Department of
HUMAN SERVICES

# *Iowa Medicaid Drug Utilization Review Commission Annual Report of Activities Fee-for-Service Program SFY22*

**September 2022**

## TABLE OF CONTENTS

# The Iowa Medicaid Drug Utilization Review Commission

Change Healthcare has developed the following report for the Iowa Department of Human Services. This report provides a summary description of the activities of the Iowa Medicaid Drug Utilization Review Commission, along with an evaluation of the Iowa Medicaid fee-for-service retrospective drug utilization review program. Information contained in this report covers projects completed and evaluated during the time period of July 2021 through June 2022.

## Background Information

Established in 1984, the DUR Commission is charged with promoting the appropriate and cost-effective use of medications within the Iowa Medicaid member population. Acting as a professional advisory group, the Commission analyzes medication utilization by the members of Iowa Medicaid and performs educational initiatives to optimize member outcomes. The Commission performs retroDUR and educational outreach through patient-focused reviews and problem-focused reviews. The Commission supports the proDUR program through criteria review and acts as a resource to the DHS on other issues concerning appropriate medication use. On April 1, 2016, the Iowa Medicaid population transitioned to managed care. With this transition, over 90 percent of the population moved to managed care leaving less than10 percent of the population in the fee-for-service (FFS) program. Managed Care Organizations (MCOs) participate in the DUR Commission meetings, provide a quarterly prevalence report with information on prescribers, pharmacies and prescription claims information for the DUR Commission to review, and have the ability to provide input during the meetings. Collaboration with the MCOs to develop retroDUR initiatives and educational outreach for the entire Iowa Medicaid population is ongoing. The DUR Commission also engaged in the ongoing development of clinical prior authorization criteria and ProDUR edits.

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

### Patient-Focused Reviews

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

The member profiles selected from this process are manually reviewed by the Commission, if needed, or the DUR Coordinator to minimize false positives generated by the computer selection process. The Commission or DUR Coordinator identifies situations where educational intervention might be appropriate. Through these interventions, suggestions regarding medication therapy are communicated to the care providers. Templates are developed for suggestions that are frequently communicated to providers.

The reviewer may also author an individualized suggestion if a template suggestion is not applicable.

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

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

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

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

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

**Problem-Focused Reviews**

Problem-focused reviews narrow the emphasis of review to a specific issue that has been determined to be an area where a targeted educational effort to providers may be valuable. Topics for review are selected from findings of patient-focused reviews, from

review of the monthly paid claims report, from review of the quarterly prevalence report, from reviews of medical literature, or suggestions by Commission members and MCOs. Criteria are developed to identify the members who may benefit from intervention and educational materials are disseminated to their providers. Providers are encouraged to voluntarily respond. The member profile is generated again in an appropriate amount of time (typically 6 to 9 months) to determine the impact rate of the intervention, along with any fiscal considerations. The policy regarding these calculations is included in Appendix B.

**Administrative Review**

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

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

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

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

## Overall Results

Activities of the DUR Commission were evaluated for SFY22 for interventions performed in the previous or the current fiscal year. Due to the small patient population in the FFS program, savings to the state are significantly less than prior to the transition to managed care. The direct cost savings from all activities of the DUR Commission are calculated to be $15,867.81*. 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 | $15,867.81* |

Patient-focused reviews resulted in $15,698.97* in direct cost savings, or $436.08* per patient evaluated. This estimate is based on the 37 suggestions made by the DUR Commission identified from the review of the medication therapy of 36 patient profiles selected for intervention. Of these 37 suggestions, 12 suggestions were implemented by the providers, resulting in a 32 percent impact rate.

Patient-Focused Profile Review

| | |
|---|---|
| Suggestions Made | 37 |
| Therapy Changed | 12 |
| IMPACT RATE | 32% |
| Cost Savings Estimates: | |
| Dollars Saved per Patient Evaluated | $436.08* |
| Dollars Saved on Medication | $15,698.97* |

*Savings reported are pre-rebate, total dollars

Problem-focused reviews resulted in an estimated cost savings of $168.84* or $11.26 saved per patient evaluated. This estimate is based on the review of profiles with 15 patients selected for interventions. Therapy was changed for 1 patient, resulting in an impact rate of 7 percent. These interventions are informative in nature.

Problem-Focused Profile Review

| | |
|---|---|
| Patients Evaluated | 15 |
| Therapy Changed | 1 |
| IMPACT RATE | 7% |
| Cost Savings Estimates: | |
| Dollars Saved per Patient Evaluated | $11.26* |
| Dollars Saved on Medication | $168.84* |

**Comparison to Previous SFY Report**

Cost savings estimates for SFY22 ($15,867.81*) are slightly higher than last year ($6,289.35*). 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 SFY22 patient-focused reviews ($15,698.97*) were higher than SFY21 ($5,733.75*). The number of suggestions made (37) vs. (28) increased while the number of suggestions that were accepted (12) vs. (11) from SFY21 also slightly increased. Again, due to the transition to managed care, cost savings, the number of suggestions made and the number of suggestions accepted fluctuate year to year. Historically there has been minimal impact from patient-focused reviews; that is attributed to the maturation of the Preferred Drug List (PDL) program and Point of Sale (POS) edits that have been implemented over the years. It is difficult to determine the actual cause for the minimal number of suggestions accepted. One theory could be, due to the voluntary participation of the prescriber and lack of the ability to enforce the educational recommendations made by the DUR Commission, prescribers do not make the recommended change due to lack of time or they do not feel it is in the best interest of the patient.

The savings from problem-focused reviews for SFY22 ($168.84*) were lower than SFY21 ($555.60*). This was due to the small number of members in the FFS program and the low cost drugs involved in the problem-focused review.

*Savings reported are pre-rebate, total dollars

# Results by Review Type

## Patient-Focused Review

During this evaluation period, 83 educational intervention letters were mailed to prescribers and pharmacies regarding medication therapy. Of this total, 46 letters (55 percent) were mailed to prescribers, and 37 letters (45 percent) were mailed to pharmacies. Providers are invited to voluntarily respond to DUR Commission letters. Providers returned 22 responses to these letters, resulting in an overall response rate by the providers of 27 percent. Of the 22 responses, 10 (45 percent) were from prescribers and 12 (55 percent) were from pharmacies. The overall response rate differed between prescribers and pharmacies; 22 percent for prescribers and 32 percent for pharmacies.

In these 83 educational letters, the DUR Commission made 37 suggestions. Of these suggestions, 36 (97 percent) were therapeutic in nature while 1 (3 percent) was cost-saving in nature. The suggested change was implemented in 12 cases, resulting in an overall impact rate of 32 percent.

Of the 37 suggestions, five types of suggestions accounted for 100 percent of the total. Those five suggestions were Inappropriate Billing (3 percent), Not Optimal Dose (5 percent), Patent Underuse (5 percent), Unnecessary Drug Therapy (3 percent) and Therapeutic Duplication (84 percent). Of the 12 changes, the only reason for the Commission's inquiry was Therapeutic Duplication (100 percent). No other single category accounted for any changes.

The suggestion(s) that resulted in change the highest percentage of the time was Therapeutic Duplication (39 percent).

Implementation of therapeutic suggestions resulted in direct drug cost savings of $15,698.97*. Zero cost-savings suggestions were implemented based on the one cost-savings suggestion, resulting in zero direct drug cost savings*. The total amount saved on medication utilization was calculated to be $15,698.97* for the 36 patients evaluated, or $436.08* per patient.

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

## Problem-Focused Reviews

Seven problem-focused reviews were evaluated during SFY22. In conducting these reviews, 15 patients were selected for intervention. Of these patients, 1 case showed evidence of a positive outcome, resulting in an impact rate of 7 percent.

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

*Savings reported are pre-rebate, total dollars

## Administrative Review

Prior Authorization

The DUR Commission annually reviews the prior authorization program for clinical appropriateness. Changes are recommended to the Department. During SFY22, the DUR Commission reviewed all therapeutic categories requiring prior authorization as well as therapeutic criteria to support operations of the Preferred Drug List. Recommendations for modifications to existing criteria, recommendations for new prior authorization criteria, and recommendations for removal of prior authorization criteria can be found in Appendix G as well as the Recommendation Letters.

Prospective Drug Review

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

## Other Activities

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

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

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

Brett Faine, Pharm.D. completed his third term on the DUR in June 2022.

Kellen Ludvigson, Pharm.D. completed two years of his third term (total of 10 years) on the DUR in June 2022, resigning early to pursue other professional endeavors.

Lisa Todd, R.Ph. began her two-year term on the Commission as the MCO representative, in July 2021.

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

*Savings reported are pre-rebate, total dollars

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

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

*Savings reported are pre-rebate, total dollars

# Appendix A
# Commission Members

**Iowa Medicaid Drug Utilization Review**
**Commission Members**
**2021-2022**

**John Ellis, Pharm.D.**
Dr. Ellis is currently the pharmacy manager at Hy-Vee Pharmacy in Winterset, Iowa, and previously worked at several other Des Moines metro Hy-Vee locations. He received his Doctorate of Pharmacy degree from Drake University, where he is also an Adjunct Assistant Professor of Pharmacy. Dr. Ellis was appointed to the DUR Commission in 2019; his first term will expire in June 2023.

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

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

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

**Kellen Ludvigson, Pharm.D.**
Dr. Ludvigson graduated with distinction from the University of Iowa College of Pharmacy in 2007. He is currently employed as a retail pharmacist at Cherokee Main Street Pharmacy and does relief work for the Cherokee Mental Health Institute in Cherokee. Dr. Ludvigson was reappointed to the DUR for a third term in 2020, set to expire in June 2024, but resigned from the DUR effective June 2022.

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

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

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

**Jason Wilbur, M.D.**
Dr. Wilbur graduated from the Saint Louis University School of Medicine in 1999. He then completed his Family Medicine Residency at the University of Iowa, where he was Chief Resident 2001-2002, followed by a Geriatric Medicine Fellowship 2002-2003. He is currently Professor of Clinical Family Medicine for the Roy J. & Lucille A. Carver College of Medicine at the University of Iowa. Prior to that, he was Medical Director of the Family Medicine Clinic in Iowa City from 2006 to 2011. The University of Iowa Hospitals and Clinics awarded him the Above and Beyond Reward in 2006 and again in 2007, along with the Teacher of the Year Award, presented by the University of Iowa Family Medicine

residents, in 2008.  Dr. Wilbur was reappointed for a third term in 2020 which will expire in June 2024.

# Appendix B
# Evaluation Procedure

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

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

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

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

<u>Patient-focused DUR</u>

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

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

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

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

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

Templates that are therapeutic in nature include:

- Not Optimal Drug
- Not Optimal Dose
- Not Optimal Duration of Use
- Unnecessary Drug Use
- Therapeutic Duplication

- High Cost Drug
- Drug-Drug Interaction
- Drug-Disease Interaction
- Adverse Drug Reaction
- Patient Overuse
- Patient Underuse
- Therapeutic Alternative
- Missing Drug Therapy

Templates that are cost saving in nature include:

- Not Optimal Dosage Form
- Potential Generic Use
- Inappropriate Billing

Problem-focused DUR

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

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

Administrative Review

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

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

appropriate utilization guidelines or parameters.

- Prior Authorization
  *Definition*: A process for obtaining approval for a drug before the drug is provided to a member, as a precondition for provider reimbursement. Prior authorization is requested at the prescriber level and is a prescriber fax-only system using the forms provided by the Iowa Medicaid Enterprise.
  *Impact:* The DUR Commission develops sound, cost-effective medication use guidelines by reviewing peer reviewed medical information from various sources. The Commission seeks outside expertise when necessary and considers public comments prior to recommending prior authorization for appropriate drug use.

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

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

# Appendix C
# Overall Program Results

# FFS Program Evaluation/Cost Savings Estimates
# Iowa Medicaid Retrospective Drug Utilization Review
# Annual Report
# SFY22

## Patient Focused Profile Review

| | |
|---|---|
| Suggestions Made | 37 |
| Therapy Changed | 12 |
| Impact Rate | 32.43% |
| Cost Savings Estimates: | |
| Dollars Saved per Patient Evaluated* | $436.08 |
| Dollars Saved on Medication* | $15,698.97 |

## Problem-Focused Profile Review

| | |
|---|---|
| Suggestions Made | 15 |
| Therapy Changed | 1 |
| Impact Rate | 6.67% |
| Cost Savings Estimates: | |
| Dollars Saved per Patient Evaluated* | $11.26 |
| Dollars Saved on Medication* | $168.84 |

## Cost Savings Estimate* **$15,867.81**

*Savings reported are pre-rebate, total dollars

# Appendix D
# Results Patient-Focused

## FFS Patient - Focused Reviews

SFY22

| | | | | |
|---|---|---|---|---|
| Initial Review Date | **October 2020 - September 2021** | | | |
| Re-review Date | **July 2021 - June 2022** | | | |
| Patient Profiles Reviewed | 406 | | | |
| Patient Profiles Selected for Intervention | 36 | | | |
| **Intervention Letters Sent** | | | | |
| Prescribers | 46 | 55.42% | | |
| Pharmacists | 37 | 44.58% | | |
| Total | **83** | 100% | | |
| **Responses Received** | | | | |
| Prescribers | 10 | 45.45% | **Overall Response Rate** | **26.51%** |
| Pharmacists | 12 | 54.55% | Prescriber Response Rate | 21.74% |
| Total | **22** | 100.00% | Pharmacy Response Rate | 32.43% |
| **Total Number of Suggestions** | | | | |
| Therapeutic | 36 | 97.30% | | |
| Cost-Saving | 1 | 2.70% | | |
| Total | **37** | 100% | | |
| **Total Number of Changes** | | | | |
| Therapeutic | 12 | 100.00% | **Impact Rate** | **32.43%** |
| Cost-Saving | 0 | 0.00% | | |
| Positive Impact Only | 0 | 0.00% | | |
| Total | **12** | 100% | | |

**FFS Patient - Focused Review**
**Month by Month Breakdown**
SFY22

| **Initial Review Date**<br>**Evaluation Date** | **Nov-20**<br>**Aug-21** | **Feb-21**<br>**Nov-21** | **May-21**<br>**Feb-22** | **Aug-21**<br>**May-22** | **Total** |
|---|---|---|---|---|---|
| **Profiles Reviewed** | 8 | 250 | 98 | 50 | **406** |
| **Patient Profiles Available for Evaluation** | 1 | 18 | 12 | 5 | **36** |
| **Total Number of Suggstions Made** | 1 | 18 | 13 | 5 | **37** |
| Therapeutic | 1 | 17 | 13 | 5 | **36** |
| Cost Saving | 0 | 1 | 0 | 0 | **1** |
| **Total Number of Changes Made** | 0 | 5 | 5 | 2 | **12** |
| Therapeutic | 0 | 5 | 5 | 2 | **12** |
| Cost Saving | 0 | 0 | 0 | 0 | **0** |
| Positive Impact Only | 0 | 0 | 0 | 0 | **0** |
| **Total Dollars Saved - Therapeutic Changes** | $0.00 | $585.60 | $14,960.40 | $152.97 | **$15,698.97** |
| **Total Dollars Saved - Cost Saving** | $0.00 | $0.00 | $0.00 | $0.00 | **$0.00** |
| **Total Dollars Saved on Medication*** | $0.00 | $585.60 | $14,960.40 | $152.97 | **$15,698.97** |
| **Total Dollars Saved per Profile Evaluated** | $0.00 | $32.53 | $1,246.70 | $30.59 | $436.08 |

*Savings reported are pre-rebate total dollars.

## FFS Medicaid DUR Impact Assessment
## Report Patient-Focused Reviews SFY22

| Initial Review Date<br>Evaluation Date | Nov-20<br>Aug-21 | Feb-21<br>Nov-21 | May-21<br>Feb-22 | Aug-21<br>May-22 | **Total** | |
|---|---|---|---|---|---|---|
| Profiles Reviewed | 8 | 250 | 98 | 50 | **406** | |
| Profiles Evaluated | 1 | 18 | 12 | 5 | **36** | |
| **Letters Sent** | 2 | 38 | 31 | 12 | **83** | 100.00% |
| Prescribers | 1 | 20 | 18 | 7 | 46 | 55.42% |
| Pharmacy | 1 | 18 | 13 | 5 | 37 | 44.58% |
| **Responses Received** | 1 | 9 | 7 | 5 | **22** | 100.00% |
| Prescribers | 0 | 3 | 4 | 3 | 10 | 45.45% |
| Pharmacy | 1 | 6 | 3 | 2 | 12 | 54.55% |
| Total Number of Templates Mentioned | 1 | 18 | 13 | 5 | **37** | 100.00% |
| Therapeutic | 1 | 17 | 13 | 5 | 36 | 97.30% |
| Cost-Saving | 0 | 1 | 0 | 0 | 1 | 2.70% |
| Total Number of Changes Made | 0 | 5 | 5 | 2 | **12** | 100.00% |
| Therapeutic | 0 | 5 | 5 | 2 | 12 | 100.00% |
| Cost-Saving | 0 | 0 | 0 | 0 | 0 | 0.00% |
| Positive Impact Only | 0 | 0 | 0 | 0 | 0 | 0.00% |
| **Total Dollars Saved - Therapeutic Changes** | $0.00 | $585.60 | $14,960.40 | $152.97 | **$15,698.97** | 100.00% |
| **Total Dollars Saved - Cost Saving Changes** | $0.00 | $0.00 | $0.00 | $0.00 | **$0.00** | 0.00% |
| **Total Dollars Saved on Medication*** | $0.00 | $585.60 | $14,960.40 | $152.97 | **$15,698.97** | 100.00% |
| **Total Dollars Saved Per Profile Evaluated** | $0.00 | $32.53 | $1,246.70 | $30.59 | **$436.08** | |

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

**Comment Type**
**FFS Patient Focused Reviews**
**SFY22**

| **Initial Review Date** | **Nov-20** | | **Feb-21** | | **May-21** | | **Aug-21** | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Evaluation Date** | **Aug-21** | | **Nov-21** | | **Feb-22** | | **May-22** | | **Total** | |
| **Template Classification** | **Suggestions** | **Changes** | **Suggestions** | **Changes** | **Suggestions** | **Changes** | **Suggestions** | **Changes** | **Total Suggestions** | **Total Changes** |
| Adverse Drug Reaction | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Drug-Disease Interaction | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Drug-Drug Interaction | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| High Cost Drug | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Innapropriate Billing | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| Missing Drug Therapy | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Not Optimal Dosage Form | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Not Optimal Dose | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 2 | 0 |
| Not Optimal Drug | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Not Optimal Duration | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Patient Overuse | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Patient Underuse | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 2 | 0 |
| Potential Generic Use | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Therapeutic Alternative | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Therapeutic Duplication | 1 | 0 | 12 | 5 | 13 | 5 | 5 | 2 | 31 | 12 |
| Unnecessary Drug Therapy | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| **Total** | **1** | **0** | **18** | **5** | **13** | **5** | **5** | **2** | **37** | **12** |

## FFS Patient Focused Reviews
## SFY22

| Template Classification | Total Suggestions | Total Changes | % of Total Suggestions | % of Total Changes | % of Suggestions Changed | % Dollars Saved |
|---|---|---|---|---|---|---|
| Adverse Drug Reaction | 0 | 0 | 0.00% | 0.00% | 0.00% | 0.00% |
| Drug-Disease Interaction | 0 | 0 | 0.00% | 0.00% | 0.00% | 0.00% |
| Drug-Drug Interaction | 0 | 0 | 0.00% | 0.00% | 0.00% | 0.00% |
| High Cost Drug | 0 | 0 | 0.00% | 0.00% | 0.00% | 0.00% |
| Inappropriate Billing | 1 | 0 | 2.70% | 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 | 2 | 0 | 5.41% | 0.00% | 0.00% | 0.00% |
| Not Optimal Drug | 0 | 0 | 0.00% | 0.00% | 0.00% | 0.00% |
| Not Optimal Duration | 0 | 0 | 0.00% | 0.00% | 0.00% | 0.00% |
| Patient Overuse | 0 | 0 | 0.00% | 0.00% | 0.00% | 0.00% |
| Patient Underuse | 2 | 0 | 5.41% | 0.00% | 0.00% | 0.00% |
| Potential Generic Use | 0 | 0 | 0.00% | 0.00% | 0.00% | 0.00% |
| Therapeutic Alternative | 0 | 0 | 0.00% | 0.00% | 0.00% | 0.00% |
| Therapeutic Duplication | 31 | 12 | 83.78% | 100.00% | 38.71% | 100.00% |
| Unnecessary Drug Therapy | 1 | 0 | 2.70% | 0.00% | 0.00% | 0.00% |
| **Total** | **37** | **12** | 100.00% | 100.00% | **32.43%** | 100.00% |

## FFS Savings By Template Class

SFY22

| Initial Review Date | Nov-20 | Feb-21 | May-21 | Aug-21 | |
|---|---|---|---|---|---|
| Evaluation Date | Aug-21 | Nov-21 | Feb-21 | May-22 | |
| | | | | | **Total** |
| **Template Classification** | | | | | |
| Adverse Drug Reaction | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| Drug-Disease Interaction | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| Drug-Drug Interaction | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| High Cost Drug | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| Inappropriate Billing | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| Missing Drug Therapy | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| Not Optimal Dosage Form | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| Not Optimal Dose | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| Not Optimal Drug | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| Not Optimal Duration | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| Patient Overuse | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| Patient Underuse* | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| Potential Generic Use | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| Therapeutic Alternative | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| Therapeutic Duplication | $0.00 | $585.60 | $14,960.40 | $152.97 | $15,698.97 |
| Unnecessary Drug Therapy | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| **Total** | **$0.00** | **$585.60** | **$14,960.40** | **$152.97** | **$15,698.97** |

*additional cost but positive impact assumed

# Appendix E
# Results Problem-Focused

# FFS Problem-Focused Studies
# Impact Rate
## SFY 2022

| Focus | Review Period | Evaluation Period | Patients Evaluated | Positive Impact | Impact Rate |
|---|---|---|---|---|---|
| Concurrent Gabapentin and Pregabalin | 12/01/2020 - 02/28/2021 | 12/01/2021 - 02/28/2022 | 0 | 0 | N/A |
| Duplicate Muscle Relaxants | 12/01/2020 - 02/28/2021 | 12/01/2021 - 02/28/2022 | 3 | 0 | 0.00% |
| Concurrent SSRI and SNRI | 12/01/2020 - 02/28/2021 | 12/01/2021 - 02/28/2022 | 2 | 1 | 50.00% |
| Concurrent Gabapentinoid and Opioid | 12/01/2020 - 02/28/2021 | 12/01/2021 - 02/28/2022 | 6 | 0 | 0.00% |
| Duplicate Anxiolytic Benzodiazepines | 02/01/2021 - 04/30/2021 | 02/01/2022 - 04/30/2022 | 4 | 0 | 0.00% |
| Duplicate Sedative/Hypnotic Benzodiazepines | 02/01/2021 - 04/30/2021 | 02/01/2022 - 04/30/2022 | 0 | 0 | N/A |
| Single Ingredient Buprenorphine | 03/01/2021 - 04/30/2021 | 03/01/2022 - 04/30/2022 | 0 | 0 | N/A |
| **TOTAL** | | | **15** | **1** | **6.67%** |

# FFS Problem-Focused Studies Savings
## SFY 2022

| Focus | Review Period | Evaluation Period | Patients Reviewed | Patients Selected | Cost Savings Calculated |
|---|---|---|---|---|---|
| Concurrent Gabapentin and Pregabalin | 12/01/2020 - 02/28/2021 | 12/01/2021 - 02/28/2022 | 0 | 0 | $0.00 |
| Duplicate Muscle Relaxants | 12/01/2020 - 02/28/2021 | 12/01/2021 - 02/28/2022 | 3 | 3 | $0.00 |
| Concurrent SSRI and SNRI | 12/01/2020 - 02/28/2021 | 12/01/2021 - 02/28/2022 | 2 | 2 | $168.84 |
| Concurrent Gabapentinoid and Opioid | 12/01/2020 - 02/28/2021 | 12/01/2021 - 02/28/2022 | 6 | 6 | $0.00 |
| Duplicate Anxiolytic Benzodiazepines | 02/01/2021 - 04/30/2021 | 02/01/2022 - 04/30/2022 | 4 | 4 | $0.00 |
| Duplicate Sedative/Hypnotic Benzodiazepines | 02/01/2021 - 04/30/2021 | 02/01/2022 - 04/30/2022 | 0 | 0 | $0.00 |
| Single Ingredient Buprenorphine | 03/01/2021 - 04/30/2021 | 03/01/2022 - 04/30/2022 | 0 | 0 | $0.00 |
| **TOTAL** | | | **15** | **15** | **$168.84 *** |

*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
# SFY22

**Concurrent Gabapentin and Pregabalin**

- Identify members with concurrent use of gabapentin and pregabalin.

**Duplicate Muscle Relaxants**

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

**Concurrent SSRI and SNRI**

- Identify members with concurrent use of an SSRI and SNRI.

**Concurrent Gabapentinoid and Opioid**

- Identify members with concurrent use of a gabapentinoid and opioid.

**Duplicate Anxiolytic Benzodiazepines**

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

**Duplicate Sedative/Hypnotic Benzodiazepines**

- Identify members with concurrent use of two or more chemically distinct sedative/hypnotic benzodiazepines.

**Single Ingredient Buprenorphine**

- Identify members using a single ingredient buprenorphine product where use of buprenorphine/naloxone would be appropriate.

# Appendix G
# Prior Authorization Recommendations

# Prior Authorization Criteria Review
# SFY22

During the fiscal year ending 2022, 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 |
|---|---|---|---|
| 08/04/2021 | • Initial Days' Supply Limit Override<br>• Mannitol Inhalation Powder (Bronchitol) | • Proton Pump Inhibitors<br>• Vesicular Monoamine Transporter (VMAT) 2 Inhibitors | • Valsartan/Sacubitril (Entresto) |
| 11/03/2021 | • Omalizumab (Xolair) Prefilled Syringe<br>• Vericiguat (Verquvo)<br>• Viloxazine (Qelbree)<br>• Select Non-Biologics for Ulcerative Colitis | • Topical Acne and Rosacea Products<br>• Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist, Oral | |
| 02/02/2022 | • Triheptanoin (Dojolvi)<br>• Baclofen Oral Solution | • Select Preventative Migraine Treatments<br>• Hepatitis C Treatments, Direct Acting Antivirals<br>• Janus Kinase Inhibitors<br>• Apremilast (Otezla)<br>• Biologicals for Arthritis | |
| 05/04/2022 | • Finerenone (Kerendia)<br>• Odevixibat (Bylvay)<br>• Pegcetacoplan (Empaveli) | • PCSK9 Inhibitors | |

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

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

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

August 5, 2021

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

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, August 4, 2021. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Proton Pump Inhibitors; Initial Days' Supply Limit Override; Mannitol Inhalation Powder (Bronchitol); Vesicular Monoamine Transporter (VMAT) 2 Inhibitors; and removal of PA criteria for Valsartan/Sacubitril (Entresto). In addition, the DUR Commission discussed ProDUR quantity limits for valsartan/sacubitril (Entresto); budesonide/formoterol (Symbicort); and mometasone/formoterol (Dulera). The following recommendations have been made by the DUR Commission:

Comments were received and reviewed from the medical/pharmacy associations in response to a May 11, 2021 letter that was sent to them detailing the proposed criteria for Proton Pump Inhibitors; Initial Days' Supply Limit Override; Mannitol Inhalation Powder (Bronchitol); Vesicular Monoamine Transporter (VMAT) 2 Inhibitors; removal of PA criteria for Valsartan/Sacubitril (Entresto); and the ProDUR quantity limits for valsartan/sacubitril (Entresto); budesonide/formoterol (Symbicort); and mometasone/formoterol (Dulera).

## Proton Pump Inhibitors

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

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

1. Barrett's esophagus (Please fax a copy of the scope results with the initial request)
2. Erosive esophagitis (Please fax a copy of the scope results with the initial request)
3. Hypersecretory conditions (Zollinger-Ellison syndrome, systemic mastocytosis, and multiple endocrine adenomas).

4. Recurrent peptic ulcer disease
5. Gastroesophageal reflux disease will be considered after documentation of a therapeutic trial and therapy failure with concomitant use of once daily PPI dosing and a bedtime dose of a histamine H2-receptor antagonist. Upon failure of the combination therapy, subsequent requests for PPIs exceeding one unit per day will be considered on a short term basis (up to 3 months). After the three month period, a retrial of the recommended once daily dosing will be required. A trial of the recommended once daily dosing will be required on an annual basis for those patients continuing to need doses beyond one unit per day.
6. Helicobacter pylori will be considered for up to 14 days of treatment with documentation of active infection.

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

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization (PA) is not required for preferred proton pump inhibitors (PPI) for doses within the established quantity limits of one unit per day.

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

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

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

**Initial Days' Supply Limit Override**

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

1. Diagnosis is provided; and
2. Medical rationale for exceeding the initial days' supply limit is provided; and
3. Requests for opioids exceeding the 7 day initial supply limit will be considered:

a. For patients with active cancer, patients experiencing acute sickle cell crises, end-of-life/palliative care, or on an individual case-by-case basis based on medical necessity documentation provided; and
b. Request must meet all other opioid requirements (quantity limits, morphine milligram equivalents (MME), and the preferred drug list (PDL). If requests do not comply with these requirements, separate, additional, prior authorization is required. Please reference and use the following prior authorization (PA) forms at www.iowamedicaidpdl.com where appropriate:
    i. Quantity Limit Override Form (exceeds established quantity limit)
    ii. High Dose Opioid PA Form (exceeds established MME limit)
    iii. Short-Acting Opioids PA Form (non-preferred short-acting opioids)
    iv. Long-Acting Opioids PA Form (non-preferred long-acting opioids); or

4. Requests for non-opioid drugs subject to the initial days' supply limit will be considered on an individual case-by-case basis, based on medical necessity documentation provided.

**Mannitol Inhalation Powder (Bronchitol)**

Newly Proposed Clinical Prior Authorization Criteria

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

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

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

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

**Vesicular Monoamine Transporter (VMAT) 2 Inhibitors**

Current Clinical Prior Authorization Criteria

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

Tardive Dyskinesia (Ingrezza or Austedo)

1. Patient meets the FDA approved age; and
2. Patient has a diagnosis of tardive dyskinesia (TD) based on the presence of ALL of the following:
    a. Involuntary athetoid or choreiform movements
    b. Documentation or claims history of current or prior chronic use (≥ 3 months or 1 month in patients ≥ 60 years old) of a dopamine receptor blocking agent

(e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.)
    c. Symptoms lasting longer than 4-8 weeks; and
3. Prescribed by or in consultation with a neurologist or psychiatrist; and
4. Prescriber has evaluated the patient's current medications for consideration of a dose reduction, withdrawal, or change of the dopamine receptor blocking agent causing the TD; and
5. Documentation of baseline AIMS (Abnormal Involuntary Movement Scale) Score (attach AIMS); and
6. For Ingrezza:
    a. Will not be used concurrently with MAO inhibitors (e.g., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine, etc.) or strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, phenobarbital, rifampin and related agents, St. John's wort, etc.); and
    b. Will not be used concurrently with other vesicular monoamine transporter 2 (VMAT2) inhibitors; and
    c. Is prescribed within the FDA approved dosing; or
7. For Austedo:
    a. Patient is not suicidal, or does not have untreated/inadequately treated depression;
    b. Patient does not have hepatic impairment;
    c. Will not be used concurrently with MAO inhibitors, reserpine, or other VMAT2 inhibitors; and
    d. Patients that are taking a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) or are poor CYP2D6 metabolizers, the daily dose does not exceed 36mg per day (18mg twice daily); and
    e. Is prescribed within the FDA approved dosing.

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

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

<u>Chorea associated with Huntington's disease</u> (Austedo or tetrabenazine)

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

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

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

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization (PA) is required for VMAT 2 inhibitors. Payment for non-preferred agents will be considered only for cases in which there is documentation of previous trial and therapy failure with a preferred agent (when applicable, based on diagnosis). Payment will be considered under the following conditions:
Tardive Dyskinesia (Ingrezza or Austedo)

1. Patient meets the FDA approved age; and
2. Patient has a diagnosis of tardive dyskinesia (TD) based on the presence of ALL of the following:
    a. Involuntary athetoid or choreiform movements
    b. Documentation or claims history of current or prior chronic use (≥ 3 months or 1 month in patients ≥ 60 years old) of a dopamine receptor blocking agent (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.)
    c. Symptoms lasting longer than 4-8 weeks; and
3. Prescribed by or in consultation with a neurologist or psychiatrist; and
4. Prescriber has evaluated the patient's current medications for consideration of a dose reduction, withdrawal, or change of the dopamine receptor blocking agent causing the TD; and
5. Documentation of baseline AIMS (Abnormal Involuntary Movement Scale) Score (attach AIMS); and
6. For Ingrezza:
    a. Will not be used concurrently with MAO inhibitors (e.g., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine, etc.) or strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, phenobarbital, rifampin and related agents, St. John's wort, etc.); and
    b. Will not be used concurrently with other vesicular monoamine transporter 2 (VMAT2) inhibitors; and
    c. Is prescribed within the FDA approved dosing; or
7. For Austedo:
    ~~a. Patient is not suicidal, or does not have untreated/inadequately treated depression;~~
    b. Patient does not have hepatic impairment;
    c. Will not be used concurrently with MAO inhibitors, reserpine, or other VMAT2 inhibitors; and
    d. Patients that are taking a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) or are poor CYP2D6 metabolizers, the daily dose does not exceed 36mg per day (18mg twice daily); and
    e. Is prescribed within the FDA approved dosing.

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

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

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

1. Patient meets the FDA approved age; and

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

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

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

**Valsartan/Sacubitril (Entresto)**

The DUR Commission reviewed information regarding a newly expanded indication for valsartan/sacubitril (Entesto), to reduce the risk of cardiovascular death and hospitalization for heart failure. The DUR Commission also reviewed The 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment. Guideline-directed therapy for heart failure with reduced ejection fraction (HFrEF) includes angiotensin-converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs) as initial treatment, with an ARNI being preferred regardless of prior treatment with an ACEI or ARB. After review of the new information and discussion, the DUR Commission determined removal of PA criteria would be in the best interest of Iowa Medicaid members given the proven efficacy of valsartan/sacubitril (Entresto) in the treatment of heart failure.

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

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

1. Patient is within the FDA labeled age for indication; and
2. Patient has a diagnosis of NYHA Functional Class II, III, or IV heart failure; and
    a. Patient has a left ventricular ejection fraction (LVEF) ≤40%; and
    b. Patient is currently tolerating treatment with an ACE inhibitor or angiotensin ll receptor blocker (ARB) at a therapeutic dose, where replacement with valsartan/sacubitril is recommended to further reduce morbidity and mortality; and
    c. Is to be administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB (list medications patient is currently taking for the treatment of heart failure); or

3. Pediatric patient has a diagnosis of symptomatic heart failure (NYHA/Ross Class ll to lV) due to systemic left ventricular systolic dysfunction with documentation of a left ventricular ejection fraction ≤40%; and
4. Will not be used in combination with an ACE inhibitor or ARB; and
5. Will not be used in combination with aliskiren (Tekturna) in diabetic patients; and
6. Patient does not have a history of angioedema associated with the use of ACE inhibitor or ARB therapy; and
7. Patient is not pregnant; and
8. Patient does not have severe hepatic impairment (Child Pugh Class C); and

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

**ProDUR Edit(s)**

The DUR Commission recommends implementing the following ProDUR quantity limits:

| **Drug Product** | **Proposed Quantity Limit per 30 Days** |
|---|---|
| Entresto 24 mg-26 mg | 60 tablets |
| Entresto 49 mg-51 mg | 60 tablets |
| Entresto 97 mg-103 mg | 60 tablets |
| Symbicort | 240 inhalations (2 inhalers) |
| Dulera | 240 inhalations (2 inhalers) |

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Proton Pump Inhibitors; Initial Days' Supply Limit Override; Mannitol Inhalation Powder (Bronchitol); Vesicular Monoamine Transporter (VMAT) 2 Inhibitors; removal of PA criteria for Valsartan/Sacubitril (Entresto); and ProDUR quantity limits for valsartan/sacubitril (Entresto); budesonide/formoterol (Symbicort); and mometasone/formoterol (Dulera).

Sincerely,

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

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

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

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

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

November 3, 2021

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

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, November 3, 2021. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Topical Acne and Rosacea Products; Omalizumab (Xolair); Vericiguat (Verquvo); Viloxazine (Qelbree); Non-Biologic Agents for Ulcerative Colitis; and Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist, Oral. In addition, the DUR Commission discussed ProDUR quantity limits for viloxazine (Qelbree). The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to an August 9, 2021 letter that was sent to them detailing the proposed criteria for Topical Acne and Rosacea Products; Omalizumab (Xolair); Vericiguat (Verquvo); Viloxazine (Qelbree); Non-Biologic Agents for Ulcerative Colitis; and Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist, Oral and ProDUR quantity limits for viloxazine (Qelbree).

## Topical Acne and Rosacea Products

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for topical acne agents (topical antibiotics and topical retinoids) and topical rosacea agents. Payment for topical acne and topical rosacea agents will be considered under the following conditions:

1. Documentation of diagnosis.
2. For the treatment of acne vulgaris, benzoyl peroxide is required for use with a topical antibiotic or topical retinoid.
3. Payment for non-preferred topical acne products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred topical agents of a different chemical entity from the requested topical class (topical antibiotic or topical retinoid).

4. Payment for non-preferred topical rosacea products will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred topical agent.
5. Requests for non-preferred combination products may only be considered after documented trials and therapy failures with two preferred combination products.
6. Requests for topical retinoid products for skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive approval with documentation of submitted diagnosis.
7. Trial and therapy failure with a preferred topical antipsoriatic agent will not be required for the preferred tazarotene (Tazorac) product for a psoriasis diagnosis.
8. Duplicate therapy with agents in the same topical class (topical antibiotic or topical retinoid) will not be considered.

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

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization (PA) is *not* required for *preferred* topical acne agents (topical antibiotics and topical retinoids) ~~or topical rosacea agents~~ *for members under 21 years of age*. ~~Payment~~ *PA is required* for *preferred topical acne agents for members 21 years or older,* non-*preferred* topical acne *agents* and *all* topical rosacea agents*. Payment* will be considered under the following conditions:

1. Documentation of diagnosis*; and*
2. For the treatment of acne vulgaris, benzoyl peroxide is required for use with a topical antibiotic or topical retinoid*; and*
3. Payment for non-preferred topical acne products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred topical agents of a different chemical entity from the requested topical class (topical antibiotic or topical retinoid)*; and*
4. Payment for non-preferred topical rosacea products will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred topical agent*; and*
5. Requests for non-preferred combination products may only be considered after documented trials and therapy failures with two preferred combination products~~.~~*; and*
6. Requests for topical retinoid products for skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive approval with documentation of submitted diagnosis*; and*
7. ~~Trial and therapy failure with a preferred topical antipsoriatic agent will not be required for the preferred tazarotene (Tazorac) product for a psoriasis diagnosis.~~
8. Duplicate therapy with agents in the same topical class (topical antibiotic or topical retinoid) will not be considered.

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

**Omalizumab (Xolair) Prefilled Syringe**

Previous Prior Authorization Criteria (prior to removal from PDL in October 2017)
Prior authorization is required for Xolair®. Payment for Xolair® will be authorized when the following criteria are met:

Moderate to Severe Persistent Asthma

1. Patient has a diagnosis of moderate to severe persistent asthma for at least one year; and
2. Patient is 6 years of age or older; and
3. 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
4. Pretreatment IgE level is within the following range:
    a. Adults and adolescent patients 12 years of age or older - 30 IU/mL to 700 IU/mL; or
    b. Pediatric patients 6 to less than 12 years of age - 30 IU/mL to 1300 IU/mL; and
5. Patient's weight is within the following range:
    a. Adults and adolescent patients 12 years of age or older - 30 kg to 150 kg; or
    b. Pediatric patients 6 to less than 12 years of age - 20 kg to 150kg; and
6. History of positive skin or RAST test to a perennial aeroallergen; and
7. Prescriber is an allergist, immunologist, or pulmonologist; and
8. Patient is currently using a high dose inhaled corticosteroid, long-acting beta-agonist, AND a leukotriene receptor antagonist, and is compliant with therapy and asthma symptoms are not adequately controlled after at least three (3) months of therapy; and
9. Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight.
10. Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of Xolair®.

If the criteria for coverage are met, the initial authorization will be given for 16 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to Xolair® therapy and for patients who do not continue concurrent use with a high dose corticosteroid, long-acting beta-agonist, and leukotriene receptor antagonist.

<u>Chronic Idiopathic Urticaria</u>

1. Patient has a diagnosis of moderate to severe chronic idiopathic urticaria; and
2. Patient is 12 years of age or older; and
3. 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
4. Patient has documentation of a trial and therapy failure with at least one preferred second-generation antihistamine, one of which must be cetirizine at a dose up to 20 mg per day; and
5. Patient has documentation of a trial and therapy failure with at least one preferred first-generation antihistamine; and
6. Patient has documentation of a trial and therapy failure with at least one preferred potent H1 receptor antagonist (hydroxyzine and/or doxepin); and
7. Patient has documentation of a trial and therapy failure with a preferred leukotriene receptor antagonist in combination with a first- or second-generation antihistamine.

If criteria for coverage are met, the initial authorization will be given for 12 weeks to assess the need for continued therapy.

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

Newly Proposed Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization *(PA)* is required for omalizumab *(*Xolair*) prefilled syringe*. *Requests for omalizumab (Xolair) lyophilized powder for reconstitution will not be considered through the pharmacy benefit.* Payment for omalizumab *(*Xolair*) prefilled syringe* will be *considered for FDA approved and compendia indications under the following conditions* ~~authorized when the following criteria are met~~:

1. *Patient meets the FDA approved age; and*
2. *Therapy will be initiated in a healthcare setting, under the guidance of a healthcare provider, where the patient can be closely observed for anaphylaxis and safety of therapy has been established after a minimum of 3 doses of omalizumab; and*
3. *The healthcare provider has determined self-administration with omalizumab is appropriate based on careful assessment of risk for anaphylaxis and mitigation strategies, as outlined in the label; and*
4. *Dose follows the FDA approved dosing for indication; and*
5. Prescriber is an allergist, *dermatologist,* immunologist, *otolaryngologist* or pulmonologist; and
6. Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of *omalizumab (*Xolair*); and*
7. *Prescriber and dispensing pharmacy will educate patient on proper storage and administration. Improperly stored medications will not be replaced.*

Moderate to Severe Persistent Asthma

1. Patient has a diagnosis of moderate to severe persistent asthma for at least one year; and
2. ~~Patient is 6 years of age or older; and~~
3. ~~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~~
4. Pretreatment IgE level is within the following range:
    a. Adults and adolescent patients 12 years of age or older - 30 IU/mL to 700 IU/mL; or
    b. Pediatric patients 6 to less than 12 years of age - 30 IU/mL to 1300 IU/mL; and
5. Patient's weight is within the following range:
    a. Adults and adolescent patients 12 years of age or older - 30 kg to 150 kg; or
    b. Pediatric patients 6 to less than 12 years of age - 20 kg to 150 kg; and
6. History of positive skin or RAST test to a perennial aeroallergen; and
7. ~~Prescriber is an allergist, immunologist, or pulmonologist; and~~
8. Patient is currently using a high dose inhaled corticosteroid, long-acting beta-agonist, AND a leukotriene receptor antagonist, and is compliant with therapy and asthma symptoms are not adequately controlled after at least three (3) months of therapy; and
9. Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight. *Note: according to the label, there is insufficient data to recommend a dose for certain pretreatment serum IgE levels and body weight. PA requests will be denied in these instances.*

~~10. Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of Xolair®.~~

If the criteria for coverage are met, the initial authorization will be given for 16 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to *omalizumab (*Xolair*)* therapy and for patients who do not continue concurrent use with a high dose corticosteroid, long-acting beta-agonist, and leukotriene receptor antagonist.

Chronic Idiopathic Urticaria

1. Patient has a diagnosis of moderate to severe chronic idiopathic urticaria; and
2. ~~Patient is 12 years of age or older; and~~
3. ~~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~~
4. Patient has documentation of a trial and therapy failure with at least one preferred second-generation antihistamine, one of which must be cetirizine at a dose up to 20 mg per day; and
5. Patient has documentation of a trial and therapy failure with at least one preferred first-generation antihistamine; and
6. Patient has documentation of a trial and therapy failure with at least one preferred potent H1 receptor antagonist (hydroxyzine and/or doxepin); and
7. Patient has documentation of a trial and therapy failure with a preferred leukotriene receptor antagonist in combination with a first- or second-generation antihistamine.

If criteria for coverage are met, the initial authorization will be given for 12 weeks to assess the need for continued therapy. *Requests for continuation of therapy will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy.*

*Nasal Polyps*

1. *Patient has a diagnosis of nasal polyps; and*
2. *Pretreatment IgE level is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 IU/mL to 1500 IU/mL; and*
3. *Patient's weight is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 kg to 150 kg; and*
4. *Patient has documentation of an adequate trial and inadequate response with at least two nasal corticosteroids at a maximally tolerated dose; and*
5. *Will be used concurrently with a nasal corticosteroid; and*
6. *Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight. Note: according to the label, there is insufficient data to recommend a dose for certain pretreatment serum IgE levels and body weight. PA requests will be denied in these instances.*

*If criteria for coverage are met, the initial authorization will be given for 24 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy and for patients who do not continue concurrent use with a nasal corticosteroid.*

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

**Vericiguat (Verquvo)**

Newly Proposed Clinical Prior Authorization Criteria

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

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

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

**Viloxazine (Qelbree)**

Newly Proposed Clinical Prior Authorization Criteria

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

1. Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV); and
2. Patient is between 6 and 17 years of age; and
3. Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more current environments (social, academic, or occupational) and
4. Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred amphetamine stimulant; and

5. Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred methylphenidate stimulant; and
6. Documentation of a previous trial and therapy failure at a therapeutic dose with atomoxetine; and
7. Is dosed based on FDA approved dosing, and dose does not exceed 400 mg per day; and
8. Documentation of a recent clinical visit that confirms improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD.

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

**Select Non-Biologics for Ulcerative Colitis**

Newly Proposed Clinical Prior Authorization
Prior authorization is required for select non-biologicals for ulcerative colitis (UC). Payment for non-preferred select non-biologics for UC may be considered only for cases in which there is documentation of a previous trial and therapy failure with the preferred agent(s). Payment will be considered under the following conditions:

1. Patient has a diagnosis of moderately to severely active ulcerative colitis (UC) and
2. Request adheres to all FDA approved labeling for indication, including age, dosing, and contraindications; and
3. A documented trial and inadequate response to two preferred conventional therapies (immunomodulators) including aminosalicylates and azathioprine/6-mercaptopurine; and
4. A documented trial and inadequate response with a preferred biological DMARD; and
5. Will not be taken concomitantly with immunomodulators or biologic therapies.

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

**Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist, Oral (Formerly Elagolix Products)**

Current Clinical Prior Authorization Criteria (Elagolix Products)
Prior authorization (PA) is required for elagolix containing drugs. Payment will be considered for patients when the following is met:

1. Pregnancy has been ruled out; and
2. Patient does not have osteoporosis; and
3. Patient does not have severe hepatic impairment; and
4. Patient is not taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g., cyclosporine and gemfibrozil); and
5. Requests for elagolix (Orilissa) will be considered under the following conditions:
    a. Patient has a diagnosis of moderate to severe pain associated with endometriosis; and
    b. Patient has documentation of a previous trial and therapy failure with at least one preferred oral NSAID and at least one preferred 3-month course of a continuous hormonal contraceptive taken concurrently; and

c. Patient has documentation of a previous trial and therapy failure with a preferred GnRH agonist.
d. Initial requests will be considered for 3 months. Additional requests will be considered upon documentation of improvement of symptoms.
e. Requests will be considered for a maximum of 24 months for the 150mg dose and six (6) months for the 200mg dose; or

6. Requests for elagolix, estradiol, and norethindrone acetate; elagolix (Oriahnn) will be considered under the following conditions:
    a. Patient is premenopausal; and
    b. Patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); and
    c. Patient has documentation of a previous trial and therapy failure with at least one preferred 3-month course of a continuous hormonal contraceptive; and
    d. Patient has documentation of a previous trial and therapy failure with tranexamic acid.
    e. Initial requests will be considered for 6 months. Additional requests will be considered upon documentation of improvement of symptoms.
    f. Requests will be considered for a maximum of 24 months treatment.

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

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

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

a. Patient is premenopausal; and
b. Patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); and
c. Patient has documentation of a previous trial and therapy failure with at least one preferred 3-month course of a continuous hormonal contraceptive; and
d. Patient has documentation of a previous trial and therapy failure with tranexamic acid.
e. Initial requests will be considered for 6 months. Additional requests will be considered upon documentation of improvement of symptoms.
f. Requests will be considered for a maximum of 24 months treatment.

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

**ProDUR Edit(s)**

The DUR Commission recommends implementing the following ProDUR quantity limits:

| **Drug Product** | **Proposed Quantity Limit per 30 Days** |
|---|---|
| Qelbree 100 mg | 30 capsules |
| Qelbree 150 mg | 60 capsules |
| Qelbree 200 mg | 60 capsules |

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Topical Acne and Rosacea Products; Omalizumab (Xolair); Vericiguat (Verquvo); Viloxazine (Qelbree); Non-Biologic Agents for Ulcerative Colitis; and Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist, Oral; and ProDUR quantity limits for viloxazine (Qelbree).

Sincerely,

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

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

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

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

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

February 2, 2022

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

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, February 2, 2022. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Select Preventative Migraine Treatments; Hepatitis C Treatments, Direct Acting Antivirals; Janus Kinase Inhibitors; Apremilast (Otezla); Biologicals for Arthritis; Triheptanoin (Dojolvi); and Baclofen Oral Solution (Ozobax). The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to November 8, 2021 letter that was sent to them detailing the proposed criteria for Select Preventative Migraine Treatments; Hepatitis C Treatments, Direct Acting Antivirals; Janus Kinase Inhibitors; Apremilast (Otezla); Biologicals for Arthritis; Triheptanoin (Dojolvi); and Baclofen Oral Solution (Ozobax).

**Select Preventative Migraine Treatments (formerly CGRP Inhibitors)**

Current Clinical Prior Authorization Criteria (CGRP Inhibitors)
Prior authorization (PA) is required for CGRP Inhibitors. Payment will be considered for a FDA approved or compendia indicated diagnosis under the following conditions:

1. Patient has one of the following diagnoses:
    a. Chronic Migraine, defined as:
        i. ≥ 15 headache days per month for a minimum of 3 months; and
        ii. ≥ 8 migraine headaches days per month for a minimum of 3 months; or
    b. Episodic Migraine, defined as:
        i. 4 to 14 migraine days per month for a minimum of 3 months; or
    c. Episodic Cluster Headache, defined as:

        i. Occurring with a frequency between one attack every other day and 8 attacks per day; and
        ii. With at least 2 cluster periods lasting 7 days to one year (when untreated) and separated by pain-free remission periods ≥3 months; and
        iii. Patient does not have chronic cluster headache (attacks occurring without a remission period, or with remissions lasting <3 months, for at least 1 year); and
2. Patient meets the FDA approved age; and
3. Patient has been evaluated for and does not have medication overuse headache; and
4. For Episodic and Chronic Migraine, patient has documentation of three trials and therapy failures, of at least 3 months per agent, at a maximally tolerated dose with a minimum of two different migraine prophylaxis drug classes (i.e., anticonvulsants [divalproex, valproate, topiramate], beta blockers [atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [amitriptyline, venlafaxine]); or
5. For Episodic Cluster Headache, patient has documentation of
    a. A previous trial and therapy failure at an adequate dose with glucocorticoids (prednisone 30mg per day or dexamethasone 8mg BID) started promptly at the start of a cluster period. Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamine, lidocaine) at least once daily for at least two days per week after the first full week of adequately dosed steroid therapy; and
    b. A previous trial and therapy failure at an adequate dose of verapamil for at least 3 weeks (total daily dose of 480mg to 960mg). Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamines, lidocaine) at least once daily for at least two days per week after three weeks of adequately dosed verapamil therapy.
6. The requested dose does not exceed the maximum FDA labeled dose for the submitted diagnosis; and
7. Lost, stolen, or destroyed medication replacement requests will not be authorized.

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

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

<u>Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted and/or stricken)</u>
Prior authorization (PA) is required for *select preventative migraine agents* ~~CGRP Inhibitors~~. *Payment for non-preferred select preventative migraine agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred, select preventative migraine agent.* Payment will be considered ~~for a FDA approved or compendia indicated diagnosis~~ under the following conditions:

1. Patient has one of the following diagnoses:
    a. Chronic Migraine, defined as:

i. ≥ 15 headache days per month for a minimum of 3 months; and
ii. ≥ 8 migraine headaches days per month for a minimum of 3 months; or

b. Episodic Migraine, defined as:
i. 4 to 14 migraine days per month for a minimum of 3 months; or

c. Episodic Cluster Headache, defined as:
i. Occurring with a frequency between one attack every other day and 8 attacks per day; and
ii. With at least 2 cluster periods lasting 7 days to one year (when untreated) and separated by pain-free remission periods ≥3 months; and
iii. Patient does not have chronic cluster headache (attacks occurring without a remission period, or with remissions lasting <3 months, for at least 1 year); and

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

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

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

## Hepatitis C Treatments, Direct Acting Antivirals

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for hepatitis C treatments. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

1. Patient has a diagnosis of chronic hepatitis C; and
2. Patient's age and/or weight is within the FDA labeled age and/or weight; and
3. Patient has had testing for hepatitis C virus (HCV) genotype; and
4. Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and
5. Patient has been tested for hepatitis B (HBV) prior to initiating treatment of HCV and individuals with active HBV infection are treated (either at same time as HCV therapy or before HCV therapy is started); and
6. Patient's prior treatment history is provided (treatment naïve or treatment experienced); and
7. If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and
8. Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test; and
9. HCV treatment is prescribed by or in consultation with a digestive disease, liver disease, or infectious disease provider practice; and
10. For patients on a regimen containing ribavirin, the following must be documented on the PA form:
    a. Patient is not a pregnant female or male with a pregnant female partner; and
    b. Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and
    c. Monthly pregnancy tests will be performed during treatment; and
11. Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the HCV medication.
12. Documentation is provided for patients who are ineligible to receive ribavirin.
13. Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved.
14. Patient does not have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.
15. If patient is recently eligible for Iowa Medicaid, and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on length of therapy for the particular treatment.
16. Lost or stolen medication replacement requests will not be authorized.
17. The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.

Only one treatment attempt will be allowed per calendar year, regardless of compliance.

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

Prior authorization (PA) is required for hepatitis C *direct-acting antivirals (DAA)* ~~treatments~~. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

1. Patient has a diagnosis of chronic hepatitis C; and
2. Patient's age and/or weight is within the FDA labeled age and/or weight; and
3. Patient has had testing for hepatitis C virus (HCV) genotype; and
4. Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and
5. Patient has been tested for hepatitis B (HBV) prior to initiating treatment of HCV and individuals with active HBV infection are treated (either at same time as HCV therapy or before HCV therapy is started); and
6. Patient's prior *HCV DAA* treatment history is provided (treatment naïve or treatment experienced); and
7. If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and
8. Patient has *been evaluated to determine the patient's readiness for HCV treatment with scales or assessment tools, such as the SAMHSA-HRSA Center for Integrated Health Solutions – Drug & Alcohol Screening Tools and the Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C); and*
9. *Patient has been educated on the importance of abstinence from IV drug use and alcohol use, the importance of compliance with HCV treatment, and how to prevent HCV transmission. If patient is currently using IV drugs and/or alcohol, recommend the patient participate in alcohol and/or substance abuse counseling* ~~abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test~~; and
10. HCV treatment is prescribed by or in consultation with a digestive disease, liver disease, or infectious disease provider practice; and
11. *FDA approved pediatric formulations of HCV DAAs and DAA approved for pediatric use will be considered for those under the age of 18 when used in accordance with current AASLD guidelines including for indication and age; and*
12. For patients on a regimen containing ribavirin, the following must be documented on the PA form:
    a. Patient is not a pregnant female or male with a pregnant female partner; and
    b. Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and
    c. Monthly pregnancy tests will be performed during treatment; and
13. Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the *DAA* ~~HCV medication~~*; and*~~.~~
14. Documentation is provided for patients who are ineligible to receive ribavirin*; and*~~.~~
15. Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved*; and*~~.~~
16. Patient does not have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.
17. If patient is recently eligible for Iowa Medicaid, and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on length of therapy for the particular treatment.
18. Lost or stolen medication replacement requests will not be authorized.
19. The 72-hour emergency supply rule does not apply to *DAAs* ~~oral hepatitis C antiviral agents~~.

~~Only one treatment attempt will be allowed per calendar year, regardless of compliance.~~

*Requests for treatment-experienced patients (with previous DAA) will be considered under*

*the following conditions:*

1. *Patient must meet all criteria for treatment approval above; and*
2. *Patients who previously achieved SVR that have HCV recurrence due to IV drug use must have documentation that the patient has completed or is participating in a recovery program, receiving alcohol or substance abuse counseling services, or seeing an addiction specialist as part of HCV treatment, and can be managed as an initial infection; and*
3. *The requested therapy is FDA approved as therapy for treatment-experienced patients and follows current AASLD guidelines; and*
4. *Patient has not been previously treated with and failed the requested DAA therapy; and*
5. *Documentation is provided patient has a documented presence of detectable HCV RNA at least 12 weeks after completing previous DAA treatment.*

**Janus Kinase Inhibitors**

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for Janus kinase (JAK) inhibitors. Payment will be considered for a 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 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.
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.
    c. Moderately to severely active ulcerative colitis; with

i. A documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and
ii. A documented trial and inadequate response with a preferred biological DMARD; and
iii. If requested dose is for tofacitinib 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit.

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

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

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

ii. A documented trial and inadequate response with a preferred *TNF inhibitor* ~~biological DMARD~~; and
*iii.* If requested dose is for tofacitinib 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit~~.~~*; OR*

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

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

**Apremilast (Otezla)**

Current Clinical Prior Authorization Criteria

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

1. Patient is 18 years of age or older; and
2. Patient has a diagnosis of active psoriatic arthritis (≥ 3 swollen joints and ≥ 3 tender joints); or
3. Patient has a diagnosis of moderate to severe plaque psoriasis; and
4. Patient does not have severe renal impairment (CrCl < 30 mL/min).

Psoriatic Arthritis

1. Patient has documentation of a trial and inadequate response to therapy with the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
2. Patient has documentation of trials and therapy failures with two preferred biological agents indicated for psoriatic arthritis.

Plaque Psoriasis

1. Patient has documentation of a trial and inadequate response to phototherapy, systemic retinoids, methotrexate, or cyclosporine; and
2. Patient has documentation of trials and therapy failures with two preferred biological agents indicated for plaque psoriasis.

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

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

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

1. *Request adheres to all FDA approved labeling for indication, including age, dosing, and contraindications* ~~Patient is 18 years of age or older~~; and
~~2. Patient does not have severe renal impairment (CrCl < 30 mL/min)*; and*~~
3. Patient has a diagnosis of active psoriatic arthritis (≥ 3 swollen joints and ≥ 3 tender joints); *with*
    a. ~~Patient has~~ ~~d~~*D*ocumentation of a trial and inadequate response to therapy with the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated)*.*~~; and~~

b. ~~Patient has documentation of trials and therapy failures with two preferred biological agents indicated for psoriatic arthritis.~~*;* or

4. Patient has a diagnosis of ~~moderate to severe~~ plaque psoriasis; *with* ~~and~~
   a. ~~Patient has d~~*Documentation* of a trial and inadequate response to phototherapy, systemic retinoids, methotrexate, or cyclosporine~~.~~*.*; ~~and~~
   b. ~~Patient has documentation of trials and therapy failures with two preferred biological agents indicated for plaque psoriasis.~~
5. *Patient has a diagnosis of Behçet disease; with*
   *a. Documentation of active oral ulcers associated with Behçet disease; and*
   *b. Documentation of a previous trial and inadequate response, at a therapeutic dose, to colchicine.*

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

**Biologicals for Arthritis**

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for biologicals used for arthritis. Request must adhere to all FDA approved labeling. Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. Payment will be considered under the following conditions:

1. Patient has been screened for hepatitis B and C. Patients with evidence of active hepatitis B infection (hepatitis surface antigen positive > 6 months) must have documentation they are receiving or have received effective antiviral treatment; and
2. Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and
3. Patient has a diagnosis of rheumatoid arthritis (RA):
   A trial and inadequate response to two preferred disease modifying antirheumatic drugs (DMARD) used concurrently. The combination must include methotrexate plus another preferred oral DMARD (hydroxycholoroquine, sulfasalazine, or leflunomide).

Upon an unsuccessful methotrexate trial in patients with established RA, the combination trial with a second DMARD may be overridden if there is evidence of severe disease documented by radiographic erosions; or

1. Patient has a diagnosis of moderate to severe psoriatic arthritis:
   A trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or
2. Patient has a diagnosis of moderate to severe juvenile idiopathic arthritis:
   A trial and inadequate response to intraarticular glucocorticoid injections and the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and

In addition to the above:

Requests for TNF Inhibitors:

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

Requests for Interleukins:

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

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

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

1. Patient has been screened for hepatitis B and C. Patients with evidence of active hepatitis B infection (hepatitis surface antigen positive > 6 months) must have documentation they are receiving or have received effective antiviral treatment; and
2. Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and
3. Patient has a diagnosis of rheumatoid arthritis (RA)~~:~~*; with*
    a. *Documentation of a* ~~A~~ trial and inadequate response*, at a maximally tolerated dose, with methotrexate* ~~to two preferred disease modifying antirheumatic drugs (DMARD) used concurrently. The combination must include methotrexate plus another preferred oral DMARD~~ (hydroxycholoroquine, sulfasalazine, or leflunomide *may be used if methotrexate is contraindicated*)~~.~~

~~Upon an unsuccessful methotrexate trial in patients with established RA, the combination trial with a second DMARD may be overridden if there is evidence of severe disease documented by radiographic erosions~~; or

4. Patient has a diagnosis of moderate to severe psoriatic arthritis~~:~~*; with*
    a. *Documentation of a* trial and inadequate response, *at a maximally tolerated dose* ~~to the preferred oral DMARD~~, *with* methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or
5. Patient has a diagnosis of moderate to severe juvenile idiopathic arthritis*; with*
    a. *Documentation of a* ~~A~~ trial and inadequate response to intraarticular glucocorticoid injections and ~~the preferred oral DMARD,~~ methotrexate *at a maximally tolerated dose* (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and

In addition to the above:
Requests for TNF Inhibitors:

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

Requests for Interleukins:

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

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

**Triheptanoin (Dojolvi)**

Newly Proposed Clinical Prior Authorization Criteria

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

1. Request adheres to all FDA approved labeling for indication, including age, dosing, contraindications, warnings and precautions; and
2. Patient has a diagnosis of long-chain fatty acid oxidation disorder (LC-FAOD), with supporting documentation of gene mutation(s) associated with LC-FAOD (LC-FAODs include: CPT I, CACT, CPT II, VLCAD, TFP, LCHAD); and
3. Patient will not be using another medium chain triglyceride (MCT) product; and
4. Documentation of patient's daily caloric intake (DCI) is provided; and
5. Patient's target daily dosage is provided as a percentage of the patient's total daily prescribed DCI, not to exceed 35%; and
6. Is prescribed by or in consultation with an endocrinologist, geneticist, or metabolic disease specialist.

If the criteria for coverage are met, initial requests will be approved for four months. Additional authorizations will be considered upon documentation of a positive clinical response to therapy.

**Baclofen Oral Solution (Ozobax)**

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for baclofen oral solution (Ozobax). Payment for a non-preferred agent will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions:

1. Patient has a diagnosis of spasticity resulting from multiple sclerosis (relief of flexor spasms and concomitant pain, clonus, and muscular rigidity) or spinal cord injuries/diseases; and
2. Patient meets the FDA approved age; and
3. Documentation of a patient-specific, clinically significant reason (beyond convenience) why the member cannot use baclofen oral tablets, even when tablets are crushed and sprinkled on soft food or liquid. Presence of a nasogastric (NG) tube/J-tube alone are not reasons for approval; and
4. Request does not exceed the maximum dosage of 80mg daily.

Based on current guidelines from the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA), the DUR Commission reviewed prior authorization criteria for the direct acting antivirals (DAAs) used in the treatment of chronic hepatitis C virus (HCV) and discussed changes to the abstinence requirement. Currently, the AASLD/IDSA HCV guidance recommends treatment for all patients with acute or chronic HCV infection, except those with a short life expectancy that cannot be remediated by HCV therapy, liver transplantation, or another directed therapy. Additionally, the DUR Commission reviewed other state Medicaid program HCV criteria regarding abstinence from illicit drug use and/or alcohol use. While some states continue to require abstinence, the trend has been for states to remove abstinence criteria or completely remove prior authorization criteria for the initial treatment of HCV. The DUR Commission voted in favor of removing the abstinence requirement, allowing treatment of all members with HCV, regardless of use of illicit drugs or alcohol, aligning the PA criteria with current guidelines. The DUR Commission felt it was important to add requirements to screen members for readiness of HCV treatment, confirming

they have received education on the importance of abstinence from IV drug use and alcohol use, compliance, and how to prevent HCV transmission.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Select Preventative Migraine Treatments; Hepatitis C Treatments, Direct Acting Antivirals; Janus Kinase Inhibitors; Apremilast (Otezla); Biologicals for Arthritis; Triheptanoin (Dojolvi); and Baclofen Oral Solution (Ozobax).

Sincerely,

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

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

# IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

1305 East Walnut – Des Moines, IA 50309 □ (515) 974-3131 □ Fax 1-866-626-0216

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

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


May 5, 2022

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

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, May 4, 2022. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for PCSK9 Inhibitors; Finerenone (Kerendia); Odevixibat (Bylvay); and Pegcetacoplan (Empaveli). The DUR Commission members also discussed ProDUR quantity limits for select medications. The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to a February 8, 2022 letter that was sent to them detailing the proposed criteria for PCSK9 Inhibitors; Finerenone (Kerendia); Odevixibat (Bylvay); and Pegcetacoplan (Empaveli); and ProDUR quantity limits.

## PCSK9 Inhibitors

Current Clinical Prior Authorization Criteria

Prior authorization is required for PCSK9 Inhibitors. Payment will be considered under the following conditions:

1. Patient is 18 years of age or older (or, for Homozygous Familial Hypercholesterolemia patient is 13 years of age or older); AND
2. Current use of a statin and documentation of adherence to prescribed lipid lowering medications for the previous 90 days is provided (further defined below, by diagnosis); AND
3. Is to be prescribed as an adjunct to a low fat diet; AND
4. A baseline and current lipid profile is provided. Baseline lipid profile is defined as a lipid profile obtained prior to pharmacologic therapy; AND

5. Documentation patient has been counseled on importance of abstinence from tobacco and, if a current smoker, be encouraged to enroll in a smoking cessation program; AND
6. Is prescribed by a lipidologist, cardiologist, or endocrinologist.
7. The 72-hour emergency supply rule does not apply to PCSK9 Inhibitors.
8. Prescriber and dispensing pharmacy will educate the patient on proper storage and administration. Improperly stored medications will not be replaced.
9. Lost or stolen medication replacement requests will not be authorized.
10. Goal is defined as a 50% reduction in untreated baseline LDL-C.
11. Is prescribed for one of the following diagnoses:

<u>Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH)</u>

1. Total cholesterol > 290mg/dL or LDL-C > 190mg/dL; AND
    a. Presence of tendon xanthomas; OR
    b. In first or second degree relative, one of the following:
        i. Documented tendon xanthomas; or
        ii. MI at age ≤60 years; or
        iii. Total cholesterol > 290mg/dL; OR
    c. Confirmation of diagnosis by gene or receptor testing (attach results); AND
2. Unable to reach goal LDL-C with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (including atorvastatin and rosuvastatin), PLUS ezetimibe (*Zetia*) 10mg daily, PLUS cholestyramine daily.

<u>Diagnosis of Clinical Atherosclerotic Cardiovascular Disease (ASCVD)</u>

1. History of MI, angina, coronary or other arterial revascularization, stroke, TIA, or PVD of atherosclerotic origin; AND
2. Unable to reach goal LDL-C with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (including atorvastatin and rosuvastatin), PLUS ezetimibe (*Zetia*) 10mg daily, PLUS cholestyramine daily.

<u>Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) – *Repatha* (evolocumab) only</u>

1. Total cholesterol and LDL-C > 600mg/dL and triglycerides within reference range; OR
2. Confirmation of diagnosis by gene or receptor testing (attach results); AND
3. Unable to reach goal LDL-C with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (including atorvastatin and rosuvastatin), PLUS ezetimibe (*Zetia*) 10mg daily, PLUS cholestyramine daily.

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

Initial and Renewal Authorizations

HeFH or ASCVD

- Initial
  - *Praluent* 75mg or *Repatha* 140mg every 2 weeks for 8 weeks (4 doses).
- Renewal
  - Lipid profile required at week 8, week 24, and every 6 months thereafter; and
  - Patient continues therapy with a maximally tolerated statin dose and remains at goal; and
  - Patient has continued compliance with a low fat diet; and

*Praluent*

  - If LDL-C at goal, continue therapy at 75mg every 2 weeks for 24 weeks.
  - If LDL-C not at goal, dose increase to 150mg every 2 weeks for 8 weeks (4 doses) and repeat LDL-C in 8 weeks.
    - If repeat LDL-C not at goal, discontinue *Praluent*.
    - If repeat LDL-C at goal, continue therapy at 150mg every 2 weeks for 24 weeks; or

*Repatha*

  - If LDL-C at goal, continue therapy at 140mg every 2 weeks for 24 weeks.
  - If LDL-C not at goal, discontinue *Repatha*.

HoFH (*Repatha* only)

- Initial
  - *Repatha* 420mg (3x140mg autoinjectors) every month for 3 months.
- Renewal
  - Lipid profile required after 3 months (third dose) and every 6 months thereafter; and
  - Continued therapy with a maximally tolerated statin dose.
    - If LDL-C at goal, continue therapy at 420mg every month for six months.
    - If LDL-C not at goal, discontinue *Repatha;* and
  - Patient has continued compliance with a low fat diet.

Quantity Limits

*Praluent/Repatha* for HeFH or ASCVD

- A quantity limit of one syringe/pen/autoinjector per fill will apply (requires refill every 14 days).

*Repatha* for HoFH only

- A quantity limit of one three-pack per month

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

Prior authorization is required for PCSK9 Inhibitors. *Payment for a non-preferred PCSK9 Inhibitor will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent.* Payment will be considered under the following conditions:

1. Patient *meets the FDA approved age for indication* ~~is 18 years of age or older (or, for Homozygous Familial Hypercholesterolemia patient is 13 years of age or older)~~; AND
2. *Dosing follows the FDA approved dose for the submitted diagnosis; AND*
3. Current use of a statin and documentation of adherence to prescribed lipid lowering medications for the previous 90 days is provided (further defined below, by diagnosis); AND
4. Is to be prescribed as an adjunct to a low-fat diet; AND
5. A baseline and current lipid profile is provided. Baseline lipid profile is defined as a lipid profile obtained prior to pharmacologic therapy; AND
6. Documentation patient has been counseled on importance of abstinence from tobacco and, if a current smoker, be encouraged to enroll in a smoking cessation program.~~; AND~~
7. ~~Is prescribed by a lipidologist, cardiologist, or endocrinologist.~~
8. The 72-hour emergency supply rule does not apply to PCSK9 Inhibitors.
9. Prescriber and dispensing pharmacy will educate the patient on proper storage and administration. Improperly stored medications will not be replaced.
10. Lost or stolen medication replacement requests will not be authorized.
11. Goal is defined as a 50% reduction in untreated baseline LDL-C.
12. Is prescribed for one of the following diagnoses:

<u>Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH)</u>

1. Total cholesterol > 290mg/dL or LDL-C > 190mg/dL; AND
    a. Presence of tendon xanthomas; OR
    b. In first or second degree relative, one of the following:
        i. Documented tendon xanthomas; or
        ii. MI at age ≤60 years; or
        iii. Total cholesterol > 290mg/dL; OR
    c. Confirmation of diagnosis by gene or receptor testing (attach results); AND
2. Unable to reach goal LDL-C with a minimum of *one* ~~two separate, chemically distinct~~ *high-intensity* statin ~~trials~~ *(atorvastatin 40-80 mg or rosuvastatin 20-40 mg)* used in combination with ~~other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (including atorvastatin and rosuvastatin), PLUS~~ ezetimibe ~~(*Zetia*)~~ 10mg daily~~, PLUS cholestyramine daily~~. *If patient is unable to tolerate high-intensity statin therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.*

<u>Diagnosis of Clinical Atherosclerotic Cardiovascular Disease (ASCVD)</u>

1. History of MI, angina, coronary or other arterial revascularization, stroke, TIA, or PVD of atherosclerotic origin; AND
2. Unable to reach goal LDL-C with a minimum of *one* ~~two separate, chemically distinct~~ *high-intensity* statin ~~trials~~ *(atorvastatin 40-80 mg or rosuvastatin 20-40 mg)* used in combination with ~~other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (including atorvastatin and rosuvastatin),~~

~~PLUS~~ ezetimibe (~~*Zetia*~~) 10mg daily~~, PLUS cholestyramine daily~~. *If patient is unable to tolerate high-intensity statin therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.*

*Diagnosis of Primary Hyperlipidemia (not associated with ASCVD or HeFH)*

1. *Baseline LDL-C ≥ 190 mg/dL; and*
2. *Unable to reach goal LDL-C < 100mg/dL while on high-intensity statin therapy (atorvastatin 40-80 mg or rosuvastatin 20-40 mg) used in combination with ezetimibe 10 mg daily. If patient is unable to tolerate high-intensity statin therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.*

Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) ~~– *Repatha* (evolocumab) only~~

1. Total cholesterol and LDL-C > 600mg/dL and triglycerides within reference range; OR
2. Confirmation of diagnosis by gene or receptor testing (attach results); AND
3. Unable to reach goal LDL-C with a minimum of *one* ~~two separate, chemically distinct~~ *high-intensity* statin ~~trials~~ *(atorvastatin 40-80 mg or rosuvastatin 20-40 mg)* used in combination with ~~other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (including atorvastatin and rosuvastatin), PLUS~~ ezetimibe (~~*Zetia*~~) 10mg daily~~, PLUS cholestyramine daily~~. *If patient is unable to tolerate high-intensity statin therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.*

The required trials ~~(excluding the statin trial)~~ may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

*Initial requests will be approved for 6 months. Additional requests will be considered under the following conditions:*

1. *Documentation of positive clinical response to PCSK9 Inhibitor therapy (current LDL-C lab provided); and*
2. *Patient continues therapy with a maximally tolerated statin; and*
3. *Patient has continued compliance with a low-fat diet.*

~~Initial and Renewal Authorizations~~

~~HeFH or ASCVD~~

- ~~Initial~~
  - ~~*Praluent* 75mg or *Repatha* 140mg every 2 weeks for 8 weeks (4 doses).~~
- ~~Renewal~~

- Lipid profile required at week 8, week 24, and every 6 months thereafter; and
- Patient continues therapy with a maximally tolerated statin dose and remains at goal; and
- Patient has continued compliance with a low fat diet; and

*Praluent*

- If LDL-C at goal *at initial dose*, continue therapy at 75mg every 2 weeks for 24 weeks.
- If LDL-C not at goal, dose increase to *a maximum of 300 mg once every 4 weeks* 150mg every 2 weeks for 8 weeks (4 doses) and repeat LDL-C in 8 weeks.
  - If repeat LDL-C not at goal, discontinue *Praluent*.
  - If repeat LDL-C at goal, continue therapy at 150mg every 2 weeks for 24 weeks; or

*Repatha*

- If LDL-C at goal, continue therapy at 140mg every 2 weeks for 24 weeks.
- If LDL-C not at goal, discontinue *Repatha*.

HoFH (*Repatha* only)

- Initial
  - *Repatha* 420mg (3x140mg autoinjectors) every month for 3 months.
- Renewal
  - Lipid profile required after 3 months (third dose) and every 6 months thereafter; and
  - Continued therapy with a maximally tolerated statin dose.
    - If LDL-C at goal, continue therapy at 420mg every month for six months.
    - If LDL-C not at goal, discontinue *Repatha;* and
  - Patient has continued compliance with a low fat diet.

Praluent/Repatha for HeFH or ASCVD

- A quantity limit of one syringe/pen/autoinjector per fill will apply (requires refill every 14 days).

Repatha for HoFH only

- A quantity limit of one three-pack per month

**Finerenone (Kerendia)**

Newly Proposed Clinical Prior Authorization Criteria

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

1. Request adheres to all FDA approved labeling, including age, dosing, contraindications, warnings and precautions, and drug interactions; and
2. Patient has a diagnosis of chronic kidney disease (CKD) associated with Type 2 Diabetes (T2D); and
3. Patient is currently receiving a maximally tolerated dose of an angiotensin converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB); and

4. Patient is currently receiving a maximally tolerated dose of a sodium-glucose co-transporter 2 (SGLT2) inhibitor indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease [i.e., dapagliflozin (Farxiga)]; and
5. Patient has the following baseline tests prior to initiation of treatment with finerenone:
    a. Serum potassium is ≤ 5.0 mEq/L; and
    b. Estimated glomerular filtration rate (eGFR) is ≥ 25 mL/min/1.73m$^2$; and
    c. Urine albumin to creatinine ration (UACR) is ≥ 30 mg/g.

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

Initial authorizations will be approved for six months. Additional PAs will be considered with the following documentation:

1. Patient's serum potassium is < 5.5 mEq/L; and
2. Patient's eGFR is ≥ 25 mL/min/1.73m$^2$; and
3. Patient remains on a maximally tolerated dose of an ACEi or ARB; and
4. Patient remains on a maximally tolerated dose of an SGLT2 inhibitor.

**Odevixibat (Bylvay)**

Newly Proposed Clinical Prior Authorization Criteria

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

1. Request adheres to all FDA approved labeling including age, dosing, contraindications, warnings and precautions, and drug interactions; and
2. Patient has a diagnosis of genetically confirmed progressive familial intrahepatic cholestasis (PFIC) type 1 or type 2; and
3. Genetic testing does not indicate PFIC type 2 with ABCB 11 variants encoding for nonfunction or absence of bile salt export pump protein (BSEP-3); and
4. Patient has moderate to severe pruritus associated with PFIC; and
5. Patient's current weight in kg is provided; and
6. Is prescribed by or in consultation with a hepatologist or gastroenterologist.

Initial authorizations will be approved for 3 months for initial treatment or after a dose increase. Additional authorizations will be considered when the following criteria are met:

1. Patient's current weight in kg is provided; and
2. Documentation is provided the patient has responded to therapy and pruritis has improved. If there is no improvement in pruritus after 3 months of treatment with the maximum 120 mcg/kg/day dose, further approval of odevixibat will not be granted.

**Pegcetacoplan (Empaveli)**

Newly Proposed Clinical Prior Authorization Criteria

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

1. Request adheres to all FDA approved labeling including age, dosing, contraindications, and warnings and precautions; and
2. Patient has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH); and

3. Flow cytometry shows detectable glycosylphosphatidylinositol (GPI)-deficient hematopoietic clones or ≥ 10% PNH cells; and
4. History of at least one red blood cell transfusion in the previous 12 months; and
5. Documentation of hemoglobin < 10.5 g/dL; and
6. Is not prescribed concurrently with eculizumab (Solaris) or ravulizumab (Ultomiris), unless the patient is in a 4 week period of cross-titration between eculizumab (Soliris) and pegcetacoplan (Empaveli); and
7. Is prescribed by or in consultation with a hematologist; and
8. Medication will be administered in the member's home; and
9. Member or member's care giver has been properly trained in subcutaneous infusion and prescriber has determined home administration is appropriate.

Initial authorizations will be approved for 4 weeks if within cross-titration period with eculizumab (Soliris) to verify eculizumab has been discontinued, or for 6 months otherwise. Additional authorizations will be considered when the following criteria are met:

1. Documentation of a positive clinical response to therapy (e.g., increased or stabilization of hemoglobin levels or reduction in transfusions); and
2. Is not prescribed concurrently with eculizumab (Solaris) or ravulizumab (Ultomiris).

**Proposed ProDUR Quantity Limits**

| Drug | Quantity Limit per 30 Days |
|---|---|
| Praluent 75 mg/mL | 2 mL |
| Praluent 150 mg/mL | 2 mL |
| Repatha 140 mg/mL syringe/autoinjector | 3 mL |
| Repatha 420 mg/3.5 mL Pushtronex system | 3.5 mL |
| Dilantin 100 mg capsule (phenytoin) | 180 |
| Dilantin 125 mg/5mL Suspension (phenytoin) | 750 mL |
| Dilantin 30 mg capsule (phenytoin) | 180 |
| Dilantin 50 mg Chewable Infatab (phenytoin) | 180 |
| Phenytek 200 mg capsule (phenytoin) | 90 |
| Phenytek 300 mg capsule (phenytoin) | 60 |
| Zarontin 250 mg capsule (ethosuximide) | 180 |
| Zarontin 250 mg/5mL syrup (ethosuximide) | 900 mL |
| Cleontin 300 mg capsule (methsuximide) | 120 |
| Tranxene-T 3.75 mg tablet (clorazepate) | 180 |
| Tranxene-T 7.5 mg tablet (clorazepate) | 180 |
| Tranxene-T 15 mg tablet (clorazepate) | 180 |
| Briviact 10 mg tablet (brivaracetam) | 60 |
| Briviact 25 mg tablet (brivaracetam) | 60 |
| Briviact 50 mg tablet (brivaracetam) | 60 |
| Briviact 75 mg tablet (brivaracetam) | 60 |
| Briviact 100 mg tablet (brivaracetam) | 60 |
| Briviact 10 mg/mL solution (brivaracetam) | 600 mL |

| | |
|---|---|
| Carbatrol ER 100 mg capsule (carbamazepine ER) | 120 |
| Carbatrol ER 200 mg capsule (carbamazepine ER) | 240 |
| Carbatrol ER 300 mg capsule (carbamazepine ER) | 150 |
| Epitol 200 mg tablet (carbamazepine) | 240 |
| Equetro 100 mg capsule (carbamazepine ER) | 120 |
| Equetro 200 mg capsule (carbamazepine ER) | 240 |
| Equetro 300 mg capsule (carbamazepine ER) | 150 |
| Tegretol 100 mg chewable tablet (carbamazepine) | 240 |
| Tegretol 200 mg tablet (carbamazepine) | 240 |
| Tegretol 100 mg/5 mL suspension (carbamazepine) | 2400 mL |
| Tegretol XR 100 mg tablet (carbamazepine) | 60 |
| Tegretol XR 200 mg tablet (carbamazepine) | 60 |
| Tegretol XR 400 mg tablet (carbamazepine) | 120 |
| Xcopri 50 mg tablet (cenobamate) | 30 |
| Xcopri 100 mg tablet (cenobamate) | 30 |
| Xcopri 150 mg tablet (cenobamate) | 60 |
| Xcopri 200 mg tablet (cenobamate) | 60 |
| Aptiom 200 mg tablet (eslicarbazepine) | 30 |
| Aptiom 400 mg tablet (eslicarbazepine) | 30 |
| Aptiom 600 mg tablet (eslicarbazepine) | 60 |
| Aptiom 800 mg tablet (eslicarbazepine) | 60 |
| Felbatol 400 mg tablet (felbamate) | 180 |
| Felbatol 600 mg tablet (felbamate) | 180 |
| Felbatol 600 mg/5 mL suspension (felbamate) | 900 mL |
| Lamictal 5 mg chewable tablet (lamotrigine) | 240 |
| Lamictal 25 mg chewable tablet (lamotrigine) | 120 |
| Lamictal 25 mg tablet & ODT (lamotrigine) | 60 |
| Lamictal 50 mg ODT (lamotrigine) | 60 |
| Lamictal 100 mg tablet & ODT (lamotrigine) | 60 |
| Lamictal 150 mg tablet (lamotrigine) | 30 |
| Lamictal 200 mg tablet & ODT (lamotrigine) | 60 |
| Lamictal XR 25 mg tablet (lamotrigine) | 60 |
| Lamictal XR 50 mg tablet (lamotrigine) | 60 |
| Lamictal XR 100 mg tablet (lamotrigine) | 60 |
| Lamictal XR 200 mg tablet (lamotrigine) | 60 |
| Lamictal XR 250 mg tablet (lamotrigine) | 60 |
| Lamictal XR 300 mg tablet (lamotrigine) | 60 |
| Keppra 250 mg tablet (levetiracetam) | 60 |
| Keppra 500 mg tablet (levetiracetam) | 60 |
| Keppra 750 mg tablet (levetiracetam) | 60 |
| Keppra 1000 mg tablet (levetiracetam) | 90 |
| Keppra Oral Soln 100 mg/mL (levetiracetam) | 900 mL |
| Keppra XR 500 mg tablet (levetiracetam) | 180 |
| Keppra XR 750 mg tablet (levetiracetam) | 120 |
| Spritam 250 mg tablet disintegrating soluble (levetiracetam) | 60 |

| | |
|---|---|
| Spritam 500 mg tablet disintegrating soluble (levetiracetam) | 60 |
| Spritam 750 mg tablet disintegrating soluble (levetiracetam) | 60 |
| Spritam 1000 mg tablet disintegrating soluble (levetiracetam) | 90 |
| Trilepta 150 mg tablet (oxcarbazepine) | 120 |
| Trilepta 300 mg tablet (oxcarbazepine) | 120 |
| Trilepta 600 mg tablet (oxcarbazepine) | 120 |
| Trilepta 300 mg/mL suspension (oxcarbazepine) | 1200 mL |
| Oxtellar XR 150 mg tablet (oxcarbazepine) | 90 |
| Oxtellar XR 300 mg tablet (oxcarbazepine) | 90 |
| Oxtellar XR 600 mg tablet (oxcarbazepine) | 120 |
| Fycompa 2 mg tablet (perampanel) | 30 |
| Fycompa 4 mg tablet (perampanel) | 30 |
| Fycompa 6 mg tablet (perampanel) | 30 |
| Fycompa 8 mg tablet (perampanel) | 30 |
| Fycompa 10 mg tablet (perampanel) | 30 |
| Fycompa 12 mg tablet (perampanel) | 30 |
| Fycompa 0.5 mg/mL suspension (perampanel) | 720 mL |
| Mysoline 50 mg tablet (primidone) | 240 |
| Mysoline 250 mg tablet (primidone) | 240 |
| Banzel 200 mg tablet (rufinamide) | 120 |
| Banzel 400 mg tablet (rufinamide) | 240 |
| Banzel 40 mg/mL suspension (rufinamide) | 2400 mL |
| Diacomit 250 mg capsule & packet (stiripentol) | 90 |
| Diacomit 500 mg capsule & packet (stiripentol) | 180 |
| Gabitril 2 mg tablet (tiagabine) | 120 |
| Gabitril 4 mg tablet (tiagabine) | 120 |
| Gabitril 12 mg tablet (tiagabine) | 120 |
| Gabitril 16 mg tablet (tiagabine) | 90 |
| Topamax 200 mg tablet (topiramate) | 60 |
| Topamax 15 mg sprinkle capsule (topiramate) | 180 |
| Topamax 25 mg sprinkle capsule (topiramate) | 180 |
| Qudexy XR  25 mg sprinkle capsule (topiramate) | 30 |
| Qudexy XR  50 mg sprinkle capsule (topiramate) | 30 |
| Qudexy XR  100 mg sprinkle capsule (topiramate) | 30 |
| Qudexy XR 150 mg sprinkle capsule (topiramate) | 60 |
| Qudexy XR  200 mg sprinkle capsule (topiramate) | 60 |
| Trokendi XR 25 mg capsule (topiramate) | 30 |
| Trokendi XR 50 mg capsule (topiramate) | 30 |
| Trokendi XR 100 mg capsule (topiramate) | 90 |
| Trokendi XR 200 mg capsule (topiramate) | 60 |
| Eprontia 25 mg/mL oral solution (topiramate) | 460 mL |
| Sabril 500 mg packet (vigabatrin) | 180 |
| Sabril 500 mg tablet (vigabatrin) | 180 |
| Vigadrone 500 mg packet (vigabatrin) | 180 |

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for PCSK9 Inhibitors; Finerenone (Kerendia); Odevixibat (Bylvay); and Pegcetacoplan (Empaveli); and ProDUR quantity limits.

Sincerely,

Pamela Smith R.Ph.

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

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

# Appendix H
# Prospective DUR Recommendations

**Prospective DUR**
**SFY22**

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

## Quantity Limits

| Drug Product | Quantity Limit per 30 Days |
|---|---|
| Entresto 24 mg-26 mg tablet | 60 |
| Entresto 49 mg-51 mg tablet | 60 |
| Entresto 97 mg-103 mg tablet | 60 |
| Symbicort | 240 inhalations (2 inhalers) |
| Dulera | 240 inhalations (2 inhalers) |
| Qelbree 100 mg capsule | 30 |
| Qelbree 150 mg capsule | 60 |
| Qelbree 200 mg capsule | 60 |
| Praluent 75 mg/mL | 2 mL |
| Praluent 150 mg/mL | 2 mL |
| Repatha 140 mg/mL syringe/autoinjector | 3 mL |
| Repatha 420 mg/3.5 mL Pushtronex system | 3.5 mL |
| Dilantin 100 mg capsule (phenytoin) | 180 |
| Dilantin 125 mg/5mL Suspension (phenytoin) | 750 mL |
| Dilantin 30 mg capsule (phenytoin) | 180 |
| Dilantin 50 mg Chewable Infatab (phenytoin) | 180 |
| Phenytek 200 mg capsule (phenytoin) | 90 |
| Phenytek 300 mg capsule (phenytoin) | 60 |
| Zarontin 250 mg capsule (ethosuximide) | 180 |
| Zarontin 250 mg/5mL syrup (ethosuximide) | 900 mL |
| Cleontin 300 mg capsule (methsuximide) | 120 |
| Tranxene-T 3.75 mg tablet (clorazepate) | 180 |
| Tranxene-T 7.5 mg tablet (clorazepate) | 180 |
| Tranxene-T 15 mg tablet (clorazepate) | 180 |
| Briviact 10 mg tablet (brivaracetam) | 60 |
| Briviact 25 mg tablet (brivaracetam) | 60 |
| Briviact 50 mg tablet (brivaracetam) | 60 |
| Briviact 75 mg tablet (brivaracetam) | 60 |
| Briviact 100 mg tablet (brivaracetam) | 60 |
| Briviact 10 mg/mL solution (brivaracetam) | 600 mL |
| Carbatrol ER 100 mg capsule (carbamazepine ER) | 120 |
| Carbatrol ER 200 mg capsule (carbamazepine ER) | 240 |

| | |
|---|---|
| Carbatrol ER 300 mg capsule (carbamazepine ER) | 150 |
| Epitol 200 mg tablet (carbamazepine) | 240 |
| Equetro 100 mg capsule (carbamazepine ER) | 120 |
| Equetro 200 mg capsule (carbamazepine ER) | 240 |
| Equetro 300 mg capsule (carbamazepine ER) | 150 |
| Tegretol 100 mg chewable tablet (carbamazepine) | 240 |
| Tegretol 200 mg tablet (carbamazepine) | 240 |
| Tegretol 100 mg/5 mL suspension (carbamazepine) | 2400 mL |
| Tegretol XR 100 mg tablet (carbamazepine) | 60 |
| Tegretol XR 200 mg tablet (carbamazepine) | 60 |
| Tegretol XR 400 mg tablet (carbamazepine) | 120 |
| Xcopri 50 mg tablet (cenobamate) | 30 |
| Xcopri 100 mg tablet (cenobamate) | 30 |
| Xcopri 150 mg tablet (cenobamate) | 60 |
| Xcopri 200 mg tablet (cenobamate) | 60 |
| Aptiom 200 mg tablet (eslicarbazepine) | 30 |
| Aptiom 400 mg tablet (eslicarbazepine) | 30 |
| Aptiom 600 mg tablet (eslicarbazepine) | 60 |
| Aptiom 800 mg tablet (eslicarbazepine) | 60 |
| Felbatol 400 mg tablet (felbamate) | 180 |
| Felbatol 600 mg tablet (felbamate) | 180 |
| Felbatol 600 mg/5 mL suspension (felbamate) | 900 mL |
| Lamictal 5 mg chewable tablet (lamotrigine) | 240 |
| Lamictal 25 mg chewable tablet (lamotrigine) | 120 |
| Lamictal 25 mg tablet & ODT (lamotrigine) | 60 |
| Lamictal 50 mg ODT (lamotrigine) | 60 |
| Lamictal 100 mg tablet & ODT (lamotrigine) | 60 |
| Lamictal 150 mg tablet (lamotrigine) | 30 |
| Lamictal 200 mg tablet & ODT (lamotrigine) | 60 |
| Lamictal XR 25 mg tablet (lamotrigine) | 60 |
| Lamictal XR 50 mg tablet (lamotrigine) | 60 |
| Lamictal XR 100 mg tablet (lamotrigine) | 60 |
| Lamictal XR 200 mg tablet (lamotrigine) | 60 |
| Lamictal XR 250 mg tablet (lamotrigine) | 60 |
| Lamictal XR 300 mg tablet (lamotrigine) | 60 |
| Keppra 250 mg tablet (levetiracetam) | 60 |
| Keppra 500 mg tablet (levetiracetam) | 60 |
| Keppra 750 mg tablet (levetiracetam) | 60 |
| Keppra 1000 mg tablet (levetiracetam) | 90 |
| Keppra Oral Soln 100 mg/mL (levetiracetam) | 900 mL |
| Keppra XR 500 mg tablet (levetiracetam) | 180 |

| | |
|---|---|
| Keppra XR 750 mg tablet (levetiracetam) | 120 |
| Spritam 250 mg tablet disintegrating soluble (levetiracetam) | 60 |
| Spritam 500 mg tablet disintegrating soluble (levetiracetam) | 60 |
| Spritam 750 mg tablet disintegrating soluble (levetiracetam) | 60 |
| Spritam 1000 mg tablet disintegrating soluble (levetiracetam) | 90 |
| Trilepta 150 mg tablet (oxcarbazepine) | 120 |
| Trilepta 300 mg tablet (oxcarbazepine) | 120 |
| Trilepta 600 mg tablet (oxcarbazepine) | 120 |
| Trilepta 300 mg/mL suspension (oxcarbazepine) | 1200 mL |
| Oxtellar XR 150 mg tablet (oxcarbazepine) | 90 |
| Oxtellar XR 300 mg tablet (oxcarbazepine) | 90 |
| Oxtellar XR 600 mg tablet (oxcarbazepine) | 120 |
| Fycompa 2 mg tablet (perampanel) | 30 |
| Fycompa 4 mg tablet (perampanel) | 30 |
| Fycompa 6 mg tablet (perampanel) | 30 |
| Fycompa 8 mg tablet (perampanel) | 30 |
| Fycompa 10 mg tablet (perampanel) | 30 |
| Fycompa 12 mg tablet (perampanel) | 30 |
| Fycompa 0.5 mg/mL suspension (perampanel) | 720 mL |
| Mysoline 50 mg tablet (primidone) | 240 |
| Mysoline 250 mg tablet (primidone) | 240 |
| Banzel 200 mg tablet (rufinamide) | 120 |
| Banzel 400 mg tablet (rufinamide) | 240 |
| Banzel 40 mg/mL suspension (rufinamide) | 2400 mL |
| Diacomit 250 mg capsule & packet (stiripentol) | 90 |
| Diacomit 500 mg capsule & packet (stiripentol) | 180 |
| Gabitril 2 mg tablet (tiagabine) | 120 |
| Gabitril 4 mg tablet (tiagabine) | 120 |
| Gabitril 12 mg tablet (tiagabine) | 120 |
| Gabitril 16 mg tablet (tiagabine) | 90 |
| Topamax 200 mg tablet (topiramate) | 60 |
| Topamax 15 mg sprinkle capsule (topiramate) | 180 |
| Topamax 25 mg sprinkle capsule (topiramate) | 180 |
| Qudexy XR  25 mg sprinkle capsule (topiramate) | 30 |
| Qudexy XR  50 mg sprinkle capsule (topiramate) | 30 |
| Qudexy XR  100 mg sprinkle capsule (topiramate) | 30 |
| Qudexy XR 150 mg sprinkle capsule (topiramate) | 60 |
| Qudexy XR  200 mg sprinkle capsule (topiramate) | 60 |

| | |
|---|---|
| Trokendi XR 25 mg capsule (topiramate) | 30 |
| Trokendi XR 50 mg capsule (topiramate) | 30 |
| Trokendi XR 100 mg capsule (topiramate) | 90 |
| Trokendi XR 200 mg capsule (topiramate) | 60 |
| Eprontia 25 mg/mL oral solution (topiramate) | 460 mL |
| Sabril 500 mg packet (vigabatrin) | 180 |
| Sabril 500 mg tablet (vigabatrin) | 180 |
| Vigadrone 500 mg packet (vigabatrin) | 180 |

# Appendix I
# Meeting Minutes

# Iowa Medicaid Drug Utilization Review Commission
# Meeting Minutes August 4, 2021

**Attendees:**

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

## Welcome & Introductions

Chairperson Brett Faine called the meeting to order at 9:33 a.m. This meeting was purely virtual and done through WebEx teleconference due to the continued COVID-19 pandemic. The minutes from the May 5, 2021 meeting were reviewed. Jason Kruse motioned to accept them, and Chuck Wadle seconded. All members were in favor. The recommendation letter sent to DHS after the last DUR meeting was also reviewed, along with a recommendation letter from the P&T Committee requesting development of prior authorization criteria for Verquvo. Annual chair and vice-chair elections were conducted. Jason Wilbur motioned to retain Brett Faine as chairperson, and Kellen Ludvigson seconded. Brett Faine then motioned to retain Kellen Ludvigson as vice-chairperson, and Jason Kruse seconded. All members in attendance were in favor of both motions. Members were also asked to complete their annual conflict of interest disclosures.

## IME Pharmacy Update

Tentatively effective November 1, 2021, the dispensing fee will be increased to $10.38, or the first day of the month following CMS approval of the State Plan Amendment just submitted, whichever is later. This is Brett Faine's last year on the DUR Commission, after which he will have served three 4-year terms. Lisa Todd from Amerigroup is now the MCO representative on the Commission, in a non-voting capacity. This position alternates between the MCO companies every two years.

## Prevalence Report Summaries

***Fee-for-Service:*** Pam Smith provided an overview of fee-for-service statistics from March 2021 through May 2021, including: total amount paid ($2,227,364), unique users (3,799); cost per user ($586.30), number of total prescriptions dispensed (23,418); and percent generic (89.3%). The top 5 therapeutic classes by paid amount were: Anticonvulsants; Anti-Inflammatories, Antipsychotics – Atypicals; Muscular Dystrophy Agents; and Stimulants – Amphetamines – Long Acting. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place,

followed by: Antipsychotics – Atypicals; Antihypertensives - Central; and GI – Proton Pump Inhibitors. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Evrysdi, Vyvanse, Humira Pen, Sabril, and Sutent. The five drugs with the highest prescription counts were: clonidine hcl, trazodone hcl, sertraline hcl, omeprazole, and Vyvanse.

***Iowa Total Care:*** Emily Rogers spoke and provided written summaries that included ITC's statistics from March 2021 through May 2021, including: total paid amount ($73,332,223.73); total prescriptions (782,408); and unique users (115,598). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy, Broadlawns Outpatient Pharmacy, and 3 Walgreens locations made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Unity Point at Home, Nucara Specialty, Walgreens, and CVS. The top 5 therapeutic classes by paid amount were: Insulin; Anti-TNF-alpha-Monoclonal Antibodies; Sympathomimetics; Antipsychotics – Misc.; and Antiretrovirals. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Sympathomimetics; Proton-Pump Inhibitors; and NSAIDs. The most expensive drugs were Humira Pen, Vyvanse, Vraylar, Invega Sustenna, and Biktarvy, while albuterol, omeprazole, sertraline, atorvastatin, and trazodone had the top 5 prescription counts.

***Amerigroup****:* Lisa Todd provided an overview for Amerigroup's statistics from March 2021 through May 2021, including: total paid amount ($112,246,474); unique users (162,733); total prescriptions (1,145,966); generic prescriptions (1,030,255 totaling $21,434,772); brand prescriptions (115,711 totaling $90,811,702). The breakdown of utilization by age shows that ages 19-64 continue to have the highest utilization. The top 100 pharmacies by prescription count had 4 Walgreens locations and the University of Iowa Ambulatory Care Pharmacy making up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Caremark Kansas Specialty, CVS Specialty, Hy-Vee Pharmacy Solutions, and Unity Point at Home. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Imflammatory; Antiasthmatic and Bronchodilator Agents; and ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, and Antihypertensives. Humira (CF) Pen was the most expensive medication, followed by Vyvanse, Vraylar, Latuda, and Invega Sustenna. Omeprazole had the highest prescription count, followed by: sertraline hcl, albuterol, trazodone hcl, and atorvastatin.

**Comparative Prevalence Report Summary**

Pam Smith also created a report that compared the FFS stats with those from each MCO. Its side-by-side statistics showed that $187,806,062 was spent in total for 282,130 unique users who had 1,951,792 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population.

Humira and Vyvanse were the two most expensive drugs for the MCO plans. Humira was in third place for FFS, but Everysdi and Vyvanse had the top 2 spots. The top 25 drugs by prescription count were also similar across FFS and both MCO plans. When all three plans were combined, Jeffrey Wilharm had the overall highest prescription count at 4,815. All three complete prevalence reports and the comparative summary can be found in the finalized meeting packet posted on https://iadur.org on the Meeting Materials page.

**Public Comment**

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

| Name | Representing | Drug/Topic |
|---|---|---|
| Joseph Dang | Novartis | Entresto |
| Mary Claire Wohletz | Merck | Verquvo |

Written Provider Comments Received:
Buprenorphine

Written Manufacturer Comments Received: Verquvo, Xolair

**Retrospective DUR Data Presentations**

***Concurrent Opioids and Benzodiazepines:*** This topic is included in the SUPPORT Act and required for CMS reporting, optional this year, but mandatory in 2 years. The Commission thought a hard POS edit preventing concurrent use and development of PA criteria would be the best course of action, but no vote was taken at this time. However, data will be run to see the top providers and number of claims involved and brought back to the next meeting, prior to any recommendationf for any ProDUR edits or PA criteria.

***Montelukast without Asthma Diagnosis:*** The Commission would like to target the prescribers of members not also on a steroid inhaler, to potentially eliminate members with a asthma but not found to have an asthma diagnosis in their medical claims, pointing out the *Boxed Warning* due to the risk of serious neuropsychiatric events, asking if the patient had an inadequate response or intolerance to alternative therapies, and if therapy with montelukast outweighs the potential risks when used for indications other than asthma. Pam Smith will update the data and bring it back to the next meeting, prior to letters being sent.

***PPI Therapy – New Start and High Dose:*** The Commission recommended tabelting this topic and monitor utilization and possibly revisit the topic in the future.

**Retrospective DUR Proposals**

***Duplicate PPIs:*** Data will be brought to the next meeting identifying members with two or more chemically distinct PPIs with 60 or more days of overlap.

***Chronic Use of Controlled Sedative/Hypnotic Agents:*** Data identifying members with claims for a controlled sedative/hypnotic agent for more than 90 days in a 120 day period will be examined and discussed at a future meeting.

**Commission Recommendations for Retrospective DUR Agenda Topics**
There were no additional topic suggestions.

**Prospective DUR**
***Oral Benzodiazepine Quantity Limits:*** Data will be re-run to identify the number of unique members with 60-89 units, 90-119 units, and 120 or more units over a 3 month period. The Commission would like to focus on clonazepam, alprazolam, lorazepam, and diazepam, though Dr. Wadle suggested limits on all bendodiazepines to prevent possible drift to other agents if these four are further restricted.

***Budesonide/Formoterol Inhalation Aerosol & Mometasone/Formoterol Inhalation Aerosol:*** As this was the second review, and the Commission had no additional changes, the recommended quantity limit, allowing 2 inhalers per 30 days, will be sent to DHS for consideration.

The Commission took a short break and open session resumed at 11:20 a.m.

**Prior Authorization**
***Topical Acne and Rosacea Products:*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is not required for preferred topical acne agents (topical antibiotics and topical retinoids) for members under 21 years of age. PA is required for preferred topical acne agents for members 21 years or older, non-preferred topical acne agents and all topical rosacea agents. Payment will be considered under the following conditions:*

1. *Documentation of diagnosis; and*
2. *For the treatment of acne vulgaris, benzoyl peroxide is required for use with a topical antibiotic or topical retinoid; and*
3. *Payment for non-preferred topical acne products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred topical agents of a different chemical entity from the requested topical class (topical antibiotic or topical retinoid); and*
4. *Payment for non-preferred topical rosacea products will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred topical agent; and*
5. *Requests for non-preferred combination products may only be considered after documented trials and therapy failures with two preferred combination products; and*
6. *Requests for topical retinoid products for skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive approval with documentation of submitted diagnosis; and*

7. *Duplicate therapy with agents in the same topical class (topical antibiotic or topical retinoid) will not be considered.*

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

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

***Omalizumab (Xolair):*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for omalizumab (Xolair) prefilled syringe. Requests for omalizumab (Xolair) lyophilized powder for reconstitution will not be considered through the pharmacy benefit. Payment for omalizumab (Xolair) prefilled syringe will be considered for FDA approved and compendia indications under the following conditions:*

1. *Patient meets the FDA approved age; and*
2. *Therapy will be initiated in a healthcare setting, under the guidance of a healthcare provider, where the patient can be closely observed for anaphylaxis and safety of therapy has been established after a minimum of 3 doses of omalizumab; and*
3. *The healthcare provider has determined self-administration with omalizumab is appropriate based on careful assessment of risk for anaphylaxis and mitigation strategies, as outlined in the label; and*
4. *Dose follows the FDA approved dosing for indication; and*
5. *Prescriber is an allergist, dermatologist, immunologist, otolaryngologist or pulmonologist; and*
6. *Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of omalizumab (Xolair); and*
7. *Prescriber and dispensing pharmacy will educate patient on proper storage and administration. Improperly stored medications will not be replaced.*

*<u>Moderate to Severe Persistent Asthma</u>*

1. *Patient has a diagnosis of moderate to severe persistent asthma for at least one year; and*
2. *Pretreatment IgE level is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 IU/mL to 700 IU/mL; or*
    b. *Pediatric patients 6 to less than 12 years of age - 30 IU/mL to 1300 IU/mL; and*
3. *Patient's weight is within the following range:*

   a. *Adults and adolescent patients 12 years of age or older - 30 kg to 150 kg; or*
   b. *Pediatric patients 6 to less than 12 years of age - 20 kg to 150 kg; and*
4. *History of positive skin or RAST test to a perennial aeroallergen; and*
5. *Patient is currently using a high dose inhaled corticosteroid, long-acting beta-agonist, AND a leukotriene receptor antagonist, and is compliant with therapy and asthma symptoms are not adequately controlled after at least three (3) months of therapy; and*
6. *Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight. Note: according to the label, there is insufficient data to recommend a dose for certain pretreatment serum IgE levels and body weight. PA requests will be denied in these instances.*

*If the criteria for coverage are met, the initial authorization will be given for 16 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy and for patients who do not continue concurrent use with a high dose corticosteroid, long-acting beta-agonist, and leukotriene receptor antagonist.*

*<u>Chronic Idiopathic Urticaria</u>*

1. *Patient has a diagnosis of moderate to severe chronic idiopathic urticaria; and*
2. *Patient has documentation of a trial and therapy failure with at least one preferred second-generation antihistamine, one of which must be cetirizine at a dose up to 20 mg per day; and*
3. *Patient has documentation of a trial and therapy failure with at least one preferred first-generation antihistamine; and*
4. *Patient has documentation of a trial and therapy failure with at least one preferred potent H1 receptor antagonist (hydroxyzine and/or doxepin); and*
5. *Patient has documentation of a trial and therapy failure with a preferred leukotriene receptor antagonist in combination with a first- or second-generation antihistamine.*

*If criteria for coverage are met, the initial authorization will be given for 12 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy.*

*<u>Nasal Polyps</u>*

1. *Patient has a diagnosis of nasal polyps; and*
2. *Pretreatment IgE level is within the following range:*

a. *Adults and adolescent patients 12 years of age or older - 30 IU/mL to 1500 IU/mL; and*

3. *Patient's weight is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 kg to 150 kg; and*
4. *Patient has documentation of an adequate trial and inadequate response with at least two nasal corticosteroids at a maximally tolerated dose; and*
5. *Will be used concurrently with a nasal corticosteroid; and*
6. *Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight. Note: according to the label, there is insufficient data to recommend a dose for certain pretreatment serum IgE levels and body weight. PA requests will be denied in these instances.*

*If criteria for coverage are met, the initial authorization will be given for 24 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy and for patients who do not continue concurrent use with a nasal corticosteroid.*

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

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

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

*Prior authorization is required for vericiguat (Verquvo). Payment will be considered under the following conditions:*

1. *Patient has a diagnosis of symptomatic chronic heart failure (NYHF class II-IV) with a left ventricular ejection fraction (LVEF) ≤ 45%; and*
2. *Patient meets one of the following:*
    a. *Recent hospitalization for heart failure (within the last 6 months); or*
    b. *Recent need for outpatient intravenous diuretics (within the last 3 months); and*
3. *Patient is within the FDA labeled age for indication; and*
4. *Female patients of reproductive potential have been advised to use effective contraception during treatment and for at least one month after the last dose; and*
5. *Will not be used concomitantly with other soluble guanylate cyclase (sGC) stimulators (e.g. riociguat) or phosphodiesterase type 5 (PDE-5) inhibitors (e.g. sildenafil, tadalafil, vardenafil); and*

6. *Documentation of prior or current therapy, at a maximally tolerated dose, with one drug from each category below:*
    a. *Renin-angiotensin system inhibitor (angiotensin converting enzyme [ACEI], angiotensin receptor blocker [ARB], or angiotensin receptor-neprilysin inhibitor [ARNI]); and*
    b. *Evidence-based beta-blocker (carvedilol, metoprolol succinate, or bisoprolol); and*
7. *Is dosed based on FDA approved dosing; and*
8. *Initial requests for Verquvo 2.5 mg and 5 mg tablets will be limited to one 14-day supply for each strength.*

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

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

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

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

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

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

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

***Non-Biologic Agents for Ulcerative Colitis:*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for select non-biologicals for ulcerative colitis (UC). Payment for non-preferred select non-biologics for UC may be considered only for cases in which there is documentation of a previous trial and therapy failure with the preferred agent(s). Payment will be considered under the following conditions:*

1. *Patient has a diagnosis of moderately to severely active ulcerative colitis (UC) and*
2. *Request adheres to all FDA approved labeling for indication, including age, dosing, and contraindications; and*
3. *A documented trial and inadequate response to two preferred conventional therapies (immunomodulators) including aminosalicylates and azathioprine/6-mercaptopurine; and*
4. *A documented trial and inadequate response with a preferred biological DMARD; and*
5. *Will not be taken concomitantly with immunomodulators or biologic therapies.*

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

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

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

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

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

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

*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 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.

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

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

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

1. *Barrett's esophagus, Erosive esophagitis, or Peptic stricture (Please fax a copy of the scope results with the initial request); or*
2. *Hypersecretory conditions (Zollinger-Ellison syndrome, systemic mastocytosis, and multiple endocrine adenomas); or*
3. *Recurrent peptic ulcer disease; or*
4. *Gastroesophageal reflux disease will be considered after documentation of a therapeutic trial and therapy failure with the requested PPI at maximal dose within the established quantity limit of one unit per day. Requests for PPIs exceeding one unit per day will be considered on a short term basis (up to 3 months). After the three month period, a dose reduction to the recommended once daily dosing will be required. A trial of the recommended once daily dosing will be required on an annual basis for those patients continuing to need doses beyond one unit per day; or*
5. *Helicobacter pylori will be considered for up to 14 days of treatment with documentation of active infection.*

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

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

***Valsartan/Sacubitril (Entresto):*** The DUR Commission reviewed information regarding a newly expanded indication for valsartan/sacubitril (Entesto), to reduce the risk of cardiovascular death and hospitalization for heart failure. The DUR Commission also reviewed The 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment. Guideline-directed therapy for heart failure with reduced ejection fraction (HFrEF) includes angiotensin-converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs) as initial treatment, with an ARNI being preferred regardless of prior treatment with an ACEI or ARB. After review of the new information and discussion, the DUR Commission determined removal of PA criteria would be in the best interest of Iowa Medicaid members given the proven efficacy of valsartan/sacubitril (Entresto) in the treatment of heart failure.

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

1. *Patient is within the FDA labeled age for indication; and*
2. *Patient has a diagnosis of NYHA Functional Class II, III, or IV heart failure; and*
    a. *Patient has a left ventricular ejection fraction (LVEF) ≤40%; and*
    b. *Patient is currently tolerating treatment with an ACE inhibitor or angiotensin ll receptor blocker (ARB) at a therapeutic dose, where replacement with valsartan/sacubitril is recommended to further reduce morbidity and mortality; and*

c. *Is to be administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB (list medications patient is currently taking for the treatment of heart failure); or*

3. *Pediatric patient has a diagnosis of symptomatic heart failure (NYHA/Ross Class ll to lV) due to systemic left ventricular systolic dysfunction with documentation of a left ventricular ejection fraction ≤40%; and*
4. *Will not be used in combination with an ACE inhibitor or ARB; and*
5. *Will not be used in combination with aliskiren (Tekturna) in diabetic patients; and*
6. *Patient does not have a history of angioedema associated with the use of ACE inhibitor or ARB therapy; and*
7. *Patient is not pregnant; and*
8. *Patient does not have severe hepatic impairment (Child Pugh Class C); and*

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

At the prior meeting review, the Commission also voted to implement a quantity limit of 60 for 30 for all strengths. No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation for PA removal will be sent to the Department for consideration.

***Initial Days Supply Limit Override:*** The Commission reviewed the prior authorization criteria as follows:

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

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

4. *Requests for non-opioid drugs subject to the initial days' supply limit will be considered on an individual case-by-case basis, based on medical necessity documentation provided.*

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.

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

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

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

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

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

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.

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

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

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

1. *Patient meets the FDA approved age; and*
2. *Patient has a diagnosis of tardive dyskinesia (TD) based on the presence of ALL of the following:*
    a. *Involuntary athetoid or choreiform movements*
    b. *Documentation or claims history of current or prior chronic use (≥ 3 months or 1 month in patients ≥ 60 years old) of a dopamine receptor*

*blocking agent (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.)*

c. *Symptoms lasting longer than 4-8 weeks; and*

3. *Prescribed by or in consultation with a neurologist or psychiatrist; and*
4. *Prescriber has evaluated the patient's current medications for consideration of a dose reduction, withdrawal, or change of the dopamine receptor blocking agent causing the TD; and*
5. *Documentation of baseline AIMS (Abnormal Involuntary Movement Scale) Score (attach AIMS); and*
6. *For Ingrezza:*
    a. *Will not be used concurrently with MAO inhibitors (e.g., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine, etc.) or strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, phenobarbital, rifampin and related agents, St. John's wort, etc.); and*
    b. *Will not be used concurrently with other vesicular monoamine transporter 2 (VMAT2) inhibitors; and*
    c. *Is prescribed within the FDA approved dosing; or*
7. *For Austedo:*
    a. *Patient does not have hepatic impairment;*
    b. *Will not be used concurrently with MAO inhibitors, reserpine, or other VMAT2 inhibitors; and*
    c. *Patients that are taking a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) or are poor CYP2D6 metabolizers, the daily dose does not exceed 36mg per day (18mg twice daily); and*
    d. *Is prescribed within the FDA approved dosing.*

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

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

*<u>Chorea associated with Huntington's disease</u> (Austedo or tetrabenazine)*

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

a. *Austedo - 36mg per day (18mg single dose) or*
b. *Tetrabenazine – 50mg per day (25mg single dose)*

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

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

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 DUR Digest Volume 33, Number 2. No additional recommendations were made. The DUR Digest will be posted to the DUR website.

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

At 12:11, Chuck Wadle motioned to adjourn, and Jason Wilbur seconded. All in attendance agreed.

**The next scheduled meeting is tentatively set for November 3, 2021, location to be determined.**

# Iowa Medicaid Drug Utilization Review Commission
# Meeting Minutes November 3, 2021

**Attendees:**

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

## Welcome & Introductions

Chairperson Brett Faine called the meeting to order at 9:31 a.m. This meeting was purely virtual and done through WebEx teleconference due to COVID-19. The minutes from the August 4, 2021, meeting were reviewed. Chuck Wadle motioned to accept them, and Jason Kruse seconded. All members were in favor. The recommendation letter sent to DHS after the last DUR meeting was also reviewed.

## IME Pharmacy Update

Informational Letter 2282 notified providers that effective November 1, 2021, the dispensing fee will be increased to $10.38. This is Brett Faine's last year on the DUR Commission, after which he will have served three 4-year terms. That will leave a pharmacist position open, in addition to the physician position recently left by Mark Graber. DHS is accepting referrals and applicants.

## Prevalence Report Summaries

***Fee-for-Service:*** Pam Smith provided an overview of fee-for-service statistics from June 2021 through August 2021, including: total amount paid ($2,306,502), unique users (3,757); cost per user ($613.92), number of total prescriptions dispensed (22,467); and percent generic (89.5%). The top 5 therapeutic classes by paid amount were: Anticonvulsants; Antipsychotics – Atypicals; Anti-Inflammatories, Non-NSAID; Muscular Dystrophy Agents; and Antiretroviral Combinations. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Antihypertensives - Central; and Antiasthmatic – Beta-Adrenergics. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Evrysdi, Vyvanse, Humira Pen, Sabril, and Invega Sustenna. The five drugs with the highest prescription counts were: sertraline hcl, trazodone hcl, clonidine hcl, albuterol, and escitalopram.

***Amerigroup**:* Lisa Todd provided an overview for Amerigroup's statistics from June 2021 through August 2021, including: total paid amount ($102,362,297); unique users (159,946); total prescriptions (1,014,236); generic prescriptions (912,117 totaling $18,609,656); brand prescriptions (102,119 totaling $83,752,641). The breakdown of utilization by age shows that ages 19-64 continue to have the highest utilization. The top 100 pharmacies by prescription count had 4 Walgreens locations and the University of Iowa Ambulatory Care Pharmacy making up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Caremark Kansas Specialty, CVS Specialty, Caremark Illinois Specialty, and Unity Point at Home. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Imflammatory; Antiasthmatic and Bronchodilator Agents; and Dermatologicals. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, and Antihypertensives. Humira (CF) Pen was the most expensive medication, followed by Vyvanse, Vraylar, Latuda, and Invega Sustenna. Omeprazole had the highest prescription count, followed by: sertraline hcl, albuterol, trazodone hcl, and atorvastatin.

***Iowa Total Care:*** Emily Rogers provided an overview for ITC's statistics from June 2021 through August 2021, including: total paid amount ($79,344,428.95); total prescriptions (786,401); and unique users (120,462). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy, Broadlawns Outpatient Pharmacy, and 3 Walgreens locations made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Nucara Specialty, CVS, Unity Point at Home, and Community (a Walgreens Pharmacy). The top 5 therapeutic classes by paid amount were: Insulin; Anti-TNF-alpha-Monoclonal Antibodies; Sympathomimetics; Antiretrovirals; and Antipsychotics – Misc. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Sympathomimetics; Proton-Pump Inhibitors; and NSAIDs. The most expensive drugs were Humira Pen, Vyvanse, Trikafta, Vraylar, and Invega Sustenna, while albuterol, omeprazole, sertraline, atorvastatin, and trazodone had the top 5 prescription counts.

**Comparative Prevalence Report Summary**

Pam Smith also created a report that compared the FFS stats with those from each MCO. Its side-by-side statistics showed that $184,013,228 was spent in total for 284,165 unique users who had 1,823,104 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Humira and Vyvanse were the two most expensive drugs for the MCO plans. Humira was in third place for FFS, but Everysdi and Vyvanse had the top 2 spots. The top 25 drugs by prescription count were also similar across FFS and both MCO plans. When all three plans were combined, Jeffrey Wilharm had the overall highest prescription count at 4,222. All three complete prevalence reports and the comparative summary can be found in the finalized meeting packet posted on https://iadur.org on the Meeting Materials page.

The three representatives from FFS and both MCOs also presented findings from claims queries for ivermectin, as there has been recent usage of that medication for off-label COVID-19 treatment. However, the Commission does not think the current quantities of members and prescriptions involved merit additional action at this point. Pam Smith and the MCOs will continue to monitor claims stats for any future issues.

**Public Comment**

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

| Name | Representing | Drug/Topic |
|---|---|---|
| Scott Anderson | Regeneron | Praluent |
| Nishil Patel | Amgen | Otezla, Repatha |
| Sean Byrne | Gilead Sciences | Hepatitis C medications |
| Joseph Dang | Novartis | Kesimpta |

Written Provider Comments Received:
CGRP monoclonal antibodies, Otezla, Medication adherence measures, Hep C DAAs

Written Manufacturer Comments Received: Ajovy

**Retrospective DUR Data Presentations**

***Concurrent Opioids and Benzodiazepines:*** This topic is included in the SUPPORT Act and required for CMS reporting, optional this year, but mandatory in 2 years. After discussion at two prior meetings, the Commission thought a hard POS edit preventing concurrent use and development of PA criteria would be the best course of action. Data was then run to see the top providers and number of claims involved. A duration limit could also be applied across the benzodiapezine class, regardless of utilization. Pam Smith suggested that since there was such a large number of members, and it's difficult to change therapy once someone is established, that new starts be targeted. If there were fewer new starts, over time the utilization would decrease. Chuck Wadle asked if there was any data proving the consequences of the risks of concurrent therapy, as he had not personally encountered issues in his practice over the years, and that obviously the biggest issue was if they misuse, overuse, or overdose. Jason Wilbur replied that he did think there was data showing an increased mortality risk for patients that were chronically on opioids and benzodiazepines together, but agreed that individual risk/benefit anyleses often found that the medication benefits outweighed the risks. However, as an organization and a society, he thought that given the known mortality risk, we should try to limit concurrent use. He also agreed that it would be far easier to prevent future use rather than trying to get 6000 people to discontinue use. The Commission would like information as to what other states are doing, prior to implementation of any edits or criteria. Pam Smith will bring the findings back to the next meeting.

***Duplicate PPIs:*** Data was run to identy members with two or more chemically distinct PPIs with 60 or more days of overlap. Iowa Total Care had no claims, while Amerigroup had

1519 and FFS 7. Emily Rogers believes this is because ITC already has an edit in place, though all plans are meant to be using the same criteria to be consistent. DHS and Pam Smith will get more information on this potential edit and bring that back to the next meeting. No letters will be sent until a decision is made on the ProDUR edit.

***Chronic Use of Controlled Sedative/Hypnotic Agents:*** Data identifying members with claims for a controlled sedative/hypnotic agent for more than 90 days in a 120-day period was examined and discussed. The Commission wondered if other treatment options would be available if sedative/hypnotics were more controlled with a POS edit or PA criteria. Pam Smith will research if the state or MCO plans provide cognitive behavioral therapy for sleep disorders and bring additional information to the next meeting. They did not feel letters would be beneficial at this point, as most physicians are likely already aware of the chronic use.

***Montelukast without Asthma Diagnosis:*** At the August meeting, the Commission reviewed data for members on montelukast without an asthma diagnosis in the previous 12 months medical claims.Given the higher than anticipated utilization of montelukast without an asthma diagnosis, it was recommended to further look at these members and review claims for an inhaled corticosteroid (ICS), and identifying those without an ICS. The COmmisison reviewed the updated data and recommended to send letters to the prescribers of members not also on an ICS, pointing out the *Boxed Warning* due to the risk of serious neuropsychiatric events, asking if patient had an inadequate response or intolerance to alternative therapies, and if therapy with montelukast outweighs the potential risks.

**Retrospective DUR Proposals**

***Concurrent use of GLP-1 RA and DPP-4 Inhibitors:*** Pam Smith will pull data to identify members with concurrent use of a GLP-1 RA and DPP-4i with 60 or more days of overlap, and bring findings back to the next meeting for discussion. Updated recommendations from the American Diabetes Association indicate combined use of these is not recommended. Use of both agents concurrently does not offer additional significant lowering of A1C and adds to the patient's pill burden and increased medical costs.

***High Dose Glucocorticoid without Bisphosphonate:*** Pam Smith will pull data to identify adults receiving the equivalent daily dosage of prednisone 7.5 mg without an oral bisphosphonate for 90 or more days, and bring findings back to the next meeting. As glucocorticoid therapy is associated with a risk of bone loss, and can also increase fracture risk, letters will likely be sent to providers and a DUR digest article created for this topic.

**Commission Recommendations for Retrospective DUR Agenda Topics**

There were no additional topic suggestions.

**Prospective DUR**

***Oral Benzodiazepine Quantity Limits:*** Data was run to identify the number of unique patients receiving 60 or more units. After review of the data, the Commission would like to focus on members receiving quantities of 120 or more per 30 days over a 6-month span, as that is the highest risk population, specifically focusing on clonazepam, alprazolam, lorazepam, and diazepam, though Dr. Wadle previously suggested limits on all bendodiazepines to prevent possible drift to other agents when these four were further restricted. They also questioned why anyone would need to take these medications four times per day. Pam Smith will re-run the data with the updated parameters, and this will be discussed again at a future meeting.

The Commission took a short break and open session resumed at 11:34 a.m.

**Prior Authorization**

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

| PA Category | Recommended Changes |
|---|---|
| Antidepressants | Check for upcoming generic releases |
| Anti-Diabetics, Non-Insulin Agents | Discuss DPP-4 trials due to reduced demonstrated benefit in cardiovascular disease compared to GLP-1 Inhibitors |
| Anti-Fungal- Oral/Injectable | Adjust criteria to align with recommended treatment duration for onychomycosis of the toes |
| Biologicals for Hidradenitis Suppurativa | Look at criteria for topical agent trials, especially those listed on the Anti-Acne PA form. Dr. Kruse has had issues getting PA requests approved for this diagnosis. |
| Cholic Acid (Cholbam) | Allow consultation with a specialist |
| CNS Stimulants and Atomoxetine | Allow consultation with a specialist under BED criteria, and potentially remove criteria for atomoxetine if PA not due to cost |
| Crisaborole (Eucrisa) | Discuss reducing to 1 topical corticosteroid trial prior to immunomodulator trial |
| Deferasirox (Exjade) | Correct to FDA-approved age |
| Linezolid (Zyvox) | Possibly remove prior authorization, or amend criteria to make it easier to obtain, PICC line issues |
| Methotrexate Injection | Allow consultation with a specialist |

***Select Preventative Migraine Treatments:*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for select preventative migraine agents. Payment for non-preferred select preventative migraine agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred, select preventative migraine agent. Payment will be considered under the following conditions:*

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

*lidocaine) at least once daily for at least two days per week after the first full week of adequately dosed steroid therapy; and*

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

7. *Lost, stolen, or destroyed medication replacement requests will not be authorized.*

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

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

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

***Hepatitis C Treatments:*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for hepatitis C direct-acting antivirals (DAA). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:*

1. *Patient has a diagnosis of chronic hepatitis C; and*
2. *Patient's age and/or weight is within the FDA labeled age and/or weight; and*
3. *Patient has had testing for hepatitis C virus (HCV) genotype; and*
4. *Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and*
5. *Patient has been tested for hepatitis B (HBV) prior to initiating treatment of HCV and individuals with active HBV infection are treated (either at same time as HCV therapy or before HCV therapy is started); and*
6. *Patient's prior HCV DAA treatment history is provided (treatment naïve or treatment experienced); and*
7. *If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and*
8. *Patient has been evaluated to determine the patient's readiness for HCV treatment with scales or assessment tools, such as the SAMHSA-HRSA Center for Integrated Health Solutions – Drug & Alcohol Screening Tools and*

*the Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C); and*

9. *Patient has been educated on the importance of abstinence from IV drug use and alcohol use, the importance of compliance with HCV treatment, and how to prevent HCV transmission. If patient is currently using IV drugs and/or alcohol, recommend the patient participate in alcohol and/or substance abuse counseling; and*
10. *HCV treatment is prescribed by or in consultation with a digestive disease, liver disease, or infectious disease provider practice; and*
11. *FDA approved pediatric formulations of HCV DAAs and DAA approved for pediatric use will be considered for those under the age of 18 when used in accordance with current AASLD guidelines including for indication and age; and*
12. *For patients on a regimen containing ribavirin, the following must be documented on the PA form:*
    a. *Patient is not a pregnant female or male with a pregnant female partner; and*
    b. *Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and*
    c. *Monthly pregnancy tests will be performed during treatment; and*
13. *Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the DAA; and*
14. *Documentation is provided for patients who are ineligible to receive ribavirin; and*
15. *Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved; and*
16. *Patient does not have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.*
17. *If patient is recently eligible for Iowa Medicaid, and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on length of therapy for the particular treatment.*
18. *Lost or stolen medication replacement requests will not be authorized.*
19. *The 72-hour emergency supply rule does not apply to DAAs.*

*Requests for treatment-experienced patients (with previous DAA) will be considered under the following conditions:*

1. *Patient must meet all criteria for treatment approval above; and*
2. *Patients who previously achieved SVR that have HCV recurrence due to IV drug use must have documentation that the patient has completed or is participating in a recovery program, receiving alcohol or substance abuse counseling services, or seeing an addiction specialist as part of HCV treatment, and can be managed as an initial infection; and*

3. *The requested therapy is FDA approved as therapy for treatment-experienced patients and follows current AASLD guidelines; and*
4. *Patient has not been previously treated with and failed the requested DAA therapy; and*
5. *Documentation is provided patient has a documented presence of detectable HCV RNA at least 12 weeks after completing previous DAA treatment.*

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

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

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

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

*ii. Documented trial and therapy failure with one preferred TNF inhibitor used for psoriatic arthritis; OR*

*c. Moderately to severely active ulcerative colitis; with*

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

*ii. A documented trial and inadequate response with a preferred TNF inhibitor; and*

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

*d. Polyarticular Course Juvenile Idiopathic Arthritis; with*

*i. A documented trial and inadequate response to intraarticular glucocorticoid injections; and*

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

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

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

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

***Apremilast (Otezla):*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for apremilast (Otezla). Payment will be considered under the following conditions:*

1. *Request adheres to all FDA approved labeling for indication, including age, dosing, and contraindications; and*
2. *Patient has a diagnosis of active psoriatic arthritis (≥ 3 swollen joints and ≥ 3 tender joints); with*
    a. *Documentation of a trial and inadequate response to therapy with the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated; or*
3. *Patient has a diagnosis of moderate to severe plaque psoriasis; with*
    a. *Documentation of a trial and inadequate response to phototherapy, systemic retinoids, methotrexate, or cyclosporine; or*
4. *Patient has a diagnosis of Behçet disease; with*
    a. *Documentation of active oral ulcers associated with Behçet disease; and*
    b. *Documentation of a previous trial and inadequate response, at a*

*therapeutic dose, to colchicine.*

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

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

***Biologicals for Arthritis:*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for biologicals used for arthritis. Request must adhere to all FDA approved labeling, including age, indication, dosing, and contraindications. Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. Payment will be considered under the following conditions:*

1. *Patient has been screened for hepatitis B and C. Patients with evidence of active hepatitis B infection (hepatitis surface antigen positive > 6 months) must have documentation they are receiving or have received effective antiviral treatment; and*
2. *Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and*
3. *Patient has a diagnosis of rheumatoid arthritis (RA); with*
    a. *Documentation of a trial and inadequate response, at a maximally tolerated dose, with methotrexate (hydroxycholoroquine, sulfasalazine, or leflunomide may be used if methotrexate is contraindicated) or*
4. *Patient has a diagnosis of moderate to severe psoriatic arthritis; with*
    a. *Documentation of a trial and inadequate response, at a maximally tolerated dose with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or*
5. *Patient has a diagnosis of moderate to severe juvenile idiopathic arthritis; with*
    a. *Documentation of a trial and inadequate response to intraarticular glucocorticoid injections and methotrexate at a maximally tolerated dose (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*

*In addition to the above:*

*Requests for TNF Inhibitors:*

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

*Requests for Interleukins:*

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

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

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

***Triheptanoin (Dojolvi):*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for triheptanoin (Dojolvi). Payment will be considered under the following conditions:*

1. *Request adheres to all FDA approved labeling for indication, including age, dosing, contraindications, warnings, and precautions; and*
2. *Patient has a diagnosis of long-chain fatty acid oxidation disorder (LC-FAOD), with supporting documentation of gene mutation(s) associated with LC-FAOD (LC-FAODs include: CPT I, CACT, CPT II, VLCAD, TFP, LCHAD); and*
3. *Patient will not be using another medium chain triglyceride (MCT) product; and*
4. *Documentation of patient's daily caloric intake (DCI) is provided; and*
5. *Patient's target daily dosage is provided as a percentage of the patient's total daily prescribed DCI, not to exceed 35%; and*
6. *Is prescribed by or in consultation with an endocrinologist, geneticist, or metabolic disease specialist.*

*If the criteria for coverage are met, initial requests will be approved for four months. Additional authorizations will be considered upon documentation of a positive clinical response to therapy.*

Jason Wilbur motioned to accept the criteria as written, 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.

***Baclofen Oral Solution (Ozobax):*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for baclofen oral solution (Ozobax). Payment for a non-preferred agent will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions:*

1. *Patient has a diagnosis of spasticity resulting from multiple sclerosis (relief of flexor spasms and concomitant pain, clonus, and muscular rigidity) or spinal cord injuries/diseases; and*
2. *Patient meets the FDA approved age; and*
3. *Documentation of a patient-specific, clinically significant reason (beyond convenience) why the member cannot use baclofen oral tablets, even when*

*tablets are crushed and sprinkled on soft food or liquid. Presence of a nasogastric (NG) tube/J-tube alone are not reasons for approval; and*

4. *Request does not exceed the maximum dosage of 80mg daily.*

Chuck Wadle motioned to accept the criteria as written, 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.

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

*Prior authorization (PA) is not required for preferred topical acne agents (topical antibiotics and topical retinoids) for members under 21 years of age. PA is required for preferred topical acne agents for members 21 years or older, non-preferred topical acne agents and all topical rosacea agents. Payment will be considered under the following conditions:*

1. *Documentation of diagnosis; and*
2. *For the treatment of acne vulgaris, benzoyl peroxide is required for use with a topical antibiotic or topical retinoid; and*
3. *Payment for non-preferred topical acne products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred topical agents of a different chemical entity from the requested topical class (topical antibiotic or topical retinoid); and*
4. *Payment for non-preferred topical rosacea products will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred topical agent; and*
5. *Requests for non-preferred combination products may only be considered after documented trials and therapy failures with two preferred combination products; and*
6. *Requests for topical retinoid products for skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive approval with documentation of submitted diagnosis; and*
7. *Duplicate therapy with agents in the same topical class (topical antibiotic or topical retinoid) will not be considered.*

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

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.

***Omalizumab (Xolair) Prefilled Syringe:*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for omalizumab (Xolair) prefilled syringe. Requests for omalizumab (Xolair) lyophilized powder for reconstitution will not be considered through the pharmacy benefit. Payment for omalizumab (Xolair)*

*prefilled syringe will be considered for FDA approved and compendia indications under the following conditions:*

1. *Patient meets the FDA approved age; and*
2. *Therapy will be initiated in a healthcare setting, under the guidance of a healthcare provider, where the patient can be closely observed for anaphylaxis and safety of therapy has been established after a minimum of 3 doses of omalizumab; and*
3. *The healthcare provider has determined self-administration with omalizumab is appropriate based on careful assessment of risk for anaphylaxis and mitigation strategies, as outlined in the label; and*
4. *Dose follows the FDA approved dosing for indication; and*
5. *Prescriber is an allergist, dermatologist, immunologist, otolaryngologist or pulmonologist; and*
6. *Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of omalizumab (Xolair); and*
7. *Prescriber and dispensing pharmacy will educate patient on proper storage and administration. Improperly stored medications will not be replaced.*

*<u>Moderate to Severe Persistent Asthma</u>*

1. *Patient has a diagnosis of moderate to severe persistent asthma for at least one year; and*
2. *Pretreatment IgE level is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 IU/mL to 700 IU/mL; or*
    b. *Pediatric patients 6 to less than 12 years of age - 30 IU/mL to 1300 IU/mL; and*
3. *Patient's weight is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 kg to 150 kg; or*
    b. *Pediatric patients 6 to less than 12 years of age - 20 kg to 150 kg; and*
4. *History of positive skin or RAST test to a perennial aeroallergen; and*
5. *Patient is currently using a high dose inhaled corticosteroid, long-acting beta-agonist, AND a leukotriene receptor antagonist, and is compliant with therapy and asthma symptoms are not adequately controlled after at least three (3) months of therapy; and*
6. *Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight. Note: according to the label, there is insufficient data to recommend a dose for certain pretreatment serum IgE levels and body weight. PA requests will be denied in these instances.*

*If the criteria for coverage are met, the initial authorization will be given for 16 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy and for patients who do not continue concurrent use with a high dose corticosteroid, long-acting beta-agonist, and leukotriene receptor antagonist.*

*Chronic Idiopathic Urticaria*

1. *Patient has a diagnosis of moderate to severe chronic idiopathic urticaria; and*
2. *Patient has documentation of a trial and therapy failure with at least one preferred second-generation antihistamine, one of which must be cetirizine at a dose up to 20 mg per day; and*
3. *Patient has documentation of a trial and therapy failure with at least one preferred first-generation antihistamine; and*
4. *Patient has documentation of a trial and therapy failure with at least one preferred potent H1 receptor antagonist (hydroxyzine and/or doxepin); and*
5. *Patient has documentation of a trial and therapy failure with a preferred leukotriene receptor antagonist in combination with a first- or second-generation antihistamine.*

*If criteria for coverage are met, the initial authorization will be given for 12 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy.*

*Nasal Polyps*

1. *Patient has a diagnosis of nasal polyps; and*
2. *Pretreatment IgE level is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 IU/mL to 1500 IU/mL; and*
3. *Patient's weight is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 kg to 150 kg; and*
4. *Patient has documentation of an adequate trial and inadequate response with at least two nasal corticosteroids at a maximally tolerated dose; and*
5. *Will be used concurrently with a nasal corticosteroid; and*
6. *Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight. Note: according to the label, there is insufficient data to recommend a dose for certain pretreatment serum IgE levels and body weight. PA requests will be denied in these instances.*

*If criteria for coverage are met, the initial authorization will be given for 24 weeks to assess the need for continued therapy. Requests for continuation of therapy*

*will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy and for patients who do not continue concurrent use with a nasal corticosteroid.*

*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.

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

*Prior authorization is required for vericiguat (Verquvo). Payment will be considered under the following conditions:*

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

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

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

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

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

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

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

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

***Non-Biologic Agents for Ulcerative Colitis:*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for select non-biologicals for ulcerative colitis (UC). Payment for non-preferred select non-biologics for UC may be considered only for cases in which there is documentation of a previous trial and therapy failure with the preferred agent(s). Payment will be considered under the following conditions:*

1. *Patient has a diagnosis of moderately to severely active ulcerative colitis (UC) and*
2. *Request adheres to all FDA approved labeling for indication, including age, dosing, and contraindications; and*
3. *A documented trial and inadequate response to two preferred conventional therapies (immunomodulators) including aminosalicylates and azathioprine/6-mercaptopurine; and*

4. *A documented trial and inadequate response with a preferred biological DMARD; and*
5. *Will not be taken concomitantly with immunomodulators or biologic therapies.*

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

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

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

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

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

c. *Patient has documentation of a previous trial and therapy failure with at least one preferred 3-month course of a continuous hormonal contraceptive; and*
d. *Patient has documentation of a previous trial and therapy failure with tranexamic acid.*
e. *Initial requests will be considered for 6 months. Additional requests will be considered upon documentation of improvement of symptoms.*
f. *Requests will be considered for a maximum of 24 months treatment.*

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

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

**Miscellaneous**

***DUR Digest:*** The Commission members conducted the initial review of DUR Digest Volume 34, Number 1.

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

At 1:03, Kellen Ludvigson motioned to adjourn, and Jason Wilbur seconded. All in attendance agreed.

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

# Iowa Medicaid Drug Utilization Review Commission
# Meeting Minutes February 2, 2022

**Attendees:**

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

## Welcome & Introductions

Chairperson Brett Faine called the meeting to order at 9:32 a.m. This meeting was held virtually due to the PHE Declaration for the COVID-19 Pandemic. The minutes from the November 3, 2021, meeting were reviewed. Jason Kruse motioned to accept them, and Jason Wilbur seconded. All members were in favor. The recommendation letter sent to DHS after the last DUR meeting was also reviewed, along with a letter from the P&T Committee to the DUR Commission recommending development of prior authorization (PA) criteria for Dojolvi, Kerendia, and Qelbree.

## IME Pharmacy Update

The 2-year cost of dispensing survey will be sent this month, with additional information in Informational Letter 2306. There will be a pharmacist position open at the end of this state fiscal year when Brett Faine reaches the end of his fourth term, in addition to the physician position recently left by Mark Graber. Interested parties are encouraged to apply. Additional information can be found on the DUR website, at www.iadur.org.

## Prevalence Report Summaries

***Iowa Total Care:*** Emily Rogers provided an overview for ITC's statistics from September 2021 through November 2021, including: total paid amount ($80,551,573.95); total prescriptions (784,608); and unique users (127,018). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy, Broadlawns, and 3 Walgreens locations made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Nucara Specialty, Hy-Vee Pharmacy Solutions, Unity Point at Home, and CVS. The top 5 therapeutic classes by paid amount were: Anti-TNF-alpha-Monoclonal Antibodies; Insulin; Sympathomimetics; Incretin Mimetic Agents (GLP-1 Receptor Agonists); and Antipsychotics – Misc. The top 5 classes by prescription count were: SSRIs; Sympathomimetics; Anticonvulsants; Proton-Pump Inhibitors; and NSAIDs.

The most expensive drugs were Humira Pen, Vyvanse, Vraylar, Trikafta, and Trulicity, while albuterol, sertraline, omeprazole, atorvastatin, and amoxicillin had the top 5 by prescription counts.

***Amerigroup**:* Lisa Todd provided an overview for ITC's statistics from September 2021 through November 2021, including: total paid amount ($110,533,942); total prescriptions (1,090,212); and unique users (172,691). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy and 4 Walgreens locations made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Caremark Kansas Specialty Pharmacy, Caremark Illinois Specialty Pharmacy, Hy-Vee Pharmacy Solutions, and Unity Point at Home. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Imflammatory; Antiasthmatic and Bronchodilator Agents; and Dermatologicals. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, and Antihypertensives. Humira (CF) Pen was the most expensive medication, followed by Vyvanse, Vraylar, Latuda, and Trikafta. Omeprazole had the highest prescription count, followed by: sertraline hcl, trazodone hcl, albuterol, and amoxicillin.

***Fee-for-Service:*** Pam Smith provided an overview of fee-for-service statistics from September 2021 through November 2021, including: total amount paid ($2,257,627), unique users (3,807); cost per user ($593.02), number of total prescriptions dispensed (21,014); and percent generic (89.3%). The top 5 therapeutic classes by paid amount were: Anticonvulsants; Antipsychotics – Atypicals; Anti-Inflammatories, Non-NSAID; Antiretroviral Combinations; and Diabetic – Insulin Penfills. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Antihypertensives - Central; and Antiasthmatic – Beta-Adrenergics. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Humira Pen, Vyvanse, Evrysdi, Trikafta, and Invega Sustenna. The five drugs with the highest prescription counts were: escitalopram, trazodone hcl, clonidine hcl, sertraline hcl, and omeprazole.

**Comparative Prevalence Report Summary**

Pam Smith also created a report that compared the FFS stats with those from each MCO. Its side-by-side statistics showed that $193,343,143 was spent in total for 303,516 users who had 1,895,834 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Humira and Vyvanse were the two most expensive drugs for both MCO plans, as well as FFS. The top 25 drugs by prescription count were also similar across FFS and both MCO plans. When all three plans were combined, Jeffrey Wilharm had the overall highest prescription count at 4,484. All three complete prevalence reports and the comparative summary can be found in the finalized meeting packet posted on https://iadur.org on the Meeting Materials page.

**Public Comment**

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

| Name | Representing | Drug/Topic |
|---|---|---|
| James Tobitt | Apellis | pegcetacoplan (Empaveli) |
| Stacy Sandate | Albireo Pharma | odevixibat (Bylavy) |
| Ray Kong | Ultragenyx | triheptanoin (Dojolvi) |
| David Miley | Teva Pharmaceuticals | Select Preventative Migraine Treatments |
| Chase Williams | Gilead Sciences | DAA therapy for HCV |
| Scott Andersen | Regeneron | Praluent (PCSK9 Inhibitor) |
| Bashir Kalayeh | Bayer Pharmaceuticals | finerenone (Kerendia) |
| Bradley Jones | Abbvie | Oriahnn and Orilissa |
| Carrie Johnson | Amgen | apremilast (Otezla) |

Written Provider Comments Received:
Humira for Hidradenitis Suppurativa, HCV DAAs

Written Manufacturer Comments Received: None

**Retrospective DUR Data Presentations**

***Concurrent use of GLP-1 RA and DPP-4 Inhibitors:*** Data was run to identify members with concurrent use of a GLP-1 RA and DPP-4i with 60 or more days of overlap. Updated recommendations from the American Diabetes Association indicate combined use of these agents is not recommended. Use of both agents concurrently does not offer additional significant lowering of A1C and adds to the patient's pill burden and increased medical costs. Letters will be sent to prescribers regarding the concurrent use of a GLP-1 RA and DPP-4i, pointing out the overlapping mechanisms of action and lack of additional significant improvements in A1C and recommending one agent be discontinued.

***High Dose Glucocorticoid without Bisphosphonate:*** Data was run to identify adults receiving the equivalent daily dosage of prednisone 7.5 mg without an oral bisphosphonate for 90 or more days. As glucocorticoid therapy is associated with a risk of bone loss, and can also increase fracture risk, letters will be sent to prescribers of members on a high-dose glucocorticoid without a bisphosphonate, pointing out the increased risk of fracture, and recommending a preferred bisphosphonate be added if the patient is to remain on high dose glucocorticoid therapy.

***SABA Overutilization:*** The 2021 GINA guidelines state that dispensing of ≥ 3 canisters per year (i.e. daily use) is associated with higher risk of severe exacerbations and dispensing of ≥ 12 canisters per year is associated with much higher risk of death. For safety reasons, GINA no longer recommends SABA-only treatment for initial, step 1, treatment in adults and adolescents. GINA now recommends an inhaled corticosteroid (ICS) containing controller

treatment to reduce the risk of serious exacerbations. The ICS can be delivered by regular daily treatment, or in mild asthma, by as needed low dose ICS-formoterol. Pam Smith will review the GOLD guidelines to check for maximum SABA dosage for use in COPD. Data will be re-run to incorporate members with and without inhaled corticosteroids in their claims histories. Findings and recommended quantity limits will be brought back to the next meeting. Letters to precribers will be postponed for now.

***Concurrent Opioids and Benzodiazepines:*** This topic is included in the SUPPORT Act and required for CMS reporting, optional this year, but mandatory in 2 years. After discussion at three prior meetings, the Commission thought a hard POS edit preventing concurrent use and development of PA criteria would be the best course of action. Data was then run to see the top providers and number of claims involved. As requested at the November meeting, Pam Smith researched what the MCOs and other states were doing to address this issue, and presented her findings to the Commission. They did not think the current POS edit was preventing duplicate therapy by itself, and agreed again that it would be far easier to prevent future use rather than trying to get thousands of members to discontinue use. Kellen Ludvigson suggested allowing only a 5-day supply of benzodizepines, requiring prior authorization for anything additional, but allowing for grandfathering of established users. Jason Wilbur thought requiring members to have naloxone filled on a regular basis would be a good idea. Missouri enforces that criteria with a look-back on the member's claims history. Pam Smith will bring proposed parameters for these suggestions and accompanying PA criteria back to the next meeting for further discussion.

***Chronic Use of Controlled Sedative/Hypnotic Agents:*** Data identifying members with claims for a controlled sedative/hypnotic agent for more than 90 days in a 120-day period was examined and discussed. At the last meeting, the Commission wondered if other treatment options would be available if sedative/hypnotics were more controlled with a POS edit or PA criteria. Pam Smith was able to confirm that both MCO plans and FFS cover CBT for sleep disorders, and she presented what she had found for criteria in other states. The Commission members said it was currently difficult for patients to get an appointment with a pschologist for a CBT for insomnia diagnosis. Jason Wilbur also noted there was very poor evidence of positive outcomes for these medications, other than brief increases in sleep duration, and it's known they disrupt sleep architecture, and that people develop a physiologic addiction to them. He suggested changing the quantity limit back to something more stringent, such as 15 for 30 days, to limit to acute use. Pam Smith said she would bring the previous non-benzodiapezine sedative hypnotic PA criteria back to the next meeting for discussion. The benzodiazepine sedative hypnotics could be subject to the new initial fill days' supply criteria, pending the DURs discussion and formal recommendation for that topic.

## Retrospective DUR Proposals

***Duplicate Therapy with Stimulants:*** Data will be pulled to identify members with concurrent use of at least two, chemically distinct stimulants (would not include members receiving an IR and ER stimulant of the same medication) for more than 35 days in a 60 day period. Findings will then be broken out by number of prescribers and member age. Use

of more than one chemically distinct stimulant is not supported in ADHD treatment guidelines and may increase the risk of adverse effects. Stimulants also have a high potential for abuse, and are continually in the top drugs by paid amount and prescription count on pharmacy claims reports.

**Commission Recommendations for Retrospective DUR Agenda Topics**

There were no additional topic suggestions, other than one previously mentioned by Jason Wilbur: LABAs used for asthma without a concurrent inhaled corticosteroid.

**Prospective DUR**

***Oral Benzodiazepine Quantity Limits:*** Data was re-run to identify the number of unique patients receiving quantities of 120 or more per 30 days over a 6-month span, as that is the highest risk population, specifically focusing on clonazepam, alprazolam, lorazepam, and diazepam, though Dr. Wadle previously suggested limits on all bendodiazepines to prevent possible drift to other agents when these four were further restricted. The Commission liked the idea of capping the cumulative number of units similar to Arkansas versus the current limit by drug and strength. A daily limit of 4 units per day, across the entire benzodiazepine class, was recommended. This will be brought back to the next meeting for further discussion and vote.

***Anticonvulsant Quantity Limits:*** Kellen Ludvigson motioned to approve the suggested quantity limits as written, 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.

The Commission took a short break and open session resumed at 11:56 a.m.

**Prior Authorization**

***PCSK9 Inhibitors:*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for PCSK9 Inhibitors. Payment for a non-preferred PCSK9 Inhibitor will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions:*

1. *Patient meets the FDA approved age for indication; AND*
2. *Dosing follows the FDA approved dose for the submitted diagnosis; AND*
3. *Current use of a statin and documentation of adherence to prescribed lipid lowering medications for the previous 90 days is provided (further defined below, by diagnosis); AND*
4. *Is to be prescribed as an adjunct to a low-fat diet; AND*
5. *A baseline and current lipid profile is provided. Baseline lipid profile is defined as a lipid profile obtained prior to pharmacologic therapy; AND*
6. *Documentation patient has been counseled on importance of abstinence from tobacco and, if a current smoker, be encouraged to enroll in a smoking cessation program.*

7. *The 72-hour emergency supply rule does not apply to PCSK9 Inhibitors.*
8. *Prescriber and dispensing pharmacy will educate the patient on proper storage and administration. Improperly stored medications will not be replaced.*
9. *Lost or stolen medication replacement requests will not be authorized.*
10. *Goal is defined as a 50% reduction in untreated baseline LDL-C.*
11. *Is prescribed for one of the following diagnoses:*

*<u>Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH)</u>*

1. *Total cholesterol > 290mg/dL or LDL-C > 190mg/dL; AND*
    a. *Presence of tendon xanthomas; OR*
    b. *In first or second degree relative, one of the following:*
        i. *Documented tendon xanthomas; or*
        ii. *MI at age ≤60 years; or*
        iii. *Total cholesterol > 290mg/dL; OR*
    c. *Confirmation of diagnosis by gene or receptor testing (attach results); AND*
2. *Unable to reach goal LDL-C with a minimum of one high-intensity statin (atorvastatin 40-80 mg or rosuvastatin 20-40 mg) used in combination with ezetimibe 10mg daily. If patient is unable to tolerate high-intensity statin therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.*

*<u>Diagnosis of Clinical Atherosclerotic Cardiovascular Disease (ASCVD)</u>*

1. *History of MI, angina, coronary or other arterial revascularization, stroke, TIA, or PVD of atherosclerotic origin; AND*
2. *Unable to reach goal LDL-C with a minimum of one high-intensity statin (atorvastatin 40-80 mg or rosuvastatin 20-40 mg) used in combination with ezetimibe 10mg daily. If patient is unable to tolerate high-intensity statin therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.*

*<u>Diagnosis of Primary Hyperlipidemia (not associated with ASCVD or HeFH)</u>*

1. *Baseline LDL-C ≥ 190 mg/dL; and*
2. *Unable to reach goal LDL-C < 100mg/dL while on high-intensity statin therapy (atorvastatin 40-80 mg or rosuvastatin 20-40 mg) used in combination with*

*ezetimibe 10 mg daily. If patient is unable to tolerate high-intensity statin therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.*

*<u>Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH)</u>*

1. *Total cholesterol and LDL-C > 600mg/dL and triglycerides within reference range; OR*
2. *Confirmation of diagnosis by gene or receptor testing (attach results); AND*
3. *Unable to reach goal LDL-C with a minimum of one high-intensity statin (atorvastatin 40-80 mg or rosuvastatin 20-40 mg) used in combination with ezetimibe 10mg daily. If patient is unable to tolerate high-intensity statin therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.*

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

*Initial requests will be approved for 6 months. Additional requests will be considered under the following conditions:*

1. *Documentation of positive clinical response to PCSK9 Inhibitor therapy (current LDL-C lab provided); and*
2. *Patient continues therapy with a maximally tolerated statin; and*
3. *Patient has continued compliance with a low-fat diet.*

Kellen Ludvigson motioned to accept the criteria as amended, and Jason Kruse seconded. All members were in favor. Kellen Ludvigson then motioned to accept the proposed quantity limits, and Jason Kruse seconded. This decision was also unanimous. The recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

***Finerenone (Kerendia):*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for finerenone (Kerendia). Payment will be considered under the following conditions:*

1. *Request adheres to all FDA approved labeling, including age, dosing, contraindications, warnings and precautions, and drug interactions; and*
2. *Patient has a diagnosis of chronic kidney disease (CKD) associated with Type 2 Diabetes (T2D); and*

3. *Patient is currently receiving a maximally tolerated dose of an angiotensin converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB); and*
4. *Patient is currently receiving a maximally tolerated dose of a sodium-glucose co-transporter 2 (SGLT2) inhibitor indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease [i.e., dapagliflozin (Farxiga)]; and*
5. *Patient has the following baseline tests prior to initiation of treatment with finerenone:*
    a. *Serum potassium is ≤ 5.0 mEq/L; and*
    b. *Estimated glomerular filtration rate (eGFR) is ≥ 25 mL/min/1.73m$^2$; and*
    c. *Urine albumin to creatinine ration (UACR) is ≥ 30 mg/g.*

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

*Initial authorizations will be approved for six months. Additional PAs will be considered with the following documentation:*

1. *Patient's serum potassium is < 5.5 mEq/L; and*
2. *Patient's eGFR is ≥ 25 mL/min/1.73m$^2$; and*
3. *Patient remains on a maximally tolerated dose of an ACEi or ARB; and*
4. *Patient remains on a maximally tolerated dose of an SGLT2 inhibitor.*

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.

***Odevixibat (Bylvay):*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for odevixibat (Bylvay). Payment will be considered under the following conditions:*

1. *Request adheres to all FDA approved labeling including age, dosing, contraindications, warnings and precautions, and drug interactions; and*
2. *Patient has a diagnosis of genetically confirmed progressive familial intrahepatic cholestasis (PFIC) type 1 or type 2; and*
3. *Genetic testing does not indicate PFIC type 2 with ABCB 11 variants encoding for nonfunction or absence of bile salt export pump protein (BSEP-3); and*
4. *Patient has moderate to severe pruritus associated with PFIC; and*
5. *Patient's current weight in kg is provided; and*
6. *Is prescribed by or in consultation with a hepatologist or gastroenterologist.*

*Initial authorizations will be approved for 3 months for initial treatment or after a dose increase. Additional authorizations will be considered when the following criteria are met:*

1. *Patient's current weight in kg is provided; and*
2. *Documentation is provided the patient has responded to therapy and pruritis has improved. If there is no improvement in pruritus after 3 months of treatment with the maximum 120 mcg/kg/day dose, further approval of odevixibat will not be granted.*

Kellen Ludvigson motioned to accept the proposed criteria, 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.

***Pegcetacoplan (Empaveli):*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for pegcetacoplan (Empaveli). Payment will be considered under the following conditions:*

1. *Request adheres to all FDA approved labeling including age, dosing, contraindications, and warnings and precautions; and*
2. *Patient has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH); and*
3. *Flow cytometry shows detectable glycosylphosphatidylinositol (GPI)-deficient hematopoietic clones or ≥ 10% PNH cells; and*
4. *History of at least one red blood cell transfusion in the previous 12 months; and*
5. *Documentation of hemoglobin < 10.5 g/dL; and*
6. *Is not prescribed concurrently with eculizumab (Solaris) or ravulizumab (Ultomiris), unless the patient is in a 4 week period of cross-titration between eculizumab (Soliris) and pegcetacoplan (Empaveli); and*
7. *Is prescribed by or in consultation with a hematologist; and*
8. *Medication will be administered in the member's home; and*
9. *Member or member's care giver has been properly trained in subcutaneous infusion and prescriber has determined home administration is appropriate.*

*Initial authorizations will be approved for 4 weeks if within cross-titration period with eculizumab (Soliris) to verify eculizumab has been discontinued, or for 6 months otherwise. Additional authorizations will be considered when the following criteria are met:*

1. *Documentation of a positive clinical response to therapy (e.g., increased or stabilization of hemoglobin levels or reduction in transfusions); and*
2. *Is not prescribed concurrently with eculizumab (Solaris) or ravulizumab (Ultomiris).*

Jason Kruse motioned to accept the proposed criteria, 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.

***Select Preventative Migraine Treatments:*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for select preventative migraine agents. Payment for non-preferred select preventative migraine agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred, select preventative migraine agent. Payment will be considered under the following conditions:*

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

a. *A previous trial and therapy failure at an adequate dose with glucocorticoids (prednisone 30mg per day or dexamethasone 8mg BID) started promptly at the start of a cluster period. Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamine, lidocaine) at least once daily for at least two days per week after the first full week of adequately dosed steroid therapy; and*
b. *A previous trial and therapy failure at an adequate dose of verapamil for at least 3 weeks (total daily dose of 480mg to 960mg). Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamines, lidocaine) at least once daily for at least two days per week after three weeks of adequately dosed verapamil therapy.*

7. *Lost, stolen, or destroyed medication replacement requests will not be authorized.*

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

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

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

***Hepatitis C Treatments:*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for hepatitis C direct-acting antivirals (DAA). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:*

1. *Patient has a diagnosis of chronic hepatitis C; and*
2. *Patient's age and/or weight is within the FDA labeled age and/or weight; and*
3. *Patient has had testing for hepatitis C virus (HCV) genotype; and*
4. *Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and*
5. *Patient has been tested for hepatitis B (HBV) prior to initiating treatment of HCV and individuals with active HBV infection are treated (either at same time as HCV therapy or before HCV therapy is started); and*
6. *Patient's prior HCV DAA treatment history is provided (treatment naïve or treatment experienced); and*
7. *If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided;*

*and*

8. *Patient has been evaluated to determine the patient's readiness for HCV treatment with scales or assessment tools, such as the SAMHSA-HRSA Center for Integrated Health Solutions – Drug & Alcohol Screening Tools and the Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C); and*
9. *Patient has been educated on the importance of abstinence from IV drug use and alcohol use, the importance of compliance with HCV treatment, and how to prevent HCV transmission. If patient is currently using IV drugs and/or alcohol, recommend the patient participate in alcohol and/or substance abuse counseling; and*
10. *HCV treatment is prescribed by or in consultation with a digestive disease, liver disease, or infectious disease provider practice; and*
11. *FDA approved pediatric formulations of HCV DAAs and DAA approved for pediatric use will be considered for those under the age of 18 when used in accordance with current AASLD guidelines including for indication and age; and*
12. *For patients on a regimen containing ribavirin, the following must be documented on the PA form:*
    a. *Patient is not a pregnant female or male with a pregnant female partner; and*
    b. *Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and*
    c. *Monthly pregnancy tests will be performed during treatment; and*
13. *Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the DAA; and*
14. *Documentation is provided for patients who are ineligible to receive ribavirin; and*
15. *Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved; and*
16. *Patient does not have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.*
17. *If patient is recently eligible for Iowa Medicaid, and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on length of therapy for the particular treatment.*
18. *Lost or stolen medication replacement requests will not be authorized.*
19. *The 72-hour emergency supply rule does not apply to DAAs.*

*Requests for treatment-experienced patients (with previous DAA) will be considered under the following conditions:*

1. *Patient must meet all criteria for treatment approval above; and*
2. *Patients who previously achieved SVR that have HCV recurrence due to IV*

*drug use must have documentation that the patient has completed or is participating in a recovery program, receiving alcohol or substance abuse counseling services, or seeing an addiction specialist as part of HCV treatment, and can be managed as an initial infection; and*

3. *The requested therapy is FDA approved as therapy for treatment-experienced patients and follows current AASLD guidelines; and*
4. *Patient has not been previously treated with and failed the requested DAA therapy; and*
5. *Documentation is provided patient has a documented presence of detectable HCV RNA at least 12 weeks after completing previous DAA 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.

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

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

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

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

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

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

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

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. However, this will be brought back to a future meeting to review again due to new agents and indications newly available.

***Apremilast (Otezla):*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for apremilast (Otezla). Payment will be considered under the following conditions:*

1. *Request adheres to all FDA approved labeling for indication, including age, dosing, and contraindications; and*
2. *Patient has a diagnosis of active psoriatic arthritis (≥ 3 swollen joints and ≥ 3 tender joints); with*
    a. *Documentation of a trial and inadequate response to therapy with the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated; or*
3. *Patient has a diagnosis of plaque psoriasis; with*
    a. *Documentation of a trial and inadequate response to phototherapy, systemic retinoids, methotrexate, or cyclosporine.*
4. *Patient has a diagnosis of Behçet disease; with*

a. *Documentation of active oral ulcers associated with Behçet disease; and*
b. *Documentation of a previous trial and inadequate response, at a therapeutic dose, to colchicine.*

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

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

***Biologicals for Arthritis:*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for biologicals used for arthritis. Request must adhere to all FDA approved labeling, including age, indication, dosing, and contraindications. Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. Payment will be considered under the following conditions:*

1. *Patient has been screened for hepatitis B and C. Patients with evidence of active hepatitis B infection (hepatitis surface antigen positive > 6 months) must have documentation they are receiving or have received effective antiviral treatment; and*
2. *Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and*
3. *Patient has a diagnosis of rheumatoid arthritis (RA); with*
    a. *Documentation of a trial and inadequate response, at a maximally tolerated dose, with methotrexate (hydroxycholoroquine, sulfasalazine, or leflunomide may be used if methotrexate is contraindicated) or*
4. *Patient has a diagnosis of moderate to severe psoriatic arthritis; with*
    a. *Documentation of a trial and inadequate response, at a maximally tolerated dose with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or*
5. *Patient has a diagnosis of moderate to severe juvenile idiopathic arthritis; with*
    a. *Documentation of a trial and inadequate response to intraarticular glucocorticoid injections and methotrexate at a maximally tolerated dose (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*

*In addition to the above:*

*Requests for TNF Inhibitors:*

1. *Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and*
2. *Patient does not have a diagnosis of congestive heart failure (CHF) that is*

*New York Heart Association (NYHA) class lll or lV and with an ejection fraction of 50% or less.*

*Requests for Interleukins:*

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

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

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.

***Triheptanoin (Dojolvi):*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for triheptanoin (Dojolvi). Payment will be considered under the following conditions:*

1. *Request adheres to all FDA approved labeling for indication, including age, dosing, contraindications, warnings, and precautions; and*
2. *Patient has a diagnosis of long-chain fatty acid oxidation disorder (LC-FAOD), with supporting documentation of gene mutation(s) associated with LC-FAOD (LC-FAODs include: CPT I, CACT, CPT II, VLCAD, TFP, LCHAD); and*
3. *Patient will not be using another medium chain triglyceride (MCT) product; and*
4. *Documentation of patient's daily caloric intake (DCI) is provided; and*
5. *Patient's target daily dosage is provided as a percentage of the patient's total daily prescribed DCI, not to exceed 35%; and*
6. *Is prescribed by or in consultation with an endocrinologist, geneticist, or metabolic disease specialist.*

*If the criteria for coverage are met, initial requests will be approved for four months. Additional authorizations will be considered upon documentation of a positive clinical response to therapy.*

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

***Baclofen Oral Solution (Ozobax):*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for baclofen oral solution (Ozobax). Payment for a non-preferred agent will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions:*

1. *Patient has a diagnosis of spasticity resulting from multiple sclerosis (relief of flexor spasms and concomitant pain, clonus, and muscular rigidity) or spinal cord injuries/diseases; and*

2. *Patient meets the FDA approved age; and*
3. *Documentation of a patient-specific, clinically significant reason (beyond convenience) why the member cannot use baclofen oral tablets, even when tablets are crushed and sprinkled on soft food or liquid. Presence of a nasogastric (NG) tube/J-tube alone are not reasons for approval; and*
4. *Request does not exceed the maximum dosage of 80mg daily.*

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.

***Tasimelteon (Hetlioz):*** The initial PA criteria limited the use only to blind individuals. This requirement is now removed consistent with the FDA approved indication, as non-24-hour sleep-wake disorder also impacts sighted individuals. Additional FDA review information can be found here as well as the Public Citizen Petition regarding the indication. Criteria has been updated as follows:

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

1. *Patient has a diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24), as confirmed by a sleep specialist; and*
2. *Patient is 18 years of age or older; and*
3. *Patient has a documented trial and therapy failure with at least one preferred sedative/hypnotic-non-benzodiazepine agent; and*
4. *Patient has a documented trial and therapy failure with ramelteon (Rozerem).*

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

No motion was necessary for this criteria change. However, Tasimelteon (Hetlioz) was also recently approved for a second indication, the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS). PA criteria will be brought back in May for revision of PA criteria for the new indication.

**Miscellaneous**

***DUR Digest:*** The Commission members conducted the second review of DUR Digest Volume 34, Number 1.

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

At 12:52, Kellen Ludvigson motioned to adjourn, and Brett Faine seconded. All in attendance agreed.

**The next scheduled meeting is tentatively set for May 4, 2022, location to be determined.**

# Iowa Medicaid Drug Utilization Review Commission
# Meeting Minutes May 4, 2022

**Attendees:**

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

## Welcome & Introductions

Chairperson Brett Faine called the meeting to order at 9:30 a.m. This meeting was held virtually due to the federal PHE Declaration for the COVID-19 Pandemic. The minutes from the February 2, 2022, meeting were reviewed. Melissa Klotz motioned to accept them, and Jason Kruse seconded. All members were in favor. The recommendation letter sent to DHS after the last DUR meeting was also reviewed.

## IME Pharmacy Update

Informational Letter 2306-MC-FFS notified providers of the 2022 pharmacy cost of dispensing survey, for which surveys were sent out to providers on February 2, 2022, and due back by March 30, 2022. IME is currently in the process of analyzing the data, and an update should be available at the August meeting. There will be two pharmacist positions open at the end of this state fiscal year, as this is the last meeting for both Brett Faine and Kellen Ludvigson. They have been serving as chairperson and vice-chairperson, respectively, since 2017, with Brett having 12 years on the Commission overall and Kellen 10 years. They were thanked for their many years of service to the state and will receive certificates of appreciation in the mail. There is also a physician position open. DHS is accepting referrals and applicants, and interviews are currently in progress.

## Prevalence Report Summaries

***Fee-for-Service:*** Pam Smith provided an overview of fee-for-service statistics from December 2021 through February 2022, including: total amount paid ($2,375,607), unique users (3,728); cost per user ($637.23), number of total prescriptions dispensed (21,022); and percent generic (88.2%). The top 5 therapeutic classes by paid amount were: Anticonvulsants; Muscular Dystrophy Agents; Anti-Inflammatories, Non-NSAID; Antipsychotics – Atypicals; and Antidepressants – Selected SSRIs. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Antihypertensives - Central; and

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

***Amerigroup****:* Lisa Todd provided an overview for ITC's statistics from December 2021 through February 2022, including: total paid amount ($118,541,721); total prescriptions (1,111,758); and unique users (173,760). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy and 4 Walgreens locations made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Caremark Kansas Specialty Pharmacy, Caremark Illinois Specialty Pharmacy, Community Walgreens Pharmacy, and Unity Point at Home. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Inflammatory; Antiasthmatic and Bronchodilator Agents; and Dermatologicals. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, and Antihypertensives. Humira (CF) Pen was the most expensive medication, followed by Vyvanse, Vraylar, Trulicity, and Latuda. Sertraline hcl had the highest prescription count, followed by: omeprazole, trazodone hcl, amoxicillin, and escitalopram.

***Iowa Total Care:*** Emily Rogers provided an overview for ITC's statistics from December 2021 through February 2022, including: total paid amount ($79,777,204.74); total prescriptions (784,907); and unique users (128,674). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy, Broadlawns, and 3 Walgreens locations made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Nucara Specialty, Caremark Kansas Specialty Pharmacy, Hy-Vee Pharmacy Solutions, and Unity Point at Home. The top 5 therapeutic classes by paid amount were: Insulin; Anti-TNF-alpha-Monoclonal Antibodies; Sympathomimetics; Incretin Mimetic Agents (GLP-1 Receptor Agonists); and Antipsychotics – Misc. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Sympathomimetics; Proton-Pump Inhibitors; and NSAIDs. The most expensive drugs were Humira Pen, Vyvanse, Vraylar, Trulicity, and Trikafta, while sertraline, omeprazole, amoxicillin, atorvastatin, and trazodone had the top 5 prescription counts.

**Comparative Prevalence Report Summary**

Pam Smith also created a report that compared the FFS stats with those from each MCO. Its side-by-side statistics showed that $ 200,694,533 was spent in total for 306,162 unique users who had 1,917,687 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Humira and Vyvanse were the two most expensive drugs for both MCO plans, and also

in the top six for FFS. The top 25 drugs by prescription count were also similar across FFS and both MCO plans. When all three plans were combined, Jeffrey Wilharm had the overall highest prescription count at 4,458. All three complete prevalence reports and the comparative summary can be found in the finalized meeting packet posted on https://iadur.org on the Meeting Materials page.

**Public Comment**

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

| Name | Representing | Drug/Topic |
|---|---|---|
| Kelly Broderick | Apellis Pharmaceuticals | pegcetacoplan (Empaveli) |
| Bashir Kalayeh | Bayer Pharmaceuticals | finerenone (Kerendia) |
| Jenna McGowan | Abbvie | adalimumab (Humira) |
| James Bauman | Pfizer | Cibinqo & Eucrisa (Atopic Dermatitis) |
| Stacy Sandate | Albireo Pharma | odevixibat (Bylvay) |

Written Provider Comments Received: None

Written Manufacturer Comments Received: Empaveli, Humira

**Retrospective DUR Data Presentations**

***SABA Overutilization:*** See the Short-Acting Beta Agonist Quantity Limit paragraph below. Suggestions for this topic were held until that point in the agenda to discuss the limits at the same time due to probable overlap.

***Duplicate Therapy with Stimulants:*** After the last meeting, data was pulled to identify members with concurrent use of at least two, chemically distinct stimulants (not including members receiving an IR and ER stimulant of the same medication) for more than 35 days in a 60 day period. Findings were then broken out by number of prescribers and member age. Language will be added to the PA criteria regarding concurrent use of methylphenidate and an amphetamine, and a ProDUR edit blocking duplicate therapy for children will need to be discussed at a future meeting. Pam Smith will bring the suggested PA revisions back to the next meeting for review. Letters will be sent to providers to provide advance notice of future changes.

**Retrospective DUR Proposals**

***High Dose Opioid (> 90 MME) without Opioid Reversal Agent:*** The Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) requires states have an automated review process in place to identify patients at high risk of opioid overdose without a reversal agent. Current prior authorization criteria for High Dose Opioids, defined as 90 morphine milligram equivalents (MME) per day, requires the prescriber to attest a prescription for a preferred naloxone product for the emergency treatment of an opioid overdose has been provided. Data will be pulled to identify members with a claim(s) for an opioid ≥ 90 MME during the month of April 2022, with a look-back at the prior 24 months to check for naloxone

prescriptions in their claim histories. The Commission would also like a report for the total number of naloxone claims per quarter during the look-back period. Pam Smith will bring results back to the next meeting.

***Opioid plus Buprenorphine for OUD:*** The Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) requires states to establish prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state, to identify patients prescribed an opioid after being prescribed one or more drugs used for medication assisted treatment (MAT). Currently, pharmacies receive a ProDUR soft edit regarding the combination. Data will be pulled to identify members with concurrent buprenorphine, indicated for the treatment of opioid use disorder (OUD), and an opioid in pharmacy claims. Chuck Wadle suggested that days supply be evaluated due to possible post-operative opioid use. Pam Smith will break out the data to show claims for 7 days or less for an initial fill, and those claims for 8 or more days, and bring findings back to the next meeting.

**Commission Recommendations for Retrospective DUR Agenda Topics**

There were no additional topic suggestions.

**Prospective DUR**

***Initial Days Supply Limit – Benzodiazepines:*** The DUR Commission made a recommendation to implement a 7-day initial limit on all benzodiazepines for new users. The ProDUR point-of-sale (POS) edit would limit to an initial 7 days' supply for a benzodiazepine if the requested benzodiazepine is not found in pharmacy claims in the preceding 90 days. Exceptions to this edit include nasal and rectal diazepam, nasal midazolam and clobazam. Prior authorization would be required for quantities exceeding 7 days and the Commission will develop PA criteria at a future meeting.

***Benzodiazepine Cumulative Quantity Limit:*** The DUR Commission made a recommendation to implement a cumulative quantity limit of 4 units per day across the benzodiazepine class for solid oral dosage forms. After reviewing the complete list of proposed quantity limits (posted in the finalized meeting packet on https://iadur.org on the Meeting Materials page), Kellen Ludvigson motioned to accept them, and Jason Kruse seconded. The decision was unanimous. The limit chart will include a statement, such as "Benzodiazepines are subject to a cumulative quantity limit of 4 units per day, unless otherwise indicated on the chart."

***Short-Acting Beta Agonist Quantity Limit:*** Current asthma and COPD guidelines do not recommend regular use of short-acting beta-agonists (SABAs), and review of pharmacy claims for SABAs finds members are overutilizing these agents. The Commission would like to send letters to the providers of members with overuse in their claim histories. They would also like to implement a quantity limit of 2 canisters per 30 days, similar to other states. Jason Wilbur made the motion for the quantity limit, Chuck Wadle seconded, and all members were in favor.

***Anticonvulsant Quantity Limits:*** The Commission had no additional changes after reviewing the complete list of proposed quantity limits (posted in the finalized meeting packet on https://iadur.org on the Meeting Materials page). As this was the second review of these quantity limits, no motion was necessary. The recommendations will be sent to the Department for consideration.

The Commission took a short break and open session resumed at 11:47 a.m.

**Prior Authorization**

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

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

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

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

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

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

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

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

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

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

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

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

Jason Kruse motioned to accept the criteria as amended, and Jason Wilbur seconded. All members were in favor. Kellen Ludvigson then motioned to accept the proposed quantity limits as shown below, and Jason Kruse seconded. This decision was unanimous, as well. The recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

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

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

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

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

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

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

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

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

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

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of mild to moderate atopic dermatitis; and*
3. *Patient has failed to respond to good skin care and regular use of emollients; and*

4. *Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*
5. *Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
6. *Patient will continue with skin care regimen and regular use of emollients.*
7. *Quantities will be limited to 60 grams for use on the face, neck, and groin and 100 grams for all other areas, per 30 days.*

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

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

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

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

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

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

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

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

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

*drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations.*

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

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

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

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

*Payment will be considered under the following conditions:*

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

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

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

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

***Sedative/Hypnotics, Non-Benzodiazepine:*** The Commission reviewed utilization data for all controlled sedative hypnotic agents at the February 2022 meeting. Based on that information, the Commission requested a review of current PA criteria for sedative/hypnotic non-benzodiazepine agents. Current PA criteria and prior PA criteria were reviewed and next steps were discussed. Jason Wilbur noted that if the objective in changing PA criteria was to reduce reliance on these medications, unfortunately, there aren't good alternatives. To be consistent, he suggested removing requirements for use of short-acting stimulant medications, and also changing #5 to expand to the entire class of drugs. Pam Smith will amend the criteria as suggested and bring it back to the next meeting for review and approval, and include language about use of benzodiazepine sedative hypnotics. The Commission did not want to implement any initial quantity limits at this time.

***Ophthalmic Agents for Presbyopia (Vuity):*** The Commission reviewed the prior authorization criteria as follows:

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

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

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

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

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

Jason Wilbur motioned to accept the criteria as amended, with the addition of a quantity limit of 2.5 mL per 30 days, and Jason Kruse seconded. All members were in favor. The recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

***PCSK9 Inhibitors:*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for PCSK9 Inhibitors. Payment for a non-preferred PCSK9 Inhibitor will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions:*

1. *Patient meets the FDA approved age for indication; AND*
2. *Dosing follows the FDA approved dose for the submitted diagnosis; AND*
3. *Current use of a statin and documentation of adherence to prescribed lipid lowering medications for the previous 90 days is provided (further defined below, by diagnosis); AND*
4. *Is to be prescribed as an adjunct to a low-fat diet; AND*
5. *A baseline and current lipid profile is provided. Baseline lipid profile is defined as a lipid profile obtained prior to pharmacologic therapy; AND*
6. *Documentation patient has been counseled on importance of abstinence from tobacco and, if a current smoker, be encouraged to enroll in a smoking cessation program.*
7. *The 72-hour emergency supply rule does not apply to PCSK9 Inhibitors.*
8. *Prescriber and dispensing pharmacy will educate the patient on proper storage and administration. Improperly stored medications will not be replaced.*
9. *Lost or stolen medication replacement requests will not be authorized.*
10. *Goal is defined as a 50% reduction in untreated baseline LDL-C.*
11. *Is prescribed for one of the following diagnoses:*

*<u>Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH)</u>*

1. *Total cholesterol > 290mg/dL or LDL-C > 190mg/dL; AND*
    a. *Presence of tendon xanthomas; OR*
    b. *In first or second degree relative, one of the following:*
        i. *Documented tendon xanthomas; or*
        ii. *MI at age ≤60 years; or*
        iii. *Total cholesterol > 290mg/dL; OR*
    c. *Confirmation of diagnosis by gene or receptor testing (attach results); AND*
2. *Unable to reach goal LDL-C with a minimum of one high-intensity statin (atorvastatin 40-80 mg or rosuvastatin 20-40 mg) used in combination with ezetimibe 10mg daily. If patient is unable to tolerate high-intensity statin*

*therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.*

*Diagnosis of Clinical Atherosclerotic Cardiovascular Disease (ASCVD)*

1. *History of MI, angina, coronary or other arterial revascularization, stroke, TIA, or PVD of atherosclerotic origin; AND*
2. *Unable to reach goal LDL-C with a minimum of one high-intensity statin (atorvastatin 40-80 mg or rosuvastatin 20-40 mg) used in combination with ezetimibe 10mg daily. If patient is unable to tolerate high-intensity statin therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.*

*Diagnosis of Primary Hyperlipidemia (not associated with ASCVD or HeFH)*

1. *Baseline LDL-C ≥ 190 mg/dL; and*
2. *Unable to reach goal LDL-C < 100mg/dL while on high-intensity statin therapy (atorvastatin 40-80 mg or rosuvastatin 20-40 mg) used in combination with ezetimibe 10 mg daily. If patient is unable to tolerate high-intensity statin therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.*

*Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH)*

1. *Total cholesterol and LDL-C > 600mg/dL and triglycerides within reference range; OR*
2. *Confirmation of diagnosis by gene or receptor testing (attach results); AND*
3. *Unable to reach goal LDL-C with a minimum of one high-intensity statin (atorvastatin 40-80 mg or rosuvastatin 20-40 mg) used in combination with ezetimibe 10mg daily. If patient is unable to tolerate high-intensity statin therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.*

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

*Initial requests will be approved for 6 months. Additional requests will be considered under the following conditions:*

1. *Documentation of positive clinical response to PCSK9 Inhibitor therapy (current LDL-C lab provided); and*
2. *Patient continues therapy with a maximally tolerated statin; and*
3. *Patient has continued compliance with a low-fat diet.*

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.

***Finerenone (Kerendia):*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for finerenone (Kerendia). Payment will be considered under the following conditions:*

1. *Request adheres to all FDA approved labeling, including age, dosing, contraindications, warnings and precautions, and drug interactions; and*
2. *Patient has a diagnosis of chronic kidney disease (CKD) associated with Type 2 Diabetes (T2D); and*
3. *Patient is currently receiving a maximally tolerated dose of an angiotensin converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB); and*
4. *Patient is currently receiving a maximally tolerated dose of a sodium-glucose co-transporter 2 (SGLT2) inhibitor indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease [i.e., dapagliflozin (Farxiga)]; and*
5. *Patient has the following baseline tests prior to initiation of treatment with finerenone:*
    a. *Serum potassium is ≤ 5.0 mEq/L; and*
    b. *Estimated glomerular filtration rate (eGFR) is ≥ 25 mL/min/1.73m$^2$; and*
    c. *Urine albumin to creatinine ration (UACR) is ≥ 30 mg/g.*

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

*Initial authorizations will be approved for six months. Additional PAs will be considered with the following documentation:*

1. *Patient's serum potassium is < 5.5 mEq/L; and*
2. *Patient's eGFR is ≥ 25 mL/min/1.73m$^2$; and*
3. *Patient remains on a maximally tolerated dose of an ACEi or ARB; and*
4. *Patient remains on a maximally tolerated dose of an SGLT2 inhibitor.*

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.

***Odevixibat (Bylvay):*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for odevixibat (Bylvay). Payment will be considered under the following conditions:*

1. *Request adheres to all FDA approved labeling including age, dosing, contraindications, warnings and precautions, and drug interactions; and*
2. *Patient has a diagnosis of genetically confirmed progressive familial intrahepatic cholestasis (PFIC) type 1 or type 2; and*
3. *Genetic testing does not indicate PFIC type 2 with ABCB 11 variants encoding for nonfunction or absence of bile salt export pump protein (BSEP-3); and*
4. *Patient has moderate to severe pruritus associated with PFIC; and*
5. *Patient's current weight in kg is provided; and*
6. *Is prescribed by or in consultation with a hepatologist or gastroenterologist.*

*Initial authorizations will be approved for 3 months for initial treatment or after a dose increase. Additional authorizations will be considered when the following criteria are met:*

1. *Patient's current weight in kg is provided; and*
2. *Documentation is provided the patient has responded to therapy and pruritis has improved. If there is no improvement in pruritus after 3 months of treatment with the maximum 120 mcg/kg/day dose, further approval of odevixibat will not be granted.*

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.

***Pegcetacoplan (Empaveli):*** The Commission reviewed the prior authorization criteria as follows:

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

*Prior authorization (PA) is required for pegcetacoplan (Empaveli). Payment will be considered under the following conditions:*

1. *Request adheres to all FDA approved labeling including age, dosing, contraindications, and warnings and precautions; and*
2. *Patient has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH); and*
3. *Flow cytometry shows detectable glycosylphosphatidylinositol (GPI)-deficient hematopoietic clones or ≥ 10% PNH cells; and*
4. *History of at least one red blood cell transfusion in the previous 12 months; and*
5. *Documentation of hemoglobin < 10.5 g/dL; and*

6. *Is not prescribed concurrently with eculizumab (Solaris) or ravulizumab (Ultomiris), unless the patient is in a 4 week period of cross-titration between eculizumab (Soliris) and pegcetacoplan (Empaveli); and*
7. *Is prescribed by or in consultation with a hematologist; and*
8. *Medication will be administered in the member's home; and*
9. *Member or member's care giver has been properly trained in subcutaneous infusion and prescriber has determined home administration is appropriate.*

*Initial authorizations will be approved for 4 weeks if within cross-titration period with eculizumab (Soliris) to verify eculizumab has been discontinued, or for 6 months otherwise. Additional authorizations will be considered when the following criteria are met:*

1. *Documentation of a positive clinical response to therapy (e.g., increased or stabilization of hemoglobin levels or reduction in transfusions); and*
2. *Is not prescribed concurrently with eculizumab (Solaris) or ravulizumab (Ultomiris).*

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

**Miscellaneous**

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

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

At 1:01, Brett Faine motioned to adjourn, and Kellen seconded. All in attendance agreed.

**The next scheduled meeting is tentatively set for August 3, 2022, location to be determined.**

# Appendix J
# Recommendations to the P&T

# P & T Recommendations
# SFY22

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

# Appendix K
# Useful Links

# Iowa Drug Utilization Review (DUR) Commission
# Useful Links

**DUR Website**
http://iadur.org/

**DUR Newsletters**
http://iadur.org/newsletters

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