exceeds 90 MME/day; Remove
OPANA ER 5MG (oxymorphone)	60	30	
OPANA ER 7.5MG (oxymorphone)	60	30	
OPANA ER 10MG (oxymorphone)	60	30	
~~OPANA ER 15MG (oxymorphone)~~	~~60~~	~~30~~	Exceeds 90 MME/day; Remove
~~OPANA ER 20MG (oxymorphone)~~	~~60~~	~~30~~	Exceeds 90 MME/day; Remove
~~OPANA ER 30MG (oxymorphone)~~	~~60~~	~~30~~	Exceeds 90 MME/day; Remove
PERCOCET 5-325MG (oxycodone w/ apap)	180 (~~360~~)	30	6 tablets per day
PERCOCET 7.5-325MG (oxycodone w/ apap)	180 (~~240~~)	30	6 tablets per day
~~PERCOCET 10-325MG (oxycodone w/ apap)~~	~~180~~	~~30~~	Exceeds 90 MME/day; Remove
TYLENOL W/ CODEINE ELIXIR (apap w/ codeine)	2700ML	30	90ML per day
TYLENOL W/ CODEINE NO. 2 (apap w/ codeine)	180 (~~390~~)	30	6 tablets per day
TYLENOL W/ CODEINE NO. 3 (apap w/ codeine)	180 (~~390~~)	30	6 tablets per day
TYLENOL W/ CODEINE NO. 4 (apap w/ codeine)	180 (~~390~~)	30	6 tablets per day
ULTRACET (tramadol/apap)	180 (~~240~~)	30	6 tablets per day
ULTRAM 50MG (tramadol)	180 (~~240~~)	30	6 tablets per day
ULTRAM ER 100MG (tramadol er)	30	30	
ULTRAM ER 200MG (tramadol er)	30	30	
ULTRAM ER 300MG (tramadol er)	30	30	
VICODIN ES 7.5-300MG(hydrocodone/apap)	150	30	5 tablets per day
VICODIN HP 10-300MG (hydrocodone/apap)	180	30	6 tablets per day
XODOL 5-300MG (hydrocodone/apap)	180 (~~360~~)	30	6 tablets per day
XODOL 7.5-300MG (hydrocodone/apap)	180	30	6 tablets per day
XODOL 10-300MG (hydrocodone/apap)	180	30	6 tablets per day
ZAMICET (hydrocodone/apap)	2700ML	30	90ML per day

Proposed New Opioid Quantity Limits

Drug Product	Quantity	Days Supply	Comments
ACETAMINOPHEN-CAFFEINE-DIHYDROCODEINE CAP 320.5-30-16 MG	180	30	6 capsules per day
ACETAMINOPHEN-CAFFEINE-DIHYDROCODEINE TAB 325-30-16 MG	180	30	6 tablets per day
BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 4.08-325 MG (APADAZ)	180	30	6 tablets per day
BUPRENORPHINE TD PATCH WEEKLY 5 MCG/HR (BUTRANS)	4	28	1 patch per week

HYDROCODONE BITARTRATE CAP ER 12HR ABUSE-DETERRENT 10 MG (ZOHYDRO ER)	60	30	2 capsules per day
HYDROCODONE BITARTRATE CAP ER 12HR ABUSE-DETERRENT 15 MG	60	30	2 capsules per day
HYDROCODONE BITARTRATE CAP ER 12HR ABUSE-DETERRENT 20 MG	60	30	2 capsules per day
HYDROCODONE BITARTRATE CAP ER 12HR ABUSE-DETERRENT 30 MG	60	30	2 capsules per day
HYDROCODONE BITARTRATE CAP ER 12HR ABUSE-DETERRENT 40 MG	60	30	2 capsules per day
HYDROCODONE BITARTRATE CAP ER 12HR ABUSE-DETERRENT 50 MG	60	30	2 capsules per day
HYDROCODONE BITARTRATE TAB ER 24HR DETER 100 MG (HYSLINGA)	30	30	
HYDROCODONE BITARTRATE TAB ER 24HR DETER 120 MG	30	30	
HYDROCODONE BITARTRATE TAB ER 24HR DETER 20 MG	30	30	
HYDROCODONE BITARTRATE TAB ER 24HR DETER 30 MG	30	30	
HYDROCODONE BITARTRATE TAB ER 24HR DETER 40 MG	30	30	
HYDROCODONE BITARTRATE TAB ER 24HR DETER 60 MG	30	30	
HYDROCODONE BITARTRATE TAB ER 24HR DETER 80 MG	30	30	
HYDROCODONE-ACETAMINOPHEN SOLN 10-300 MG/15ML (LORTAB ELIXIR)	2700	30	90 ml per day
HYDROCODONE-ACETAMINOPHEN TAB 10-300 MG (VICODIN HP)	180	30	6 tablets per day
HYDROCODONE-ACETAMINOPHEN TAB 2.5-325 MG	180	30	6 tablets per day
HYDROCODONE-ACETAMINOPHEN TAB 5-300 MG (VICODIN)	180	30	6 tablets per day
HYDROCODONE-IBUPROFEN TAB 10-200 MG	150	30	5 tablets per day
HYDROCODONE-IBUPROFEN TAB 5-200 MG	150	30	5 tablets per day
HYDROCODONE-IBUPROFEN TAB 7.5-200 MG	150	30	5 tablets per day
HYDROMORPHONE HCL SUPPOS 3 MG	120	30	4 supp. per day
HYDROMORPHONE HCL TAB ER 24HR DETER 12 MG (EXALGO)	30	30	
HYDROMORPHONE HCL TAB ER 24HR DETER 16 MG	30	30	
HYDROMORPHONE HCL TAB ER 24HR DETER 8 MG	30	30	
LEVORPHANOL TARTRATE TAB 2 MG	120	30	4 tablets per day
MEPERIDINE HCL TAB 100 MG	180	30	6 tablets per day
MEPERIDINE HCL TAB 50 MG	180	30	6 tablets per day
MORPHINE SULFATE SUPPOS 10 MG	180	30	6 supp. per day
MORPHINE SULFATE SUPPOS 5 MG	180	30	6 supp. per day
MORPHINE SULFATE TAB ER 12HR DETER 15 MG (MORPHABOND)	90	30	3 tablets per day
MORPHINE SULFATE TAB ER ABUSE-DETERRENT 15 MG (ARYMO ER)	90	30	3 tablets per day
OXYCODONE CAP ER 12HR ABUSE-DETERRENT 13.5 MG (XTAMPZA ER)	60	30	2 capsules per day
OXYCODONE CAP ER 12HR ABUSE-DETERRENT 18 MG	60	30	2 capsules per day
OXYCODONE CAP ER 12HR ABUSE-DETERRENT 27 MG	60	30	2 capsules per day
OXYCODONE CAP ER 12HR ABUSE-DETERRENT 9 MG	60	30	2 capsules per day
OXYCODONE HCL CAP 5 MG	180	30	6 capsules per day
OXYCODONE HCL CONC 100 MG/5ML (20 MG/ML)	87	30	2.9 ml per day
OXYCODONE HCL SOLN 5 MG/5ML	1770	30	59 ml per day
OXYCODONE HCL TAB 5 MG	180	30	6 tablets per day
OXYCODONE HCL TAB ABUSE DETER 5 MG (ROXYBOND OR OXAYDO)	180	30	6 tablets per day
OXYCODONE HCL TAB ABUSE DETER 7.5 MG (OXAYDO)	180	30	6 tablets per day

OXYCODONE HCL TAB ER 12HR DETER 10 MG (OXYCONTIN)	60	30	2 tablets per day
OXYCODONE HCL TAB ER 12HR DETER 15 MG	60	30	2 tablets per day
OXYCODONE HCL TAB ER 12HR DETER 20 MG	60	30	2 tablets per day
OXYCODONE W/ ACETAMINOPHEN TAB 2.5-300 MG	180	30	6 tablets per day
OXYCODONE W/ ACETAMINOPHEN TAB 2.5-325 MG	180	30	6 tablets per day
OXYCODONE-ASPIRIN TAB 4.8355-325 MG	180	30	6 tablets per day
OXYCODONE-IBUPROFEN TAB 5-400 MG	120	30	4 tablets per day
TAPENTADOL HCL TAB ER 12HR 50 MG (NUCYNTA ER)	60	30	2 tablets per day

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Linezolid; Dupilumab (Dupixent); Biologicals for Axial Spondyloarthritis; Ivabradine (Corlanor); Anti-Diabetic Non-Insulin Agents; removal of Chronic Pain Syndromes clinical PA criteria; and the ProDUR quantity limits for opioid agents.

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
SFY20

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

Quantity Limits

- Gabapentin Daily Quantity Limit per Strength

Strength	Daily Quantity Limit	Monthly Quantity Limit
100 mg	6 capsules	180 capsules
300 mg	9 capsules	270 capsules
400 mg	9 capsules/tablets	270 capsules/tablets
600 mg	6 tablets	180 capsules
800 mg	4.5 tablets	135 tablets
50 mg/mL	72 mL	2160 mL

- Gabapentin maximum milligram per day edit of 3600 mg across all strengths.
- Pregabalin maximum milligram per day edit of 600 mg across all strengths.
- Opioid Agents
    - Remove opioids from the current Iowa Medicaid Quantity Limit list that total ≥ 90 morphine milligram eqivalents (MME) per day, leaving current quantity limits in place for liquid agents. See Current Opioid Quantity Limits table found in Appendix G > March 2020 Recommendation Letter. Drug product stricken.
    - Current short-acting opioid quantity limits – six (6) units per day on all solid oral dosage forms where the quantity exceeds 6 units per day on the current Iowa Medicaid Quantity Limit list. See Current Opioid Quantity Limits table found in Appendix G > March 2020 Recommendation Letter. Quantities stricken and updated.
    - Establish quantity limits for opioids that fall below 90 MME per day, that do not have current quantity limits, including a maximum limit of six (6) units per day on all short-acting solid oral doage forms. See Proposed New Opioid Quantity Limits table found in Appendix G > March 2020 Recommendation Letter.

Initial Seven-Day Opioid Supply Limit

- Hard edit to stop claims for opioid naïve members, defined as not having an opioid in their claims history in the previous 60 days, to allow pharmacist and prescriber DUR interventions at the point of sale (POS).

Appendix I
Meeting Minutes

Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes August 7, 2019

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; Jason Wilbur, M.D. Chuck Wadle, D.O.; and Susan Parker, Pharm.D.
Staff
Pam Smith, R.Ph.
Guests
Erin Halverson, R.Ph., IME; Melissa Biddle, IME; and Sandy Pranger, R.Ph., Amerigroup.

Welcome & Introductions

Chairperson Brett Faine called the meeting to order at 9:33 a.m. in Capitol Room 116 in Des Moines. The minutes from the May 1, 2019 meeting were reviewed. Jason Wilbur motioned to accept them, and Jason Kruse seconded. All members were in favor. The recommendation letter sent to DHS after the last meeting was also reviewed. Members were asked to complete their annual conflict of interest disclosures. Jason Wilbur motioned to retain Brett Faine as chairperson and Kellen Ludvigson as vice-chairperson. Mark Graber seconded, and all members in attendance were in favor. Following up from previous meetings, Pam Smith announced that CMS had finally provided guidance on H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act. The associated required edits and/or Pro-DUR or retrospective initiatives will likely result in some additional DUR reviews in the future, though DHS will do what is required to meet the given deadlines and then potentially strengthen the criteria through DUR input down the line, given the time constraints and length of time between DUR meetings.

IME Pharmacy Update

House File 623 removed prior authorization requirements for Medication Assisted Treatment (MAT); DHS is currently in the process of creating rules to allow at least one form of MAT medication without PA, effective February 1, 2020. Susan Parker suggested Retro DUR actions to control these medications due to the process needed to follow the State Plan Amendment for opioids. There is still an opening for a pharmacist on the DUR Commission, hopefully filled by the November meeting. DHS is in the process of reviewing applications and conducting interviews.

MCO Prevalence Report Summary and Updates

Amerigroup: Sandy Pranger provided an overview for Amerigroup's statistics from March 2019 through May 2019, including: a breakdown of utilization by age and gender, top 100 pharmacies by prescription count, top 100 pharmacies by paid amount, top 100 prescribing providers by prescription count, and top 100 prescribing providers by paid

amount. The Bi-Monthly Statistics report reflected that expenditures totaled $57,404,281, a 12.5% increase from the total for December through February. Similar to previous reports, the top 5 therapeutics classes by paid amount were: ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; Antidiabetics; Antipsychotics/Antimanic Agents; Antiasthmatic and Bronchodilator Agents; and Analgesics – Anti-Inflammatory. The following 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 Concerta, Humira Pen, Latuda, and Humalog. Omeprazole had the highest prescription count, followed by: levothyroxine sodium, lisinopril, atorvastatin calcium, and sertraline hcl.

United Healthcare Community Plan: Commission members were provided written summaries that included United's statistics from March 2019 through May 2019, and were encouraged to contact Pam Smith with any questions, now that United Healthcare is no longer a contracted managed care organization for Iowa Medicaid.

Fee-for-Service Prevalence Report Summary

Pam Smith provided an overview of fee-for-service statistics from March 2019 through May 2019, including: total amount paid ($3,098,407), cost per user ($293.49), and number of total prescriptions dispensed (46,830). There were 10,557 unique users, which is 7.8% more than the total for December through February. The top 5 therapeutics classes by paid amount were: Anticonvulsants; Anti-Inflammatories, Non-NSAID; Antipsychotics – Atypicals; Diabetic – Insulin Penfills; and Antiretroviral Combinations. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Beta-Lactams/Clavulanate Combos; and Narcotics – Miscellaneous. The top 100 drugs were also reviewed, by paid amount and prescription count. The ten most expensive medications were: Vyvanse, Concerta, Epclusa, Humira Pen, Biktarvy, Tamiflu, Humalog, Invega Systenna, Novolog Flexpen, and ProAir HFA. The five drugs with the highest prescription count were: amoxicillin, sertraline hcl, lisinopril, gabapentin, 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 $154,673,364 was spent in total for 292,611 unique users who had 2,045,840 prescriptions.

Public Comment

In addition to the written public comments provided to Commission members as part of their meeting materials, they heard oral public comment from the speakers listed below. Also, in response to the written comment regarding Zyvox, Brett Faine requested that the criteria for that be brought back to the next meeting for review.

Name	Representing	Drug/Topic
Maggie Murphy	Teva	Ajovy
Tammy Sova	Biogen	Tecfidera

Christina Brandmejer	Amgen	CGRP Inhibitors
Joseph Cirrincione	Otsuka	Abilify MyCite
Kevin Duhrkopf	Sanofi Genzyme	Dupixent
Kerri Hoernemann	Novartis	Mayzent

ProDUR Edits

Gabapentin Quantity Limit: To reduce the risk of misuse and abuse of both gabapentin and pregabalin, a recommendation was made to implement ProDUR quantity limits based on maximum recommended daily doses in addition to programming for both gabapentin and pregabalin based on maximum milligrams per day across all the different strengths of each drug. Jason Wilbur made the motion to accept the recommendation, and Jason Kruse seconded. The decision was unanimous. Mark Graber also suggested using this for a possible retrospective DUR study. FFS and MCOs will run numbers to see how many members are utilizing gabapentin and pregabalin concurrently and bring the results back as requested to a future meeting.

Initial Seven Day Opioid Supply Limit: At the May meeting, the Commission recommended a POS hard edit that could be overridden with DUR codes should be implemented, with a 60-day look-back on member claims. 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.

Retrospective DUR Proposals

Overutilization of Short-Acting Beta$_2$-Agonist Inhalers in Patients with Asthma: FFS and MCOs will run numbers to see how many members have gotten 3,4,5, or 6+ canisters within a six-month time frame. Current quantity limits allow 3 albuterol inhalers per month. Mark Graber suggested a retrospective study to identify members using both canisters and nebulizer solutions, and he also asked if data could be run to see how many members were on controller medications. Jason Kruse requested that those with multiple providers be flagged. Data will be brought back to a future meeting.

CNS Stimulant Therapy without Indication: FFS and MCOs will run numbers to identify members with no diagnosis codes in their histories, breaking them into groups under 21 years of age and 21 and older, and looking back at 12 months of medical claims (to catch the diagnosis codes) and 2 months of pharmacy claims (to identify the stimulants). Prior authorization including diagnosis code is already required for adults. Melissa Klotz suggested that summer months be avoided for the pharmacy claim histories, as children often skip taking stimulants during summer break. Data will be brought back to a future meeting.

The Commission took a short break; open session resumed at 11:03.

Prior Authorization

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

For patients initiating therapy with a preferred oral medication, a manual prior

authorization 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 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):

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 on 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.*

Jason Kruse motioned to accept the criteria as amended, and Mark Graber 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.

Ospemifene (Osphena): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for ospemifene (Osphena). Requests for a diagnosis of moderate to severe dyspareunia are considered not medically necessary and will be denied. Payment will be considered under the following conditions:

1. *Patient is a post-menopausal woman with a diagnosis of moderate to severe vaginal dryness due to vulvar and vaginal atrophy; and*
2. *Patient has documentation of an adequate trial and therapy failure with a preferred vaginal estrogen agent; and*
3. *Patient does not have any contraindications to ospemifene as listed in the FDA approved label; and*
4. *Will not be used with estrogens, estrogen agonist/antagonists, fluconazole, or rifampin; and*
5. *Patient does not have severe hepatic impairment (Child-Pugh Class C); and*
6. *Patient will be evaluated periodically as clinically appropriate to determine if treatment is still necessary as ospemifene should be used for the shortest duration consistent with treatment goals and risks for the individual woman; and*
7. *Dose does not exceed the FDA approved dose.*

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

Initial requests will be approved for 3 months. Additional prior authorizations will be considered upon documentation of clinical response to therapy.

Kellen Ludvigson motioned to accept the criteria as amended, 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. Additionally, Pam Smith will look into whether any over-the-counter products are rebate eligible, and if trials of those could be required if so.

Abilify MyCite: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for aripiprazole tablets with sensor (Abilify MyCite). Payment will be considered under the following conditions:

1. *Patient has a diagnosis of Schizophrenia, Bipolar I Disorder, or Major Depressive Disorder; and*
2. *Patient meets the FDA approved age for use of the Abilify MyCite device; and*
3. *Dosing follows the FDA approved dose for the submitted diagnosis; and*
4. *Documentation of patient adherence to generic aripiprazole tablets is less than 80% within the past 6 months (prescriber must provide documentation of the previous 6 months' worth of pharmacy claims for aripiprazole documenting non-adherence); and*
5. *Documentation all the following strategies to improve patient adherence have been tried without success:*
    a. *Utilization of a pill box*
    b. *Utilization of a reminder device (e.g. alarm, application, or text reminder)*
    c. *Involving family members or friends to assist*
    d. *Coordinating timing of dose with dosing of another daily medication; and*
6. *Documentation of a trial and intolerance to the long-acting injectable Abilify Maintena; and*
7. *Prescriber agrees to track and document adherence of Abilify MyCite through the web-based portal for health care providers and transition member to generic aripiprazole tablets after a maximum of 4 months use of Abilify MyCite. Initial approvals will be given for one month. Prescriber must review member adherence in the web-based portal and document adherence for additional consideration. If non-adherence continues, prescriber must document a plan to improve adherence. If adherence is improved, consideration to switch member to generic aripiprazole tablets*

must be considered. Note, the ability of the Abilify MyCite to improve patient compliance has not been established.

8. *Requests will not be considered for patients in long-term care facilities.*
9. *A once per lifetime approval will be allowed.*

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

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

CGRP Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for CGRP Inhibitors. Payment will be considered for a FDA approved or compendia indicated diagnosis under the following conditions:

1. *Patient has one of the following diagnoses:*
    a. *Chronic Migraine, defined as:*
        i. *≥ 15 headache days per month for a minimum of 3 months; and*
        ii. *≥ 8 migraine headaches days per month for a minimum of 3 months; or*
    b. *Episodic Migraine, defined as:*
        i. *4 to 14 migraine days per month for a minimum of 3 months; or*
    c. *Episodic Cluster Headache, defined as:*
        i. *Occurring with a frequency between one attack every other day and 8 attacks per day; and*
        ii. *With at least 2 cluster periods lasting 7 days to one year (when untreated) and separated by pain-free remission periods of ≥3 months; and*
        iii. *Patient does not have chronic cluster headache (attacks occurring without a remission period, or with remissions lasting <3 months, for at least 1 year); and*
2. *Patient meets the FDA approved age for submitted diagnosis; and*
3. *Patient has been evaluated for and does not have medication overuse headache; and*
4. *For Episodic and Chronic Migraine, patient has documentation of three trials and therapy failures, of at least 3 months per agent, at a maximally tolerated dose with a minimum of two different migraine prophylaxis drug classes (i.e. anticonvulsants [divalproex, valproate, topiramate], beta blockers [atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [amitriptyline, venlafaxine]); or*

5. *For Episodic Cluster Headache, patient has documentation of*
    a. *A previous trial and therapy failure at an adequate dose with glucocorticoids (prednisone 30mg per day or dexamethasone 8mg BID) started promptly at the start of a cluster period. Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamine, lidocaine) at least once daily for at least two days per week after the first full week of adequately dosed steroid therapy; and*
    b. *A previous trial and therapy failure at an adequate dose of verapamil for at least 3 weeks (total daily dose of 480 mg to 960 mg). Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamines, lidocaine) at least once daily for at least two days per week after three weeks of adequately dosed verapamil therapy.*
6. *The requested dose does not exceed the maximum FDA labeled dose for the submitted diagnosis; and*
7. *Lost, stolen, or destroyed medication replacement requests will not be authorized.*

Initial requests will be approved for 3 months. Additional prior authorizations will be considered upon documentation of clinical response to therapy (i.e., reduced migraine frequency, reduced migraine headache days, reduced weekly cluster headache attack frequency).

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 Mark Graber 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.

Benzodiazepines: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for non-preferred benzodiazepines. Payment for non-preferred benzodiazepines will be authorized in cases with documentation of previous trial and therapy failure with two preferred products. If a long-acting medication is requested, one of the therapeutic trials must include the immediate release form of the requested benzodiazepine. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determine if the use of a benzodiazepine is appropriate for this member.

Prior authorization will be approved for up to 12 months for documented:

1. *Generalized anxiety disorder.*

2. *Panic attack with or without agoraphobia.*
3. *Seizure.*
4. *Non-progressive motor disorder.*
5. *Dystonia.*

Prior authorization requests will be approved for up to a three-month period for all other diagnoses related to the use of benzodiazepines.

For patients taking concurrent opioids, the prescriber must document the following:

1. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
2. *Documentation as to why concurrent use is medically necessary is provided; and*
3. *A plan to taper the opioid or benzodiazepine is provided, if appropriate.*

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

Chuck Wadle questioned if psychiatric therapy should be added as a requirement, but ultimately, 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.

Lupron Depot – Adult: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Lupron Depot (leuprolide acetate). Payment will be considered for patients under the following conditions:

1. *Patient meets the FDA approved age; and*
2. *Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and*
3. *Patient has a diagnosis of endometriosis for which concurrent therapy with a preferred NSAID and at least one preferred 3 month continuous course of hormonal contraceptive has failed; or*
4. *Patient has a diagnosis of uterine leiomyomata with anemia (hematocrit < 30 g/dL or hemoglobin < 10 g/dL) that did not respond to treatment with at least a one month trial of iron and is to be used preoperatively; or*
5. *Patient has a diagnosis of advanced prostate cancer.*

Therapy will be limited as follows:

1. *Endometriosis – initial 6 month approval. If symptoms of endometriosis recur after the first course of therapy, a second course of therapy with concomitant norethindrone acetate 5 mg daily will be considered. Retreatment is not recommended for longer than one additional 6 month course.*
2. *Uterine leiomyomata – 3 month approval.*

3. *Advanced prostate cancer – initial 6 month approval. Renewal requests must document suppression of testosterone levels towards a castrate level of < 50 ng/dL (attach lab).*

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

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

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

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

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

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

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.

Cannabidiol (Epidiolex): The Commission reviewed the prior authorization criteria as follows:

Prior authorization 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 20mg/kg/day.*

If criteria for coverage are met, initial requests will be approved for 3 months. Additional prior authorization requests will be considered when the following criteria are met:

1. *Documentation of clinical response to therapy (i.e. reduction in the frequency of seizures); and*
2. *The total daily dose does not exceed 20mg/kg/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.

Growth Hormones: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for therapy with growth hormones. Requests will only be considered for FDA approved dosing. Payment for non-preferred growth hormones will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. The following FDA approved indications for Growth Hormone therapy are considered not medically necessary and requests will be denied: Idiopathic Short Stature (ISS) and Small for Gestational Age (SGA). Payment will be considered under the following conditions:

Children with Growth Hormone Deficiency

1. *Standard deviation of 2.0 or more below mean height for chronological age; and*
2. *No expanding intracranial lesion or tumor diagnosed by MRI; and*
3. *Growth rate below five centimeters per year; and*
4. *Failure of any two stimuli tests to raise the serum growth hormone level above ten nanograms per milliliter; and*
5. *Annual bone age testing is required. A Bone age 14 to 15 years or less in females and 15 to 16 years or less in males is required; and*
6. *Epiphyses open.*

Pediatric Chronic Kidney Disease

1. *Is prescribed by or in consultation with a nephrologist; and*
2. *Standard deviation of 2.0 or more below mean height for chronological age; and*
3. *No expanding intracranial lesion or tumor diagnosed by MRI; and*
4. *Growth rate below five centimeters per year; and*
5. *Bone age of 14-15 years or less in females and 15-16 years or less in males; and*
6. *Epiphyses open.*

Turner's Syndrome

1. *Chromosomal abnormality showing Turners syndrome; and*
2. *Prescribed by or in consultation with an endocrinologist; and*
3. *Standard deviation of 2.0 or more below mean height for chronological age; and*
4. *No expanding intracranial lesion or tumor diagnosed by MRI; and*
5. *Growth rate below five centimeters per year; and*
6. *Bone age of 14-15 years or less in females and 15-16 years or less in*

males; and
7. *Epiphyses open.*

Prader Willi Syndrome
1. *Diagnosis is confirmed by appropriate genetic testing (attach results); and*
2. *Prescribed by or in consultation with an endocrinologist; and*
3. *Bone age of 14-15 years or less in females and 15-16 years or less in males; and*
4. *Epiphyses open.*

Noonan Syndrome
1. *Diagnosis is confirmed by the appropriate genetic testing (attach results); and*
2. *Prescribed by or in consultation with an endocrinologist; and*
3. *Standard deviation of 2.0 or more below mean height for chronological age; and*
4. *Bone age of 14-15 years or less in females and 15-16 years or less in males; and*
5. *Epiphyses open.*

SHOX (Short Stature Homeobox)
1. *Diagnosis is confirmed by the appropriate genetic testing (attach results); and*
2. *Prescribed by or in consultation with an endocrinologist; and*
3. *Bone age of 14-15 years or less in females and 15-16 years or less in males; and*
4. *Epiphyses open.*

Adults with Growth Hormone Deficiency
1. *Patients who were growth hormone deficient during childhood (childhood onset) and who have a continued deficiency; or*
2. *Patients who have growth hormone deficiency (adult onset) as a result of pituitary or hypothalamic disease (e.g., panhypopituitarism, pituitary adenoma, trauma, cranial irradiation, pituitary surgery); and*
3. *Failure of at least one growth hormone stimulation test as an adult with a peak growth hormone value of ≤5 mcg/L after stimulation.*

Adults with AIDS Wasting/Cachexia
1. *Greater than 10% of baseline weight loss over 12 months that cannot be explained by a concurrent illness other than HIV infection; and*
2. *Patient is currently being treated with antiviral agents; and*
3. *Patient has documentation of a previous trial and therapy failure with an appetite stimulant (i.e. dronabinol or megestrol).*

Short Bowel Syndrome

*If the request is for **Zorbtive**® [somatropin (rDNA origin) for injection] approval will be granted in patients receiving specialized nutritional support. Zorbtive® therapy should be used in conjunction with optimal management of Short Bowel Syndrome. PA will be considered for a maximum of 4 weeks.*

If the criteria for coverage is met, initial requests will be given for 12-months, unless otherwise stated above. Additional prior authorizations will be considered upon documentation of clinical response to therapy and patient continues to meet the criteria for the submitted diagnosis.

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 32, Number 1.

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

At 11:55, Chuck Wadle motioned to adjourn, and Jason Kruse seconded. All in attendance agreed.

The next meeting will be held at 9:30 a.m. on Wednesday, November 6, 2019, at the Iowa State Capitol, Room 116.

Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes November 6, 2019

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; Chuck Wadle, D.O.; John Ellis, Pharm.D.; and Susan Parker, Pharm.D.

Staff
Pam Smith, R.Ph.

Guests
Erin Halverson, R.Ph., IME; Melissa Biddle, IME; Emily Rogers, Pharm.D., Iowa Total Care; and Jeannine Murray, Amerigroup.

Welcome & Introductions

Chairperson Brett Faine called the meeting to order at 9:33 a.m. in Capitol Room 116 in Des Moines. The minutes from the August 7, 2019 meeting were reviewed. Jason Kruse motioned to accept them, and Mark Graber seconded. All members were in favor. The recommendation letter sent to DHS after the last meeting and a recommendation letter to the DUR Commission from the P&T Committee requesting creation of PA criteria for Mavenclad, Mayzent, and Osphena were also reviewed.

Commission Recommendations for Retrospective DUR Agenda Topics

The Commission did not have any new recommendations.

IME Pharmacy Update

House File 623 removed prior authorization requirements for Medication Assisted Treatment (MAT); DHS is currently in the process of creating rules to allow at least one form of MAT medication without PA, effective February 1, 2020. The new rules also address dispensing fees for maintenance drugs, encouraging pharmacies to dispense a 30 day supply for maintenance drugs. An informational letter will go out shortly regarding pharmacist enrollment for ordering and dispensing of naloxone, nicotine replacement, and the immunization process, corresponding to rules going into effect July 1, 2020. A second informational letter, likely sent early next spring, will address the billing for immunizations. There will soon be an opening for a doctor on the DUR Commission, as Mark Graber is in the last year of his 3 allowable terms. This is the first meeting for the newest Commission member, John Ellis, Pharm.D.

Prevalence Report Summaries

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from June 2019 through August 2019, including: total amount paid ($2,743,177), cost per user ($391.88), and number of total prescriptions dispensed (32,000). There were 7,000

unique users, which is 34.5% less than the total for March through May, likely due to newly eligible members being immediately assigned an MCO rather than temporarily going to FFS as they had previously. The top 5 therapeutic classes by paid amount were: Glucocorticoids – Corticotropin; Anti-Inflammatories, Non-NSAID; Anticonvulsants; Antiretroviral Combinations; and Antipsychotics – Atypicals. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Antihypertensives - Central; and Narcotics – Miscellaneous. The top 100 drugs were also reviewed, by paid amount and prescription count. The ten most expensive medications were: Acthar, Humira Pen, Vyvanse, Concerta, ProAir HFA, Sutent, Invega Systenna, Enbrel Sureclick, Latuda, and Emflaza. The five drugs with the highest prescription counts were: hydrocodone/acetaminophen, trazodone hcl, omeprazole, lisinopril, and ProAir HFA.

Amerigroup: Jeannine Murray provided an overview for Amerigroup's statistics from June 2019 through August 2019, including: a breakdown of utilization by age and gender, top 100 pharmacies by prescription count, top 100 pharmacies by paid amount, top 100 prescribing providers by prescription count, and top 100 prescribing providers by paid amount. The Bi-Monthly Statistics report reflected that expenditures totaled $93,693,230, a 44% increase from the total for March through May due to members previously on United Healthcare changing to Amerigroup. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; Antipsychotics/Antimanic Agents; Antiasthmatic and Bronchodilator Agents; and Analgesics – Anti-Imflammatory. These were the top five classes by prescription count: Antidepressants, Anticonvulsants, Antiasthmatic and Bronchodilator Agents, Antihypertensives, and Ulcer Drugs/Antispasmodics/ Anticholinergics. Vyvanse was the most expensive medication, followed by Concerta, Latuda, Humira Pen, and Humalog. Omeprazole had the highest prescription count, followed by: lisinopril, atorvastatin calcium, levothyroxine sodium, and sertraline hcl. Kellen Ludvigson noted that some of the prescription counts per prescriber seemed a little high, especially when combined with the other plans. Pam Smith will look at the prescribers with the highest counts on each plan report and research the issue. Erin Halverson added that IME was working with the data warehouse on a report that combines information from all MCO and FFS plans that could better clarify questions on these prevalence reports in the future.

Iowa Total Care: Emily Rogers spoke and provided written summaries that included ITC's statistics from July through August 2019, including: total paid amount ($38,628,854.94), unique users (91,173), and cost per user ($423.69). There was also a handout showing utilization by age and gender; females age 19-64 had the highest utilization. On the top 100 pharmacies by prescription count report, 4 Walgreens locations and the University of Iowa Ambulatory Care Pharmacy made up the top 5. University of Iowa Ambulatory Care Pharmacy was also the top pharmacy by paid amount. Lists of the top 100 prescribers by prescription count and paid amount were provided. The top 5 therapeutic classes by paid amount were: Insulin; Sympathomimetics; Anti-TNF-alpha – Monoclonal Antibodies; Antiretrovirals; and Amphetamines. 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, Latuda, Invega Sustenna, and Humalog, while omeprazole, lisinopril, atorvastatin, sertraline, and levothyroxine sodium had the top 5 prescription counts.

Comparative Prevalence Report Summary

Pam Smith also created a report that compared the FFS stats with those from each MCO (including the last month of United Healthcare utilization). Its side-by-side statistics showed that $163,155,301 was spent in total for 357,236 unique users who had 1,931,692 prescriptions.

Public Comment

In addition to the written public comments provided to Commission members as a part of their meeting materials, they heard oral public comment from the speakers listed below.

Name	Representing	Drug/Topic
Jim Baumann	Pfizer	Eucrisa
Kevin Duhrkopf	Sanofi Genzyme	Dupixent
Jenna Gianninoto	Abbvie	Mavyret
Christina Brandmeyer	Amgen	Amovig, Enbrel, Corlanor

ProDUR Edits

Review of Current and Proposed Opioid Quantity Limits: The DUR Commission unanimously recommended implementing ProDUR quantity limits on opioids as below. Given this was the first review, the recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

- Remove opioids from the current Iowa Medicaid Quantity Limit list that total ≥ 90 morphine milligram eqivalents (MME) per day, leaving current quantity limits in place for liquid agents. See Current Opioid Quantity Limits table below (drugs stricken to be removed from current list). Motion by Mark Graber, and second by Kellen Ludvigson.
- Current short-acting opioid quantity limits – six (6) units per day on all solid oral dosage forms where the quantity exceeds 6 units per day on the current Iowa Medicaid Quantity Limit list. See Current Opioid Quantity Limits table below, current quantities stricken and newly recommended quantity limit listed. Motion by Jason Kruse, and second by Kellen Ludvigson.
- Establish quantity limits for long- and short-acting opioids that fall below 90 MME per day, that do not have current quantity limits, including a maximum limit of six (6) units per day on all short-acting solid oral doage forms. See Proposed New Opioid Quantity Limits table below. Long-acting opioids - motion by Jason Kruse, and second by Brett Faine; Short-acting opioids - motion by Jason Kruse, and second by Mark Graber.

Current Opioid Quantity Limits – Proposed Changes (changes stricken)

Drug Product	Quantity	Days Supply	Comments
AVINZA 30MG (morphine er)	30	30	
AVINZA 45MG (morphine er)	30	30	
AVINZA 60MG (morphine er)	30	30	
AVINZA 75MG (morphine er)	30	30	
~~AVINZA 90MG (morphine er)~~	~~30~~	~~30~~	Exceeds 90 MME/day; Remove
~~AVINZA 120MG (morphine er)~~	~~150~~	~~30~~	Exceeds 90 MME/day; Remove
CODEINE SULFATE 15MG	180	30	6 tablets per day
CODEINE SULFATE 30MG	180	30	6 tablets per day
CODEINE SULFATE 60MG	180	30	6 tablets per day
COMBUNOX (oxycodone/ibuprofen)	28	30	
DURAGESIC 25MCG (fentanyl)	10	30	
~~DURAGESIC 50MCG (fentanyl)~~	~~10~~	~~30~~	Exceeds 90 MME/day; Remove
~~DURAGESIC 75MCG (fentanyl)~~	~~10~~	~~30~~	Exceeds 90 MME/day; Remove
~~DURAGESIC 100MCG (fentanyl)~~	~~10~~	~~30~~	Exceeds 90 MME/day; Remove
~~EMBEDA 20-0.8MG (morphine/naltrexone)~~	~~60~~	~~30~~	Removed from market
~~EMBEDA 30-1.2MG (morphine/naltrexone)~~	~~60~~	~~30~~	Removed from market
~~EMBEDA 50-2MG (morphine/naltrexone)~~	~~60~~	~~30~~	Removed from market
~~EMBEDA 60-2.4MG (morphine/naltrexone)~~	~~60~~	~~30~~	Removed from market
~~EMBEDA 80-3.2MG (morphine/naltrexone)~~	~~60~~	~~30~~	Removed from market
~~EMBEDA 100-4MG (morphine/naltrexone)~~	~~60~~	~~30~~	Removed from market
FIORICET/CODEINE 50-300-40-30MG (butalbital-apap-caffeine w/ codeine)	60	30	
FIORICET/CODEINE 50-325-40-30MG (butalbital-apap-caffeine w/ codeine)	60	30	
FIORINAL/CODEINE 50-325-40-30MG(butalbital-asa-caffeine-codeine)	60	30	
HYCET SOL (hydrocodone/apap)	3600ML	30	120ML per day
KADIAN 10MG (morphine sulfate er capsule)	60	30	
KADIAN 20MG (morphine sulfate er capsule)	60	30	
KADIAN 30MG (morphine sulfate er capsule)	60	30	
KADIAN 40MG (morphine sulfate er capsule)	60	30	
~~KADIAN 50MG (morphine sulfate er capsule)~~	~~60~~	~~30~~	Exceeds 90 MME/day; Remove
~~KADIAN 60MG (morphine sulfate er capsule)~~	~~60~~	~~30~~	Exceeds 90 MME/day; Remove
~~KADIAN 80MG (morphine sulfate er capsule)~~	~~60~~	~~30~~	Exceeds 90 MME/day; Remove
~~KADIAN 100MG (morphine sulfate er capsule)~~	~~60~~	~~30~~	Exceeds 90 MME/day; Remove
MSCONTIN 15MG (morphine sulfate sa)	90	30	
~~MSCONTIN 30MG (morphine sulfate sa)~~	~~90~~	~~30~~	Exceeds 90 MME/day; Remove
~~MSCONTIN 60MG (morphine sulfate sa)~~	~~90~~	~~30~~	Exceeds 90 MME/day; Remove
~~MSCONTIN 100MG (morphine sulfate sa)~~	~~300~~	~~30~~	Exceeds 90 MME/day; Remove
NORCO 5-325MG (hydrocodone/apap)	180 (~~360~~)	30	6 tablets per day
NORCO 7.5-325MG (hydrocodone/apap)	180 (~~240~~)	30	6 tablets per day
NORCO 10-325MG (hydrocodone/apap)	180	30	6 tablets per day
~~NUCYNTA 50MG (tapentadol)~~	~~180~~	~~30~~	Exceeds 90 MME/day; Remove

~~NUCYNTA 75MG (tapentadol)~~	~~180~~	~~30~~	Exceeds 90 MME/day; Remove
~~NUCYNTA 100MG (tapentadol)~~	~~180~~	~~30~~	Exceeds 90 MME/day; Remove
OPANA ER 5MG (oxymorphone)	60	30	
OPANA ER 7.5MG (oxymorphone)	60	30	
OPANA ER 10MG (oxymorphone)	60	30	
~~OPANA ER 15MG (oxymorphone)~~	~~60~~	~~30~~	Exceeds 90 MME/day; Remove
~~OPANA ER 20MG (oxymorphone)~~	~~60~~	~~30~~	Exceeds 90 MME/day; Remove
~~OPANA ER 30MG (oxymorphone)~~	~~60~~	~~30~~	Exceeds 90 MME/day; Remove
PERCOCET 5-325MG (oxycodone w/ apap)	180 (~~360~~)	30	6 tablets per day
PERCOCET 7.5-325MG (oxycodone w/ apap)	180 (~~240~~)	30	6 tablets per day
~~PERCOCET 10-325MG (oxycodone w/ apap)~~	~~180~~	~~30~~	Exceeds 90 MME/day; Remove
TYLENOL W/ CODEINE ELIXIR (apap w/ codeine)	2700ML	30	90ML per day
TYLENOL W/ CODEINE NO. 2 (apap w/ codeine)	180 (~~390~~)	30	6 tablets per day
TYLENOL W/ CODEINE NO. 3 (apap w/ codeine)	180 (~~390~~)	30	6 tablets per day
TYLENOL W/ CODEINE NO. 4 (apap w/ codeine)	180 (~~390~~)	30	6 tablets per day
ULTRACET (tramadol/apap)	180 (~~240~~)	30	6 tablets per day
ULTRAM 50MG (tramadol)	180 (~~240~~)	30	6 tablets per day
ULTRAM ER 100MG (tramadol er)	30	30	
ULTRAM ER 200MG (tramadol er)	30	30	
ULTRAM ER 300MG (tramadol er)	30	30	
VICODIN ES 7.5-300MG(hydrocodone/apap)	150	30	5 tablets per day
VICODIN HP 10-300MG (hydrocodone/apap)	180	30	6 tablets per day
XODOL 5-300MG (hydrocodone/apap)	180 (~~360~~)	30	6 tablets per day
XODOL 7.5-300MG (hydrocodone/apap)	180	30	6 tablets per day
XODOL 10-300MG (hydrocodone/apap)	180	30	6 tablets per day
ZAMICET (hydrocodone/apap)	2700ML	30	90ML per day

Proposed New Opioid Quantity Limits

Drug Product	Quantity	Days Supply	Comments
ACETAMINOPHEN-CAFFEINE-DIHYDROCODEINE CAP 320.5-30-16 MG	180	30	6 capsules per day
ACETAMINOPHEN-CAFFEINE-DIHYDROCODEINE TAB 325-30-16 MG	180	30	6 tablets per day
BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 4.08-325 MG (APADAZ)	180	30	6 tablets per day
BUPRENORPHINE TD PATCH WEEKLY 5 MCG/HR (BUTRANS)	4	28	1 patch per week
HYDROCODONE BITARTRATE CAP ER 12HR ABUSE-DETERRENT 10 MG (ZOHYDRO ER)	60	30	2 capsules per day
HYDROCODONE BITARTRATE CAP ER 12HR ABUSE-DETERRENT 15 MG	60	30	2 capsules per day
HYDROCODONE BITARTRATE CAP ER 12HR ABUSE-DETERRENT 20 MG	60	30	2 capsules per day

HYDROCODONE BITARTRATE CAP ER 12HR ABUSE-DETERRENT 30 MG	60	30	2 capsules per day
HYDROCODONE BITARTRATE CAP ER 12HR ABUSE-DETERRENT 40 MG	60	30	2 capsules per day
HYDROCODONE BITARTRATE CAP ER 12HR ABUSE-DETERRENT 50 MG	60	30	2 capsules per day
HYDROCODONE BITARTRATE TAB ER 24HR DETER 100 MG (HYSLINGA)	30	30	
HYDROCODONE BITARTRATE TAB ER 24HR DETER 120 MG	30	30	
HYDROCODONE BITARTRATE TAB ER 24HR DETER 20 MG	30	30	
HYDROCODONE BITARTRATE TAB ER 24HR DETER 30 MG	30	30	
HYDROCODONE BITARTRATE TAB ER 24HR DETER 40 MG	30	30	
HYDROCODONE BITARTRATE TAB ER 24HR DETER 60 MG	30	30	
HYDROCODONE BITARTRATE TAB ER 24HR DETER 80 MG	30	30	
HYDROCODONE-ACETAMINOPHEN SOLN 10-300 MG/15ML (LORTAB ELIXIR)	2700	30	90 ml per day
HYDROCODONE-ACETAMINOPHEN TAB 10-300 MG (VICODIN HP)	180	30	6 tablets per day
HYDROCODONE-ACETAMINOPHEN TAB 2.5-325 MG	180	30	6 tablets per day
HYDROCODONE-ACETAMINOPHEN TAB 5-300 MG (VICODIN)	180	30	6 tablets per day
HYDROCODONE-IBUPROFEN TAB 10-200 MG	150	30	5 tablets per day
HYDROCODONE-IBUPROFEN TAB 5-200 MG	150	30	5 tablets per day
HYDROCODONE-IBUPROFEN TAB 7.5-200 MG	150	30	5 tablets per day
HYDROMORPHONE HCL SUPPOS 3 MG	120	30	4 supp. per day
HYDROMORPHONE HCL TAB ER 24HR DETER 12 MG (EXALGO)	30	30	
HYDROMORPHONE HCL TAB ER 24HR DETER 16 MG	30	30	
HYDROMORPHONE HCL TAB ER 24HR DETER 8 MG	30	30	
LEVORPHANOL TARTRATE TAB 2 MG	120	30	4 tablets per day
MEPERIDINE HCL TAB 100 MG	180	30	6 tablets per day
MEPERIDINE HCL TAB 50 MG	180	30	6 tablets per day
MORPHINE SULFATE SUPPOS 10 MG	180	30	6 supp. per day
MORPHINE SULFATE SUPPOS 5 MG	180	30	6 supp. per day
MORPHINE SULFATE TAB ER 12HR DETER 15 MG (MORPHABOND)	90	30	3 tablets per day
MORPHINE SULFATE TAB ER ABUSE-DETERRENT 15 MG (ARYMO ER)	90	30	3 tablets per day
OXYCODONE CAP ER 12HR ABUSE-DETERRENT 13.5 MG (XTAMPZA ER)	60	30	2 capsules per day
OXYCODONE CAP ER 12HR ABUSE-DETERRENT 18 MG	60	30	2 capsules per day
OXYCODONE CAP ER 12HR ABUSE-DETERRENT 27 MG	60	30	2 capsules per day
OXYCODONE CAP ER 12HR ABUSE-DETERRENT 9 MG	60	30	2 capsules per day
OXYCODONE HCL CAP 5 MG	180	30	6 capsules per day
OXYCODONE HCL CONC 100 MG/5ML (20 MG/ML)	87	30	2.9 ml per day
OXYCODONE HCL SOLN 5 MG/5ML	1770	30	59 ml per day
OXYCODONE HCL TAB 5 MG	180	30	6 tablets per day
OXYCODONE HCL TAB ABUSE DETER 5 MG (ROXYBOND OR OXAYDO)	180	30	6 tablets per day
OXYCODONE HCL TAB ABUSE DETER 7.5 MG (OXAYDO)	180	30	6 tablets per day

OXYCODONE HCL TAB ER 12HR DETER 10 MG (OXYCONTIN)	60	30	2 tablets per day
OXYCODONE HCL TAB ER 12HR DETER 15 MG	60	30	2 tablets per day
OXYCODONE HCL TAB ER 12HR DETER 20 MG	60	30	2 tablets per day
OXYCODONE W/ ACETAMINOPHEN TAB 2.5-300 MG	180	30	6 tablets per day
OXYCODONE W/ ACETAMINOPHEN TAB 2.5-325 MG	180	30	6 tablets per day
OXYCODONE-ASPIRIN TAB 4.8355-325 MG	180	30	6 tablets per day
OXYCODONE-IBUPROFEN TAB 5-400 MG	120	30	4 tablets per day
TAPENTADOL HCL TAB ER 12HR 50 MG (NUCYNTA ER)	60	30	2 tablets per day

Gabapentinoid Quantity Limit: The DUR Commission recommended implementing a ProDUR quantity limit on gabapentin (see table below). Additionally, the DUR Commission recommended implementing a maximum milligram per day edit on gabapentin (3600 mg) and pregabalin immediate release (600 mg), limiting each medication to the maximum milligram per day across all strengths. As this was the second review, the recommendations will be sent to the Department for consideration.

Recommended Quantity Limits for Gabapentin		
Strength	**Daily Quantity Limit**	**Monthly Quantity Limit**
100 mg	6 capsules	180 capsules
300 mg	9 capsules	270 capsules
400 mg	9 capsules/tablets	270 capsules/tablets
600 mg	6 tablets	180 capsules
800 mg	4.5 tablets	135 tablets
50 mg/mL	72 mL	2160 mL

Retrospective DUR Proposals

The DUR Commission reviewed the retrospective DUR proposals below and requested claims data for each proposal be brought back to a future meeting.

High Dose Gabapentin: To identify members exceeding the maximum recommended daily dose of 3,600 mg gabapentin. The MCOs and FFS will bring back the number of members exceeding 3,600 mg gabapentin per day. Additionally, it was suggested once pregabalin moves to a preferred status, claims will be reviewed to see how many members are using pregabalin and gabapentin concurrently.

Duplicate SSRIs: To identify member with concurrent claims of SSRIs. The MCOs and FFS will bring back the number of members identified as having claims for two or more chemically distinct SSRIs. Mark Graber suggested looking at concurrent SSRI and SNRI usage as a possible retrospective study.

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

Prior Authorization

Annual Review of Prior Authorization Criteria: Changes were suggested for the following categories, to be discussed at upcoming meetings. The Commission requested that PA statistics per category as had been previously provided during the annual review (prior to Managed Care) be brought back (for both MCOs and FFS), as they found the numbers helpful in determining any necessary PA criteria changes. IME staff will work with the MCOs to develop this reporting.

PA Category	Recommended Changes
Alpha1-Proteinase Inhibitor Enzymes	Change wording on #5 to say patient is actively attempting smoking cessation.
Amylino Mimetic (Symlin)	Potentially add to Anti-Diabetics, Non-Insulin Agents PA form. Utilization for each plan will be brought back to a future meeting to determine if change is needed.
Cannabidiol (Epidiolex)	Specify that LFTs that are contraindicated.
CNS Stimulants and Atomoxetine	Allow physician assistants working under a psychiatrist to prescribe for Binge Eating Disorder.
Crisaborole (Eucrisa)	Possibly create separate criteria for adults and children due to differences in standards of care in pediatric patients. PA stats will be researched by all entities, including reason for denials, and brought back for review.
Hematopoietics/ Chronic ITP	On #1 rather than say insufficient response to a corticosteroid, require a platelet goal of 50,000 to define failure of steroids.
Hepatitis C Treatments	Strike #6 which requires a Metavir score of 2 or greater fibrosis.
Idiopathic Pulmonary Fibrosis	Require that patient is actively attempting smoking cessation vs being a nonsmoker or abstinent for at least 6 weeks.
Lesinurad (Zurampic)	May no longer be commercially available.
PCSK9 Inhibitors	Allow consultation with specialists rather than requiring they prescribe.
Potassium Binders	Review due to new agents and suggest the P&T Committee consider making one of the newer agents preferred based on lack of efficacy and side effects. SPS can cause GI necrosis, especially when used in combination with a laxative.
Pulmonary Arterial Hypertension Agents	Specify that it's a primary disease and not secondary to COPD.
Roflumilast (Daliresp)	Update criteria to use new GOLD criteria definitions (very severe stage D COPD, require CAT score or MMRC score).
Valsartan/Sacubitril (Entresto)	Strike #11 requiring consultation with or prescribed by cardiologist. Pam Smith said this was slated for review at a future meeting due to the new indications.

Linezolid (Zyvox): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for linezolid. Payment for linezolid will be authorized when there is documentation that:

1. The patient has one of the following diagnostic criteria:

a. Vancomycin-resistant Enterococcus (VRE); or
b. Methicillin-resistant Staph aureus (MRSA); or
c. Methicillin-resistant Staph epidermis (MRSE); or
d. Other multiply resistant gram positive infection (e.g. penicillin resistant Streptococcus spp); and

2. Patient meets ONE of the following criteria:
   a. Patient is severely intolerant to vancomycin with no alternative regimens with documented efficacy available*, or
   b. VRE in a part of body other than lower urinary tract**, or
   c. Patient discharged on linezolid and requires additional quantity (up to 10 days oral therapy will be allowed).
3. A current culture and sensitivity report is provided documenting sensitivity to linezolid.

*Severe intolerance to vancomycin is defined as:

1. Severe rash, immune-complex mediated, determined to be directly related to vancomycin administration
2. Red-man's syndrome (histamine-mediated), refractory to traditional counter measures (e.g., prolonged IV infusion, premedicated with diphenhydramine)

**VRE in lower urinary tract, considered to be pathogenic, may be treated with linezolid if severe renal insufficiency exists and/or patient is receiving hemodialysis or has known hypersensitivity to nitrofurantoin.

Jason Kruse motioned to accept the criteria as amended, and Mark Graber 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. Linezolid utilization reports, for each plan, will be brought back as Kellen Ludvigson requested.

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

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

1. Patient is within the FDA labeled age for indication; and
2. Patient has a diagnosis of moderate-to-severe atopic dermatitis; and
   a. Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and
   b. Patient has failed to respond to good skin care and regular use of emollients; and
   c. Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
   d. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
   e. Patient has documentation of a previous trial and therapy failure with

cyclosporine or azathioprine; and

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

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

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

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

Jason Kruse motioned to accept the criteria as amended, 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.

Biologicals for Axial Spondyloarthritis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for biologicals used for axial spondyloarthritis conditions. Payment will be considered under the following conditions:

1. Patient has a diagnosis of:

    - ankylosing spondylitis (AS) or
    - nonradiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; and
2. The requested dose does not exceed the maximum FDA labeled or compendia recommended dose for the submitted diagnosis; and
3. Patient has been screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and
4. Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and
5. Patient has documentation of an inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at maximum therapeutic doses, unless there are documented adverse responses or contraindications to NSAID use. These trials should be at least one month in duration; and
6. Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include sulfasalazine and methotrexate; and
7. Requests for non-preferred biologicals for axial spondyloarthritis conditions will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents that are FDA approved or compendia indicated for the submitted diagnosis, when applicable.

In addition to the above:
Requests for TNF Inhibitors:

1. Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and
2. Patient does not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or lV and with an ejection fraction of 50% or less.

Requests for Interleukins:

1. Medication will not be given concurrently with live vaccines.

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

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

Ivabradine (Corlanor): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for ivabradine. Only FDA approved dosing will be considered. Payment will be considered under the following conditions:

1. Patient has a diagnosis of stable, symptomatic heart failure (NYHA Class II, III, or IV); and
    a. Patient is 18 years of age or older; and
    b. Patient has documentation of a left ventricular ejection fraction ≤35%; and
    c. Patient is in sinus rhythm with a resting heart rate of ≥70 beats per minute; and
    d. Patient has documentation of blood pressure ≥90/50 mmHg; or
2. Patient has a diagnosis of stable symptomatic heart failure (NYHA/Ross class II to IV) due to dilated cardiomyopathy, and
    a. Pediatric patient age 6 months and less than 18 years old; and
    b. Patient has documentation of a left ventricular ejection fraction ≤45%; and
    c. Patient is in sinus rhythm with a resting heart rate (HR) defined below;
        i. 6 to 12 months - HR ≥ 105 bpm
        ii. 1 to 3 years - HR ≥ 95 bpm
        iii. 3 to 5 years - HR ≥ 75 bpm
        iv. 5 to 18 years - HR ≥ 70 bpm; and
3. Heart failure symptoms persist with maximally tolerated doses of at least one beta-blocker with proven mortality benefit in a heart failure clinical trial (e.g. carvedilol 50mg daily, metoprolol succinate 200mg daily, or bisoprolol 10mg daily) or weight appropriate dosing for pediatric patients, or patient has a documented intolerance or FDA labeled contraindication to beta-blockers; and
4. Patient has documentation of a trial and continued use with a preferred angiotensin system blocker at a maximally tolerated dose.

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

Mark Graber 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.

Chronic Pain Syndromes: The Commission reviewed the prior authorization criteria below, and made a recommendation to remove it.

A prior authorization (PA) is required for pregabalin (Lyrica) and milnacipran (Savella). These drugs will be considered for their FDA indications(s) and other conditions as listed in the compendia. Requests for doses above the manufacturer recommended dose will not be considered. For patients with a chronic pain diagnosis who are currently taking opioids, as seen in pharmacy claims, a plan to

decrease and/or discontinue the opioid(s) must be provided with the initial request. Initial authorization will be given for three (3) months. Requests for renewal must include an updated opioid treatment plan and documentation of improvement in symptoms and quality of life. Requests for non-preferred brand name drugs, when there is a preferred A-rated bioequivalent generic product available, are also subject to the Selected Brand Name prior authorization criteria and must be included with this request. Payment will be considered under the following conditions:

1. A diagnosis of fibromyalgia (Lyrica and Savella)
   a. a trial and therapy failure at a therapeutic dose with gabapentin plus one of the following preferred generic agents: tricyclic antidepressant or SNRI **WITH**
   b. documented non-pharmacologic therapies (cognitive behavior therapies, exercise, etc.)
2. A diagnosis of post-herpetic neuralgia (Lyrica)
   A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, topical lidocaine, or valproate.
3. A diagnosis of diabetic peripheral neuropathy (duloxetine and Lyrica)
   A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant or duloxetine.
4. A diagnosis of partial onset seizures, as adjunct therapy (Lyrica)
5. A diagnosis of neuropathic pain associated with spinal cord injury (Lyrica)

Jason Kruse motioned to remove the criteria, contingent on action from the P&T Committee making generic Lyrica preferred, 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.

Anti-Diabetic Non-Insulin Agents: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for preferred anti-diabetic, non-insulin agents subject to clinical criteria. Payment will be considered under the following conditions:

1. Patient has an FDA approved or compendia indicated diagnosis, and
2. Patient meets the FDA approved or compendia indicated age, and
3. For the treatment of Type 2 Diabetes Mellitus, the patient has not achieved HgbA1C goals after a minimum three month trial with metformin at maximally tolerated dose.
4. Requests for non-preferred anti-diabetic, non-insulin agents, subject to clinical criteria, will be authorized only for cases in which there is documentation of previous trials and therapy failures with a preferred drug in the same class. Requests for a non-preferred agent for the treatment of Type 2 Diabetes Mellitus must document previous trials and therapy failures with metformin, a preferred DPP-4 Inhibitor or DPP-4 Inhibitor Combination, a preferred Incretin Mimetic, and a preferred SGLT2 Inhibitor at maximally tolerated doses.

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

Initial authorizations will be approved for six months. Additional PAs will be considered on an individual basis after review of medical necessity and documented continued improvement in symptoms (such as HgbA1C for Type 2 Diabetes).

Mark Graber 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.

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

For patients initiating therapy with a preferred oral medication, a manual prior authorization 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/lV heart failure; and
2. Patient does not have a history or presence of Mobitz Type ll 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 lll 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):

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 on 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.

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.

Ospemifene (Osphena): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for ospemifene (Osphena). Requests for a diagnosis of moderate to severe dyspareunia are considered not medically necessary and will be denied. Payment will be considered under the following conditions:

1. Patient is a post-menopausal woman with a diagnosis of moderate to severe vaginal dryness due to vulvar and vaginal atrophy; and
2. Patient has documentation of an adequate trial and therapy failure with a preferred vaginal estrogen agent; and
3. Patient does not have any contraindications to ospemifene as listed in the FDA approved label; and
4. Will not be used with estrogens, estrogen agonist/antagonists, fluconazole, or rifampin; and
5. Patient does not have severe hepatic impairment (Child-Pugh Class C); and
6. Patient will be evaluated periodically as clinically appropriate to determine if treatment is still necessary as ospemifene should be used for the shortest duration consistent with treatment goals and risks for the individual woman; and
7. Dose does not exceed the FDA approved dose.

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

Initial requests will be approved for 3 months. Additional prior authorizations will be considered upon documentation of clinical response to 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.

Abilify MyCite: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for aripiprazole tablets with sensor (Abilify MyCite). Payment will be considered under the following conditions:

1. Patient has a diagnosis of Schizophrenia, Bipolar I Disorder, or Major Depressive Disorder; and
2. Patient meets the FDA approved age for use of the Abilify MyCite device; and
3. Dosing follows the FDA approved dose for the submitted diagnosis; and
4. Documentation of patient adherence to generic aripiprazole tablets is less than 80% within the past 6 months (prescriber must provide documentation of the previous 6 months' worth of pharmacy claims for aripiprazole documenting non-adherence); and
5. Documentation all the following strategies to improve patient adherence have been tried without success:
    a. Utilization of a pill box
    b. Utilization of a reminder device (e.g. alarm, application, or text reminder)
    c. Involving family members or friends to assist

d. Coordinating timing of dose with dosing of another daily medication; and

6. Documentation of a trial and intolerance to a preferred long-acting aripiprazole injectable agent; and
7. Prescriber agrees to track and document adherence of Abilify MyCite through the web-based portal for health care providers and transition member to generic aripiprazole tablets after a maximum of 4 months use of Abilify MyCite. Initial approvals will be given for one month. Prescriber must review member adherence in the web-based portal and document adherence for additional consideration. If non-adherence continues, prescriber must document a plan to improve adherence. If adherence is improved, consideration to switch member to generic aripiprazole tablets must be considered. Note, the ability of the Abilify MyCite to improve patient compliance has not been established.
8. Requests will not be considered for patients in long-term care facilities.
9. A once per lifetime approval will be allowed.

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.

CGRP Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for CGRP Inhibitors. Payment will be considered for a FDA approved or compendia indicated diagnosis under the following conditions:

1. Patient has one of the following diagnoses:
    a. Chronic Migraine, defined as:
        i. ≥ 15 headache days per month for a minimum of 3 months; and
        ii. ≥ 8 migraine headaches days per month for a minimum of 3 months; or
    b. Episodic Migraine, defined as:
        i. 4 to 14 migraine days per month for a minimum of 3 months; or
    c. Episodic Cluster Headache, defined as:
        i. Occurring with a frequency between one attack every other day and 8 attacks per day; and
        ii. With at least 2 cluster periods lasting 7 days to one year (when untreated) and separated by pain-free remission periods of ≥3 months; and

iii. Patient does not have chronic cluster headache (attacks occurring without a remission period, or with remissions lasting <3 months, for at least 1 year); and

2. Patient meets the FDA approved age for submitted diagnosis; and
3. Patient has been evaluated for and does not have medication overuse headache; and
4. For Episodic and Chronic Migraine, patient has documentation of three trials and therapy failures, of at least 3 months per agent, at a maximally tolerated dose with a minimum of two different migraine prophylaxis drug classes (i.e. anticonvulsants [divalproex, valproate, topiramate], beta blockers [atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [amitriptyline, venlafaxine]); or
5. For Episodic Cluster Headache, patient has documentation of
    a. A previous trial and therapy failure at an adequate dose with glucocorticoids (prednisone 30mg per day or dexamethasone 8mg BID) started promptly at the start of a cluster period. Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamine, lidocaine) at least once daily for at least two days per week after the first full week of adequately dosed steroid therapy; and
    b. A previous trial and therapy failure at an adequate dose of verapamil for at least 3 weeks (total daily dose of 480 mg to 960 mg). Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamines, lidocaine) at least once daily for at least two days per week after three weeks of adequately dosed verapamil therapy.
6. The requested dose does not exceed the maximum FDA labeled dose for the submitted diagnosis; and
7. Lost, stolen, or destroyed medication replacement requests will not be authorized.

Initial requests will be approved for 3 months. Additional prior authorizations will be considered upon documentation of clinical response to therapy (i.e., reduced migraine frequency, reduced migraine headache days, reduced weekly cluster headache attack frequency).

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.

Miscellaneous

DUR Digest: The Commission members conducted the second review of the draft DUR Digest Volume 32, Number 1. The DUR Digest will be posted to the DUR website.

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

At 12:17, Chuck Wadle and Mark Graber simultaneously motioned to adjourn, and Melissa Klotz seconded. All in attendance agreed.

The next meeting will be held at 9:30 a.m. on Wednesday, March 4, 2020, at a location to be determined.

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

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; Chuck Wadle, D.O.; John Ellis, Pharm.D.; and Susan Parker, Pharm.D.

Staff
Pam Smith, R.Ph.

Guests
Erin Halverson, R.Ph., IME; Melissa Biddle, IME; Dawn Grittman, Pharm.D., Iowa Total Care; and Sandy Pranger, R.Ph., Amerigroup.

Welcome & Introductions

Chairperson Brett Faine called the meeting to order at 9:31 a.m. at the Learning Resource Center in West Des Moines. The minutes from the November 6, 2019 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 meeting was also reviewed. Pam Smith provided follow-up information from previous meetings regarding claims data for linezolid, Symlin, and Eucrisa, as well as prior authorization data for Eucrisa. The MCOs will look further into the data results for Eucrisa to provide more detail on the PA denials and reasoning behind them as Jason Kruse requested.

Commission Recommendations for Retrospective DUR Agenda Topics

The Commission did not have any new recommendations.

IME Pharmacy Update

Commission members were emailed links to four recent informational letters. Informational Letter 2086-MC-FFS explained changes effective March 18, 2020, including dispensing fees for maintenance drugs and Medication Assisted Treatment (MAT). Informational Letter 2109-MC-FFS provided a pharmacy claim submission update effective April 6, 2020. Informational Letter 2105-MC-FFS provided a clarification on information regarding the new provider type for pharmacists and associated enrollment. Informational Letter 2095-MC-FFS gave pharmacies directions for participation in the cost of dispensing survey. There is still an opening for a doctor on the DUR Commission, as Mark Graber is in the last year of his 3 allowable terms.

Prevalence Report Summaries

Amerigroup: Sandy Pranger provided an overview for Amerigroup's statistics from September 2019 through December 2019, including: number of enrolled eligible members (380,000); total paid amount ($98,097,014); unique users (163,015); total prescriptions

(1,193,791); generic prescriptions (1,047,977 totaling $24,666,600); brand prescriptions (145,814 totaling $73,430,414). She noted that the specialty drugs keep increasing. The breakdown of utilization by age shows that ages 19-64 continue to have the highest utilization, with 62% female and 38% male utilization across all age groups. 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, Hy-Vee Pharmacy Solutions, Accredo Health Group, and Nucara Specialty. On the top 100 prescribing providers by prescription count report, Roy Overton (Geriatrics) took the top spot due to the large volume of recent flu vaccines, followed by: Thomas Earwood, Jeffrey Wilham, Charles Tilley, and Bobbita Nag. Also noted was the fact that #36 Stephen Mandler did average 10 prescriptions per member, but this was just due to the billing as he does long term care. Three of the top five prescribers on the top 100 prescribing providers by paid amount practice at the University of Iowa: Janice Staber, Michael Ciliberto, and Laura Ramsey. There was nothing out of the ordinary on that report. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; Antipsychotics/Antimanic Agents; Antiasthmatic and Bronchodilator Agents; and Analgesics – Anti-Imflammatory. Opioid utilization continues to trend downward, though Chuck Wadle wondered if Suboxone utilization had gone up with the removal of the PA criteria. Sandy Pranger confirmed that was correct and said she would bring the analysis back to the next meeting. 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 Concerta, Humira (CF) Pen, Latuda, and Invega Sustenna. Sandy Pranger noted the shift to the CF Pen for members using Humira, as well as an increase in expenditures for antibiotics and flu vaccines. Omeprazole had the highest prescription count, followed by: atorvastatin calcium, lisinopril, sertraline hcl, and ProAir HFA. This report also showed an increase in prescriptions for antibiotics and flu vaccines. Melissa Klotz noted that 7 of the top 10 drugs by prescription count had experienced an increase in prescription count but decrease in paid amount since the previous reporting period. Sandy Pranger said she would look into this.

Iowa Total Care: Dawn Grittman spoke and provided written summaries that included ITC's statistics from September through December 2019, including: number of enrolled eligible members (approximately 262,000); total paid amount ($55,376,369.40); total prescriptions (739,251); and unique users (108,642). The greatest utilization of the pharmacy benefit was for the age group of 19-64, with females in that age group getting about 1.8 prescriptions per every male in the same age group. 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, Optum Pharmacy, Hy-Vee Pharmacy Solutions, and Accredo Health Group. The top 5 therapeutic classes by paid amount were: Insulin; Sympathomimetics; Stimulants – Misc.;

Amphetamines, and Antiretrovirals. The top 5 classes by prescription count were: SSRIs; Sympathomimetics; Anticonvulsants; Proton-Pump Inhibitors; and HMG CoA Reductase Inhibitors. The most expensive drugs were Vyvanse, Humira Pen, Concerta, Latuda, and Invega Sustenna, while omeprazole, lisinopril, atorvastatin, sertraline, and levothyroxine sodium had the top 5 prescription counts.

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from September 2019 through December 2019, including: total amount paid ($2,072,620), unique users (4,875); cost per user ($425.15), number of total prescriptions dispensed (25,705); percent generic (86.7%); and number of enrolled eligible members (approximately 10,000). Pam Smith noted that there were a lot of pharmacies from Sioux City at the top of the top 100 pharmacies by prescription count report; there were also several increases in ranking due to vaccines. She also added that since the FFS population is so small, a pharmacy can easily experience a rank shift just from adding one new member. 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: Leighton Frost, Shawn Salmen, Molly Earleywine, Joada Jean Best, and Michael Ciliberto. Pam Smith also looked at other providers that had a high average script per member number; long term care billing at 7 days per prescription often skews the averages. The top prescribing providers by paid amount were largely specialists, tending toward oncology, neurology, and hematology, with the big rank changes mainly due to no claims being submitted under those NPI numbers in the previous reporting period. There were some family medicine physicians toward the bottom of the list as they saw an increase in cough and cold medications. The top 5 therapeutic classes by paid amount were: Anticonvulsants; Anti-Inflammatories, Non-NSAID; Antipsychotics – Atypicals; Antiretroviral Combinations; and Stimulants – Amphetamines – Long Acting. NSAIDs and ACE Inhibitors did move into the top 20. 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. There was a rank change from 22 to 19 for the Stimulants – Methylphenidate – Long Acting, possibly due to the new requirement that adults use the long-acting formulations rather than the short-acting. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Vyvanse, Humira Pen, Concerta, Invega Systenna, and ProAir HFA. The report reflects the seasonal changes, with increased utilization on multiple antibiotics, TamiFlu, and albuterol. The Chantix starter pack also entered the top 100, when it didn't before when PA criteria was in place. The five drugs with the highest prescription counts were: ProAir HFA, trazodone hcl, lisinopril, omeprazole, and montelukast sodium. Hydrocodone/acetaminophen fell from 1 to 13. Pam Smith also noted that the prescriptions for several medications including ibuprofen were down while the cost went up, likely due to the encounter claims.

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 $155,556,003 was spent in total for 276,532 unique

users who had 1,958,747 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Vyvanse was the most expensive drug for all 3 plans, with Humira and Concerta also appearing in the top 3 for all. The top 25 drugs by prescription count were also similar across FFS and both MCO plans. When all three plans were combined, Roy Overton had the overall highest prescription count at 5,469.

Public Comment

In addition to the written public comments provided to Commission members, they heard oral public comment from the speakers listed below.

Name	Representing	Drug/Topic
Syed Mahmud	Global Blood Therapeutics	Oxbryta
Peter Zoob	Vertex	Trikafta
Jim Baumann	Pfizer	Eucrisa
Nisha Rizvi	Novartis	Entresto
Christina Brandmeyer	Amgen	Enbrel
Alicia Duyvejonck	Genesis Health Group	Acute Migraine Medications

ProDUR Edits

Review of Current and Proposed Opioid Quantity Limits: The DUR Commission previously unanimously recommended implementing ProDUR quantity limits on opioids as detailed below, and had no additional changes. As this was the second review, no motion was necessary. The recommendations will be sent to the Department for consideration. See the 11/06/19 meeting minutes for a complete listing of current and proposed quantity limit changes.

- Remove opioids from the current Iowa Medicaid Quantity Limit list that total ≥ 90 morphine milligram eqivalents (MME) per day, leaving current quantity limits in place for liquid agents.
- Current short-acting opioid quantity limits – six (6) units per day on all solid oral dosage forms where the quantity exceeds 6 units per day on the current Iowa Medicaid Quantity Limit list.
- Establish quantity limits for opioids that fall below 90 MME per day, that do not have current quantity limits, including a maximum limit of six (6) units per day on all short-acting solid oral doage forms.

Retrospective DUR

Claims Data Review

Duplicate SSRIs: Letters will be sent to the prescribers and pharmacies of members with claims for two or more chemically distinct SSRIs. Mark Graber suggested looking at concurrent SSRI and SNRI usage as a possible retrospective study.

High Dose Gabapentin: Letters will be sent to the providers of members with claims for gabapentin exceeding 3600 mg per day, also warning them about the POS edit that will soon be implemented as well.

Proposals

Duplicate SNRIs: 60 days of claims data will be reviewed to check for members with fills of 2 or more concurrent SNRIs in that timeframe.

Baclofen Utilization: 30 and 60 days of claims data will be reviewed identify members with 1.) baclofen claims, 2.) those exceeding 80 mg baclofen per day, and 3.) those with concurrent use of baclofen and an opioid (regardless of baclofen dose). Mark Graber asked that both a 30-day 60-day claim report be run for comparison.

The Commission took a short break and open session resumed at 10:55.

Prior Authorization

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.*

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

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.

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.

Mark Graber 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.

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.

Jason Kruse motioned to accept the criteria as recommended (with the caveat that utilization data be reviewed after six months to see if any changes to criteria are needed

or if guidelines have been updated), and Mark Graber 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 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.

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.

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

Prior authorization (PA) is required for preferred acute migraine treatments for quantities exceeding 12 unit doses of tablets, syringes or sprays per 30 days. Payment for acute migraine treatments beyond this limit will be considered on an individual basis after review of submitted documentation. PA will be required for all non-preferred acute migraine treatments as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. Payment for non-preferred acute migraine treatments 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; and*
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.

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

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.

Kellen Ludvigson motioned to remove 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.

Linezolid (Zyvox): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for linezolid. Payment for linezolid will be authorized when there is documentation that:

1. *The patient has one of the following diagnostic criteria:*
    a. *Vancomycin-resistant Enterococcus (VRE); or*
    b. *Methicillin-resistant Staph aureus (MRSA); or*
    c. *Methicillin-resistant Staph epidermis (MRSE); or*
    d. *Other multiply resistant gram positive infection (e.g. penicillin resistant Streptococcus spp); and*
2. *Patient meets ONE of the following criteria:*
    a. *Patient is severely intolerant to vancomycin with no alternative regimens with documented efficacy available*, or*
    b. *VRE in a part of body other than lower urinary tract**, or*
    c. *Patient discharged on linezolid and requires additional quantity (up*

to 10 days oral therapy will be allowed).

3. *A current culture and sensitivity report is provided documenting sensitivity to linezolid.*

**Severe intolerance to vancomycin is defined as:*

1. *Severe rash, immune-complex mediated, determined to be directly related to vancomycin administration*
2. *Red-man's syndrome (histamine-mediated), refractory to traditional counter measures (e.g., prolonged IV infusion, premedicated with diphenhydramine)*

***VRE in lower urinary tract, considered to be pathogenic, may be treated with linezolid if severe renal insufficiency exists and/or patient is receiving hemodialysis or has known hypersensitivity to nitrofurantoin.*

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

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

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

1. *Patient is within the FDA labeled age for indication; and*
2. *Patient has a diagnosis of moderate-to-severe atopic dermatitis; and*
    a. *Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and*
    b. *Patient has failed to respond to good skin care and regular use of emollients; and*
    c. *Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*
    d. *Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
    e. *Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and*
    f. *Patient will continue with skin care regimen and regular use of emollients; or*
3. *Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) OR with oral corticosteroid dependent asthma; and*
    a. *Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and*
    b. *Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted; and*
    c. *Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in*

combination with a controller medication (e.g. long acting beta$_2$ agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and

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

4. *Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and*
   a. *Documentation dupilumab will be used as an add-on maintenance treatment; and*
   b. *Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:*
      i. *Nasal corticosteroid spray; and*
      ii. *Oral corticosteroid; and*
5. *Dose does not exceed the FDA approved dosing for indication.*

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

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

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

Biologicals for Axial Spondyloarthritis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for biologicals used for axial spondyloarthritis conditions. Payment will be considered under the following conditions:

1. *Patient has a diagnosis of:*
   - *ankylosing spondylitis (AS) or*
   - *nonradiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; and*
2. *The requested dose does not exceed the maximum FDA labeled or compendia recommended dose for the submitted diagnosis; and*
3. *Patient has been screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and*
4. *Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and*
5. *Patient has documentation of an inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at maximum*

therapeutic doses, unless there are documented adverse responses or contraindications to NSAID use. These trials should be at least one month in duration; and

6. *Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include sulfasalazine and methotrexate; and*
7. *Requests for non-preferred biologicals for axial spondyloarthritis conditions will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents that are FDA approved or compendia indicated for the submitted diagnosis, when applicable.*

In addition to the above:
Requests for TNF Inhibitors:

1. *Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and*
2. *Patient does not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or IV and with an ejection fraction of 50% or less.*

Requests for Interleukins:

1. *Medication will not be given concurrently with live vaccines.*

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.

Ivabradine (Corlanor): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for ivabradine. Only FDA approved dosing will be considered. Payment will be considered under the following conditions:

1. *Patient has a diagnosis of stable, symptomatic heart failure (NYHA Class II, III, or IV); and*
    a. *Patient is 18 years of age or older; and*
    b. *Patient has documentation of a left ventricular ejection fraction ≤35%; and*
    c. *Patient is in sinus rhythm with a resting heart rate of ≥70 beats per minute; and*
    d. *Patient has documentation of blood pressure ≥90/50 mmHg; or*
2. *Patient has a diagnosis of stable symptomatic heart failure (NYHA/Ross class II to IV) due to dilated cardiomyopathy, and*

a. *Pediatric patient age 6 months and less than 18 years old; and*
b. *Patient has documentation of a left ventricular ejection fraction ≤45%; and*
c. *Patient is in sinus rhythm with a resting heart rate (HR) defined below;*
    i. *6 to 12 months - HR ≥ 105 bpm*
    ii. *1 to 3 years - HR ≥ 95 bpm*
    iii. *3 to 5 years - HR ≥ 75 bpm*
    iv. *5 to 18 years - HR ≥ 70 bpm; and*

3. *Heart failure symptoms persist with maximally tolerated doses of at least one beta-blocker with proven mortality benefit in a heart failure clinical trial (e.g. carvedilol 50mg daily, metoprolol succinate 200mg daily, or bisoprolol 10mg daily) or weight appropriate dosing for pediatric patients, or patient has a documented intolerance or FDA labeled contraindication to beta-blockers; and*
4. *Patient has documentation of a trial and continued use with a preferred angiotensin system blocker at a maximally tolerated dose.*

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.

Chronic Pain Syndromes: The Commission reviewed the prior authorization criteria below, and made a recommendation to remove it.

A prior authorization (PA) is required for pregabalin (Lyrica) and milnacipran (Savella). These drugs will be considered for their FDA indications(s) and other conditions as listed in the compendia. Requests for doses above the manufacturer recommended dose will not be considered. For patients with a chronic pain diagnosis who are currently taking opioids, as seen in pharmacy claims, a plan to decrease and/or discontinue the opioid(s) must be provided with the initial request. Initial authorization will be given for three (3) months. Requests for renewal must include an updated opioid treatment plan and documentation of improvement in symptoms and quality of life. Requests for non-preferred brand name drugs, when there is a preferred A-rated bioequivalent generic product available, are also subject to the Selected Brand Name prior authorization criteria and must be included with this request. Payment will be considered under the following conditions:

1. *A diagnosis of fibromyalgia (Lyrica and Savella)*
    a. *a trial and therapy failure at a therapeutic dose with gabapentin plus one of the following preferred generic agents: tricyclic antidepressant or SNRI* ***WITH***
    b. *documented non-pharmacologic therapies (cognitive behavior therapies, exercise, etc.)*

2. *A diagnosis of post-herpetic neuralgia (Lyrica)*
   A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, topical lidocaine, or valproate.
3. *A diagnosis of diabetic peripheral neuropathy (duloxetine and Lyrica)*
   A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant or duloxetine.
4. *A diagnosis of partial onset seizures, as adjunct therapy (Lyrica)*
5. *A diagnosis of neuropathic pain associated with spinal cord injury (Lyrica)*

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.

Anti-Diabetic Non-Insulin Agents: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for preferred anti-diabetic, non-insulin agents subject to clinical criteria. Payment will be considered under the following conditions:

1. *Patient has an FDA approved or compendia indicated diagnosis, and*
2. *Patient meets the FDA approved or compendia indicated age, and*
3. *For the treatment of Type 2 Diabetes Mellitus, the patient has not achieved HgbA1C goals after a minimum three month trial with metformin at maximally tolerated dose.*
4. *Requests for non-preferred anti-diabetic, non-insulin agents, subject to clinical criteria, will be authorized only for cases in which there is documentation of previous trials and therapy failures with a preferred drug in the same class. Requests for a non-preferred agent for the treatment of Type 2 Diabetes Mellitus must document previous trials and therapy failures with metformin, a preferred DPP-4 Inhibitor or DPP-4 Inhibitor Combination, a preferred Incretin Mimetic, and a preferred SGLT2 Inhibitor at maximally tolerated doses.*

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

Initial authorizations will be approved for six months. Additional PAs will be considered on an individual basis after review of medical necessity and documented continued improvement in symptoms (such as HgbA1C for Type 2 Diabetes).

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

Miscellaneous

DUR Digest: The Commission members conducted the first review of the draft DUR

Digest Volume 32, Number 2. No recommended changes were made.

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

At 11:47, Kellen Ludvigson motioned to adjourn, and Jason Kruse seconded. All in attendance agreed.

The next meeting will be held at 9:30 a.m. on Wednesday, May 6, 2020, at the Department for the Blind in Des Moines.

Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes May 6, 2020

Meeting cancelled due to COVID-19.

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 SFY20.

Appendix K
Recommendations to the P&T

P & T Recommendations
SFY20

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