Iowa Department of Human Services

Iowa Medicaid Drug Utilization Review Commission Annual Report of Activities Fee-for-Service Program SFY19

September 30, 2019

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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 2018 through June 2019.

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 bi-monthly 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. While the focus has shifted to the development of clinical prior authorization and ProDUR edits, collaboration with the MCOs continues to develop the most efficient way to perform retroDUR and educational outreach for the entire Iowa Medicaid population.

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 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 SFY19 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 $7,913.23* which equates to 3 cents* for every $1.00 of combined federal and state dollars spent administratively. 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	$7,913.23*
Cost of the Program (state and federal dollars)	$270,000.00
Net Cost Savings Estimate	($262,086.77)*
Savings per Total Dollar Spent (state and federal)	$0.03*
Savings per State Dollar Spent	$0.06*

Patient-focused reviews resulted in $1,317.31* in direct cost savings, or $39.92* per patient evaluated. This estimate is based on the 34 suggestions made by the DUR Commission identified from the review of the medication therapy of 527 patient profiles selected for intervention. Of these 34 suggestions, 5 suggestions were implemented by the providers, resulting in a 15 percent impact rate.

Patient-Focused Profile Review	
Suggestions Made	34
Therapy Changed	5
IMPACT RATE	14.7%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated	$39.92*
Dollars Saved on Medication	$1,317.31*

*Savings reported are pre-rebate, total dollars

Problem-focused reviews were conducted based on the review of monthly paid claims report. The interventions were informative in nature.

Problem-Focused Profile Review	
Patients Evaluated	5
Therapy Changed	2
IMPACT RATE	40%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated	$1,319.18*
Dollars Saved on Medication	$6,595.92*

Comparison to Previous SFY Report

Cost savings estimates for SFY19 ($7,913.23*) are slightly higher than last year. 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 SFY19 patient-focused reviews ($1,317.31*) were lower than SFY18 ($6,943.04*), and the number of suggestions made (34) vs. (65) decreased as well as the number of suggestions that were accepted (5) vs. (8) from SFY18. Again, due to the transition to managed care, cost savings, the number of suggestions made and the number of suggestions accepted have decreased. Historically there has been minimal impact from patient-focused reviews; that is attriubuted 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 SFY19 ($6,595.92*) were higher than SFY18 ($0*). This was due to the problem-focused reviews dealing with drug therapy related issues versus last year where the interventions conducted were informative in nature only; impact and cost savings were not expected.

*Savings reported are pre-rebate, total dollars

Results by Review Type

Patient-Focused Review

During this evaluation period, 80 educational intervention letters were mailed to prescribers and pharmacies regarding medication therapy. Of this total, 44 letters (55 percent) were mailed to prescribers, and 36 (45 percent) letters were mailed to pharmacies. Providers are invited to voluntarily respond to DUR Commission letters. Providers returned 25 responses to these letters, resulting in an overall response rate by the providers of 31.25 percent. Of the 25 responses, 10 (40 percent) responses were from prescribers and 15 (60 percent) were from pharmacies. The overall response rate differed between physicians and pharmacies; 23 percent for physicians and 42 percent for pharmacies.

In these 80 educational letters, the DUR Commission made 34 suggestions. Of these suggestions, 34 (100 percent) were therapeutic in nature while 0 (0 percent) were cost-saving in nature. The suggested change was implemented in 5 cases, resulting in an overall impact rate of 14.71 percent.

Of the 34 suggestions, two types of suggestions accounted for over 85 percent of the total. Those two suggestions were Patient Overuse (8.82 percent) and Therapeutic Duplication (76.47 percent). No other single category accounted for more than 3 percent of the total suggestions. Of the 5 changes, the most common reasons for the Commission's inquiry were Patient Underuse (20 percent) and Therapeutic Duplication (80 percent). No other single category accounted for any changes.

The suggestions that resulted in change the highest percentage of the time were Patient Underuse (100 percent) and Therapeutic Duplication (15.38 percent).

Implementation of therapeutic suggestions resulted in direct drug cost savings of $1,317.31*. 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 $1,317.31* for the 33 patients evaluated, or $39.92* per patient.

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

Problem-Focused Reviews

Four problem-focused reviews were evaluated during SFY19. In conducting these reviews, five patients were selected for intervention. Of these five interventions, two interventions showed a positive outcome resulting in an impact rate of 40 percent. This change in therapy resulted in annualized cost savings of $6,595.92* or $1,319.18* per patient evaluated.

Results of the focused studies are detailed in Appendix E. A description of the problem-focused reviews 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 SFY19, 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.

Charles Wadle, D.O. joined the Commission. His first term will expire in May 2022.

Laurie Anderson, Pharm.D. completed her third term on the DUR in June 2019.

Sandy Pranger, R.Ph. completed her two year term on the Commission as the MCO representative.

Bimonthly 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.

*Savings reported are pre-rebate, total dollars

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

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

*Savings reported are pre-rebate, total dollars

Appendix A
Commission Members

Iowa Medicaid Drug Utilization Review
Commission Members
2018-2019

Laurie Anderson, Pharm,D
Dr. Anderson is the pharmacy manager at Hy-Vee in Red Oak, Iowa. She graduated with her Doctor of Pharmacy degree from Creighton University in 2000. She served on the Board of Professional Affairs as a member of the Iowa Pharmacy Association in 2006. Dr. Anderson has experience with both long-term care and retail pharmacy. Dr. Anderson was reappointed for a third term in 2015, which expired in June 2019.

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 will expire 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 second term in 2016, which will expire in June 2020.

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.

Sandy Pranger, R.Ph.
Sandy Pranger is the Pharmacy Account Manager for Amerigroup, Iowa and serves as the MCO liaison to the Commission. She graduated from Drake University in Des Moines, Iowa and has 19 years of Medicaid experience. Sandy Pranger brings to the Commission a variety of experience in health care as an Iowa Medicaid drug prior authorization pharmacist, retail pharmacist and PBM consultant pharmacist.

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 second term in 2016 which will expire in June 2020.

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 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. Consider this *cost saving* example:

Template sent to the provider:
According to the profile, this patient is receiving Lexapro 10mg tablets. Substantial cost savings can be realized by using one-half of a Lexapro 20mg tablet which is scored and easily broken. Would this patient be a good candidate for this cost-saving measure?

Information on initial profile sent to provider:
Lexapro 10 mg #30= $83.04
Lexapro 10 mg #30= $83.04
Lexapro 10 mg #30= $83.04
Lexapro 10 mg #30= $83.04
Lexapro 10 mg #30= $83.04
Lexapro 10 mg #30= $83.04
Total Amount Paid $498.24

Information on re-review profile used internally for evaluation:
Lexapro 20 mg #15 = $45.92
Lexapro 20 mg #15 = $45.92
Lexapro 20 mg #15 = $45.92
Lexapro 20 mg #15 = $45.92
Lexapro 20 mg #15 = $45.92
Lexapro 20 mg #15 = $45.92
Total Amount Paid $275.52

Calculation of annualized savings
$498.24 - $275.52 = $222.72 (savings for 6 months)
$222.72 x 2 = $445.44 (savings for 12 months)
Reported total pre-rebate annualized savings is $445.44

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 and example:

- 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.
  Example: The DUR Commission recommended that an age edit be placed on Provigil®, restricting its use in patients to those 16 years of age and older.
- 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 form various sources. The Commission seeks outside expertise when necessary and considers public comments prior to

recommending step therapy for appropriate drug use.
Example: The DUR Commission developed the criteria for the Nicotine Replacement Therapy prior authorization.
Prior Authorization is required for over-the-counter nicotine replacement patches and nicotine gum. Requests for authorization must include:
1) Diagnosis of nicotine dependence and referral to the Quitline Iowa program for counseling.
2) Confirmation of enrollment in the Quitline Iowa counseling program is required for approval.
3) Approvals will only be granted for patients eighteen years of age and older.
4) The maximum allowed duration of therapy is twelve weeks within a twelve-month period.
5) A maximum quantity of 14 nicotine replacement patches and/or 110 pieces of nicotine gum may be dispensed with the initial prescription. Subsequent prescription refills will be allowed to be dispensed as a 4 week supply at one unit per day of nicotine replacement patches and/or 330 pieces of nicotine gum. Following the first 28 days of therapy, continuation is available only with documentation of ongoing participation in the Quitline Iowa program.

- 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.
  Example: The DUR Commission recommended that the Iowa Medicaid Pharmacy and Therapeutics Committee change the status of products containing carisoprodol on the PDL from preferred to nonpreferred.
- 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.
  Example: The DUR Commission requested that the Iowa Medicaid P&T Committee review the different dosage forms of nicotine replacement therapy and share information as to which products were the most cost effective.

Appendix C
Overall Programs Results

FFS Program Evaluation/Cost Savings Estimates
Iowa Medicaid Retrospective Drug Utilization Review
Annual Report
SFY19

Patient Focused Profile Review

Suggestions Made	34
Therapy Changed	5
Impact Rate	14.71%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated*	$39.92
Dollars Saved on Medication*	$1,317.31

Problem-Focused Profile Review

Suggestions Made	5
Therapy Changed	2
Impact Rate	40.00%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated*	$1,319.18
Dollars Saved on Medication*	$6,595.92

Cost Savings Estimate*	**$7,913.23**
Cost of the Program (State & Federal)	$270,000.00
Net Cost Savings Estimate	($262,086.77)

Savings Per Dollar Spent (State and Federal)*	**$0.03**
Savings Per State Dollar Spent*	**$0.06**

*Savings reported are pre-rebate, total dollars

Appendix D
Results Patient-Focused

FFS Patient - Focused Reviews

SFY19

Initial Review Date	**October 2017 - September 2018**			
Re-review Date	**July 2018 - June 2019**			
Patient Profiles Reviewed	527			
Patient Profiles Selected for Intervention	33			
Intervention Letters Sent				
Prescribers	44	55.00%		
Pharmacists	36	45.00%		
Total	**80**	100%		
Responses Received				
Prescribers	10	40.00%	**Overall Response Rate**	**31.25%**
Pharmacists	15	60.00%	Prescriber Response Rate	22.73%
Total	**25**	100.00%	Pharmacy Response Rate	41.67%
Total Number of Suggestions				
Therapeutic	34	100.00%		
Cost-Saving	0	0.00%		
Total	**34**	100%		
Total Number of Changes				
Therapeutic	4	80.00%	**Impact Rate**	**14.71%**
Cost-Saving	0	0.00%		
Positive Impact Only	1	20.00%		
Total	**5**	100%		

FFS Patient - Focused Review
Month by Month Breakdown
SFY19

Initial Review Date **Evaluation Date**	**Oct-17** **Jul-18**	**Dec-17** **Sep-18**	**Feb-18** **Nov-18**	**Apr-18** **Jan-19**	**Jun-18** **Mar-19**	**Aug-18** **May-19**	**Total**
Profiles Reviewed	44	90	144	96	29	124	**527**
Patient Profiles Available for Evaluation	2	7	7	9	2	6	**33**
Total Number of Suggstions Made	2	7	7	9	2	7	**34**
Therapeutic	2	7	7	9	2	7	**34**
Cost Saving	0	0	0	0	0	0	**0**
Total Number of Changes Made	0	0	1	2	1	1	**5**
Therapeutic	0	0	0	2	1	1	**4**
Cost Saving	0	0	0	0	0	0	**0**
Positive Impact Only	0	0	1	0	0	0	**1**
Total Dollars Saved - Therapeutic Changes	$0.00	$0.00	$0.00	$371.18	$83.81	$862.32	**$1,317.31**
Total Dollars Saved - Cost Saving	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	**$0.00**
Total Dollars Saved on Medication*	$0.00	$0.00	$0.00	$371.18	$83.81	$862.32	**$1,317.31**
Total Dollars Saved per Profile Evaluated	$0.00	$0.00	$0.00	$41.24	$41.91	$143.72	$39.92

*Savings reported are pre-rebate total dollars.

FFS Medicaid DUR Impact Assessment
Report Patient-Focused Reviews SFY19

Initial Review Date Evaluation Date	Oct-17 Jul-18	Dec-17 Sep-18	Feb-18 Nov-18	Apr-18 Jan-19	Jun-18 Mar-19	Aug-18 May-19	**Total**	
Profiles Reviewed	44	90	144	96	29	124	**527**	
Profiles Evaluated	2	7	7	9	2	6	**33**	
Letters Sent	4	17	15	23	4	17	**80**	100.00%
Prescribers	2	9	8	13	2	10	44	55.00%
Pharmacy	2	8	7	10	2	7	36	45.00%
Responses Received	1	5	5	7	2	5	**25**	100.00%
Prescribers	0	2	1	3	1	3	10	40.00%
Pharmacy	1	3	4	4	1	2	15	60.00%
Total Number of Templates Mentioned	2	7	7	9	2	7	**34**	100.00%
Therapeutic	2	7	7	9	2	7	34	100.00%
Cost-Saving	0	0	0	0	0	0	0	0.00%
Total Number of Changes Made	0	0	1	2	1	1	**5**	100.00%
Therapeutic	0	0	0	2	1	1	4	80.00%
Cost-Saving	0	0	0	0	0	0	0	0.00%
Positive Impact Only	0	0	1	0	0	0	1	20.00%
Total Dollars Saved - Therapeutic Changes	$0.00	$0.00	$0.00	$371.18	$83.81	$862.32	**$1,317.31**	100.00%
Total Dollars Saved - Cost Saving Changes	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	**$0.00**	0.00%
Total Dollars Saved on Medication*	$0.00	$0.00	$0.00	$371.18	$83.81	$862.32	**$1,317.31**	100.00%
Total Dollars Saved Per Profile Evaluated	$0.00	$0.00	$0.00	$41.24	$41.91	$143.72	**$39.92**	

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

Comment Type
FFS Patient Focused Reviews
SFY19

Initial Review Date	**Oct-17**		**Dec-17**		**Feb-18**		**Apr-18**		**Jun-18**		**Aug-18**		
Evaluation Date	**Jul-18**		**Sep-18**		**Nov-18**		**Jan-19**		**Mar-19**		**May-19**		**Total**
Template Classification	**Suggestions**	**Changes**	**Suggestions**	**Changes**	**Suggestions**	**Changes**	**Suggestions**	**Changes**	**Suggestions**	**Changes**	**Suggestions**	**Changes**	**Total Suggestions**	**Total Changes**
Adverse Drug Reaction	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Drug-Disease Interaction	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Drug-Drug Interaction	0	0	0	0	1	0	0	0	0	0	0	0	1	0
High Cost Drug	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Innapropriate Billing	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Missing Drug Therapy	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Optimal Dosage Form	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Optimal Dose	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Optimal Drug	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Not Optimal Duration	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Patient Overuse	0	0	1	0	0	0	0	0	0	0	2	0	3	0
Patient Underuse	0	0	0	0	1	1	0	0	0	0	0	0	1	1
Potential Generic Use	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Therapeutic Alternative	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Therapeutic Duplication	1	0	6	0	4	0	8	2	2	1	5	1	26	4
Unnecessary Drug Therapy	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Total	**2**	**0**	**7**	**0**	**7**	**1**	**9**	**2**	**2**	**1**	**7**	**1**	**34**	**5**

FFS Patient Focused Reviews
SFY19

Template Classification	Total Suggestions	Total Changes	% of Total Suggstions	% of Total Changes	% of Suggestions Changed	% Dollars Saved
Adverse Drug Reaction	1	0	2.94%	0.00%	0.00%	0.00%
Drug-Disease Interaction	0	0	0.00%	0.00%	0.00%	0.00%
Drug-Drug Interaction	1	0	2.94%	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	2.94%	0.00%	0.00%	0.00%
Not Optimal Duration	0	0	0.00%	0.00%	0.00%	0.00%
Patient Overuse	3	0	8.82%	0.00%	0.00%	0.00%
Patient Underuse	1	1	2.94%	20.00%	100.00%	0.00%
Potential Generic Use	0	0	0.00%	0.00%	0.00%	0.00%
Therapeutic Alternative	0	0	0.00%	0.00%	0.00%	0.00%
Therapeutic Duplication	26	4	76.47%	80.00%	15.38%	100.00%
Unnecessary Drug Therapy	1	0	2.94%	0.00%	0.00%	0.00%
Total	**34**	**5**	100.00%	100.00%	**14.71%**	100.00%

FFS Savings By Template Class

SFY19

Initial Review Date Evaluation Date	Oct-17 Jul-18	Dec-17 Sep-18	Feb-18 Nov-18	Apr-18 Jan-19	Jun-18 Mar-19	Aug-18 May-19	**Total**
Template Classification							
Adverse Drug Reaction	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Drug-Disease Interaction	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Drug-Drug Interaction	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
High Cost Drug	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Inappropriate Billing	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Missing Drug Therapy	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Not Optimal Dosage Form	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Not Optimal Dose	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Not Optimal Drug	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Not Optimal Duration	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Patient Overuse	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Patient Underuse*	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Potential Generic Use	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Therapeutic Alternative	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Therapeutic Duplication	$0.00	$0.00	$0.00	$371.18	$83.81	$862.32	$1,317.31
Unnecessary Drug Therapy	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Total	**$0.00**	**$0.00**	**$0.00**	**$371.18**	**$83.81**	**$862.32**	**$1,317.31**

*additional cost but positive impact assumed

Appendix E
Results Problem-Focused

FFS Problem-Focused Studies
Impact Rate
SFY 2019

Focus	Review Period	Evaluation Period	Patients Evaluated	Positive Impact	Impact Rate
Pediatric Electrolyte Dosing	11/01/2018 - 11/30/2018	04/01/2019 - 04/30/2019	1	0	0.00%
Prazosin Dosing	11/01/2018 - 11/30/2018	04/01/2019 - 04/30/2019	1	0	0.00%
Adrenalin Claims	12/01/2018 - 12/31/2018	05/01/2019 - 05/31/2019	1	0	0.00%
Duplicate LA Stimulants	02/01/2019 - 02/29/2019	05/01/2019 - 05/31/2019	2	2	100.00%
TOTAL			**5**	**2**	**40.00%**

FFS Problem-Focused Studies
SFY 2019

Focus	Review Period	Evaluation Period	Patients Reviewed	Patients Selected	Cost Savings Calculated
Pediatric Electrolyte Dosing	11/01/2018 - 11/30/2018	04/01/2019 - 04/30/2019	1	1	$0.00
Prazosin Dosing	11/01/2018 - 11/30/2018	04/01/2019 - 04/30/2019	1	1	$0.00
Adrenalin Claims	12/01/2018 - 12/31/2018	05/01/2019 - 05/31/2019	1	1	$0.00
Duplicate LA Stimulants	02/01/2019 - 02/29/2019	05/01/2019 - 05/31/2019	2	2	$6,595.92
TOTAL			**5**	**5**	**$6,595.92 ***

*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
SFY19

Four problem focused studies were conducted in SFY19 based on review of the monthly paid claims report. Individual member profiles were reviewed for drug specific issues. Educational letters were sent to the prescriber and pharmacy. The intent of the educational letters was to be informative in nature, alerting providers of cost effective alternative treatments or therapeutic duplication.

Appendix G
Prior Auth Recommendations

Prior Authorization Criteria Review
SFY19

During the fiscal year ending 2019, 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
08/01/2018	• Tezacaftor/Ivacaftor (Symdeko) • Letermovir (Prevymis)	• Chronic Pain Syndromes • CNS Stimulants and Atomoxetine	
11/07/2018	• CGRP Inhibitors	• Multiple Sclerosis Agents • Janus Kinase Inhibitors	
02/06/2019	• Elagolix (Orilissa) • Desmopressin Acetate (Noctiva)	• Ivacaftor (Kalydeco) • Orkambi (Lumacaftor/Ivacaftor) • Hematopoietics/Chronic ITP • Oral Constipation Agents	
05/01/2019		• Sodium Oxybate (Xyrem) • Buprenorphine/Naloxone • Short-Acting Opioids • Long-Acting Opioids	

IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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August 2, 2018

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, August 1, 2018. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Chronic Pain Syndromes; CNS Stimulants and Atomoxetine; Tezacaftor/Ivacaftor (Symdeko); and Letermovir (Prevymis). The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to a June 12, 2018 letter that was sent to them detailing the proposed criteria for Chronic Pain Syndromes; CNS Stimulants and Atomoxetine; Tezacaftor/Ivacaftor (Symdeko); and Letermovir (Prevymis).

Chronic Pain Syndromes

Proposed Clinical Prior Authorization Criteria *(changes highlighted/stricken/italicized)*
A prior authorization 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. ~~There must be a significant decrease in opioid use or discontinuation of opioid(s) after the initial three (3) month authorization for further approval consideration. Additional prior authorizations will be considered with documentation of a continued decrease in opioid utilization.~~ *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 ~~or topical lidocaine~~.
4. A diagnosis of partial onset seizures, as adjunct therapy (Lyrica®)
5. *A diagnosis of neuropathic pain associated with spinal cord injury (Lyrica®)*

CNS Stimulants and Atomoxetine

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization (PA) is required for CNS stimulants and atomoxetine for patients 21 years of age or older. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. *If a non-preferred long-acting medication is requested, a trial with the preferred ~~immediate release and~~ extended release product of the same chemical entity (methylphenidate class) or chemically related agent (amphetamine class) is required. *Requests will be considered for an FDA approved age for the submitted diagnosis*. Prior to requesting prior authorization for any covered diagnosis, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website ~~at~~ ~~https://pmp.iowa.gov/IAPMPWebCenter/~~. Payment for CNS stimulants and atomoxetine will be considered under the following conditions:

1. ~~Attention Deficit Disorder (ADD) or~~ Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV). Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more **current** environments (social, academic, or occupational). Documentation of a recent clinical visit that confirms *improvement in symptoms from baseline* ~~the patient continues to require medication to treat the symptoms of ADD/ADHD~~ will be required for renewals or patients newly eligible that are established on medication to treat ~~ADD/~~ADHD. *Adults (≥ 21 years of age) are limited to the use of long-acting agents only. If a supplemental dose with a short-acting agent is needed for an adult in the mid to late afternoon, requests will be considered under the following circumstances: the dose of the long-acting agent has been optimized, documentation is provided a short-acting agent of the same chemical entity is medically necessary (e.g. employed during the day with school in the evening), and will be limited to one unit dose per day.*
2. Narcolepsy with diagnosis confirmed with a recent sleep study (ESS, MSLT, PSG).
3. Excessive sleepiness from obstructive sleep apnea/hypopnea syndrome (OSAHS) with documentation of non-pharmacological therapies tried (weight loss, position therapy, CPAP at maximum titration, BiPAP at maximum titration or surgery) and results from a recent sleep study (ESS, MSLT, PSG) with the diagnosis confirmed by a sleep specialist.

The required trials may be overridden when documented evidence is provided that the use of

these agents would be medically contraindicated.

Tezacaftor/Ivacaftor (Symdeko)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for Symdeko (tezacaftor/ivacaftor). 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 is homozygous for the F508del mutation or patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor (listed in the FDA approved labeling) based on *in vitro* data and/or clinical evidence.
4. Prescriber is a CF specialist or pulmonologist; and
5. Baseline liver function tests (AST/ALT) are provided.

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 tezacaftor/ivacaftor therapy is confirmed; and
2. Liver function tests (AST/ALT) are assessed every 3 months during the first year of treatment and annually thereafter.

Letermovir (Prevymis)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for oral letermovir. Requests for intravenous letermovir should be directed to the members medical benefit. Payment will be considered under the following conditions:

1. Medication is to be used for the prophylaxis of cytomegalovirus (CMV) infection and disease; and
2. Patient or donor is CMV-seropositive R+ (attach documentation); and
3. Patient has received an allogeneic hematopoietic stem cell transplant (HSCT) within the last 28 days (provide date patient received HSCT); and
4. Is prescribed by or in consultation with a hematologist, oncologist, infectious disease or transplant specialist; and
5. Patient is 18 years of age or older; and
6. Dose does not exceed:
    a. 240mg once daily when co-administered with cyclosporine;
    b. 480mg once daily; and
7. Patient must not be taking the following medications:
    a. Pimozide; or
    b. Ergot alkaloids (e.g., ergotamine, dihydroergotamine); or
    c. Rifampin; or
    d. Atorvastatin, lovastatin, pitavastatin, simvastatin, or repaglinide when co-administered with cyclosporine; and
8. Patient does not have severe (Child-Pugh Class C) hepatic impairment (provide score); and
9. Therapy duration will not exceed 100 days post-transplantation.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Chronic Pain Syndromes; CNS Stimulants and Atomoxetine; Tezacaftor/Ivacaftor (Symdeko); and Letermovir (Prevymis).

Sincerely,

Pamela Smith R.Ph.

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

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

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November 9, 2018

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, November 7, 2018. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Multiple Sclerosis Agents – Oral; Janus Kinase Inhibitors; and Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitors. 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 3, 2018 letter that was sent to them detailing the proposed criteria for Multiple Sclerosis Agents – Oral; Janus Kinase Inhibitors; and Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitors.

Multiple Sclerosis Agents

Proposed Clinical Prior Authorization Criteria *(changes highlighted/stricken/italicized)*
For patients initiating therapy with *a preferred oral agent* ~~fingolimod (Gilenya™)~~, 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:
~~Prior authorization is required for fingolimod (Gilenya™), teriflunomide (Aubagio®), or dimethyl fumarate (Tecfidera™). Payment will be considered for patients 18 years of age and older under the following conditions:~~

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

trial and therapy failure with a preferred oral multiple sclerosis agent.

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.
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.
3. Patient does not have a baseline QTc interval ≥ 500ms.
4. Patient is not being treated with Class la or Class lll anti-arrhythmic drugs.

For patients initiating therapy with teriflunomide (Aubagio®)~~, documentation of the following must be provided~~:

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

For patients initiating therapy with dimethyl fumarate (Tecfidera™)~~, documentation of the following must be provided~~:

1. Patient does not have a low lymphocyte count as documented by a recent (within 6 months) CBC prior to initiating therapy.
2. Upon renewal, documentation of an updated CBC.

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

Janus Kinase Inhibitors

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization is required for Janus kinase (JAK) inhibitors. Payment will be considered *for an FDA approved or compendia indicated diagnosis* when the following conditions are met:

1. Patient meets the FDA approved age: and
2. Patient is not using or planning to use ~~tofacitinib~~ *a JAK inhibitor* in combination with *other JAK inhibitors,* biologic DMARDs or potent immunosuppressants (azathioprine or cyclosporine); and
3. Has been tested for latent tuberculosis prior to initiating therapy and will be monitored for active tuberculosis during treatment; and
4. Recommended laboratory monitoring of lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids are being conducted according to the manufacturer labeling; and
5. Patient does not have a history of malignancy, except for those successfully treated for non-melanoma skin cancer (NMSC); and
6. Patient is not at an increased risk of gastrointestinal perforation; and
7. Patient does not have an active, serious infection, including localized infections; and
8. Medication will not be given concurrently with live vaccines; and
9. Follows FDA approved dosing based on indication; and
10. Patient has a diagnosis of:
    a. Moderate to severe rheumatoid arthritis with
        i. A documented trial and inadequate response to two preferred oral disease modifying antirheumatic drugs (DMARD) used concurrently.

The combination must include methotrexate plus another preferred oral DMARD (hydroxychloroquine, sulfasalazine, or leflunomide); and

ii. A documented trial and inadequate response to two preferred biological DMARDs; OR

b. Psoriatic arthritis with

i. A documented trial and inadequate response to therapy with the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and

ii. Documented trial and therapy failure with two preferred biological agents used for psoriatic arthritis*; OR*.

c. Patient has a diagnosis of moderately to severely active ulcerative colitis, and

i. Has a documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and

ii. Has a documented trial and inadequate response with a preferred biological DMARD; and

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

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

CGRP Inhibitors

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for CGRP Inhibitors. Payment will be considered for patients when the following is met:

1. Patient has a diagnosis of migraine as defined by one of the following:
    a. Chronic Migraine
        i. ≥ 15 headache days per month for a minimum of 3 months; and
        ii. ≥ 8 migraine headache days per month for a minimum of 3 months; or
    b. Episodic Migraine
        i. 4 to 14 migraine days per month for a minimum of 3 months; and
2. Patient meets the FDA approved age; and
3. Patient has been evaluated for and does not have medication overuse headache; and
4. 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, nadalol, propranolol, timolol], antidepressants, [amitriptyline, venlafaxine]); and
5. The requested dose does not exceed the maximum FDA labeled dose; and
6. 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).

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

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Multiple Sclerosis Agents – Oral; Janus Kinase Inhibitors; and Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitors

Sincerely,

Pamela Smith R.Ph.

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

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

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February 8, 2019

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
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100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, February 6, 2019. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Kalydeco (Ivacaftor); Orkambi (Lumicaftor/Ivacaftor); Hematopoietics/Chronic ITP; Elagolix (Orilissa); Oral Constipation Agents; and Desmopressin Acetate Nasal Spray (Noctiva). The DUR Commission members also discussed proposed ProDUR edits for duplicate antipsychotics in adults; concurrent therapy with CNS stimulants and atomoxetine; and age edits for CNS stimulants and atomoxetine. 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 November 20, 2018 letter that was sent to them detailing the proposed criteria for Kalydeco (Ivacaftor); Orkambi (Lumicaftor/Ivacaftor); Hematopoietics/Chronic ITP; Elagolix (Orilissa); Oral Constipation Agents; and Desmopressin Acetate Nasal Spray (Noctiva) in addition to the proposed ProDUR edits for duplicate antipsychotics in adults; concurrent therapy with CNS stimulants and atomoxetine; and age edits for CNS stimulants and atomoxetine.

Kalydeco (Ivacaftor)

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted/stricken)
Prior authorization is required for Kalydeco™ (ivacaftor). Payment will be considered for patients when the following criteria are met:

1. Patient *meets the FDA approved age* ~~is 2 years of age or older~~; and
2. Has a diagnosis of cystic fibrosis; and
3. Patient has one of the CFTR gene mutations as indicated in the FDA approved label as detected by an FDA-cleared CF mutation test; and
4. Prescriber is a CF specialist or pulmonologist; and
5. Baseline liver function tests (AST/ALT) are provided.

If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met:

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

Orkambi (Lumacaftor/Ivacaftor)

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted/stricken)
Prior authorization is required for Orkambi™ (lumacaftor/ivacaftor). Dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator will not be considered. Payment will be considered for patients when the following criteria are met:

1. Patient *meets the FDA approved age* ~~is 6 years of age or older~~; and
2. Has a diagnosis of cystic fibrosis; and
3. Patient is homozygous for the *F508del* mutation in the *CFTR* gene as confirmed by a FDA-cleared CF mutation test; and
4. Baseline liver function tests (AST/ALT) and bilirubin levels are provided and
5. Prescriber is a CF specialist or pulmonologist.

If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met:

1. Adherence to lumacaftor/ivacaftor 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.

Hematopoietics/Chronic ITP (formerly Thrombopoietin Receptor Agonists)

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted/stricken)
~~Payment~~ Prior authorization is required for *hematopoietics/chronic ITP agents* ~~a preferred thrombopoietin receptor agonist~~. *Request must adhere to all FDA approved labeling.* Payment for a non-preferred *hematopoietic/chronic ITP agent* ~~thrombopoietin receptor agonist~~ will be considered following documentation of a recent trial and therapy failure with a preferred *hematopoietic/chronic ITP agent* ~~thrombopoietin receptor agonist~~, when applicable, unless such a trial would be medically contraindicated*. Payment* will ~~only~~ be considered *under the following conditions*: ~~for cases in which there is~~

1. A diagnosis of *thrombocytopenia with* chronic immune *thrombocytopenia* ~~thrombocytopenic purpura~~ (ITP) (Promacta, Nplate, or Tavalisse)
    a. *Patient has* documentation of an insufficient response to a corticosteroid, ~~an~~ immunoglobulin, or ~~the patient has undergone a~~ splenectomy.
2. ~~Payment for eltrombopag (Promacta®) for the treatment of chronic hepatitis C associated thrombocytopenia will only be considered to allow for initiation and/or maintenance of interferon-based therapy with ribavirin when the patient has a baseline platelet count less than 75 x 10^9 L. Requests will not be considered under the following conditions:~~
    a. ~~Patient taking direct acting antiviral agents for the treatment of chronic hepatitis C genotype 1 infection in addition to interferon-based therapy with ribavirin.~~
    b. ~~Patients taking direct acting antiviral agents used without interferon for treatment of chronic hepatitis C infection.~~
    c. ~~Patients with decompensated liver disease with a Child-Pugh score > 6 (Class B & C).~~

~~d. Patients with a history of ascites.~~
~~e. Patients with hepatic encephalopathy.~~

3. ~~Payment for eltrombopag (Promacta®) for the treatment~~ A *diagnosis* of severe aplastic anemia (Promacta) ~~will only be considered under the following conditions:~~
    a. Patient has documentation of an insufficient response or intolerance to at least one prior immunosuppressive therapy; and
    b. Patient has a platelet count less than or equal to 30 $x10^9$/L.
    c. If criteria for coverage are met, initial authorization will be given for 16 weeks. Documentation of hematologic response after 16 weeks of therapy will be required for further consideration.
4. *A diagnosis of thrombocytopenia with chronic liver disease in patients who are scheduled to undergo a procedure (Mulpleta)*
    a. *Patient has a platelet count less than 50 x 10^9/L; and*
    b. *Dosing will begin 8 to 14 days prior to a scheduled procedure; and*
    c. *Patient is scheduled to undergo a procedure within 2 to 8 days after the last dose; and*
    d. *A platelet count will be obtained no more than 2 days before starting treatment.*

Elagolix (Orilissa)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for gonadotropin-releasing hormone (GnRH) antagonists. Payment will be considered for patients when the following is met:

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

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

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

Oral Constipation Agents

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

Prior authorization is required for oral constipation agents *subject to clinical criteria*. *Payment for non-preferred oral constipation agents will be considered only for cases in which there is*

documentation of a previous trial and therapy failure with a preferred oral constipation agent.
Payment will be considered under the following conditions:

1. Patient *meets the FDA approved age* ~~is 18 years of age or older~~; and
2. Patient must have documentation of adequate trials and therapy failures with both of the following:
    a. Stimulant laxative (senna) plus saline laxative (milk of magnesia); and
    b. Stimulant laxative (senna) plus osmotic laxative (polyethylene glycol or lactulose); and
3. Patient does not have a known or suspected mechanical gastrointestinal obstruction; and
4. Patient has one of the following diagnoses:
    a. A diagnosis of chronic idiopathic constipation (Amitiza®, Linzess™, Trulance®)
        i. Patient has less than 3 spontaneous bowel movements (SBMs) per week; and
        ii. Patient has two or more of the following symptoms within the last 3 months:
            1. Straining during at least 25% of bowel movements;
            2. Lumpy or hard stools for at least 25% of bowel movements; and
            3. Sensation of incomplete evacuation for at least 25% of bowel movements; and
        iii. Documentation the patient is not currently taking constipation causing therapies
    b. A diagnosis of irritable bowel syndrome with constipation (Amitiza®, Linzess™, Trulance®)
        i. Patient is female (Amitiza® only); and
        ii. Patient has *recurrent* abdominal pain ~~or discomfort at least 3~~ *on average at least 1* day~~s~~ per *week* ~~month~~ in the last 3 months associated with two (2) or more of the following:
            1. ~~Improvement with~~ *Related to* defecation;
            2. ~~Onset~~ Associated with a change in stool frequency; and/or
            3. ~~Onset~~ Associated with a change in stool form
    c. A diagnosis of opioid-induced constipation with chronic, non-cancer pain (Amitiza®, Movantik™, Relistor®, or Symproic®)
        i. Patient has been receiving stable opioid therapy for at least 30 days as seen in the patient's pharmacy claims; and
        ii. Patient has less than 3 spontaneous bowel movements (SBMs) per week, with at least 25% associated with one or more of the following:
            1. Hard to very hard stool consistency;
            2. Moderate to very severe straining; and/or
            3. Having a sensation of incomplete evacuation
        ~~iii. Patient has documentation of an adequate trial and therapy failure with Amitiza®, if prior authorization request is for a different oral constipation agent.~~

If the criteria for coverage are met, initial authorization will be given for 12 weeks to assess the response to treatment. Requests for continuation of therapy may be provided if prescriber documents adequate response to treatment.

Desmopressin Acetate (Noctiva)

Newly Proposed Clinical Prior Authorization Criteria

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

1. Patient is 50 years of age or older; and
2. Patient has a diagnosis of nocturnal polyuria as confirmed by a 24-hour collection which notes the presence of greater than 33% of 24-hour urine production occurring at night; and
3. Patient wakens at least 2 times at night to void; and
4. Patient has attempted fluid restriction in the evenings without improvement in nocturnal polyuria; and
5. Patient is not taking a diuretic in the evening; and
6. Patient does not have any of the following contraindications:
    a) Current or previous history of hyponatremia; and
    b) Primary nocturnal enuresis; and
    c) Polydipsia; and
    d) Concomitant use with loop diuretics, systemic or inhaled glucocorticoids; and
    e) Known or suspected syndrome of inappropriate antidiuretic hormone (SIADH) secretion; and
    f) Estimated glomerular filtration rate < 50 mL/min/1.73 m^2; and
    g) Illnesses that can cause fluid or electrolyte imbalance; and
    h) New York Heart Association (NYHA) Class II-IV congestive heart failure; and
    i) Uncontrolled hypertension.

Initial requests will be considered for 3 months. Requests for continuation of therapy will require the following:

1. Patient continues to meet above criteria; and
2. Patient has experienced a decrease in nocturnal voiding; and
3. There is no evidence of toxicity (e.g., hyponatremia, fluid retention, or electrolyte imbalances).

ProDUR Recommendations

- Antipsychotics in Adults – Duplicate Therapy
    - ProDUR edit to limit members 18 years of age and older to two chemically distinct antipsychotics.
- CNS Stimulants and Atomoxetine – Concurrent Therapy
    - For members under 21 years of age, allow one unit of a short-acting stimulant with a long-acting stimulant by implementing a quantity limit on all short-acting stimulants to one unit per day (i.e., 30 units per 30 days). The intent is to require the use of long-acting stimulants, while allowing for one dose of a short-acting stimulant if needed.
- CNS Stimulants and Atomoxetine – Age Edit

Medication	**Drug Name***	**Minimum FDA Approved Age**
Amphetamines	Adderall Adzenys XR ODT Desoxyn Dexedrine	3 years of age

	Dynavel XR Evekeo Mydayis Vyvanse	
	Adderall XR Dexedrine ER	6 years of age
Dexmethylphenidate	Focalin Focalin XR	6 years of age
Methylphenidate	Aptensio XR Concerta Cotempla XR ODT Daytrana Metadate CD Methylin QuilliChew Quillivant XR Ritalin IR/LA/SR	6 years of age
Atomoxetine	Strattera	6 years of age

* ProDUR age edit would apply to brand and generic

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Kalydeco (Ivacaftor); Orkambi (Lumicaftor/Ivacaftor); Hematopoietics/Chronic ITP; Elagolix (Orilissa); Oral Constipation Agents; and Desmopressin Acetate Nasal Spray (Noctiva) in addition to the proposed ProDUR edits for duplicate antipsychotics in adults; concurrent therapy with CNS stimulants and atomoxetine; and age edits for CNS stimulants and atomoxetine.

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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May 2, 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, May 1, 2019. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Sodium Oxybate (Xyrem); Buprenorphine/Naloxone; Short-Acting Opioids; and Long-acting Opioids. The DUR Commission members also discussed proposed ProDUR edits for concurrent use of opioids and benzodiazepines and concurrent use of opioids and antipsychotics. 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 February 12, 2019 letter that was sent to them detailing the proposed criteria for Sodium Oxybate (Xyrem); Buprenorphine/Naloxone; Short-Acting Opioids; and Long-acting Opioids in addition to the proposed ProDUR edits for concurrent use of opioids and benzodiazepines and concurrent use of opioids and antipsychotics.

Sodium Oxybate (Xyrem)

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted/stricken)
Prior authorization is required for sodium oxybate (Xyrem®). Payment will be considered ~~for patients 18 years of age or older~~ under the following conditions:

1. A diagnosis of cataplexy associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trial and therapy failure with one of the following tricyclic antidepressants: clomipramine, imipramine, or protriptyline*; or*~~.~~
2. A diagnosis of excessive daytime sleepiness associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trials and therapy failures at a therapeutic dose with a preferred amphetamine and non-amphetamine stimulant*; and*~~.~~
3. *Patient meets the FDA approved age; and*
4. *Is prescribed within the FDA approved dosing; and*

5. Patient *and provider are* ~~is~~ enrolled in the Xyrem® REMS Program*; and*~~.~~
6. Patient has been instructed to not drink alcohol when using Xyrem®*; and*~~.~~
7. Patient~~s with and without a history of substance abuse have~~ *has* been counseled regarding the potential for abuse and dependence and will be closely monitored for signs of abuse and dependence*; and*~~.~~
8. Requests for patients with concurrent use of a sedative hypnotic or a semialdehyde dehydrogenase deficiency will not be considered*; and*~~.~~
9. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website ~~at~~ https://pmp.iowa.gov/IAPMPWebCenter/ prior to requesting prior authorization.

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

Buprenorphine/Naloxone

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted/stricken)
Prior authorization is required for *transmucosal* buprenorphine or buprenorphine/naloxone. *Requests will be considered for FDA approved dosing, including induction and maintenance dose.* Requests for doses above 24mg per day ~~or greater than once daily dosing~~ will not be considered. Initial requests will be considered for up to 3 months. Requests for maintenance doses above 16mg per day will not be considered on a long-term basis. *After the initial 3 month prior authorization, renewal requests for doses ≤ 16mg per day may be considered for 12 month renewals as long as the member meets all other prior authorization criteria.* ~~Concomitant use with opioids or tramadol will be prohibited.~~ Payment for a non-preferred agent will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent, unless evidence is provided that use of these agents would be medically contraindicated. Requests for surgically implanted buprenorphine *or buprenorphine depot injection* products will not be considered through the pharmacy benefit and should be directed to the member's medical benefit. Payment will be considered for patients when the following is met:

1. Patient has a diagnosis of opioid dependence and meets the FDA approved age: AND
2. Prescriber meets qualification criteria to prescribe buprenorphine/naloxone for opioid dependence and has a "X" DEA number *(provide X DEA number)*; AND
3. ~~Patient is participating in and compliant with formal substance abuse counseling/psychosocial therapy: AND~~
4. Documentation the Iowa Prescription Monitoring Program *(PMP)* website has been reviewed for the patient's use of controlled substances; AND
5. ~~A projected treatment plan is provided, including:~~
   a. ~~Anticipated induction/stabilization dose,~~
   b. ~~Anticipated maintenance dose,~~
   c. ~~Expected frequency of office visits, and~~
   d. ~~Expected frequency of counseling/psychosocial therapy visits.~~
6. ~~A treatment plan is provided for patients taking buprenorphine in combination with a benzodiazepine or central nervous system (CNS) depressant, including:~~
   a. ~~Documentation patient has been educated on the serious risks of combined use;~~
   b. ~~A plan to taper the benzodiazepine or CNS depressant to discontinuation, if possible;~~
   c. ~~Consideration of alternate anxiety or insomnia treatment options when the benzodiazepine or CNS depressant is used for anxiety or insomnia; and~~
   d. ~~Other prescribers involved in the care of the patient are aware of the patient's~~

~~use of buprenorphine; AND~~

7. Documentation is provided that transmucosal buprenorphine will not be used concomitantly with the buprenorphine implant *or depot injection*.
8. Requests for single ingredient buprenorphine will only be considered for pregnant patients.

Requests for renewal must include:

~~1. An updated treatment plan, documenting the following:~~
   ~~a. Consideration of a medical taper to the lowest effective dose based on a self-assessment scale and~~
   ~~b. Assessment of concomitant benzodiazepine or CNS depressant use (if applicable) as outlined above, AND~~
2. Documentation the Iowa ~~Prescription Monitoring Program~~ *PMP* website has been reviewed for the patient's use of controlled substances since the last prior authorization request, AND
3. *Patient does not have documentation of concomitant use of an opioid or tramadol with the requested buprenorphine product, as seen in paid pharmacy claims, AND*

~~4. Documentation of a current, negative drug screen,~~

~~5. Documentation the patient has been compliant with office visits and counseling/psychosocial therapy visits.~~

6. ~~Documentation the p~~Patient is not using transmucosal buprenorphine with ~~the~~ buprenorphine implant *or depot injection*.

Short-Acting Opioids

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted/stricken)
Prior authorization is required for all non-preferred short acting opioids. *Prior authorization (PA) is also required for members when the total daily opioid dose (combined across all opioids) exceeds the set morphine milligram equivalent (MME) threshold (include High Dose Opioids PA form with request).* Payment will be considered under the following conditions:

1. Patient has pain severe enough to require opioid treatment; and
2. Patient has tried and failed at least two non-pharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and
3. Patient has tried and failed at least two non-opioid pharmacologic therapies (*e.g.* acetaminophen or NSAIDs); and
4. Patient has documentation of previous trials and therapy failures with three (3) chemically distinct preferred short acting opioids (based on opioid ingredient only) at therapeutic doses; and
5. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program (PMP) website and has determined that use of a short-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and
6. Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids~~.~~*; and*
7. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*

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

If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met:

1. Patient has experienced improvement in pain control and level of functioning; and
2. Prescriber has reviewed the patient's use of controlled substances on the Iowa PMP website ~~at~~ https://pmp.iowa.gov/IAPMPWebCenter/ and has determined continued use of a short-acting opioid is appropriate for this member~~.~~*; and*
3. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*
   a. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
   b. *Documentation as to why concurrent use is medically necessary is provided; and*
   c. *A plan to taper the benzodiazepine is provided, if appropriate.*

The required trials may be overridden when documented evidence is provided that use of these agents and/or non-pharmacologic therapies would be medically contraindicated.

Long-Acting Opioids

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted/stricken)
Prior authorization is required for all non-preferred long-acting opioids. *Prior authorization (PA) is also required for members when the total daily opioid dose (combined across all opioids) exceeds the set morphine milligram equivalent (MME) threshold (include High Dose Opioids PA form with request).* Payment will be considered under the following conditions:

1. Patient has a diagnosis of chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment; and
2. Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and
3. Patient has tried and failed at least two nonopioid pharmacologic therapies (*e.g.* acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants); and
4. There is documentation of previous trial and therapy failure with one preferred long-acting opioid at maximally tolerated dose; and
5. A signed chronic opioid therapy management plan between the prescriber and patient must be included with the prior authorization; and
6. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program (PMP) website ~~at~~ https://pmp.iowa.gov/IAPMPWebCenter/ and determine if use of a long-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and
7. Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids.
8. Requests for long-acting opioids will only be considered for FDA approved dosing intervals. As-needed (PRN) dosing will not be considered~~.~~*; and*

9. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*
    a. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
    b. *Documentation as to why concurrent use is medically necessary is provided; and*
    c. *A plan to taper the benzodiazepine is provided, if appropriate.*

If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met:

1. Patient has experienced improvement in pain control and level of functioning; and
2. Prescriber has reviewed the patient's use of controlled substances on the Iowa ~~Prescription Monitoring Program~~ *PMP* website ~~at~~ ~~https://pmp.iowa.gov/IAPMPWebCenter/~~ and has determined continued use of a long-acting opioid is appropriate for this member~~.~~*; and*
3. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*
    a. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
    b. *Documentation as to why concurrent use is medically necessary is provided; and*
    c. *A plan to taper the 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.

ProDUR Edit Recommendations

Due to requirements specific to Drug Utilization Review in H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, the DUR Commission made the following recommendations:

- Concurrent use of Opioids and Benzodiazepines
    - A soft edit that would identify members with concurrent use of an opioid and benzodiazepine in their recently paid pharmacy claims. A message regarding the concurrent therapy would be sent to pharmacies via the point of sale (POS). Claims would not be blocked.
- Concurrent use of Opioids and Antipsychotics
    - A soft edit that would identify members with concurrent use of an opioid and antipsychotic in their recently paid pharmacy claims. A message regarding the concurrent therapy would be sent to pharmacies via the POS. Claims would not be blocked.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Sodium Oxybate (Xyrem); Buprenorphine/Naloxone; Short-Acting Opioids; and Long-acting Opioids in addition to the proposed ProDUR edits for concurrent use of opioids and benzodiazepines and concurrent use of opioids and antipsychotics.

Sincerely,

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

Prospective DUR
SFY19

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

- Quantity Limits
  - CNS Stimulants and Atomoxetine
    - For members under 21 years of age, limit all short-acting stimulants to one unit per day (i.e., 30 units per 30 days) to encourage the use of long-acting stimulants.
- Age Edit
  - Antipsychotics
    - Limit members 18 years of age and older to two chemically distinct antipsychotics
  - CNS Stimulants and Atomoxetine

Medication	**Drug Name***	**Minimum FDA Approved Age**
Amphetamines	Adderall Adzenys XR ODT Desoxyn Dexedrine Dynavel XR Evekeo Mydayis Vyvanse	3 years of age
	Adderall XR Dexedrine ER	6 years of age
Dexmethylphenidate	Focalin Focalin XR	6 years of age
Methylphenidate	Aptensio XR Concerta Cotempla XR ODT Daytrana Metadate CD Methylin QuilliChew Quillivant XR Ritalin IR/LA/SR	6 years of age
Atomoxetine	Strattera	6 years of age

- Concurrent Therapy
  - Soft edit for opioids and benzodiazepines
  - Soft edit for opioids and antipsychotics

Appendix I
Meeting Minutes

Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes August 1, 2018

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Laurie Anderson, Pharm.D.; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; Chuck Wadle, D.O.; Jason Wilbur, M.D.; Susan Parker, Pharm.D.; and Sandy Pranger, R.Ph. (Amerigroup).

Staff
Pam Smith, R.Ph.

Guests
Mark Randleman, D.O., IME; Erin Halverson, R.Ph., IME; Melissa Biddle, IME; and Karrie Hansotia, United Healthcare Plan of the River Valley.

Welcome & Introductions

Brett Faine called the meeting to order at 9:34 a.m. at the State Capitol in Des Moines. The minutes from the June 6, 2018 meeting were reviewed. Mark Graber motioned to accept them, and Jason Kruse seconded. The recommendation letter sent to DHS after the last meeting was also reviewed. Members were asked to complete their annual conflict of interest disclosures. Mark Graber motioned to retain Brett Faine as chairperson and Kellen Ludvigson as vice-chairperson. Jason Wilbur seconded, and all members in attendance were in favor (Kellen Ludvigson arrived late due to a meeting location mix-up, and was not yet present for the vote). There will only be four DUR meetings per year now, scheduled for the first Wednesday every August, November, February, and May.

IME Pharmacy Update

The dispensing fee will be increasing from $10.02 to $10.07, pending CMS approval.

Fee-for-Service Prevalence Report Summary

Pam Smith provided an overview for fee-for service statistics from May through June 2018, including: total amount paid ($1,716,916), cost per user ($227.83), and number of total prescriptions dispensed (29,922). There were 7,536 unique users, which is 8.4% less than the total for March and April. The top 5 therapeutics classes by paid amount were: Antipsychotics – Atypicals; Anticonvulsants; Anti-Imflammatories, Non-NSAID; Diabetic – Insulin Penfills; and Diabetic – Insulin. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Narcotics – Miscellaneous; and Antiasthmatic – Beta - Adrenergics. The top 100 drugs were also reviewed, by paid amount and prescription count. The top ten drugs by paid amount were: Vyvanse, Humalog, Invega Sustenna, Novolog Flexpen, Emflaza, Latuda, Genvoya, Advair Diskus, Focalin XR, and Aubagio. The five drugs with the highest prescription count were: hydrocodone/apap, sertraline hcl, gabapentin, lisinopril, and trazodone hcl. Pam Smith also created a

report that compared the FFS stats above with those from each MCO below. Its side-by-side statistics showed that $92,741,300 was spent in total for 239,103 unique users who had 1,303,311 prescriptions. Mark Graber asked that the diagnoses for anticonvulsant medications be researched to see if they were being used for back pain or neuropathic pain, as data shows these medications do not work for chronic back pain.

MCO Prevalence Report Summary and Updates

Amerigroup: Sandy Pranger provided an overview for Amerigroup's statistics from May through June 2018, 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 $32,559,345, a 0.1% decrease from March and April. Similar to previous reports, the top 5 therapeutic classes by paid amount were: ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; Antidiabetics; Antiasthmatic and Bronchodilator Agents; Antipsychotics/Antimanic Agents; and Analgesics – Anti-Inflammatory. The top five classes by prescription count were: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Antihypertensives, and Ulcer Drugs. Vyvanse was the costliest medication to the program, followed by Humira Pen, Latuda, Humalog, and Lantus. Omeprazole had the highest prescription count, followed by: lisinopril, levothyroxine sodium, atorvastatin calcium, and gabapentin.

United Healthcare Community Plan: Karrie Hansotia spoke and provided written summaries that included United's statistics from May through June 2018, including: total paid amount ($58,465,039.10), unique users (154,918), and cost per user ($377.39). Utilization by age and gender was reviewed; females age 19-64 had the highest utilization. On the top 100 pharmacies by prescription count report, Broadlawns, U of I Ambulatory Care, and 3 Walgreens locations made up the top 5. BriovaRx was 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: Insulins; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; Anti-Inflammatory Tumor Necrosis Factor Inhibitor; Tx for Attention Deficit-Hyperact (ADHD)/Narcolepsy; and Adrenergics, Aromatic, Non-Catecholamine. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Proton-Pump Inhibitors; Analgesics, Narcotics; and NSAIDs, Cyclooxygenase Inhibitor – Type Analgesics. The costliest drugs to the program were Vyvanse, Humira Pen, Latuda, Humalog, and Lantus, while omeprazole, lisinopril, levothyroxine sodium, atorvastatin calcium, and hydrocodone-acetaminophen had the top 5 prescription counts.

Public Comment

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

Name	Representing	Drug/Topic
Roya Motarjemi	Merck	Prevymis
Tammy Sova	Biogen	Tecfidera

Erin Conley	Amgen	CGRB Inhibitor Class - Aimovig
Tim Birner	Alkermes	Vivitrol - Addiction

ProDUR Edits

Duplicate Antipsychotics in Adults: Data reported was not consistent between the 3 plans. Data for Amerigroup and United Healthcare was not unique to the drug (i.e. counted same drug if multiple strengths were found in claims). The data will be rerun to remove multiple strengths of same drug and broken out to identify the number of unique providers as well as number of long-acting and short-acting medications. It was suggested letters be sent to the prescribers of members on 3 or more antipsychotics concurrently once the data is updated. Existing quantity limits will also be reviewed, and Pam Smith will look into how Medicare handles duplicate antipsychotics.

CNS Stimulants and Atomoxetine Concurrent Therapy ProDUR Edit: The Commission wants to focus on children on short-acting agents. The Commission requested additional data to look at the number of units of the short-acting agent per day. Data will be brought to the next meeting to further discuss. The quantity limit for short-acting medications will potentially be changed to 1 per day, and allow for a 3-month titration period, should it be needed, before the use of a long-acting agent would be required. Prior authorization criteria language will need to be updated as well, to encourage the use of long-acting agents for members under 21 years of age.

CNS Stimulants and Atomoxetine Age Edit: The minimum FDA approved ages will be followed, and prior authorization criteria needs to be updated to reflect this. No vote was conducted to implement ProDUR age edits as updated PA criteria was requested.

Prior Authorization

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

Prior authorization is required for fingolimod (Gilenya™), teriflunomide (Aubagio®), or dimethyl fumarate (Tecfidera™). Payment will be considered under the following conditions:

1. *A diagnosis of relapsing forms of multiple sclerosis; and*
2. *Patient meets the FDA approved age; and*
3. *A previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis.*
4. *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™), 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. *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.*
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.*
3. *Patient does not have a baseline QTc interval ≥ 500ms.*
4. *Patient is not being treated with Class la or Class lll anti-arrhythmic drugs.*

For patients initiating therapy with teriflunomide (Aubagio®), documentation of the following must be provided:

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

For patients initiating therapy with dimethyl fumarate (Tecfidera™), documentation of the following must be provided:

1. *Patient does not have a low lymphocyte count as documented by a recent (within 6 months) CBC prior to initiating therapy.*
2. *Upon renewal, documentation of an updated CBC.*

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 groups for comment and brought back to the next meeting for further discussion.

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

Prior authorization is required for Janus kinase (JAK) inhibitors. Payment will be considered when the following conditions are met:

1. *Patient meets the FDA approved age and*
2. *Patient is not using or planning to use tofacitinib in combination with biologic DMARDs or potent immunosuppressants (azathioprine or cyclosporine); and*
3. *Has been tested for latent tuberculosis prior to initiating therapy and will be monitored for active tuberculosis during treatment; and*
4. *Recommended laboratory monitoring of lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids are being conducted according to the manufacturer labeling; and*
5. *Patient does not have a history of malignancy, except for those successfully treated for non-melanoma skin cancer (NMSC); and*
6. *Patient is not at an increased risk of gastrointestinal perforation; and*
7. *Is prescribed within the FDA approved dosing for the submitted diagnosis; and*
8. *Patient has a diagnosis of moderate to severe rheumatoid arthritis, and*

a. *Has a documented trial and inadequate response to two preferred oral disease modifying antirheumatic drugs (DMARD) used concurrently. The combination must include methotrexate plus another preferred oral DMARD (hydroxychloroquine, sulfasalazine, leflunomide, or minocycline); and*
b. *Has a documented trial and inadequate response to two preferred biological DMARDs; or*

9. *Patient has a diagnosis of active psoriatic arthritis, and*
   a. *Has a documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated), and*
   b. *Has a documented trial and therapy failure with two preferred biological DMARDs; and*
   c. *Will be used in combination with a nonbiologic DMARD; or*
10. *Patient has a diagnosis of moderately to severely active ulcerative colitis, and*
    a. *Has a documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and*
    b. *Has a documented trial and inadequate response with a preferred biological DMARD; and*
    c. *If requested dose is for 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit.*

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 Melissa Klotz seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy groups for comment and brought back to the next meeting for further discussion.

Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for CGRP Inhibitors. Payment will be considered for patients when the following is met:

1. *Patient has a diagnosis of migraine as defined by one of the following:*
   a. *Chronic Migraine*
      i. *≥ 15 headache days per month for a minimum of 3 months; and*
      ii. *≥ 8 migraine headache days per month for a minimum of 3 months; or*
   b. *Episodic Migraine*
      i. *4 to 14 migraine days per month for a minimum of 3 months; and*
2. *Patient meets the FDA approved age; and*

3. *Patient has been evaluated for and does not have medication overuse headache; and*
4. *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, nadalol, propranolol, timolol], antidepressants, [amitriptyline, venlafaxine]); and*
5. *The requested dose does not exceed the maximum FDA labeled dose; and*
6. *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).

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 newly proposed criteria and Melissa Klotz seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy groups for comment and brought back to the next meeting for further discussion.

Chronic Pain Syndromes: The Commission reviewed the prior authorization criteria as follows:

A prior authorization 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.

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

*Prior authorization (PA) is required for CNS stimulants and atomoxetine for patients 21 years of age or older. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. *If a non-preferred long-acting medication is requested, a trial with the preferred extended release product of the same chemical entity (methylphenidate class) or chemically related agent (amphetamine class) is required. Requests will be considered for an FDA approved age for the submitted diagnosis. Prior to requesting prior authorization for any covered diagnosis, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website. Payment for CNS stimulants and atomoxetine will be considered under the following conditions:*

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

(weight loss, position therapy, CPAP at maximum titration, BiPAP at maximum titration or surgery) and results from a recent sleep study (ESS, MSLT, PSG) with the diagnosis confirmed by a sleep specialist.

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.

Tezacaftor/Ivacaftor (Symdeko): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Symdeko (tezacaftor/ivacaftor). 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 is homozygous for the F508del mutation or patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor (listed in the FDA approved labeling) based on in vitro data and/or clinical evidence.*
4. *Prescriber is a CF specialist or pulmonologist; and*
5. *Baseline liver function tests (AST/ALT) are provided.*

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 tezacaftor/ivacaftor therapy is confirmed; and*
2. *Liver function tests (AST/ALT) are assessed every 3 months during the first year of treatment and annually thereafter.*

Jason Kruse motioned to accept the criteria as amended, and Mark Graber seconded. All members were in favor. As this was the second review of these criteria, the recommendation will be sent to the Department for consideration.

Letermovir (Prevymis): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for oral letermovir. Requests for intravenous letermovir should be directed to the member's medical benefit. Payment will be considered under the following conditions:

1. *Medication is to be used for the prophylaxis of cytomegalovirus (CMV) infection and disease; and*
2. *Patient or donor is CMV-seropositive R+ (attach documentation); and*
3. *Patient has received an allogeneic hematopoietic stem cell transplant (HSCT) within the last 28 days (provide date patient received HSCT); and*
4. *Is prescribed by or in consultation with a hematologist, oncologist, infectious disease or transplant specialist; and*
5. *Patient is 18 years of age or older; and*

6. *Dose does not exceed:*
    a. *240mg once daily when co-administered with cyclosporine;*
    b. *480mg once daily; and*
7. *Patient must not be taking the following medications:*
    a. *Pimozide; or*
    b. *Ergot alkaloids (e.g., ergotamine, dihydroergotamine); or*
    c. *Rifampin; or*
    d. *Atorvastatin, lovastatin, pitavastatin, simvastatin, or repaglinide when co-administered with cyclosporine; and*
8. *Patient does not have severe (Child-Pugh Class C) hepatic impairment (provide score); and*
9. *Therapy duration will not exceed 100 days post-transplantation.*

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 31, Number 1. A spacing typo was found and will be corrected.

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

At 11:56, Kellen Ludvigson motioned to move to closed session just to review and approve the minutes from the April closed session, and Mark Graber seconded.

The next meeting will be held at 9:30 a.m. on Wednesday, November 7, 2018, at the State Capitol, Room 116, in Des Moines.

Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes November 7, 2018

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Laurie Anderson, Pharm.D.; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; Jason Wilbur, M.D.; Susan Parker, Pharm.D.; and Sandy Pranger, R.Ph. (Amerigroup).
Staff
Pam Smith, R.Ph.
Guests
David Smith, M.D., IME; Erin Halverson, R.Ph., IME; Melissa Biddle, IME; and Karrie Hansotia, United Healthcare Plan of the River Valley.

Welcome & Introductions

Brett Faine called the meeting to order at 9:32 a.m. at the State Capitol in Des Moines. The minutes from the August 1, 2018 meeting were reviewed. Jason Kruse motioned to accept them, and Mark Graber seconded. The recommendation letter sent to DHS after the last meeting was also reviewed.

IME Pharmacy Update

CMS has approved the dispensing fee increase from $10.02 to $10.07 effective November 1, 2018. The federal Support of Patients and Community Act recently passed will impact the Medicaid program, specifically drug utilization review committees, with section 1004. The new regulations include claims review limitations and safety edits on opioids, concurrent use of opioids with benzodiazepines and/or antipsychotics, monitoring antipsychotic medications in children, fraud and abuse, and use of the PMP.

Fee-for-Service Prevalence Report Summary

Pam Smith provided an overview of fee-for-service statistics from July through August 2018, including: total amount paid ($1,879,743), cost per user ($249.77), and number of total prescriptions dispensed (30,092). There were 7,526 unique users, which is 1.1% less than the total for May and June. The top 5 therapeutics classes by paid amount were: Anti-Inflammatories, Non-NSAID; Antipsychotics – Atypicals; Anticonvulsants; Antiretroviral Combinations; and Diabetic – Insulin Penfill. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Narcotics – Miscellaneous; Antipsychotics – Atypicals; and Antihypertensives – Central. The top 100 drugs were also reviewed, by paid amount and prescription count. The ten most expensive medications were: Vyvanse, Epclusa, Concerta, Humira Pen, Enbrel Sureclick, Hemlibra, Latuda, Emflaza, Novolog Flexpen, and Humalog. The five drugs with the highest prescription count were: hydrocodone/apap, gabapentin, sertraline hcl, lisinopril, and trazodone hcl. Pam Smith

also created a report that compared the FFS stats above with those from each MCO below. Its side-by-side statistics showed that $93,956,512 was spent in total for 233,801 unique users who had 1,303,808 prescriptions.

MCO Prevalence Report Summary and Updates

Amerigroup: Sandy Pranger provided an overview for Amerigroup's statistics from July through August 2018, 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 $32,225,801, a 1.0% decrease from May and June. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; Antiasthmatic and Bronchodilator Agents; Antipsychotics/Antimanic Agents; and Analgesics – Anti-Imflammatory. These were the top five classes by prescription count: Antidepressants, Anticonvulsants, Antiasthmatic and Bronchodilator Agents, Antihypertensives, and Ulcer Drugs. Vyvanse was the most expensive medication, followed by Humira Pen, Latuda, Concerta, and Humalog. Omeprazole had the highest prescription count, followed by: lisinopril, levothyroxine sodium, atorvastatin calcium, and gabapentin.

United Healthcare Community Plan: Karrie Hansotia spoke and provided written summaries that included United's statistics from July through August 2018, including: total paid amount ($59,850,968.45), unique users (151,325), and cost per user ($395.51). 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, Broadlawns, U of I Ambulatory Care, and 3 Walgreens locations made up the top 5. U of I Ambulatory Care was 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: Insulins; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; Tx for Attention Deficit-Hyperact (ADHD)/Narcolepsy; Anti-Inflammatory Tumor Necrosis Factor Inhibitor; and Anticonvulsants. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Proton-Pump Inhibitors; Antihyperlipidemic – HMG COA Reductase Inhibitors; and NSAIDs, Cyclooxygenase Inhibitor – Type Analgesics. The most expensive drugs were Vyvanse, Concerta, Humira Pen, Latuda, and Humalog, while omeprazole, lisinopril, levothyroxine sodium, atorvastatin calcium, and sertraline hcl had the top 5 prescription counts.

Public Comment

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

Name	Representing	Drug/Topic
Nancy Bell	Pfizer	Annual Class Review, Eucrisa
Leslie Zanetti	Sarepta	Exondys 51
Jamie Vora	Abbvie	Orilissa
Josh Bishop	Allergan	Vraylar

ProDUR Edits

Duplicate Antipsychotics in Adults: Pam Smith could not find clear information as to how Medicare handles duplicate antipsychotics, which had been requested at the last meeting. Letters will be sent to the prescribers of members on 3 or more antipsychotics concurrently after final recommendation is sent to DHS. A POS edit was recommended to be put into place allowing 2 unique chemical entities, with no 30-day grace period for a third agent. Jason Wilbur motioned to accept this recommendation, and Jason Kruse seconded. The decision was unanimous. Quantity limits may also be utilized in the future to address the members on multiple strengths of the same medication. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

CNS Stimulants and Atomoxetine Concurrent Therapy ProDUR Edit: A recommendation was made to allow one unit of a short-acting stimulant with a long acting stimulant for members under 21 years of age. This would be accomplished by implementing a quantity limit on all short-acting stimulants to one unit per day (i.e., 30 units per 30 days). Kellen Ludvigson motioned to accept these recommendations, and Jason Kruse seconded. Jason Wilbur opposed, and Mark Graber abstained. All others were in favor, and the motion passed. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

CNS Stimulants and Atomoxetine Age Edit: A recommendation was made to implement ProDUR age edits on stimulants. The minimum FDA approved ages will be followed for brand and generic agents, and prior authorization criteria updated to reflect this. Mark Graber motioned to accept this change 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.

Prior Authorization

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

PA Category	Recommended Changes
Becaplermin (Regranex)	Check trials to see if 2 weeks allows for adequate response time to wound debridement and topical moist dressing.
Benzodiazepines	Add criteria for concomitant use with opiates, and look into creating a ProDUR edit to catch the concomitant preferred agents.
Buprenorphine/Naloxone	Remove #5 and potentially #3, and define negative drug screen.
Feboxostat (Uloric)	Keep an eye out for a future Black Box Warning.
Growth Hormone	Create pathway for continuity of care for renewals for #5 and #6. Check compendia for use in adults.

Long-Acting Opioids	Remove PMP link from #6, and add criteria for concomitant use of benzodiazepines.
Lupron Depot – Adult	For #3, clarify concurrent therapy with NSAIDs.
Narcan (Naloxone) Nasal Spray	No update is needed but a suggestion was made to monitor for naloxone claims but no opioids in claims.
Short Acting Opioids	Remove PMP link and add criteria for concomitant use of benzodiazepines.
Sodium Oxybate	Adjust age range to include new pediatric indication for ages 7 and older.

Kalydeco (Ivacaftor): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient meets the FDA approved age; and*
2. *Has a diagnosis of cystic fibrosis; and*
3. *Patient has one of the CFTR gene mutations as indicated in the FDA approved label as detected by an FDA-cleared CF mutation test; and*
4. *Prescriber is a CF specialist or pulmonologist; and*
5. *Baseline liver function tests (AST/ALT) are provided.*

If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met:

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

Mark Graber 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.

Orkambi (Lumacaftor/Ivacaftor): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Orkambi™ (lumacaftor/ivacaftor). Dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator will not be considered. Payment will be considered for patients when the following criteria are met:

1. *Patient meets the FDA approved age; and*
2. *Has a diagnosis of cystic fibrosis; and*
3. *Patient is homozygous for the F508del mutation in the CFTR gene as confirmed by a FDA-cleared CF mutation test; and*
4. *Baseline liver function tests (AST/ALT) and bilirubin levels are provided and*
5. *Prescriber is a CF specialist or pulmonologist.*

If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met:

1. *Adherence to lumacaftor/ivacaftor 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 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.

Hematopoietics/Chronic ITP (Thrombopoeitin Receptor Agonists): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for hematopoietics/chronic ITP agents. Request must adhere to all FDA approved labeling. Payment for a non-preferred hematopoietic/chronic ITP agent will be considered following documentation of a recent trial and therapy failure with a preferred hematopoietic/chronic ITP agent when applicable, unless such a trial would be medically contraindicated. Payment will be considered under the following conditions:

1. *A diagnosis of thrombocytopenia with chronic immune thrombocytopenia (ITP) (Promacta, Nplate, or Tavalisse)*
    a. *Patient has documentation of an insufficient response to a corticosteroid, immunoglobulin, or splenectomy.*
2. *A diagnosis of severe aplastic anemia (Promacta)*
    a. *Patient has documentation of an insufficient response or intolerance to at least one prior immunosuppressive therapy; and*
    b. *Patient has a platelet count less than or equal to 30 $x10^9$/L.*
    c. *If criteria for coverage are met, initial authorization will be given for 16 weeks. Documentation of hematologic response after 16 weeks of therapy will be required for further consideration.*
3. *A diagnosis of thrombocytopenia with chronic liver disease in patients who are scheduled to undergo a procedure (Mulpleta)*
    a. *Patient has a platelet count less than 50 x 10^9/L; and*
    b. *Dosing will begin 8 to 14 days prior to a scheduled procedure; and*
    c. *Patient is scheduled to undergo a procedure within 2 to 8 days after the last dose; and*
    d. *A platelet count will be obtained no more than 2 days before starting treatment.*

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.

Elagolix (Orilissa): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for gonadotropin-releasing hormone (GnRH) antagonists. Payment will be considered for patients when the following is met:

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

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

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

Melissa Klotz 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.

Oral Constipation Agents: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for oral constipation agents subject to clinical criteria. Payment for non-preferred oral constipation agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred oral constipation agent. Payment will be considered under the following conditions:

1. *Patient meets the FDA approved age; and*
2. *Patient must have documentation of adequate trials and therapy failures with both of the following:*
    a. *Stimulant laxative (senna) plus saline laxative (milk of magnesia); and*
    b. *Stimulant laxative (senna) plus osmotic laxative (polyethylene glycol or lactulose); and*
3. *Patient does not have a known or suspected mechanical gastrointestinal obstruction; and*
4. *Patient has one of the following diagnoses:*
    a. *A diagnosis of chronic idiopathic constipation (Amitiza®, Linzess™, Trulance®)*

i. *Patient has less than 3 spontaneous bowel movements (SBMs) per week; and*
ii. *Patient has two or more of the following symptoms within the last 3 months:*
    1. *Straining during at least 25% of bowel movements;*
    2. *Lumpy or hard stools for at least 25% of bowel movements; and*
    3. *Sensation of incomplete evacuation for at least 25% of bowel movements; and*
iii. *Documentation the patient is not currently taking constipation causing therapies*

b. *A diagnosis of irritable bowel syndrome with constipation (Amitiza®, Linzess™, Trulance®)*
    i. *Patient is female (Amitiza® only); and*
    ii. *Patient has recurrent abdominal pain on average at least 1 day per week in the last 3 months associated with two (2) or more of the following:*
        1. *Related to defecation;*
        2. *Associated with a change in stool frequency; and/or*
        3. *Associated with a change in stool form*

c. *A diagnosis of opioid-induced constipation with chronic, non-cancer pain (Amitiza®, Movantik™, Relistor®, or Symproic®)*
    i. *Patient has been receiving stable opioid therapy for at least 30 days as seen in the patient's pharmacy claims; and*
    ii. *Patient has less than 3 spontaneous bowel movements (SBMs) per week, with at least 25% associated with one or more of the following:*
        1. *Hard to very hard stool consistency;*
        2. *Moderate to very severe straining; and/or*
        3. *Having a sensation of incomplete evacuation*

If the criteria for coverage are met, initial authorization will be given for 12 weeks to assess the response to treatment. Requests for continuation of therapy may be provided if prescriber documents adequate response to treatment.

Jason Wilbur 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.

Desmopressin Acetate Nasal Spray (Noctiva): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient is 50 years of age or older; and*

2. *Patient has a diagnosis of nocturnal polyuria as confirmed by a 24-hour collection which notes the presence of greater than 33% of 24-hour urine production occurring at night; and*
3. *Patient wakens at least 2 times at night to void; and*
4. *Patient has attempted fluid restriction in the evenings without improvement in nocturnal polyuria; and*
5. *Patient is not taking a diuretic in the evening; and*
6. *Patient does not have any of the following contraindications:*
    a) *Current or previous history of hyponatremia; and*
    b) *Primary nocturnal enuresis; and*
    c) *Polydipsia; and*
    d) *Concomitant use with loop diuretics, systemic or inhaled glucocorticoids; and*
    e) *Known or suspected syndrome of inappropriate antidiuretic hormone (SIADH) secretion; and*
    f) *Estimated glomerular filtration rate < 50 mL/min/1.73 m^2; and*
    g) *Illnesses that can cause fluid or electrolyte imbalance; and*
    h) *New York Heart Association (NYHA) Class II-IV congestive heart failure; and*
    i) *Uncontrolled hypertension.*

Initial requests will be considered for 3 months. Requests for continuation of therapy will require the following:

1. *Patient continues to meet above criteria; and*
2. *Patient has experienced a decrease in nocturnal voiding; and*
3. *There is no evidence of toxicity (e.g., hyponatremia, fluid retention, or electrolyte imbalances).*

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.

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

For patients initiating therapy with a preferred oral agent, 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. *A previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis.*
4. *Requests for a non-preferred oral multiple sclerosis agent must document a previous trial and therapy failure with a preferred oral multiple sclerosis agent.*

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.*
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.*
3. *Patient does not have a baseline QTc interval ≥ 500ms.*
4. *Patient is not being treated with Class la or Class lll anti-arrhythmic drugs.*

For patients initiating therapy with teriflunomide (Aubagio®):

1. *Patient does not have severe hepatic impairment.*
2. *A negative pregnancy test for females of childbearing age.*
3. *Use of a reliable form of contraception for females of childbearing age.*
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.*
2. *Upon renewal, documentation of an updated CBC.*

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.

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

Prior authorization is required for Janus kinase (JAK) inhibitors. Payment will be considered when the following conditions are met:

1. *Patient meets the FDA approved age and*
2. *Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, biologic DMARDs or potent immunosuppressants (azathioprine or cyclosporine); and*
3. *Has been tested for latent tuberculosis prior to initiating therapy and will be monitored for active tuberculosis during treatment; and*
4. *Recommended laboratory monitoring of lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids are being conducted according to the manufacturer labeling; and*
5. *Patient does not have a history of malignancy, except for those successfully treated for non-melanoma skin cancer (NMSC); and*
6. *Patient is not at an increased risk of gastrointestinal perforation; and*

7. *Patient does not have an active, serious infection, including localized infections; and*
8. *Medication will not be given concurrently with live vaccines; and*
9. *Follows FDA approved dosing based on indication; and*
10. *Patient has a diagnosis of:*
    a. *Moderate to severe rheumatoid arthritis with*
        i. *A documented trial and inadequate response to two preferred oral disease modifying antirheumatic drugs (DMARD) used concurrently. The combination must include methotrexate plus another preferred oral DMARD (hydroxychloroquine, sulfasalazine, or leflunomide); and*
        ii. *A documented trial and inadequate response to two preferred biological DMARDs; OR*
    b. *Psoriatic arthritis with*
        i. *A documented trial and inadequate response to therapy with the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*
        ii. *Documented trial and therapy failure with two preferred biological agents used for psoriatic arthritis; OR.*
    c. *Patient has a diagnosis of moderately to severely active ulcerative colitis, and*
        i. *Has a documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and*
        ii. *Has a documented trial and inadequate response with a preferred biological DMARD; and*
        iii. *If requested dose is for 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit.*

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.

Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for CGRP Inhibitors. Payment will be considered for patients when the following is met:

1. *Patient has a diagnosis of migraine as defined by one of the following:*
    a. *Chronic Migraine*
        i. *≥ 15 headache days per month for a minimum of 3 months; and*
        ii. *≥ 8 migraine headache days per month for a minimum of 3 months; or*
    b. *Episodic Migraine*

i. *4 to 14 migraine days per month for a minimum of 3 months; and*

2. *Patient meets the FDA approved age; and*
3. *Patient has been evaluated for and does not have medication overuse headache; and*
4. *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, nadalol, propranolol, timolol], antidepressants, [amitriptyline, venlafaxine]); and*
5. *The requested dose does not exceed the maximum FDA labeled dose; and*
6. *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).

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 31, Number 1. The final document will be posted to the DUR website.

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

Articles of Interest: The Commission members were provided a link to an article recently published regarding empathy as a foundation for legislative medical policy.

At 12:32, Kellen Ludvigson motioned to adjourn, and Mark Graber seconded. All in attendance agreed.

The next meeting will be held at 9:30 a.m. on Wednesday, February 6, 2019, at the Department for the Blind in Des Moines.

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

Attendees:

Commission Members
Mark Graber, M.D., FACEP (via phone); Laurie Anderson, Pharm.D.; Brett Faine, Pharm.D. (via phone); Kellen Ludvigson, Pharm.D. (via phone); Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; Jason Wilbur, M.D. (via phone); Chuck Wadle, D.O.; Susan Parker, Pharm.D.; and Sandy Pranger, R.Ph. (Amerigroup).

Staff
Pam Smith, R.Ph.

Guests
Erin Halverson, R.Ph., IME; Gina Kuebler, R.Ph., IME; Melissa Biddle, IME; and Karrie Hansotia, United Healthcare Plan of the River Valley.

Welcome & Introductions

Pam Smith ran the meeting as both the chairperson and vice-chairperson were connecting via phone due to inclement weather. She called the meeting to order at 9:35 a.m. at the Iowa Medicaid Enterprise in Des Moines. The minutes from the November 7, 2018 meeting were reviewed. Mark Graber motioned to accept them, and Jason Kruse seconded. Chuck Wadle abstained as he had been absent, but all others were in favor. The recommendation letter sent to DHS after the last meeting was also reviewed.

IME Pharmacy Update

There was nothing notable to report.

Fee-for-Service Prevalence Report Summary

Pam Smith provided an overview of fee-for-service statistics from September through November 2018, including: total amount paid ($2,790,494), cost per user ($264.65), and number of total prescriptions dispensed (46,357). There were 10,544 unique users, which is 5.4% more than the total for June through August. The top 5 therapeutics classes by paid amount were: Antiretroviral Combinations; Antipsychotics – Atypicals; Anticonvulsants; Stimulants – Amphetamines – Long Acting; and Antiasthmatic – Adrenergic Combos. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Narcotics – Miscellaneous; and Beta-Lactams/Clavulanate Combos. The top 100 drugs were also reviewed, by paid amount and prescription count. The ten most expensive medications were: Vyvanse, Epclusa, Concerta, Genvoya, Latuda, Biktarvy, Emflaza, Humalog, ProAir HFA, and Symbicort. The five drugs with the highest prescription count were: hydrocodone/apap, amoxicillin, sertraline hcl, gabapentin, and trazodone hcl. Pam Smith also created a report that compared the FFS stats above with those

from each MCO below. Its side-by-side statistics showed that $142,344,043 was spent in total for 284,282 unique users who had 2,000,116 prescriptions.

MCO Prevalence Report Summary and Updates

United Healthcare Community Plan: Karrie Hansotia spoke and provided written summaries that included United's statistics from September through November 2018, including: total paid amount ($88,606,728.93), unique users (180,845), and cost per user ($489.96). 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, Broadlawns and 4 Walgreens locations made up the top five. U of I Ambulatory Care was 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: Insulins; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; Tx for Attention Deficit-Hyperact (ADHD)/Narcolepsy; Anti-Inflammatory Tumor Necrosis Factor Inhibitor; and Anticonvulsants. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Proton-Pump Inhibitors; Beta-Adrenergic Agents, Inhaled, Short Acting; and Antihyperlipidemic – HMG COA Reductase Inhibitors. The most expensive drugs were Vyvanse, Concerta, Humira Pen, Latuda, and Humalog, while omeprazole, lisinopril, levothyroxine sodium, atorvastatin calcium, and sertraline hcl had the top 5 prescription counts.

Amerigroup: Sandy Pranger provided an overview for Amerigroup's statistics from September through November 2018, 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 $50,946,820, a 5.0% increase from the total for June through August. Similar to previous reports, the top 5 therapeutics classes by paid amount were: ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; Antidiabetics; Antiasthmatic and Bronchodilator Agents; Antipsychotics/Antimanic Agents; and Analgesics – Anti-Imflammatory. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Antihypertensives, and Ulcer Drugs/Antispasmodics/ Anticholinergics. Vyvanse was the most expensive medication, followed by Humira Pen, Concerta, Latuda, and Humalog. Omeprazole had the highest prescription count, followed by: lisinopril, levothyroxine sodium, atorvastatin calcium, and gabapentin.

Public Comment

In addition to the written public comments provided to Commission members, they heard oral public comment from Flora Schmidt, Executive Director for the Iowa Behavioral Health Association, concerning prior authorization (PA) requirements for Medication-Assisted Treatment (MAT) medications. She summarized the emails sent in by clinicians from several of the MAT providers they represent (which are posted on the www.iowamedicaidpdl.com site), expressing their wishes and reasoning to request removal of the PA criteria to allow for immediate access to MAT medications often

needed urgently. Charles Wadle, DUR Commission member, then provided some additional counter-points, admitting that his own practice had some issues when the PA was initially put in place. He suggested on-site induction as an option to allow for PA processing time, and acceptance of walk-in patients for those truly in need of immediate medical attention. He reminded her that the PA criteria was being reviewed at this meeting, with many requirements set to be removed (see revised criteria below), and that issues with the way individual MCO companies handled the PAs should be taken up with those MCOs directly. He thought the providers might also be missing things necessary for approved prior authorization, as his office had at first. He also reiterated that requiring prior authorization for this was not a decision based on cost. This is a drug to treat an epidemic that was not addressed appropriately, and that's why there is an epidemic. We don't need to create another epidemic with another opioid just because it's a good opioid to treat other opioids. Caution is necessary as it does get diverted, does get misused, and overzealous prescribing of it does lend to street value and street exchange. He believes there's still value in the PA, but it will be tweaked.

H.R. 6 SUPPORT for Patients and Communities Act

H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act is legislation intended to address the opioid epidemic, including treatment, prevention, recovery, and enforcement. This legislation contains several provisions related to Medicaid. Section 1004 is specific to DUR. The full bill can be found here: https://www.govtrack.us/congress/bills/115/hr6/text. Section 1004, Medicaid Drug Review and Utilization, identifies new requirements for DUR, to be effective October 1, 2019, including: claims review limitations, program to monitor antipsychotic medications by children, fraud and abuse identification, reports, and exceptions. The Commission reviewed the required changes. For opioids, it was suggested a 7-day initial fill limit be implemented, with PA in conjunction with existing MME requirements needed after that. The MME limit is set to drop to 150 in March and eventually to 90. Kellen suggested opioid naïve POS edits that he had seen other payers use, that would allow the claim to pay if the member was already established. Pam Smith will do some additional research and bring this back to a future meeting.

ProDUR Edits

Concurrent Use of Opioids and Benzodiazepines: Due to requirements in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, the DUR Commission made the recommendation to implement a soft edit that would identify members with concurrent use of an opioid and benzodiazepine in their recently paid pharmacy claims. A message regarding the concurrent therapy would be sent to pharmacies via the point of sale (POS). Claims would not be blocked. Jason Kruse made the motion to put the edit in place, and Melissa Klotz seconded. The decision was unanimous.

Concurrent Use of Opioids and Antipsychotics: Due to requirements in the SUPPORT for Patients and Communities Act, the DUR Commission made the recommendation to implement a soft edit that would identify members with concurrent use of an opioid and antipsychotic in their recently paid pharmacy claims. A message regarding the concurrent therapy would be sent to pharmacies via the POS. Claims would not be blocked. Jason Kruse made the motion to put the edit in place, and Melissa Klotz seconded. The decision was unanimous.

Duplicate Antipsychotics in Adults: A ProDUR edit to limit members 18 years of age and older to two chemically distinct antipsychotics will be implemented. No further changes were recommended. As this was the second review, no motion was necessary. The recommendation will be sent to the Department for consideration.

CNS Stimulants and Atomoxetine Concurrent Therapy ProDUR Edit: For members under 21 years of age, the DUR Commission recommended to allow one unit of a short-acting stimulant with a long-acting stimulant by implementing a quantity limit on all short-acting stimulants to one unit per day (i.e., 30 units per 30 days). The intent is to require the use of long-acting stimulants, while allowing for one dose of a short-acting stimulant if needed. No further changes were recommended. As this was the second review, no motion was necessary. The recommendation will be sent to the Department for consideration.

CNS Stimulants and Atomoxetine Age Edit: The minimum FDA approved ages will be followed, and prior authorization criteria updated to reflect this. No further changes were recommended. As this was the second review, no motion was necessary. The recommendation will be sent to the Department for consideration.

The Commission took a short break and open session resumed at 11:19.

Prior Authorization

Sodium Oxybate (Xyrem): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for sodium oxybate (Xyrem®). Payment will be considered under the following conditions:

1. *A diagnosis of cataplexy associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trial and therapy failure with one of the following tricyclic antidepressants: clomipramine, imipramine, or protriptyline; or*
2. *A diagnosis of excessive daytime sleepiness associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trials and therapy failures at a therapeutic dose with a preferred amphetamine and non-amphetamine stimulant; and*
3. *Patient meets the FDA approved age; and*
4. *Is prescribed within the FDA approved dosing; and*
5. *Patient and provider are enrolled in the Xyrem® REMS Program; and*

6. *Patient has been instructed to not drink alcohol when using Xyrem®; and*
7. *Patient has been counseled regarding the potential for abuse and dependence and will be closely monitored for signs of abuse and dependence; and*
8. *Requests for patients with concurrent use of a sedative hypnotic or a semialdehyde dehydrogenase deficiency will not be considered; and.*
9. *The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website prior to requesting prior authorization.*

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

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

Buprenorphine/Naloxone: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for transmucosal buprenorphine or buprenorphine/naloxone. Requests will be considered for FDA approved dosing, including induction and maintenance dose. Requests for doses above 24mg per day will not be considered. Initial requests will be considered for up to 3 months. Requests for maintenance doses above 16mg per day will not be considered on a long-term basis. After the initial 3 month prior authorization, renewal requests for doses ≤ 16mg per day may be considered for 12 month renewals as long as the member meets all other prior authorization criteria. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent, unless evidence is provided that use of these agents would be medically contraindicated. Requests for surgically implanted buprenorphine or buprenorphine depot injection products will not be considered through the pharmacy benefit and should be directed to the member's medical benefit. Payment will be considered for patients when the following is met:

1. *Patient has a diagnosis of opioid dependence and meets the FDA approved age: AND*
2. *Prescriber meets qualification criteria to prescribe buprenorphine/naloxone for opioid dependence and has a "X" DEA number (provide X DEA number); AND*
3. *Documentation the Iowa Prescription Monitoring Program (PMP) website has been reviewed for the patient's use of controlled substances; AND*
4. *Documentation is provided that transmucosal buprenorphine will not be used concomitantly with the buprenorphine implant or depot injection.*
5. *Requests for single ingredient buprenorphine will only be considered for pregnant patients.*

Requests for renewal must include:

1. *Documentation the Iowa PMP website has been reviewed for the patient's use of controlled substances since the last prior authorization request, AND*
2. *Patient does not have documentation of concomitant use of an opioid or tramadol with the requested buprenorphine product, as seen in paid pharmacy claims, AND*
3. *Patient is not using transmucosal buprenorphine with buprenorphine implant or depot injection.*

Chuck Wadle motioned to accept the criteria as amended, and Jason Kruse seconded. All members were in favor. Additionally, it was recommended to add extra lines to the PA form to provide more writing space for strength and dosage instructions, as well as lines for induction and maintenance doses. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Short-Acting Opioids: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for all non-preferred short acting opioids. Prior authorization (PA) is also required for members when the total daily opioid dose (combined across all opioids) exceeds the set morphine milligram equivalent (MME) threshold (include High Dose Opioids PA form with request). Payment will be considered under the following conditions:

1. *Patient has pain severe enough to require opioid treatment; and*
2. *Patient has tried and failed at least two non-pharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and*
3. *Patient has tried and failed at least two non-opioid pharmacologic therapies (e.g. acetaminophen or NSAIDs); and*
4. *Patient has documentation of previous trials and therapy failures with three (3) chemically distinct preferred short acting opioids (based on opioid ingredient only) at therapeutic doses; and*
5. *The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program (PMP) website and has determined that use of a short-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and*
6. *Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids; and*
7. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*

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

If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met:

1. *Patient has experienced improvement in pain control and level of functioning; and*
2. *Prescriber has reviewed the patient's use of controlled substances on the Iowa PMP website and has determined continued use of a short-acting opioid is appropriate for this member; and*
3. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*
    a. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
    b. *Documentation as to why concurrent use is medically necessary is provided; and*
    c. *A plan to taper the benzodiazepine is provided, if appropriate.*

The required trials may be overridden when documented evidence is provided that use of these agents and/or non-pharmacologic therapies 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.

Long-Acting Opioids: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for all non-preferred long-acting opioids. Prior authorization (PA) is also required for members when the total daily opioid dose (combined across all opioids) exceeds the set morphine milligram equivalent (MME) threshold (include High Dose Opioids PA form with request). Payment will be considered under the following conditions:

1. *Patient has a diagnosis of chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment; and*
2. *Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and*
3. *Patient has tried and failed at least two nonopioid pharmacologic therapies (e.g. acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants); and*

4. *There is documentation of previous trial and therapy failure with one preferred long-acting opioid at maximally tolerated dose; and*
5. *A signed chronic opioid therapy management plan between the prescriber and patient must be included with the prior authorization; and*
6. *The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program (PMP) website and determine if use of a long-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and*
7. *Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids.*
8. *Requests for long-acting opioids will only be considered for FDA approved dosing intervals. As-needed (PRN) dosing will not be considered; and*
9. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*
    a. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
    b. *Documentation as to why concurrent use is medically necessary is provided; and*
    c. *A plan to taper the benzodiazepine is provided, if appropriate.*

If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met:

1. *Patient has experienced improvement in pain control and level of functioning; and*
2. *Prescriber has reviewed the patient's use of controlled substances on the Iowa PMP website and has determined continued use of a long-acting opioid is appropriate for this member; and*
3. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*
    a. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
    b. *Documentation as to why concurrent use is medically necessary is provided; and*
    c. *A plan to taper the 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.

Melissa Klotz 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.

Kalydeco (Ivacaftor): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient meets the FDA approved age; and*
2. *Has a diagnosis of cystic fibrosis; and*
3. *Patient has one of the CFTR gene mutations as indicated in the FDA approved label as detected by an FDA-cleared CF mutation test; and*
4. *Prescriber is a CF specialist or pulmonologist; and*
5. *Baseline liver function tests (AST/ALT) are provided.*

If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met:

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

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

Orkambi (Lumacaftor/Ivacaftor): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Orkambi™ (lumacaftor/ivacaftor). Dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator will not be considered. Payment will be considered for patients when the following criteria are met:

1. *Patient meets the FDA approved age; and*
2. *Has a diagnosis of cystic fibrosis; and*
3. *Patient is homozygous for the F508del mutation in the CFTR gene as confirmed by a FDA-cleared CF mutation test; and*
4. *Baseline liver function tests (AST/ALT) and bilirubin levels are provided and*
5. *Prescriber is a CF specialist or pulmonologist.*

If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met:

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

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

Hematopoietics/Chronic ITP (Thrombopoeitin Receptor Agonists): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for hematopoietics/chronic ITP agents. Request must adhere to all FDA approved labeling. Payment for a non-preferred hematopoietic/chronic ITP agent will be considered following documentation of a recent trial and therapy failure with a preferred hematopoietic/chronic ITP agent when applicable, unless such a trial would be medically contraindicated. Payment will be considered under the following conditions:

1. *A diagnosis of thrombocytopenia with chronic immune thrombocytopenia (ITP) (Promacta, Nplate, or Tavalisse)*
    a. *Patient has documentation of an insufficient response to a corticosteroid, immunoglobulin, or splenectomy.*
2. *A diagnosis of severe aplastic anemia (Promacta)*
    a. *Patient has documentation of an insufficient response or intolerance to at least one prior immunosuppressive therapy; and*
    b. *Patient has a platelet count less than or equal to 30 $x10^9$/L.*
    c. *If criteria for coverage are met, initial authorization will be given for 16 weeks. Documentation of hematologic response after 16 weeks of therapy will be required for further consideration.*
3. *A diagnosis of thrombocytopenia with chronic liver disease in patients who are scheduled to undergo a procedure (Mulpleta)*
    a. *Patient has a platelet count less than 50 x 10^9/L; and*
    b. *Dosing will begin 8 to 14 days prior to a scheduled procedure; and*
    c. *Patient is scheduled to undergo a procedure within 2 to 8 days after the last dose; and*
    d. *A platelet count will be obtained no more than 2 days before starting treatment.*

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.

Elagolix (Orilissa): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for gonadotropin-releasing hormone (GnRH) antagonists. Payment will be considered for patients when the following is met:

1. *Patient has a diagnosis of moderate to severe pain associated with endometriosis; and*
2. *Pregnancy has been ruled out; and*
3. *Patient does not have osteoporosis; and*
4. *Patient does not have severe hepatic impairment; and*
5. *Patient is not taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g., cyclosporine and gemfibrozil); and*
6. *Patient has documentation of a previous trial and therapy failure with at least*

one preferred oral NSAID and at least one preferred 3-month course of a continuous hormonal contraceptive taken concurrently; and

7. *Patient has documentation of a previous trial and therapy failure with a preferred GnRH agonist.*
8. *Requests will be considered for a maximum of 24 months for the 150mg dose and six (6) months for the 200mg dose.*

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

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

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.

Oral Constipation Agents: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for oral constipation agents subject to clinical criteria. Payment for non-preferred oral constipation agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred oral constipation agent. Payment will be considered under the following conditions:

1. *Patient meets the FDA approved age; and*
2. *Patient must have documentation of adequate trials and therapy failures with both of the following:*
   a. *Stimulant laxative (senna) plus saline laxative (milk of magnesia); and*
   b. *Stimulant laxative (senna) plus osmotic laxative (polyethylene glycol or lactulose); and*
3. *Patient does not have a known or suspected mechanical gastrointestinal obstruction; and*
4. *Patient has one of the following diagnoses:*
   a. *A diagnosis of chronic idiopathic constipation (Amitiza®, Linzess™, Trulance®)*
      i. *Patient has less than 3 spontaneous bowel movements (SBMs) per week; and*
      ii. *Patient has two or more of the following symptoms within the last 3 months:*
         1. *Straining during at least 25% of bowel movements;*
         2. *Lumpy or hard stools for at least 25% of bowel movements; and*
         3. *Sensation of incomplete evacuation for at least 25% of bowel movements; and*

iii. *Documentation the patient is not currently taking constipation causing therapies*

b. *A diagnosis of irritable bowel syndrome with constipation (Amitiza®, Linzess™, Trulance®)*
   i. *Patient is female (Amitiza® only); and*
   ii. *Patient has recurrent abdominal pain on average at least 1 day per week in the last 3 months associated with two (2) or more of the following:*
      1. *Related to defecation;*
      2. *Associated with a change in stool frequency; and/or*
      3. *Associated with a change in stool form*

c. *A diagnosis of opioid-induced constipation with chronic, non-cancer pain (Amitiza®, Movantik™, Relistor®, or Symproic®)*
   i. *Patient has been receiving stable opioid therapy for at least 30 days as seen in the patient's pharmacy claims; and*
   ii. *Patient has less than 3 spontaneous bowel movements (SBMs) per week, with at least 25% associated with one or more of the following:*
      1. *Hard to very hard stool consistency;*
      2. *Moderate to very severe straining; and/or*
      3. *Having a sensation of incomplete evacuation*

If the criteria for coverage are met, initial authorization will be given for 12 weeks to assess the response to treatment. Requests for continuation of therapy may be provided if prescriber documents adequate response to treatment.

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.

Desmopressin Acetate Nasal Spray (Noctiva): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient is 50 years of age or older; and*
2. *Patient has a diagnosis of nocturnal polyuria as confirmed by a 24-hour collection which notes the presence of greater than 33% of 24-hour urine production occurring at night; and*
3. *Patient wakens at least 2 times at night to void; and*
4. *Patient has attempted fluid restriction in the evenings without improvement in nocturnal polyuria; and*
5. *Patient is not taking a diuretic in the evening; and*
6. *Patient does not have any of the following contraindications:*
   a) *Current or previous history of hyponatremia; and*
   b) *Primary nocturnal enuresis; and*

c) *Polydipsia; and*
d) *Concomitant use with loop diuretics, systemic or inhaled glucocorticoids; and*
e) *Known or suspected syndrome of inappropriate antidiuretic hormone (SIADH) secretion; and*
f) *Estimated glomerular filtration rate < 50 mL/min/1.73 m^2; and*
g) *Illnesses that can cause fluid or electrolyte imbalance; and*
h) *New York Heart Association (NYHA) Class II-IV congestive heart failure; and*
i) *Uncontrolled hypertension.*

Initial requests will be considered for 3 months. Requests for continuation of therapy will require the following:

1. *Patient continues to meet above criteria; and*
2. *Patient has experienced a decrease in nocturnal voiding; and*
3. *There is no evidence of toxicity (e.g., hyponatremia, fluid retention, or electrolyte imbalances).*

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 31, Number 2. They asked that statistics on the last page be combined to include those from both MCOs and FFS when possible.

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

At 12:10, Jason Kruse motioned to adjourn, and Chuck Wadle seconded. All in attendance agreed.

The next meeting will be held at 9:30 a.m. on Wednesday, May 1, 2019, at the Department for the Blind in Des Moines.

Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes May 1, 2019

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Laurie Anderson, Pharm.D.; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; Jason Wilbur, M.D. Chuck Wadle, D.O.; Susan Parker, Pharm.D.; and Sandy Pranger, R.Ph. (Amerigroup).

Staff
Pam Smith, R.Ph.

Guests
David Smith, M.D., IME; Erin Halverson, R.Ph., IME; Melissa Biddle, IME; and Karrie Hansotia, United Healthcare Plan of the River Valley.

Welcome & Introductions

Chairperson Brett Faine called the meeting to order at 9:31 a.m. at the Iowa Department for the Blind in Des Moines. The minutes from the February 6, 2019 meeting were reviewed. Mark Graber motioned to accept them, and Jason Kruse seconded. All members were in favor. The recommendation letter sent to DHS after the last meeting and the recommendation letter from the P&T Committee regarding development of criteria for Epidiolex were also reviewed. Following up from previous meetings, Pam Smith announced that the prior authorization requirement would be removed for smoking cessation and nicotine replacement products, and that prior authorization for Nucala and Exondys 51 would no longer be available through the pharmacy benefit and needs to go through the Medical benefit.

IME Pharmacy Update

There is a legislative bill in process that would require removal of the clinical prior authorization for the preferred Medical Assisted Treatment (MAT) medications if signed by the governor. Prior authorization would still be allowed for the non-preferred products, but at least one preferred agent must be available without PA in the following categories: methadone, buprenorphine, naloxone, buprenorphine and naloxone combination, and naltrexone. Rules would have to be put in place within six months of initiating the process. DHS did try to make some technical corrections to the bill as naloxone is not used for treatment of substance abuse disorder, but they were not initiated. Thus DHS will have to work with the lawyers to figure out how to put everything into rules and correct the problematic areas if the bill goes through as written. Pam Smith provided a letter and certificate of appreciation to Laurie Anderson for her twelve years of service to the DUR Commission as this was her last meeting. There is now an opening for a pharmacist.

Fee-for-Service Prevalence Report Summary

Pam Smith provided an overview of fee-for-service statistics from December 2018 through February 2019, including: total amount paid ($2,760,948), cost per user ($270.71), and number of total prescriptions dispensed (44,919). There were 10,199 unique users, which is 3.1% less than the total for September through November. The top 5 therapeutics classes by paid amount were: Anticonvulsants; Antiretroviral Combinations; Antipsychotics – Atypicals; Anti-Inflammatories, Non-NSAID; and Stimulants – Amphetamines – Long Acting. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; 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, Tamiflu, Synagis, Latuda, Humalog, Invega Systenna, Biktarvy, Advair Diskus, and Aubagio. The five drugs with the highest prescription count were: amoxicillin, sertraline hcl, hydrocodone/apap, trazodone hcl, and gabapentin. Pam Smith also created a report that compared the FFS stats above with those from each MCO below. Its side-by-side statistics showed that $143,597,344 was spent in total for 283,629 unique users who had 1,969,165 prescriptions.

MCO Prevalence Report Summary and Updates

Amerigroup: Sandy Pranger provided an overview for Amerigroup's statistics from December 2018 through February 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 $51,015,412, a 0.7% increase from the total for September through November. Similar to previous reports, the top 5 therapeutics classes by paid amount were: ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; Antidiabetics; Antiasthmatic and Bronchodilator Agents; Antipsychotics/Antimanic Agents; and Analgesics – Anti-Imflammatory. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Antihypertensives, and Ulcer Drugs/Antispasmodics/ Anticholinergics. Vyvanse was the most expensive medication, followed by Humira Pen, Concerta, Latuda, and Humalog. Omeprazole had the highest prescription count, followed by: lisinopril, levothyroxine sodium, atorvastatin calcium, and sertraline hcl.

United Healthcare Community Plan: Karrie Hansotia spoke and provided written summaries that included United's statistics from December 2018 through February 2019, including: total paid amount ($89,820,984.49), unique users (180,074), and cost per user ($489.80). 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, Broadlawns, U of I Ambulatory Care, and 3 Walgreens locations made up the top 5. U of I Ambulatory Care was 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: Insulins; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; Tx for Attention Deficit-Hyperact

(ADHD)/Narcolepsy; Anti-Inflammatory Tumor Necrosis Factor Inhibitor; and Anticonvulsants. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Proton-Pump Inhibitors; Antihyperlipidemic – HMG COA Reductase Inhibitors; and Beta-Adrenergic Agents, Inhaled, Short Acting. The most expensive drugs were Vyvanse, Concerta, Latuda, Humalog, and Humira Pen, while omeprazole, lisinopril, amoxicillin, levothyroxine sodium, and atorvastatin calcium had the top 5 prescription counts.

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.

Name	Representing	Drug/Topic
Jennifer Triemstra	Greenwich Biosciences	Epidiolex
Kevin Duhrkopf	Sanofi Genzyme	Dupixent

ProDUR Edits

Initial Seven Day Opioid Supply Limit: The Commission discussed and recommended a POS hard edit, that could be overridden at the POS by the pharmacist with DUR codes, be implemented with a 60-day look-back on member claims. Kellen Ludvigson made the motion, and Jason Kruse seconded. The decision was unanimous.

Concurrent Use of Opioids and Benzodiazepines: Due to requirements in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, at the February meeting the DUR Commission made the recommendation to implement a soft edit that would identify members with concurrent use of an opioid and benzodiazepine in their recently paid pharmacy claims. A message regarding the concurrent therapy would be sent to pharmacies via the point of sale (POS). Claims would not be blocked. 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.

Concurrent Use of Opioids and Antipsychotics: Due to requirements in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, at the February meeting the DUR Commission made the recommendation to implement a soft edit that would identify members with concurrent use of an opioid and antipsychotic in their recently paid pharmacy claims. A message regarding the concurrent therapy would be sent to pharmacies via the POS. Claims would not be blocked. No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

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

Prior Authorization

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.

Jason Wilbur motioned to accept the criteria as amended, and Mark Graber seconded. The motion passed unanimously. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

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; 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).*

Jason Kruse motioned to accept the criteria as amended, and Mark Graber seconded. The motion passed unanimously. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Dupilumab (Dupixent): The Commission reviewed the 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.

Jason Kruse motioned to accept the criteria as amended, and Melissa Klotz seconded. The motion passed unanimously. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

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 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.

Mark Graber motioned to accept the recommended criteria, and Jason Kruse seconded. The motion passed unanimously. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

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.

Jason Kruse motioned to accept the recommended criteria, and Jason Wilbur seconded. The motion passed unanimously. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Sodium Oxybate (Zyrem): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for sodium oxybate (Xyrem®). Payment will be considered under the following conditions:

1. *A diagnosis of cataplexy associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trial and therapy failure with one of the following tricyclic antidepressants: clomipramine, imipramine, or protriptyline; or*
2. *A diagnosis of excessive daytime sleepiness associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trials and therapy failures at a therapeutic dose with a preferred amphetamine and non-amphetamine stimulant; and*
3. *Patient meets the FDA approved age; and*

4. *Is prescribed within the FDA approved dosing; and*
5. *Patient and provider are enrolled in the Xyrem® REMS Program; and*
6. *Patient has been instructed to not drink alcohol when using Xyrem®; and*
7. *Patient has been counseled regarding the potential for abuse and dependence and will be closely monitored for signs of abuse and dependence; and*
8. *Requests for patients with concurrent use of a sedative hypnotic or a semialdehyde dehydrogenase deficiency will not be considered; and.*
9. *The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website prior to requesting prior authorization.*

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.

Buprenorphine/Naloxone: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for transmucosal buprenorphine or buprenorphine/naloxone. Requests will be considered for FDA approved dosing, including induction and maintenance dose. Requests for doses above 24mg per day will not be considered. Initial requests will be considered for up to 3 months. Requests for maintenance doses above 16mg per day will not be considered on a long-term basis. After the initial 3 month prior authorization, renewal requests for doses ≤ 16mg per day may be considered for 12 month renewals as long as the member meets all other prior authorization criteria. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent, unless evidence is provided that use of these agents would be medically contraindicated. Requests for surgically implanted buprenorphine or buprenorphine depot injection products will not be considered through the pharmacy benefit and should be directed to the member's medical benefit. Payment will be considered for patients when the following is met:

1. *Patient has a diagnosis of opioid dependence and meets the FDA approved age: AND*
2. *Prescriber meets qualification criteria to prescribe buprenorphine/naloxone for opioid dependence and has a "X" DEA number (provide X DEA number); AND*
3. *Documentation the Iowa Prescription Monitoring Program (PMP) website has been reviewed for the patient's use of controlled substances; AND*
4. *Documentation is provided that transmucosal buprenorphine will not be used concomitantly with the buprenorphine implant or depot injection.*
5. *Requests for single ingredient buprenorphine will only be considered for*

pregnant patients.

Requests for renewal must include:

1. *Documentation the Iowa PMP website has been reviewed for the patient's use of controlled substances since the last prior authorization request, AND*
2. *Patient does not have documentation of concomitant use of an opioid or tramadol with the requested buprenorphine product, as seen in paid pharmacy claims, AND*
3. *Patient is not using transmucosal buprenorphine with buprenorphine implant or depot injection.*

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.

Short-Acting Opioids: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for all non-preferred short acting opioids. Prior authorization (PA) is also required for members when the total daily opioid dose (combined across all opioids) exceeds the set morphine milligram equivalent (MME) threshold (include High Dose Opioids PA form with request). Payment will be considered under the following conditions:

1. *Patient has pain severe enough to require opioid treatment; and*
2. *Patient has tried and failed at least two non-pharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and*
3. *Patient has tried and failed at least two non-opioid pharmacologic therapies (e.g. acetaminophen or NSAIDs); and*
4. *Patient has documentation of previous trials and therapy failures with three (3) chemically distinct preferred short acting opioids (based on opioid ingredient only) at therapeutic doses; and*
5. *The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program (PMP) website and has determined that use of a short-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and*
6. *Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids; and*
7. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*
    a. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*

b. *Documentation as to why concurrent use is medically necessary is provided; and*
c. *A plan to taper the benzodiazepine is provided, if appropriate.*

If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met:

1. *Patient has experienced improvement in pain control and level of functioning; and*
2. *Prescriber has reviewed the patient's use of controlled substances on the Iowa PMP website and has determined continued use of a short-acting opioid is appropriate for this member; and*
3. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*
   a. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
   b. *Documentation as to why concurrent use is medically necessary is provided; and*
   c. *A plan to taper the benzodiazepine is provided, if appropriate.*

The required trials may be overridden when documented evidence is provided that use of these agents and/or non-pharmacologic therapies 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.

Long-Acting Opioids: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for all non-preferred long-acting opioids. Prior authorization (PA) is also required for members when the total daily opioid dose (combined across all opioids) exceeds the set morphine milligram equivalent (MME) threshold (include High Dose Opioids PA form with request). Payment will be considered under the following conditions:

1. *Patient has a diagnosis of chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment; and*
2. *Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and*
3. *Patient has tried and failed at least two nonopioid pharmacologic therapies (e.g. acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants); and*
4. *There is documentation of previous trial and therapy failure with one preferred long-acting opioid at maximally tolerated dose; and*

5. *A signed chronic opioid therapy management plan between the prescriber and patient must be included with the prior authorization; and*
6. *The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program (PMP) website and determine if use of a long-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and*
7. *Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids.*
8. *Requests for long-acting opioids will only be considered for FDA approved dosing intervals. As-needed (PRN) dosing will not be considered; and*
9. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*
    a. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
    b. *Documentation as to why concurrent use is medically necessary is provided; and*
    c. *A plan to taper the benzodiazepine is provided, if appropriate.*

If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met:

1. *Patient has experienced improvement in pain control and level of functioning; and*
2. *Prescriber has reviewed the patient's use of controlled substances on the Iowa PMP website and has determined continued use of a long-acting opioid is appropriate for this member; and*
3. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*
    a. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
    b. *Documentation as to why concurrent use is medically necessary is provided; and*
    c. *A plan to taper the 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.

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 31, Number 2. The DUR Digest will be posted to the DUR website.

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

At 11:29, 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, August 7, 2019, at a location to be determined.**

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 SFY19.

Appendix K
Recommendations to the P&T

P & T Recommendations
SFY19

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 included the bi-monthly prevalence report reviewed by the DUR Commission.
http://iadur.org/agendas