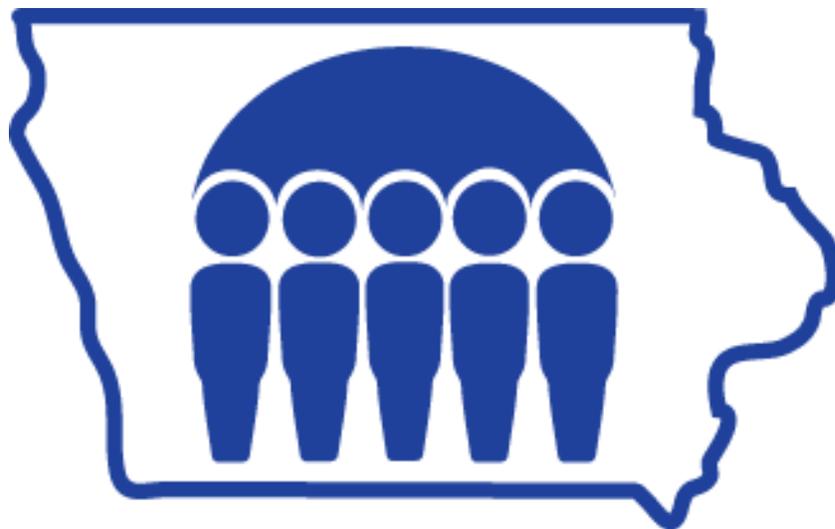


Iowa Department of Human Services



Iowa Medicaid Drug Utilization Review Commission Annual Report of Activities SFY16

September 30, 2016



Iowa Department of Human Services

Terry E. Branstad
Governor

Kim Reynolds
Lt. Governor

Charles M. Palmer
Director

September 23, 2016

Michael Marshall
Secretary of Senate
State Capitol Building
LOCAL

Carmine Boal
Chief Clerk of the House
State Capitol Building
LOCAL

Dear Mr. Marshall and Ms. Boal:

Enclosed please find copies of reports to the General Assembly relative to the Iowa Medicaid Annual Drug Utilization Review (DUR) Report.

This report was prepared pursuant to the directive contained in Iowa Code 249A.24, subpart 3.

The DUR Commission realized an overall direct cost savings of \$26.34 for every dollar spent on the program administratively. State money for this program is matched by the federal government at a 1 to 1 ratio (federal to state), so savings can also be stated as \$52.68 per state dollar spent. Total annualized cost savings estimates for SFY16 (\$7,111,493.58) were higher than SFY15 (\$669,337.04) by approximately 91 percent (an increase of \$6,442,156.54). This is further explained below.

Savings from patient-focused reviews for SFY16 (\$263,026.39) were higher than SFY15 (\$129,145.36) by 104 percent (an increase of \$133,881.03). This increase in savings was, in part, due to the costs associated with the medications involved in the suggestions made by the DUR Commission versus those of the previous year.

Savings from problem-focused reviews for SFY16 (\$6,848,467.19) were higher than SFY15 (\$540,191.68) by 1,168 percent (an increase of \$6,308,275.51). This increase in savings was the result of the type of interventions selected and the size of the patient population in each intervention for SFY16. Additionally, in SFY16 one intervention alone, related to concurrent use of second generation antipsychotics where duplicate therapy was discontinued, realized a savings of over \$6 million.

The format of this year's report has changed slightly from last year. Several documents provided in previous reports have not been included in this report, including the DUR Digest, screen shot of the website, and the Prevalence Reports. This information is referenced in the report under Appendix L, Useful Links, and can be accessed on the DUR Commission website, www.iadur.org.

Please feel free to contact me if you need additional information.

Sincerely,

Paige M. Thorson
Policy Advisor

PT:slp:ps

Enclosure

cc: Terry E. Branstad, Governor
Senator Amanda Ragan
Senator Mark Segebart
Representative David Heaton
Representative Lisa Heddens
Legislative Service Agency
Kris Bell, Senate Democrat Caucus
Josh Bronsink, Senate Republican Caucus
Carrie Malone, House Republican Caucus
Zeke Furlong, House Democrat Caucus

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The Iowa Medicaid Drug Utilization Review Commission

Change Healthcare has developed the following report for the Iowa Department of Human Services. This report provides a summary description of the activities of the Iowa Medicaid Drug Utilization Review Commission, along with an evaluation of the Iowa Medicaid retrospective drug utilization review program. Information contained in this report covers projects completed and evaluated during the time period of July 2015 through June 2016.

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.

Patient-Focused Reviews

Patient-focused reviews are completed with the review of 300 member profiles at each meeting (six times annually). The DUR contractor generates these 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 the Commission to 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 to minimize false positives generated by the computer selection process. The Commission 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 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 from the Commission. Responses 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 or from reviews of medical literature. 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 also 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 reviews the criteria utilized by Change Healthcare and provides input regarding therapeutic validity. Special attention is given to eliminating false positive messaging.

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 guidelines 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 reviews 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 SFY16 for interventions performed in the previous or the current fiscal year. The direct cost savings from all activities of the DUR Commission are calculated to be \$7,111,493.58* which equates to \$26.34* for every \$1.00 of combined federal and state dollars spent administratively. This calculation is based on estimates regarding two types of reviews: patient-focused reviews and problem-focused reviews. These results are also found in Appendix C.

Cost Savings Estimate	\$7,111,493.58*
Cost of the Program (state and federal dollars)	\$270,000.00
Net Cost Savings Estimate	\$6,841,493.58*
Savings per Total Dollar Spent (state and federal)	\$26.34*
Savings per State Dollar Spent	\$52.68*

Patient-focused reviews resulted in \$263,026.39* in direct cost savings, or \$218.82* per patient evaluated. This estimate is based on the 1,234 suggestions made by the DUR Commission identified from the review of the medication therapy of 1,202 patient profiles selected for intervention. Of these 1,234 suggestions, 61 suggestions were implemented by the providers, resulting in a 4.94 percent impact rate.

Patient-Focused Profile Review	
Suggestions Made	1,234
Therapy Changed	61
IMPACT RATE	4.94%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated	\$218.82*
Dollars Saved on Medication	\$263,026.39*

Problem-focused reviews resulted in an estimated cost savings of \$6,848,467.19* or \$1,612.92 saved per patient evaluated. This estimate is based on the review of profiles with 4,246 patients selected for interventions. Therapy was changed for 1,630 patients, resulting in an impact rate of 38.4 percent.

Problem-Focused Profile Review	
Patients Evaluated	4,246
Therapy Changed	1,630
IMPACT RATE	38.4%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated	\$1,612.92*
Dollars Saved on Medication	<u>\$6,848,467.19*</u>

Comparison to Previous SFY Report

Cost savings estimates for SFY16 (\$7,111,493.58*) are higher than last year. This increase is due largely to the type of problem-focused reviews the DUR members selected for intervention and the number of members in each intervention. One of the interventions involved the use of multiple antipsychotics in adults. Typically, when the number of antipsychotics is reduced, there is a significant cost savings due to the high cost of these medications. This intervention alone contributed to 85 percent of the total cost savings for SFY 16.

The savings from SFY16 patient-focused reviews (\$263,026.39*) were higher than SFY15 (\$129,145.36*), yet the number of suggestions made (1,234) vs. (1,262) decreased as well as the number of suggestions that were accepted (61) vs. (71) from SFY15. While the number of suggestions made and the number of suggestions that were accepted decreased over the previous period, the cost savings increased due to the type of medications involved in the interventions. The minimal impact from patient-focused reviews can be contributed to the maturation of the Preferred Drug List (PDL) and Point of Sale edits (POS) 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 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 SFY16 (\$6,848,467.19*) were higher than SFY15 (\$540,191.68*). This again was due to the type of problem-focused reviews selected for intervention, with one intervention alone contributing to 88 percent of the total savings from problem-focused interventions.

*Savings reported are pre-rebate, total dollars

Results by Review Type

Patient-Focused Review

During this evaluation period, 2,721 educational intervention letters were mailed to prescribers and pharmacies regarding medication therapy. Of this total, 1,451 letters (53.33 percent) were mailed to prescribers, and 1,270 (46.67 percent) letters were mailed to pharmacies. Providers are invited to voluntarily respond to DUR Commission letters. Providers returned 969 responses to these letters, resulting in an overall response rate by the providers of 35.61 percent. Of this total, 550 (56.76 percent) responses were from prescribers and 419 (43.24 percent) were from pharmacies. The response rate differed slightly between physicians and pharmacies; 38 percent for physicians and 33 percent for pharmacies.

In these 2,721 educational letters, the DUR Commission made 1,234 suggestions. Of these suggestions, 1,209 (97.97 percent) were therapeutic in nature while 25 (2.03 percent) were cost-saving in nature. The suggested change was implemented in 61 cases, resulting in an overall impact rate of 4.94 percent.

Of the 1,234 suggestions, four types of suggestions accounted for over 89 percent of the total. Those four suggestions were Drug-Drug Interaction (6.24 percent), Not Optimal Drug (6.89 percent), Therapeutic Duplication (68.15 percent), and Unnecessary Drug Therapy (7.94 percent). No other single category accounted for more than 3 percent of the total suggestions. Of the 61 changes, the most common reasons for the Commission's inquiry were Not Optimal Dose (6.56 percent), Therapeutic Duplication (60.66 percent), Unnecessary Drug Therapy (11.48 percent), and Not Optimal Drug (9.84 percent). No other single category accounted for more than 5 percent of the changes.

The suggestions that resulted in change the highest percentage of the time were Patient Underuse (8 percent), Inappropriate Billing (9.09 percent), Unnecessary Drug Therapy (7.14 percent), and Not Optimal Dose (13.33 percent).

Implementation of therapeutic suggestions resulted in direct drug cost savings of \$261,987.13*. Implementation of the cost-saving suggestions resulted in direct drug cost savings of \$1,039.26*. The total amount saved on medication utilization was calculated to be \$263,026.39* for the 1,234 patients evaluated, or \$218.82* per patient.

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

Problem-Focused Reviews

Twenty problem-focused reviews were evaluated during SFY16. In conducting these studies, 4,246 patient profiles were reviewed and selected for intervention. Of these patients, 1,630 cases showed evidence of a positive outcome, resulting

*Savings reported are pre-rebate, total dollars

in an impact rate of 38.4 percent. These changes in therapy resulted in annualized cost savings of \$6,848,467.19* or \$1,612.92* per patient evaluated.

Results of all focus studies are detailed in Appendix E. The purpose for each problem-focused review and a complete description of results are available in Appendix F.

Administrative Review

Prior Authorization

The DUR Commission annually reviews the prior authorization program for clinical appropriateness. Changes are recommended to the Department. During SFY16, 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 were made for the following categories: Ivacaftor (Kalydeco); Alpha1-Proteinase Inhibitor Enzymes; Biologicals for Ankylosing Spondylitis, Inflammatory Bowel Disease & Plaque Psoriasis; Growth Hormone; Binge Eating Disorder Agents; Sodium Oxybate (Xyrem); Non-Parenteral Vasopressin Derivatives of Posterior Pituitary Hormone; Long-Acting Opioids; and Deferasirox. The following is a list for which new categories of clinical prior authorization criteria were developed: Topical Corticosteroids; Idiopathic Pulmonary Fibrosis; Edoxaban (Savaysa); Topical Antifungals for Onychomycosis; Lumacaftor/Ivacaftor (Orkambi); Select Oncology Agents; Cholic Acid (Cholbam); PCSK9 Inhibitors; Valsartan/Sacubitril (Entresto); Biologicals for Hidradenitis Suppurativa; Rifaximin (Xifaxan); Ivabradine (Corlanor); and Eluxadoline (Viberzi)

Information regarding the DUR Commission recommendations can be found in the meeting minutes in Appendix G.

Prospective Drug Review

The DUR Commission reviews and recommends prospective drug utilization review criteria to be used by the Department. The following prospective DUR edits were recommended to the Department by the Commission in SFY16:

- Quantity Limits

Drug/Strength	Proposed Quantity Limit per 30 Days
Ondansetron 4mg & 8mg tablet	60 tablets
Ondansetron 4mg & 8mg ODT tablet	60 tablets
Desmopressin 0.1mg tablet	90 tablets
Desmopressin 0.2mg tablet	90 tablets

- Age Edit
 - Desmopressin 0.1mg & 0.2mg tablets – Payable for members 6 years of age or older

Information regarding the DUR Commission recommendations for prospective DUR can be found in the DUR Recommendation Letters in Appendix G and Appendix H for the list of recommendations.

*Savings reported are pre-rebate, total dollars

Public Comment Policy

The DUR Commission made the recommendation to decrease the number of public comment periods from two per meeting to one per meeting.

Other Activities

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

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

Daniel Gillette, M.D. was appointed to the DUR Commission. His first term started in July 2015 which will expire in June 2019.

Mark Graber, M.D. was reappointed to a third term, beginning July 2016, which will expire in June 2020.

Kellen Ludvigson, Pharm.D. was reappointed for a second term, beginning July 2016, which will expire in June 2020.

Bimonthly prevalence reports were developed to allow the DUR Commission to analyze changes in medication use across the entire Medicaid patient population which can be viewed on the DUR Commission website.

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

Periodically the DUR Commission will make recommendations to the Iowa Medicaid Pharmacy & Therapeutics Committee regarding the status of a medication on the Preferred Drug List (PDL). A copy of SFY16 recommendations can be found in Appendix K.

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

Appendix A

Commission Members

**Iowa Medicaid Drug Utilization Review
Commission Members
2015-2016**

Larry Ambrosion, R.Ph.

Larry Ambrosion currently owns and operates The Medicine Shoppe Pharmacy in Newton, Iowa. Mr. Ambrosion graduated from the University of Iowa in 1992. He worked for Columbia Regional Hospital in Columbia, MO from 1992 to 1998. Mr. Ambrosion returned to Iowa in 1998 and opened The Medicine Shoppe. Mr. Ambrosion was reappointed for a second term in 2013 which will expire in June 2017.

Brian Couse, M.D.

Dr. Couse graduated from the University of Nebraska College of Medicine in 1998. He then completed his Primary Care Rural Training Residency Program in 2001 and is board certified in Family Medicine. Dr. Couse currently sees patients at the Methodist Physicians Clinic in Red Oak, Iowa. He treats patients of all ages and has clinical areas of interest in obstetric care including deliveries and C-sections and upper and lower gastrointestinal endoscopy. Dr. Couse was appointed to the DUR Commission in 2013; His first term will expire in June 2017.

Brett Faine, Pharm.D.

Dr. Faine is a Clinical Pharmacy Specialist in Emergency Medicine at the University of Iowa Hospital. He serves as a preceptor to residents and Pharm.D. students in the Emergency Treatment Center. Dr. Faine received his Pharm.D. degree from University of Iowa and completed an ASHP-accredited PGY1 Pharmacy Residency at the University of Iowa Hospitals and Clinics. Dr. Faine was reappointed for a second term in 2014 which will expire in June 2018.

Daniel Gillette, M.D.

Dr. Gillette completed his undergraduate work at Yankton College, where he graduated Magna Cum Laude as valedictorian in 1985. He then attended medical school at the University of Nebraska, followed by a residency at the University of Kansas, and a fellowship at the University of New Mexico. He is board certified in General Psychiatry, as well as Child and Adolescent Psychiatry, and also has a Master's degree in Health Care Management from the Harvard School of Public Health. During his 10 years at the Cherokee Mental Health Institute he served in several roles, including Clinical Director and Superintendent. Currently, in addition to offering direct clinical psychiatric care at Dean and Associates and Opportunities Unlimited, he is Senior Physician Leader of Behavioral Health for UnityPoint Health - St. Luke's in Sioux City, past president of the Iowa Psychiatric Society, and provides clinical consultation for Wellmark Blue Cross Blue Shield of Iowa and South Dakota. Dr. Gillette was appointed to the DUR Commission in 2015; his first term will expire in June 2019.

Mark Graber, M.D., FACEP, MSHCE

Dr. Graber is a Professor of Emergency Medicine and Family Medicine at the University of Iowa Carver College of Medicine. Dr. Graber graduated from Eastern Virginia Medical School and completed his Family Practice Residency at the University of Iowa. In addition to his clinical duties, Dr. Graber serves as an advisor to medical students and residents, and has published numerous text books, reviews, and papers in publications such as *The Annals of Pharmacotherapy*, *Emergency Medicine*, and *American Family Physician*. Dr. Graber also serves as an associate Clinical Editor of the Prescribers Letter. Through his travels, Dr. Graber has presented throughout the United States as well as Ukraine, Russia, and China. In 2007, Dr. Graber was honored by appearing on the “Best Doctors in America” list. Dr. Graber was reappointed for a third term in 2016 which will expire in June 2020.

Kellen Ludvigson, Pharm.D.

Dr. Ludvigson graduated with distinction from the University of Iowa College of Pharmacy in 2007, and he is kept busy working full-time at three different independent pharmacies: both the Holstein and Cherokee branches of Main Street Pharmacy, and also the Cherokee Mental Health Institute in Cherokee. Additionally, he is employed as a relief pharmacist at the Sioux City Target. This diversity in employment allows him to encounter a variety of prescribers and patients in the Medicaid program, and has resulted in a great deal of experience with the Iowa Medicaid PDL. Dr. Ludvigson was reappointed for a second term in 2016 which will expire in June 2020.

Susan Parker, Pharm.D.

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

Laurie Pestel, Pharm,D

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

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 Associate Professor of Clinical Family Medicine for the Roy J. & Lucille A. Carver College of Medicine at the University of Iowa. Prior to that, he was Medical Director of the Family Medicine Clinic in Iowa City from 2006 to 2011. The University of Iowa Hospitals and Clinics awarded him the Above and Beyond Reward in 2006 and again in 2007, along with the Teacher of the Year Award, presented by the University of Iowa Family Medicine residents, in 2008. Dr. Wilbur was reappointed for a second term in 2016 which will expire in June 2020.

Appendix B

Evaluation Procedure

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

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

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

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

Patient-focused DUR

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

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

Template sent to the provider:

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

Information on initial profile sent to provider:

Lexapro 10 mg #30= \$83.04
Total Amount Paid \$498.24

Information on re-review profile used internally for evaluation:

Lexapro 20 mg #15 = \$45.92
Total Amount Paid \$275.52

Calculation of annualized savings

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

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

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

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

Templates that are therapeutic in nature include:

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

Templates that are cost saving in nature include:

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

Problem-focused DUR

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

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

Administrative Review

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

- Prospective DUR

Definition: A process in which a request for a drug product for a particular patient is screened for potential drug therapy problems before the product is dispensed.

Impact: The DUR Commission reviews scientific literature regarding specific medications and makes recommendations to DHS on appropriate utilization guidelines or parameters.

Example: The DUR Commission recommended that an age edit be placed on Provigil®, restricting its use in patients to those 16 years of age and older.

- Prior Authorization

Definition: A process for obtaining approval for a drug before the drug is provided to a member, as a precondition for provider reimbursement. Prior authorization is requested at the prescriber level and is a prescriber fax-only system using the forms provided by the Iowa Medicaid Enterprise.

Impact: The DUR Commission develops sound, cost-effective medication use guidelines by reviewing peer reviewed medical information from various sources. The Commission seeks outside expertise when necessary and considers public comments prior to

recommending step therapy for appropriate drug use.

Example: The DUR Commission developed the criteria for the Nicotine Replacement Therapy prior authorization.

Prior Authorization is required for over-the-counter nicotine replacement patches and nicotine gum. Requests for authorization must include:

- 1) Diagnosis of nicotine dependence and referral to the Quitline Iowa program for counseling.
- 2) Confirmation of enrollment in the Quitline Iowa counseling program is required for approval.
- 3) Approvals will only be granted for patients eighteen years of age and older.
- 4) The maximum allowed duration of therapy is twelve weeks within a twelve-month period.
- 5) A maximum quantity of 14 nicotine replacement patches and/or 110 pieces of nicotine gum may be dispensed with the initial prescription. Subsequent prescription refills will be allowed to be dispensed as a 4 week supply at one unit per day of nicotine replacement patches and/or 330 pieces of nicotine gum. Following the first 28 days of therapy, continuation is available only with documentation of ongoing participation in the Quitline Iowa program.

- Preferred Drug List (PDL)

Definition: A list comprised of drugs recommended to the Iowa Department of Human Services by the Iowa Medicaid Pharmaceutical and Therapeutics Committee that have been identified as being therapeutically equivalent within a drug class and that provide cost benefit to the Medicaid program.

Impact: The DUR Commission makes referrals to and considers requests from the Pharmacy and Therapeutics (P&T) Committee to improve drug therapy.

Example: The DUR Commission recommended that the Iowa Medicaid Pharmacy and Therapeutics Committee change the status of products containing carisoprodol on the PDL from preferred to nonpreferred.

- Disease management

Definition: A coordinated process by which Iowa Medicaid identifies and treats diseases within defined patient populations. This goal is achieved by identifying and delivering the most effective and efficient combination of available resources.

Impact: The Commission reviews disease state guidelines to determine appropriate drug use, shares drug utilization information, and makes recommendations to improve therapeutic outcomes.

Example: DUR exchanged patient specific information with case management regarding utilization patterns of Advair®.

- Supplemental rebates

Definition: A rebate given in addition to rebates received under the CMS Rebate Agreement, pursuant to Section 1927 of the Social Security Act (42 USC 1396r-8).

Impact: The existence of a supplemental rebate and how it may impact the price of a medication is taken into consideration when the DUR Commission makes recommendations.

Example: The DUR Commission requested that the Iowa Medicaid P&T Committee review the different dosage forms of nicotine replacement therapy and share information as to which products were the most cost effective.

Appendix C

Overall Programs Results

**Program Evaluation/Cost Savings Estimates
Iowa Medicaid Retrospective Drug Utilization Review
Annual Report
SFY16**

Patient Focused Profile Review

Suggestions Made	1,234
Therapy Changed	61
Impact Rate	4.94%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated*	\$218.82
Dollars Saved on Medication*	\$263,026.39

Problem-Focused Profile Review

Suggestions Made	4,246
Therapy Changed	1,630
Impact Rate	38.39%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated*	\$1,612.92
Dollars Saved on Medication*	\$6,848,467.19

Cost Savings Estimate*	\$7,111,493.58
Cost of the Program (State & Federal)	\$270,000.00
Net Cost Savings Estimate	\$6,841,493.58

Savings Per Dollar Spent (State and Federal)* **\$26.34**

Savings Per State Dollar Spent* **\$52.68**

*Savings reported are pre-rebate, total dollars

Appendix D

Results Patient-Focused

Patient - Focused Reviews

SFY16

Initial Review Date

October 2014 - September 2015

Re-review Date

July 2015 - June 2016

Patient Profiles Reviewed 1,800
Profiles Selected for Intervention 1,202

Intervention Letters Sent

Prescribers 1,451 53.33%
Pharmacists 1,270 46.67%
Total **2,721** 100%

Responses Received

Prescribers 550 56.76%
Pharmacists 419 43.24%
Total **969** 100.00%

Overall Response Rate 35.61%
Prescriber Response Rate 37.90%
Pharmacy Response Rate 32.99%

Total Number of Suggestions

Therapeutic 1,209 97.97%
Cost-Saving 25 2.03%
Total **1,234** 100%

Total Number of Changes

Therapeutic 60 98.36%
Cost-Saving 1 1.64%
Positive Impact Only 0 0.00%
Total **61** 100%

Impact Rate 4.94%

Patient - Focused Review
Month by Month Breakdown
 SFY16

Initial Review Date Evaluation Date	Oct-14 Jul-15	Dec-14 Sep-15	Feb-15 Nov-15	Apr-15 Jan-16	Jun-15 Mar-16	Aug-15 May-16	Total
Profiles Reviewed	300	300	300	300	300	300	1,800
Profiles Available for Evaluation	204	202	198	202	200	196	1,202
Total Number of Suggstions Made	215	207	208	207	200	197	1,234
Therapeutic	212	203	201	202	196	195	1,209
Cost Saving	3	4	7	5	4	2	25
Total Number of Changes Made	10	11	12	10	8	10	61
Therapeutic	10	11	12	10	7	10	60
Cost Saving	0	0	0	0	1	0	1
Positive Impact Only	0	0	0	0	0	0	0
Total Dollars Saved - Therapeutic	\$27,053.20	\$108,815.94	\$34,977.10	\$30,646.59	\$15,281.57	\$45,212.73	\$261,987.13
Total Dollars Saved - Cost Saving	\$0.00	\$0.00	\$0.00	\$0.00	\$1,039.26	\$0.00	\$1,039.26
Total Dollars Saved on Medication*	\$27,053.20	\$108,815.94	\$34,977.10	\$30,646.59	\$16,320.83	\$45,212.73	\$263,026.39
Total Dollars Saved per Profile	\$132.61	\$538.69	\$176.65	\$151.72	\$81.60	\$230.68	\$218.82

*Savings reported are pre-rebate total dollars.

**Medicaid DUR Impact Assessment
Report Patient-Focused Reviews SFY16**

Initial Review Date Evaluation Date	Oct-14 Jul-15	Dec-14 Sep-15	Feb-15 Nov-15	Apr-15 Jan-16	Jun-15 Mar-16	Aug-15 May-16	Total	
Profiles Reviewed	300	300	300	300	300	300	1,800	
Profiles Evaluated	204	202	198	202	200	196	1,202	
<u>Letters Sent</u>	485	454	457	452	439	434	2,721	100.00%
Prescribers	260	240	245	241	237	228	1,451	53.33%
Pharmacy	225	214	212	211	202	206	1,270	46.67%
<u>Responses Received</u>	151	174	166	153	153	172	969	100.00%
Prescribers	92	92	86	83	93	104	550	56.76%
Pharmacy	59	82	80	70	60	68	419	43.24%
Total Number of Templates Mentioned	215	207	208	207	200	197	1,234	100.00%
Therapeutic	212	203	201	202	196	195	1,209	97.97%
Cost-Saving	3	4	7	5	4	2	25	2.03%
Total Number of Changes Made	10	11	12	10	8	10	61	100.00%
Therapeutic	10	11	12	10	7	10	60	98.36%
Cost-Saving	0	0	0	0	1	0	1	1.64%
Positive Impact Only	0	0	0	0	0	0	0	0.00%
Total Dollars Saved - Therapeutic Changes	\$27,053.20	\$108,815.94	\$34,977.10	\$30,646.59	\$15,281.57	\$45,212.73	\$261,987.13	99.60%
Total Dollars Saved - Cost Saving Changes	\$0.00	\$0.00	\$0.00	\$0.00	\$1,039.26	\$0.00	\$1,039.26	0.40%
Total Dollars Saved on Medication*	\$27,053.20	\$108,815.94	\$34,977.10	\$30,646.59	\$16,320.83	\$45,212.73	\$263,026.39	100.00%
Total Dollars Saved Per Profile Evaluated	\$132.61	\$538.69	\$176.65	\$151.72	\$81.60	\$230.68	\$218.82	

*Savings reported are pre-rebate, total dollars

Comment Type
Patient Focused Reviews
SFY16

Initial Review Date	Oct-14		Dec-14		Feb-15		Apr-15		Jun-15		Aug-15		Total	
Evaluation Date	Jul-15		Sep-15		Nov-15		Jan-16		Mar-16		May-16			
Template Classification	Suggestions	Changes	Total Suggestions	Total Changes										
Adverse Drug Reaction	0	0	0	0	3	0	0	0	0	0	1	0	4	0
Drug-Disease Interaction	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Drug-Drug Interaction	5	0	30	1	9	1	10	1	11	0	12	0	77	3
High Cost Drug	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Innapropriate Billing	1	0	0	0	3	0	4	0	2	1	1	0	11	1
Missing Drug Therapy	0	0	0	0	0	0	0	0	0	0	3	0	3	0
Not Optimal Dosage Form	1	0	0	0	3	0	0	0	2	0	1	0	7	0
Not Optimal Dose	8	0	5	0	6	4	2	0	3	0	6	0	30	4
Not Optimal Drug	7	0	20	1	7	0	25	2	7	1	19	2	85	6
Not Optimal Duration	10	0	8	1	6	0	2	0	1	0	4	0	31	1
Patient Overuse	1	0	6	0	2	0	3	0	0	0	1	0	13	0
Patient Underuse	3	0	6	1	1	1	7	0	5	0	3	0	25	2
Potential Generic Use	1	0	4	0	1	0	1	0	0	0	0	0	7	0
Therapeutic Alternative	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Therapeutic Duplication	161	9	106	7	153	5	129	4	151	4	141	8	841	37
Unnecessary Drug Therapy	17	1	22	0	14	1	22	3	18	2	5	0	98	7
Total	215	10	207	11	208	12	207	10	200	8	197	10	1,234	61

**Patient Focused Reviews
SFY16**

Template Classification	Total Suggestions	Total Changes	% of Total Suggstions	% of Total Changes	% of Suggestions Changed	% Dollars Saved
Adverse Drug Reaction	4	0	0.32%	0.00%	0.00%	0.00%
Drug-Disease Interaction	0	0	0.00%	0.00%	0.00%	0.00%
Drug-Drug Interaction	77	3	6.24%	4.92%	3.90%	0.42%
High Cost Drug	1	0	0.08%	0.00%	0.00%	0.00%
Inappropriate Billing	11	1	0.89%	1.64%	9.09%	0.12%
Missing Drug Therapy	3	0	0.24%	0.00%	0.00%	0.00%
Not Optimal Dosage Form	7	0	0.57%	0.00%	0.00%	0.00%
Not Optimal Dose	30	4	2.43%	6.56%	13.33%	0.25%
Not Optimal Drug	85	6	6.89%	9.84%	7.06%	9.30%
Not Optimal Duration	31	1	2.51%	1.64%	3.23%	0.07%
Patient Overuse	13	0	1.05%	0.00%	0.00%	0.00%
Patient Underuse	25	2	2.03%	3.28%	8.00%	0.00%
Potential Generic Use	7	0	0.57%	0.00%	0.00%	0.00%
Therapeutic Alternative	1	0	0.08%	0.00%	0.00%	0.00%
Therapeutic Duplication	841	37	68.15%	60.66%	4.40%	83.19%
Unnecessary Drug Therapy	98	7	7.94%	11.48%	7.14%	6.66%
Total	1,234	61	100.00%	100.00%	4.94%	100.00%

Savings By Template Class

SFY16

Initial Review Date Evaluation Dte	Oct-14 Jul-15	Dec-14 Sep-15	Feb-15 Nov-15	Apr-15 Jan-16	Jun-15 Mar-16	Aug-15 May-16	Total
<u>Template Classification</u>							
Adverse Drug Reaction	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Drug-Disease Interaction	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Drug-Drug Interaction	\$0.00	\$457.31	\$274.47	\$373.19	\$0.00	\$0.00	\$1,104.97
High Cost Drug	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Inappropriate Billing	\$0.00	\$0.00	\$0.00	\$0.00	\$304.74	\$0.00	\$304.74
Missing Drug Therapy	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Not Optimal Dosage Form	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Not Optimal Dose	\$0.00	\$0.00	\$654.03	\$0.00	\$0.00	\$0.00	\$654.03
Not Optimal Drug	\$0.00	\$6,031.66	\$0.00	\$8,473.02	\$473.05	\$9,480.19	\$24,457.92
Not Optimal Duration	\$0.00	\$192.46	\$0.00	\$0.00	\$0.00	\$0.00	\$192.46
Patient Overuse	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Patient Underuse*	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Potential Generic Use	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Therapeutic Alternative	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Therapeutic Duplication	\$22,901.27	\$102,134.51	\$28,797.35	\$21,224.65	\$8,008.71	\$35,732.54	\$218,799.03
Unnecessary Drug Therapy	\$4,151.93	\$0.00	\$5,251.25	\$575.73	\$7,534.33	\$0.00	\$17,513.24
Total	\$27,053.20	\$108,815.94	\$34,977.10	\$30,646.59	\$16,320.83	\$45,212.73	\$263,026.39

*additional cost but positive impact assumed

Appendix E

Results Problem-Focused

**Problem-Focused Studies
SFY 2016**

Focus	Review Period	Evaluation Period	Patients Reviewed	Patients Selected	Cost Savings Calculated
Duplicate Benzodiazepines	07/01/2014 - 07/31/2014	01/01/2015 - 07/31/2015	291	291	\$28,615.80
Niacin plus Statin	07/01/2014 - 07/31/2014	07/01/2015 - 07/31/2015	73	73	\$74,522.52
Duplicate Antipsychotics in Children	02/01/2014 - 07/31/2014	02/01/2015 - 07/31/2015	220	220	\$73,883.80
Duplicate Antipsychotics in Adults	02/01/2014 - 07/31/2014	02/01/2015 - 07/31/2015	666	666	\$6,043,534.51
Duplicate Benzodiazepines	09/01/2014 - 09/30/2015	09/01/2015 - 09/30/2015	574	574	\$288,762.84
High Dose Amphetamine IR	09/01/2014 - 09/30/2014	09/01/2015 - 09/30/2015	67	67	\$88,524.48
High Dose Methylphenidate IR	09/01/2014 - 09/30/2014	09/01/2015 - 09/30/2015	25	25	\$14,154.00
Anxiolytic Benzodiazepine Use without an SSRI or SNRI	09/01/2014 - 09/30/2014	09/01/2015 - 09/30/2015	989	989	\$45,197.16
Members Exceeding Proposed Quantity Limit for Select Benzodiazepines	01/01/2015 - 01/31/2015	01/01/2016 - 01/31/2016	213	213	\$11,404.20
Duplicate Beta-Blockers	01/01/2015 - 01/31/2015	01/01/2016 - 01/31/2016	37	37	\$5,364.12
Vimpat Dose Exceeding 400mg/Day	07/01/2014 - 12/31/2014	07/01/2015 - 12/31/2015	19	19	\$4,707.23
Anticholinergics with SGAs	01/01/2015 - 03/31/2015	01/01/2016 - 03/31/2016	724	724	\$24,517.72
Metoclopramide Utilization > 90 Days	10/01/2014 - 03/31/2015	10/01/2015 - 03/31/2016	95	95	\$3,899.12
Modafinil Utilization in Members < 21 Years of Age	01/01/2015 - 03/31/2015	01/01/2016 - 03-31/2016	9	9	\$34,836.44
Duplicate Antidepressants - 4 or More Agents	01/01/2015 - 03/31/2015	01/01/2016 - 03/31/2016	11	11	-\$3,702.72 #
Duplicate SSRIs	01/01/2015 - 03/31/2015	01/01/2016 - 03/31/2016	21	21	\$607.56
Duplicate SNRIs	01/01/2015 - 03/31/2015	01/01/2016 - 03/31/2016	15	15	\$12,092.48
Duplicate Therapy - SSRI plus SNRI	01/01/2015 - 03/31/2015	01/01/2016 - 03/31/2016	162	162	\$5,781.44
Duplicate Inhaled Corticosteroids	12/01/2014 - 03/31/2015	12/01/2015 - 03/31/2016	23	23	\$56,392.77
Duplicate Long-Acting Beta-Agonists	01/01/2015 - 03/31/2015	01/01/2016 - 03/31/2016	12	12	\$35,371.72
TOTAL			4246	4246	\$6,848,467.19 *

* Savings reported are pre-rebate, total dollars.

Postive Impact - While a change was made, the medication the member switched to was more expensive than the combined use of 4 or more antidepressants

Problem-Focused Studies
Impact Rate
SFY 2016

Focus	Review Period	Evaluation Period	Patients Evaluated	Positive Impact	Impact Rate
Duplicate Benzodiazepines	07/01/2014 - 07/31/2014	01/01/2015 - 07/31/2015	291	189	64.95%
Niacin plus Statin	07/01/2014 - 07/31/2014	07/01/2015 - 07/31/2015	73	39	53.42%
Duplicate Antipsychotics in Children	02/01/2014 - 07/31/2014	02/01/2015 - 07/31/2015	220	132	60.00%
Duplicate Antipsychotics in Adults	02/01/2014 - 07/31/2014	02/01/2015 - 07/31/2015	666	386	57.96%
Duplicate Benzodiazepines	09/01/2014 - 09/30/2015	09/01/2015 - 09/30/2015	574	428	74.56%
High Dose Amphetamine IR	09/01/2014 - 09/30/2014	09/01/2015 - 09/30/2015	67	25	37.31%
High Dose Methylphenidate IR	09/01/2014 - 09/30/2014	09/01/2015 - 09/30/2015	25	6	24.00%
Anxiolytic Benzodiazepine Use without an SSRI or SNRI	09/01/2014 - 09/30/2014	09/01/2015 - 09/30/2015	989	25	2.53%
Members Exceeding Proposed Quantity Limit for Select Benzodiazepines	01/01/2015 - 01/31/2015	01/01/2016 - 01/31/2016	213	91	42.72%
Duplicate Beta-Blockers	01/01/2015 - 01/31/2015	01/01/2016 - 01/31/2016	37	17	45.95%
Vimpat Dose Exceeding 400mg/Day	07/01/2014 - 12/31/2014	07/01/2015 - 12/31/2015	19	2	10.53%
Anticholinergics with SGAs	01/01/2015 - 03/31/2015	01/01/2016 - 03/31/2016	724	183	25.28%
Metoclopramide Utilization > 90 Days	10/01/2014 - 03/31/2015	10/01/2015 - 03/31/2016	95	32	33.68%
Modafinil Utilization in Members < 21 Years of Age	01/01/2015 - 03/31/2015	01/01/2016 - 03-31/2016	9	3	33.33%
Duplicate Antidepressants - 4 or More Agents	01/01/2015 - 03/31/2015	01/01/2016 - 03/31/2016	11	4	36.36%
Duplicate SSRIs	01/01/2015 - 03/31/2015	01/01/2016 - 03/31/2016	21	3	14.29%
Duplicate SNRIs	01/01/2015 - 03/31/2015	01/01/2016 - 03/31/2016	15	3	20.00%
Duplicate Therapy - SSRI plus SNRI	01/01/2015 - 03/31/2015	01/01/2016 - 03/31/2016	162	38	23.46%
Duplicate Inhaled Corticosteroids	12/01/2014 - 03/31/2015	12/01/2015 - 03/31/2016	23	17	73.91%
Duplicate Long-Acting Beta-Agonists	01/01/2015 - 03/31/2015	01/01/2016 - 03/31/2016	12	7	58.33%
TOTAL			4246	1630	38.39%

Appendix F

Descriptions Problem-Focused



IOWA DUR FOCUS STUDY
 Based on Iowa Paid Non-Reversed Claims
 Duplicate Benzodiazepines

Follow-up on the unique members identified as taking more than one anxiolytic benzodiazepine concurrently

Number of unique members from original study	291
Number of unique members that changed therapy	189
Number of unique members that did not change therapy	70
Number of members who lost Medicaid eligibility since 8/1/2014	32

Number of surveys sent to prescribers	360	Number of surveys received from prescribers	162	Percent of surveys from prescribers	45.00%
Number of surveys sent to pharmacies	313	Number of surveys received from pharmacies	80	Percent of surveys from pharmacies	25.56%
Total number of surveys sent	673	Total number of surveys received	242	Percent of surveys received	35.96%

Costs (Pre-Rebate)	Original Costs (7/1/2014 - 7/31/2014)*	Costs After DUR Intervention (7/1/2015 - 7/31/2015)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$6,092.59	\$4,265.94	\$1,826.65	\$21,919.80
Total Dollars State	\$2,192.49	\$1,634.49	\$558.00	\$6,696.00
Total Dollars (State and Federal)	\$8,285.08	\$5,900.43	\$2,384.65	\$28,615.80

* Federal FMAP: 0.57930 State: 0.42070

** Federal FMAP: 0.55540 State: 0.44460

**Includes IHAWP Federal FMAP 1.00000 State: 0.00000

*** Some savings may be due to changes in reimbursement from the original time period to the follow-up time period.

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.



IOWA DUR FOCUS STUDY
 Based on Iowa Paid Non-Reversed Claims
 Niacin Utilization

Follow-up on the unique members identified as taking niacin with a statin

Number of unique members from original study	73				
Number of unique members that changed therapy	39				
Number of unique members that did not change therapy	31				
Number of members who lost Medicaid eligibility since 8/1/2014	3				
Number of surveys sent to prescribers	89	Number of surveys received from prescribers	34	Percent of surveys from prescribers	38.20%
Number of surveys sent to pharmacies	75	Number of surveys received from pharmacies	23	Percent of surveys from pharmacies	30.67%
Total number of surveys sent	164	Total number of surveys received	57	Percent of surveys received	34.76%

Costs (Pre-Rebate)	Original Costs (7/1/2014 - 7/31/2014)*	Costs After DUR Intervention (7/1/2015 - 7/31/2015)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$8,584.08	\$5,013.57	\$3,570.50	\$42,846.00
Total Dollars State	\$4,859.20	\$2,219.50	\$2,639.71	\$31,676.52
Total Dollars (State and Federal)	\$13,443.28	\$7,233.07	\$6,210.21	\$74,522.52

* Federal FMAP: 0.57930 State: 0.42070

** Federal FMAP: 0.55540 State: 0.44460

** Includes IHAWP Federal FMAP 1.00000 State: 0.00000

*** Some savings may be due to changes in reimbursement from the original time period to the follow-up time period.

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.



IOWA DUR FOCUS STUDY

Based on Iowa Paid Non-Reversed Claims
Duplicate Antipsychotics in Children

Follow-up on the unique members identified as taking two or more antipsychotics for more than 90 days

Number of unique members from original study	220				
Number of unique members that changed therapy	132				
Number of unique members that did not change therapy	78				
Number of members who lost Medicaid eligibility since 7/31/2014	10				
Number of surveys sent to prescribers	345	Number of surveys received from prescribers	179	Percent of surveys from prescribers	51.88%
Number of surveys sent to pharmacies	276	Number of surveys received from pharmacies	87	Percent of surveys from pharmacies	31.52%
Total number of surveys sent	621	Total number of surveys received	266	Percent of surveys received	42.83%

Costs (Pre-Rebate)	Original Costs (2/1/2014 - 7/31/2014)*	Costs After DUR Intervention (2/1/2015 - 7/31/2015)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$250,722.90	\$230,205.37	\$20,517.53	\$41,035.06
Total Dollars State	\$182,080.31	\$165,655.94	\$16,424.37	\$32,848.74
Total Dollars (State and Federal)	\$432,803.21	\$395,861.31	\$36,941.90	\$73,883.80

* Federal FMAP: 0.58350 State: 0.41650

** Federal FMAP: 0.57290 State: 0.42710

*** Some savings may be due to changes in reimbursement from the original time period to the follow-up time period.

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.



IOWA DUR FOCUS STUDY

Based on Iowa Paid Non-Reversed Claims
Duplicate Antipsychotics in Adults

Follow-up on the unique members identified as taking two or more antipsychotics for more than 90 days.

Number of unique members from original study	666				
Number of unique members that changed therapy	386				
Number of unique members that did not change therapy	246				
Number of members who lost Medicaid eligibility since 7/31/2014	34				
Number of surveys sent to prescribers	1115	Number of surveys received from prescribers	485	Percent of surveys from prescribers	43.50%
Number of surveys sent to pharmacies	820	Number of surveys received from pharmacies	259	Percent of surveys from pharmacies	31.59%
Total number of surveys sent	1935	Total number of surveys received	744	Percent of surveys received	38.45%

Costs (Pre-Rebate)	Original Costs (2/1/2014 - 7/31/2014)*	Costs After DUR Intervention (2/1/2015 - 7/31/2015)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$1,506,129.38	\$2,250,378.98	\$2,152,103.64	\$4,304,207.28
Total Dollars State	\$1,075,069.22	\$961,136.86	\$869,663.62	\$1,739,327.23
Total Dollars (State and Federal)	\$2,581,198.60	\$3,211,515.84	\$3,021,767.26	\$6,043,534.51

* Federal FMAP: 0.58350 State: 0.41650

** Federal FMAP: 0.57290 State: 0.42710

*** Some savings may be due to changes in reimbursement from the original time period to the follow-up time period.

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.



IOWA DUR FOCUS STUDY
Based on Iowa Paid Non-Reversed Claims
Duplicate Benzodiazepines



Follow-up on the unique members identified as taking more than one anxiolytic benzodiazepine concurrently

Number of unique members from original study	574				
Number of unique members that changed therapy	428				
Number of unique members that did not change therapy	73				
Number of unique members who lost Medicaid eligibility since 10/1/2014	73				
Number of surveys sent to prescribers	1387	Number of surveys received from prescribers	627	Percent of surveys from prescribers	27.05%
Number of surveys sent to pharmacies	931	Number of surveys received from pharmacies	332	Percent of surveys from pharmacies	14.32%
Total number of surveys sent	2318	Total number of surveys received	959	Percent of surveys received	41.37%

Costs (Pre-Rebate)	Original Costs (9/1/2014 - 9/30/2014)*	Costs After DUR Intervention (9/1/2015 - 9/30/2015)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$34,676.49	\$16,864.91	\$17,811.58	\$213,738.94
Total Dollars State	\$9,832.77	\$3,580.78	\$6,251.99	\$75,023.90
Total Dollars (State and Federal)	\$44,509.26	\$20,445.69	\$24,063.57	\$288,762.84

* Federal FMAP: 0.5793 State: 0.4207

** Federal FMAP: 0.5554 State: 0.4446

*** IHAWP Federal FMAP: 1.0000 State: 0.0000

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.



IOWA DUR FOCUS STUDY Based on Iowa Paid Non-Reversed Claims



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High Dose Amphetamine Salt Combo Immediate Release (Dose Greater than 40mg Per Day)

Follow-up on the unique members identified as taking greater than 40mg per day of amphetamine salt combo immediate-release tablets.

Number of unique members from original study	67				
Number of unique members that changed therapy	25				
Number of unique members that did not change therapy	37				
Number of unique members who lost Medicaid eligibility since 10/1/2014	5				
Number of surveys sent to prescribers	68	Number of surveys received from prescribers	34	Percent of surveys from prescribers	25.19%
Number of surveys sent to pharmacies	67	Number of surveys received from pharmacies	19	Percent of surveys from pharmacies	14.07%
Total number of surveys sent	135	Total number of surveys received	53	Percent of surveys received	39.26%

Costs (Pre-Rebate)	Original Costs (9/1/2014 - 9/30/2014)*	Costs After DUR Intervention (9/1/2015 - 9/30/2015)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$13,128.62	\$9,031.41	\$4,097.21	\$49,166.50
Total Dollars State	\$9,534.28	\$6,254.45	\$3,279.83	\$39,357.98
Total Dollars (State and Federal)	\$22,662.90	\$15,285.86	\$7,377.04	\$88,524.48

* Federal FMAP: 0.5793 State: 0.4207

** Federal FMAP: 0.5554 State: 0.4446

*** IHAWP Federal FMAP: 1.0000 State: 0.0000

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.



IOWA DUR FOCUS STUDY Based on Iowa Paid Non-Reversed Claims



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High Dose Methylphenidate Immediate Release (Dose Greater than 60mg Per Day)

Follow-up on the unique members identified as taking greater than 60mg per day of methylphenidate immediate-release tablets.

Number of unique members from original study	25				
Number of unique members that changed therapy	6				
Number of unique members that did not change therapy	19				
Number of unique members who lost Medicaid eligibility since 10/1/2014	0				
Number of surveys sent to prescribers	26	Number of surveys received from prescribers	9	Percent of surveys from prescribers	17.65%
Number of surveys sent to pharmacies	25	Number of surveys received from pharmacies	11	Percent of surveys from pharmacies	21.57%
Total number of surveys sent	51	Total number of surveys received	20	Percent of surveys received	39.22%

Costs (Pre-Rebate)	Original Costs (9/1/2014 - 9/30/2014)*	Costs After DUR Intervention (9/1/2015 - 9/30/2015)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$2,509.32	\$1,854.23	\$655.09	\$7,861.13
Total Dollars State	\$1,822.33	\$1,297.92	\$524.41	\$6,292.87
Total Dollars (State and Federal)	\$4,331.65	\$3,152.15	\$1,179.50	\$14,154.00

* Federal FMAP: 0.5793 State: 0.4207

** Federal FMAP: 0.5554 State: 0.4446

*** IHAWP Federal FMAP: 1.0000 State: 0.0000

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.



IOWA DUR FOCUS STUDY

Based on Iowa Paid Non-Reversed Claims



Anxiolytic Benzodiazepine Use without an SSRI or SNRI

Follow-up on the unique members identified as taking an anxiolytic benzodiazepine without the use of an SSRI or SNRI.

Number of unique members from original study	989				
Number of unique members that changed therapy	25				
Number of unique members that did not change therapy	841				
Number of unique members who lost Medicaid eligibility since 10/1/2014	123				
Number of surveys sent to prescribers	1603	Number of surveys received from prescribers	737	Percent of surveys from prescribers	24.70%
Number of surveys sent to pharmacies	1381	Number of surveys received from pharmacies	454	Percent of surveys from pharmacies	15.21%
Total number of surveys sent	2984	Total number of surveys received	1191	Percent of surveys received	39.91%

Costs (Pre-Rebate)	Original Costs (9/1/2014 - 9/30/2014)*	Costs After DUR Intervention (9/1/2015 - 9/30/2015)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$13,907.29	\$11,154.88	\$2,752.41	\$33,028.96
Total Dollars State	\$5,070.10	\$4,056.08	\$1,014.02	\$12,168.20
Total Dollars (State and Federal)	\$18,977.39	\$15,210.96	\$3,766.43	\$45,197.16

* Federal FMAP: 0.5793 State: 0.4207

** Federal FMAP: 0.5554 State: 0.4446

*** IHAWP Federal FMAP: 1.0000 State: 0.0000

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.



IOWA DUR FOCUS STUDY Based on Iowa Paid Non-Reversed Claims



Members Exceeding the Proposed Quantity Limit for Select Benzodiazepines

Follow-up on the unique members identified as exceeding the proposed quantity limit of 4 tablets per day for alprazolam, clonazepam, or lorazepam.

Number of unique members from original study	213				
Number of unique members that changed therapy	91				
Number of unique members that did not change therapy	110				
Number of unique members who lost Medicaid eligibility since 2/1/2015	12				
Number of surveys sent to prescribers	216	Number of surveys received from prescribers	103	Percent of surveys from prescribers	47.69%
Number of surveys sent to pharmacies	215	Number of surveys received from pharmacies	73	Percent of surveys from pharmacies	33.95%
Total number of surveys sent	431	Total number of surveys received	176	Percent of surveys received	40.84%

Costs (Pre-Rebate)	Original Costs (1/1/2015 - 1/31/2015)*	Costs After DUR Intervention (1/1/2016 - 1/31/2016)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$2,663.31	\$1,867.91	\$795.41	\$9,544.89
Total Dollars State	\$961.10	\$806.15	\$154.94	\$1,859.31
Total Dollars (State and Federal)	\$3,624.41	\$2,674.06	\$950.35	\$11,404.20

* Federal FMAP: 0.5554 State: 0.4446

** Federal FMAP: 0.5491 State: 0.4509

*** IHAWP Federal FMAP: 1.0000 State: 0.0000

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.



IOWA DUR FOCUS STUDY Based on Iowa Paid Non-Reversed Claims



Duplicate Beta-Blockers

Follow-up on the unique members identified as taking two or more chemically distinct beta-blockers.

Number of unique members from original study	34				
Number of unique members that changed therapy	17				
Number of unique members that did not change therapy	15				
Number of unique members who lost Medicaid eligibility since 2/1/2015	2				
Number of surveys sent to prescribers	67	Number of surveys received from prescribers	27	Percent of surveys from prescribers	40.30%
Number of surveys sent to pharmacies	37	Number of surveys received from pharmacies	17	Percent of surveys from pharmacies	45.95%
Total number of surveys sent	104	Total number of surveys received	44	Percent of surveys received	42.31%

Costs (Pre-Rebate)	Original Costs (1/1/2015 - 1/31/2015)*	Costs After DUR Intervention (1/1/2016 - 1/31/2016)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$672.74	\$334.31	\$338.42	\$4,061.09
Total Dollars State	\$247.79	\$139.21	\$108.59	\$1,303.03
Total Dollars (State and Federal)	\$920.53	\$473.52	\$447.01	\$5,364.12

* Federal FMAP: 0.5554 State: 0.4446

** Federal FMAP: 0.5491 State: 0.4509

*** IHAWP Federal FMAP: 1.0000 State: 0.0000

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.



IOWA DUR FOCUS STUDY Based on Iowa Paid Non-Reversed Claims Vimpat Dose Exceeding 400mg per Day



Follow-up on the unique members identified as taking lacosamide (Vimpat) at a dose exceeding 400mg per day.

Number of unique members from original study	19			
Number of unique members that changed therapy	2			
Number of unique members that did not change therapy	15			
Number of unique members who lost Medicaid eligibility since 1/1/2015	2			
Number of surveys sent to prescribers	26	Number of surveys received from prescribers	15	Percent of surveys from prescribers 57.69%
Number of surveys sent to pharmacies	20	Number of surveys received from pharmacies	8	Percent of surveys from pharmacies 40.00%
Total number of surveys sent	46	Total number of surveys received	23	Percent of surveys received 50.00%

Costs (Pre-Rebate)	Original Costs (7/1/2014 - 12/31/2014)*	Costs After DUR Intervention (7/1/2015 - 12/31/2015)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$30,814.11	\$29,514.34	\$1,299.77	\$2,599.54
Total Dollars State	\$12,153.52	\$11,099.68	\$1,053.84	\$2,107.69
Total Dollars (State and Federal)	\$42,964.82	\$40,611.44	\$2,353.62	\$4,707.23

* Federal FMAP: 0.5674 State: 0.4327

** Federal FMAP: 0.5523 State: 0.4478

*** IHAWP Federal FMAP: 1.0000 State: 0.0000

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.



IOWA DUR FOCUS STUDY Based on Iowa Paid Non-Reversed Claims



Anticholinergics with SGAs

Follow-up on the unique members identified as taking a second generation antipsychotic (SGA) with an anticholinergic (benztropine or trihexyphenidyl).

Number of unique members from original study	724				
Number of unique members that changed therapy	183				
Number of unique members that did not change therapy	511				
Number of unique members who lost Medicaid eligibility since 4/1/2015	30				
Number of surveys sent to prescribers	928	Number of surveys received from prescribers	389	Percent of surveys from prescribers	41.92%
Number of surveys sent to pharmacies	817	Number of surveys received from pharmacies	218	Percent of surveys from pharmacies	26.68%
Total number of surveys sent	1745	Total number of surveys received	607	Percent of surveys received	34.79%

Costs (Pre-Rebate)	Original Costs (1/1/2015 - 3/31/2015)*	Costs After DUR Intervention (1/1/2016 - 3/31/2016)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$16,128.74	\$11,969.65	\$4,159.10	\$16,636.38
Total Dollars State	\$9,473.45	\$7,503.11	\$1,970.33	\$7,881.34
Total Dollars (State and Federal)	\$25,602.19	\$19,472.76	\$6,129.43	\$24,517.72

* Federal FMAP: 0.5554 State: 0.4446

** Federal FMAP: 0.5491 State: 0.4509

*** IHAWP Federal FMAP: 1.0000 State: 0.0000

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.



IOWA DUR FOCUS STUDY Based on Iowa Paid Non-Reversed Claims



Metoclopramide Utilization Greater than 90 days

Follow-up on the unique members identified as taking metoclopramide for greater than 90 days without an indicated diagnosis/medical reason.

Number of unique members from original study	95				
Number of unique members that changed therapy	32				
Number of unique members that did not change therapy	56				
Number of unique members who lost Medicaid eligibility since 4/1/2015	7				
Number of surveys sent to prescribers	114	Number of surveys received from prescribers	53	Percent of surveys from prescribers	46.49%
Number of surveys sent to pharmacies	108	Number of surveys received from pharmacies	44	Percent of surveys from pharmacies	40.74%
Total number of surveys sent	222	Total number of surveys received	97	Percent of surveys received	43.69%

Costs (Pre-Rebate)	Original Costs (10/1/2014 - 3/31/2015)*	Costs After DUR Intervention (10/1/2015 - 3/31/2016)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$4,314.19	\$2,973.95	\$1,340.25	\$2,680.49
Total Dollars State	\$2,615.66	\$2,006.34	\$609.31	\$1,218.63
Total Dollars (State and Federal)	\$6,929.85	\$4,980.29	\$1,949.56	\$3,899.12

* Federal FMAP: 0.5554 State: 0.4446

** Federal FMAP: 0.5491 State: 0.4509

*** IHAWP Federal FMAP: 1.0000 State: 0.0000

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.



IOWA DUR FOCUS STUDY Based on Iowa Paid Non-Reversed Claims



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Modafinil Utilization in Members under 21 Years of age

Follow-up on the unique members under 21 years of age identified as taking modafinil.

Number of unique members from original study	9			
Number of unique members that changed therapy	3			
Number of unique members that did not change therapy	6			
Number of unique members who lost Medicaid eligibility since 4/1/2015	0			
Number of surveys sent to prescribers	13	Number of surveys received from prescribers	6	Percent of surveys from prescribers 46.15%
Number of surveys sent to pharmacies	10	Number of surveys received from pharmacies	4	Percent of surveys from pharmacies 40.00%
Total number of surveys sent	23	Total number of surveys received	10	Percent of surveys received 43.48%

Costs (Pre-Rebate)	Original Costs (1/1/2015 - 3/31/2015)*	Costs After DUR Intervention (1/1/2016 - 3/31/2016)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$12,182.95	\$7,135.81	\$5,047.14	\$20,188.57
Total Dollars State	\$9,282.09	\$5,620.12	\$3,661.97	\$14,647.87
Total Dollars (State and Federal)	\$21,465.04	\$12,755.93	\$8,709.11	\$34,836.44

* Federal FMAP: 0.5554 State: 0.4446

** Federal FMAP: 0.5491 State: 0.4509

*** IHAWP Federal FMAP: 1.0000 State: 0.0000

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.



IOWA DUR FOCUS STUDY
Based on Iowa Paid Non-Reversed Claims
Duplicate Antidepressants – 4 or More Agents



Follow-up on the unique members identified as taking 4 distinct antidepressants.

Number of unique members from original study	11				
Number of unique members that changed therapy	4				
Number of unique members that did not change therapy	4				
Number of unique members who lost Medicaid eligibility since 4/1/2015	3				
Number of surveys sent to prescribers	16	Number of surveys received from prescribers	7	Percent of surveys from prescribers	43.75%
Number of surveys sent to pharmacies	11	Number of surveys received from pharmacies	3	Percent of surveys from pharmacies	27.27%
Total number of surveys sent	27	Total number of surveys received	10	Percent of surveys received	37.04%

Costs (Pre-Rebate)	Original Costs (1/1/2015 - 3/31/2015)*	Costs After DUR Intervention (1/1/2016 - 3/31/2016)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$3,846.41	\$4,210.31	(\$363.89)	(\$1,455.58)
Total Dollars State	\$2,336.36	\$2,898.14	(\$561.79)	(\$2,247.14)
Total Dollars (State and Federal)	\$6,182.77	\$7,108.45	(\$925.68)	(\$3,702.72)

* Federal FMAP: 0.5554 State: 0.4446

** Federal FMAP: 0.5491 State: 0.4509

*** IHAWP Federal FMAP: 1.0000 State: 0.0000

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.



IOWA DUR FOCUS STUDY Based on Iowa Paid Non-Reversed Claims



Duplicate SSRIs

Follow-up on the unique members identified as taking 2 distinct SSRIs.

Number of unique members from original study	21			
Number of unique members that changed therapy	3			
Number of unique members that did not change therapy	17			
Number of unique members who lost Medicaid eligibility since 4/1/2015	1			
Number of surveys sent to prescribers	45	Number of surveys received from prescribers	20	Percent of surveys from prescribers 44.44%
Number of surveys sent to pharmacies	22	Number of surveys received from pharmacies	7	Percent of surveys from pharmacies 31.82%
Total number of surveys sent	67	Total number of surveys received	27	Percent of surveys received 40.30%

Costs (Pre-Rebate)	Original Costs (1/1/2015 - 3/31/2015)*	Costs After DUR Intervention (1/1/2016 - 3/31/2016)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$1,753.65	\$1,670.25	\$83.40	\$333.61
Total Dollars State	\$1,188.61	\$1,120.12	\$68.49	\$273.95
Total Dollars (State and Federal)	\$2,942.26	\$2,790.37	\$151.89	\$607.56

* Federal FMAP: 0.5554 State: 0.4446

** Federal FMAP: 0.5491 State: 0.4509

*** IHAWP Federal FMAP: 1.0000 State: 0.0000

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.



IOWA DUR FOCUS STUDY Based on Iowa Paid Non-Reversed Claims



Duplicate SNRIs

Follow-up on the unique members identified as taking 2 distinct SNRIs.

Number of unique members from original study	15				
Number of unique members that changed therapy	3				
Number of unique members that did not change therapy	10				
Number of unique members who lost Medicaid eligibility since 4/1/2015	2				
Number of surveys sent to prescribers	38	Number of surveys received from prescribers	24	Percent of surveys from prescribers	63.16%
Number of surveys sent to pharmacies	16	Number of surveys received from pharmacies	5	Percent of surveys from pharmacies	31.25%
Total number of surveys sent	54	Total number of surveys received	29	Percent of surveys received	53.70%

Costs (Pre-Rebate)	Original Costs (1/1/2015 - 3/31/2015)*	Costs After DUR Intervention (1/1/2016 - 3/31/2016)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$7,916.12	\$4,893.00	\$3,023.12	\$12,092.48
Total Dollars State	\$895.26	\$895.26	\$0.00	\$0.00
Total Dollars (State and Federal)	\$8,811.38	\$5,788.26	\$3,023.12	\$12,092.48

* Federal FMAP: 0.5554 State: 0.4446

** Federal FMAP: 0.5491 State: 0.4509

*** IHAWP Federal FMAP: 1.0000 State: 0.0000

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.



IOWA DUR FOCUS STUDY Based on Iowa Paid Non-Reversed Claims Duplicate Therapy – SSRI plus SNRI



Follow-up on the unique members identified as taking an SSRI concurrently with an SNRI.

Number of unique members from original study	162				
Number of unique members that changed therapy	38				
Number of unique members that did not change therapy	116				
Number of unique members who lost Medicaid eligibility since 4/1/2015	8				
Number of surveys sent to prescribers	230	Number of surveys received from prescribers	90	Percent of surveys from prescribers	39.13%
Number of surveys sent to pharmacies	184	Number of surveys received from pharmacies	63	Percent of surveys from pharmacies	34.24%
Total number of surveys sent	414	Total number of surveys received	153	Percent of surveys received	36.96%

Costs (Pre-Rebate)	Original Costs (1/1/2015 - 3/31/2015)*	Costs After DUR Intervention (1/1/2016 - 3/31/2016)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$5,460.61	\$4,306.66	\$1,153.94	\$4,615.77
Total Dollars State	\$1,784.56	\$1,493.15	\$291.42	\$1,165.67
Total Dollars (State and Federal)	\$7,245.17	\$5,799.81	\$1,445.36	\$5,781.44

* Federal FMAP: 0.5554 State: 0.4446

** Federal FMAP: 0.5491 State: 0.4509

*** IHAWP Federal FMAP: 1.0000 State: 0.0000

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.



IOWA DUR FOCUS STUDY Based on Iowa Paid Non-Reversed Claims Duplicate Inhaled Corticosteroids



Follow-up on the unique members identified as using 2 distinct inhaled corticosteroids.

Number of unique members from original study	23				
Number of unique members that changed therapy	17				
Number of unique members that did not change therapy	5				
Number of unique members who lost Medicaid eligibility since 4/1/2015	1				
Number of surveys sent to prescribers	38	Number of surveys received from prescribers	15	Percent of surveys from prescribers	39.47%
Number of surveys sent to pharmacies	25	Number of surveys received from pharmacies	7	Percent of surveys from pharmacies	28.00%
Total number of surveys sent	63	Total number of surveys received	22	Percent of surveys received	34.92%

Costs (Pre-Rebate)	Original Costs (12/1/2014 - 3/31/2015)*	Costs After DUR Intervention (12/1/2015 - 3/31/2016)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$29,173.07	\$14,305.23	\$14,867.85	\$44,603.54
Total Dollars State	\$8,284.29	\$4,354.54	\$3,929.74	\$11,789.23
Total Dollars (State and Federal)	\$37,457.36	\$18,659.77	\$18,797.59	\$56,392.77

* Federal FMAP: 0.5554 State: 0.4446

** Federal FMAP: 0.5491 State: 0.4509

*** IHAWP Federal FMAP: 1.0000 State: 0.0000

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.



IOWA DUR FOCUS STUDY

Based on Iowa Paid Non-Reversed Claims

Duplicate Long-Acting Beta-Agonists



Follow-up on the unique members identified as using 2 distinct long-acting beta-agonists.

Number of unique members from original study	12				
Number of unique members that changed therapy	7				
Number of unique members that did not change therapy	5				
Number of unique members who lost Medicaid eligibility since 4/1/2015	0				
Number of surveys sent to prescribers	20	Number of surveys received from prescribers	3	Percent of surveys from prescribers	15.00%
Number of surveys sent to pharmacies	16	Number of surveys received from pharmacies	4	Percent of surveys from pharmacies	25.00%
Total number of surveys sent	36	Total number of surveys received	7	Percent of surveys received	19.44%

Costs (Pre-Rebate)	Original Costs (1/1/2015 - 3/31/2015)*	Costs After DUR Intervention (1/1/2016 - 3/31/2016)**	Cost Savings***	Annualized Cost Savings****
Total Dollars Federal	\$12,577.41	\$6,039.93	\$6,537.48	\$26,149.91
Total Dollars State	\$2,941.73	\$636.28	\$2,305.45	\$9,221.81
Total Dollars (State and Federal)	\$15,519.14	\$6,676.21	\$8,842.93	\$35,371.72

* Federal FMAP: 0.5554 State: 0.4446

** Federal FMAP: 0.5491 State: 0.4509

*** IHAWP Federal FMAP: 1.0000 State: 0.0000

**** Annualized Cost Savings is based on the reported interval. Some savings may be due to changes in reimbursement from the original time period to the follow-up period.

Appendix G

Prior Auth Recommendations

Therapeutic Prior Authorization Criteria Review SFY16

During the fiscal year ending 2016, the Commission reviewed the following categories of medications covered under the prior authorization program.

The following criteria were reviewed with recommended changes:

- **Ivacaftor (Kalydeco)** – Modifications were made to add additional mutations, and criteria for additional approval by documenting response to therapy, adherence, and updated liver function tests.
- **Alpha₁-Proteinase Inhibitor Enzymes** – Modifications were made to strengthen criteria to look at pretreatment serum concentrations of ATT, phenotypes, age, etc.
- **Biologicals for Ankylosing Spondylitis, Inflammatory Bowel Disease & Plaque Psoriasis** – Modifications were made to add criteria to require TB screening, Hepatitis B & C screening, verification patient not treated for solid malignancies, nonmelanoma skin cancer or lymphoproliferative malignancy in previous 5 years; verification patient does not have CHF that is NYHA Class III or IV prior to initiating therapy.
- **Growth Hormone** – Modifications were made that eliminated requirement for Stimuli testing for chronic renal failure and HIV/AIDS; added diagnosis of small for gestational age (SGA) as not medically necessary and will not be covered.
- **Binge Eating Disorder Agents** – Modifications were made to remove pharmacologic trials prior to the use of BED agents.
- **Sodium Oxybate (Xyrem)** - Modifications were made to add criteria to allow for treatment of patients 18 years of age or older.
- **Non-Parenteral Vasopressin Derivatives of Posterior Pituitary Hormone** – Modifications were made to criteria to indicate desmopressin nasal spray would not be considered for nocturnal enuresis and criteria for nocturnal enuresis was removed.
- **Long-Acting Opioids** – Modifications were made based on CDC guidelines (chronic pain severe enough to require daily around the clock, long term opioid treatment; failure of 2 non-prescription therapies; failure of 2 non-opioid pharmacologic therapies; patient informed of common and serious adverse effects) and only require failure with one preferred long-acting opioid at maximally tolerated dose.
- **Deferasirox** – Modifications were made to add dosing information for Jadenu.

The following are new classes for which clinical prior authorization criteria were developed and recommended:

Topical Corticosteroids – Prior authorization criteria was developed and accepted as follows:

Prior authorization is required for non-preferred topical corticosteroids. Payment will be considered for patients when there is documentation of adequate trials and therapy failures with at least two preferred, chemically distinct, topical corticosteroid agents within the same potency class or a higher potency class in the past 12 months. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Idiopathic Pulmonary Fibrosis – Prior authorization criteria was developed and accepted as follows:

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

1. Patient is 40 years of age or older; and
2. Is prescribed by a pulmonologist; and
3. Patient has a diagnosis of idiopathic pulmonary fibrosis as confirmed by one of the following (attach documentation):
 - Findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP); or
 - A surgical lung biopsy demonstrating usual interstitial pneumonia (UIP); and
4. Prescriber has excluded other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity; and
5. Patient has documentation of pulmonary function tests within the prior 60 days with a forced vital capacity (FVC) $\geq 50\%$ predicted; and
6. Patient has a carbon monoxide diffusion capacity (%DLco) of $\geq 30\%$ predicted; and
7. Patient does not have hepatic impairment as defined below:
 - Nintedanib - Patient does not have moderate or severe hepatic impairment (Child Pugh B or C) or
 - Pifenidone - Patient does not have severe hepatic impairment (Child Pugh C); and
8. Patient does not have renal impairment as defined below:
 - Nintedanib - Patient does not have severe renal impairment (CrCl < 30 ml/min) or end-stage renal disease or
 - Pirfenidone – Patient does not have end-stage renal disease requiring dialysis; and

9. Patient is a nonsmoker or has been abstinent from smoking for at least six weeks.

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

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

Edoxaban (Savaysa) – Prior authorization criteria was developed and accepted as follows:

Prior authorization is required for edoxaban (Savaysa[®]). Payment will be considered for patients when the following criteria are met:

1. Patient does not have a mechanical heart valve; and
2. Patient does not have moderate to severe mitral stenosis; and
3. Patient does not have active pathological bleeding; and
4. A recent creatinine clearance (CrCl) is provided and is within specified range listed below; and
5. Patient does not have moderate or severe hepatic impairment (Child-Pugh B or C); and
6. Patient has documentation of a previous trial and therapy failure with warfarin (TIA, stroke, or inability to maintain a therapeutic INR with a minimum 6 month trial); and
7. Patient has documentation of a previous trial and therapy failure with apixaban or rivaroxaban, where applicable.

Atrial Fibrillation

1. Patient has documentation of a diagnosis of non-valvular atrial fibrillation; with
2. Presence of at least one additional risk factor for stroke, with a CHADS₂ score ≥1; and
3. Patient does not have a creatinine clearance (CrCl) > 95 mL/min.
4. Requests will be considered for the following dosing:
 - a. 60mg once daily in patients with a CrCl of > 50 mL/min to ≤ 95 mL/min; or
 - b. 30mg once daily in patients with a CrCl of 15 to 50 mL/min

Treatment of Deep Vein Thrombosis or Pulmonary Embolism

1. Patient has documentation of a current deep vein thrombosis or pulmonary embolism; with
2. Documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin).
3. Requests will be considered for the following dosing:
 - a. 60mg once daily; or
 - b. 30mg once daily in patients with any of the following:
 - i. CrCl 15 mL/min to 50 mL/min
 - ii. Body weight \leq 60 kg

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

Topical Antifungals for Onychomycosis – Prior authorization criteria was developed and accepted as follows:

Jublia[®] (efinaconazole) and Kerydin[®] (tavaborole) will be considered when the following criteria are met:

1. Patient has a diagnosis of onychomycosis of the toenail(s) confirmed by a positive potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy (attach results) without dermatophytomas or lunula (matrix) involvement; and
2. Patient is 18 years of age or older; and
3. Patient has documentation of a complete trial and therapy failure or intolerance to oral terbinafine; and
4. Patient has documentation of a complete trial and therapy failure or intolerance to ciclopirox 8% topical solution; and
5. Patient is diabetic or immunosuppressed/immunocompromised.

If the criteria for coverage are met, a one-time authorization of 48 weeks will be given. Requests for reoccurrence of infection will not be considered.

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

Lumacaftor/Ivacaftor (Orkambi) – Prior authorization criteria was developed and accepted as follows:

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

1. Patient is 12 years of age or older; and
2. Has a diagnosis of cystic fibrosis; and
3. Patient is homozygous for the *F508del* mutation in the *CFTR* gene as confirmed by a FDA-cleared CF mutation test; and

4. Baseline liver function tests (AST/ALT) and bilirubin levels are provided and
5. Baseline percent predicted forced expiratory volume (ppFEV₁) is provided and is greater than or equal to (\geq) 40; and
6. Prescriber is a CF specialist or pulmonologist; and
7. Patient does not have one of the following infections: *Burkholderia cenocepacia*, *Burkholderia dolosa*, or *Mycobacterium abscessus*.

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

1. Adherence to lumacaftor/ivacaftor therapy is confirmed; and
2. Response to therapy is documented by prescriber (e.g., improved ppFEV₁ from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and
3. Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter.

Select Oncology Agents – Prior authorization criteria was developed and accepted as follows:

Prior authorization is required for select oncology agents. Patient must have a diagnosis that is indicated in the FDA approved package insert or the use is for an indication supported by the compendia (including National Comprehensive Cancer Network (NCCN) compendium level of evidence 1, 2A, or 2B). The following must be submitted with the prior authorization request: copies of medical records (i.e. diagnostic evaluations and recent chart notes), location of treatment (provider office, facility, home health, etc.) if medication requested is not an oral agent, the original prescription, and the most recent copies of related laboratory results. If criteria for coverage are met, initial authorization will be given for three (3) months. Additional authorizations will be considered for up to six (6) month intervals when criteria for coverage are met. Updates on disease progression must be provided with each renewal request. If disease progression is noted, therapy will not be continued unless otherwise justified.

Cholic Acid (Cholbam) – Prior authorization criteria was developed and accepted as follows:

Prior authorization is required for cholic acid (Cholbam). Payment will be considered under the following conditions:

1. Is prescribed by a hepatologist or pediatric gastroenterologist; and
2. Is prescribed for a diagnosis of bile acid synthesis disorder due to a single enzyme defect (SED) including:
 - 3-beta-hydroxy-delta-5C27-steroid oxidoreductase deficiency (3 β -HSD),

- aldo-keto reductase 1D1 (AKR1D1),
 - alpha-methylacyl-CoA racemase deficiency (AMACR deficiency),
 - sterol 27-hydroxylase deficiency (cerebrotendinous xanthomatosis [CTX]),
 - cytochrome P450 7A1 (CYP7A1),
 - 25-hydroxylation pathway (Smith-Lemli-Opitz); OR
3. Is prescribed as an adjunctive treatment of a peroxisomal disorder (PD) in patients who exhibit manifestations of liver disease, steatorrhea, or complications from fat soluble vitamin absorption. Peroxisomal disorders include Zellweger syndrome (ZWS), neonatal adrenoleukodystrophy (NALD), or infantile refsum disease (IRD); and
 4. Diagnosis is confirmed by mass spectrometry or other biochemical testing or genetic testing (attach results); and
 5. Baseline liver function tests are taken prior to initiation of therapy (AST, ALT, GGT, ALP, total bilirubin, INR) and provided with request; and
 6. Patient must have elevated serum aminotransferases (AST and ALT) with normal serum gamma glutamyltransferase (GTT); and
 7. Patient is at least 3 weeks old.

When criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 12 months at a time requiring documentation of response to therapy by meeting two of the following criteria:

- Body weight has increased by 10% or is stable at $\geq 50^{\text{th}}$ percentile,
- Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) < 50 U/L or baseline levels reduced by 80%,
- Total bilirubin level reduced to ≤ 1 mg/dL.

PCSK9 Inhibitors – Prior authorization criteria was developed and accepted as follows:

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:

Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH)

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.

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 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.

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 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.

Valsartan/Sacubitril (Entresto) – Prior authorization criteria was developed and accepted as follows:

Prior authorization 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 18 years of age or older; and
2. Patient has a diagnosis of NYHA Functional Class II, III, or IV heart failure; and
3. Patient has a left ventricular ejection fraction (LVEF) $\leq 40\%$; and
4. Patient has documentation of a previous trial and therapy failure or intolerance to an ACE inhibitor at a maximally tolerated dose; and
5. Patient has documentation of a previous trial and therapy failure or intolerance to an angiotensin II receptor blocker (ARB); and
6. 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); and
7. Will not be used in combination with an ACE inhibitor or ARB; and
8. Will not be used in combination with aliskiren (Tekturna) in diabetic patients; and
9. Patient does not have a history of angioedema associated with the use of ACE inhibitor or ARB therapy; and
10. Patient is not pregnant; and
11. Patient does not have severe hepatic impairment (Child Pugh Class C); and
12. Prescriber is a cardiologist or has consulted with a cardiologist (telephone consultation is acceptable).

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

If the criteria for coverage are met, initial authorization will be given for 3 months. Requests for continuation of therapy may be provided if prescriber documents adequate response to therapy.

Biologicals for Hidradenitis Suppurativa – Prior authorization criteria were developed and accepted as follows:

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

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

Payment will be considered under the following conditions:

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

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

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

Rifaximin (Xifaxan) - Prior authorization criteria were developed and accepted as follows:

Prior authorization is required for rifaximin. Only FDA approved dosing will be considered. Payment will be considered under the following conditions:

1. A diagnosis of travelers' diarrhea:
 - a. Patient is 12 years of age or older; and
 - b. Patient has a diagnosis of travelers' diarrhea not complicated by fever or blood in the stool or diarrhea due to pathogens other than *Escherichia coli*; and
 - c. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with a preferred generic fluoroquinolone or azithromycin.
 - d. A maximum 3 day course of therapy (9 tablets) of the 200mg tablets per 30 days will be allowed.
2. A diagnosis of hepatic encephalopathy:
 - a. Patient is 18 years of age or older; and
 - b. Patient has a diagnosis of hepatic encephalopathy; and
 - c. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with lactulose.
3. A diagnosis of irritable bowel syndrome with diarrhea:
 - a. Patient is 18 years of age or older; and
 - b. Patient has a diagnosis of irritable bowel syndrome with diarrhea; and
 - c. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with a preferred antispasmodic agent (dicyclomine, hyoscyamine); and
 - d. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with amitriptyline and loperamide.
 - e. If criteria for coverage are met, a single 14-day course will be approved.
 - f. Subsequent requests will require documentation of recurrence of IBS-D symptoms. A minimum 10 week treatment-free period between courses is required.
 - g. A maximum of 3 treatment courses of rifaximin will be allowed per lifetime.

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

Ivabradine (Corlanor) - Prior authorization criteria were developed and accepted as follows:

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

1. Patient is 18 years of age or older; and
2. Patient has a diagnosis of stable, symptomatic heart failure (NYHA Class II, III, or IV); and
3. Patient has documentation of a left ventricular ejection fraction $\leq 35\%$; and
4. Patient is in sinus rhythm with a resting heart rate of ≥ 70 beats per minute; and

5. Patient has documentation of blood pressure $\geq 90/50$ mmHg; and
6. Heart failure symptoms persist with maximally tolerated doses of at least one beta-blocker with proven mortality benefit in a heart failure clinical trial (e.g. carvedilol 50mg daily, metoprolol succinate 200mg daily, or bisoprolol 10mg daily), or patient has a documented intolerance or FDA labeled contraindication to beta-blockers; and
7. Patient has documentation of a trial and continued use with a preferred ACE inhibitor or preferred ARB at a maximally tolerated dose.

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

Eluxadoline (Viberzi) - Prior authorization criteria were developed and accepted as follows:

Prior authorization is required for eluxadoline. Only FDA approved dosing will be considered. Payment will be considered under the following conditions:

1. Patient is 18 years of age or older.
2. Patient has a diagnosis of irritable bowel syndrome with diarrhea (IBS-D).
3. Patient does not have any of the following contraindications to therapy:
 - a. Known or suspected biliary duct obstruction, or sphincter of Oddi disease/dysfunction.
 - b. Alcoholism, alcohol abuse, alcohol addiction, or consumption of more than 3 alcoholic beverages per day.
 - c. A history of pancreatitis or structural diseases of the pancreas (including known or suspected pancreatic duct obstruction).
 - d. Severe hepatic impairment (Child-Pugh Class C).
 - e. Severe constipation or sequelae from constipation.
 - f. Known or suspected mechanical gastrointestinal obstruction.
4. Patient has documentation of a previous trial and therapy failure at a therapeutic dose with both of the following:
 - a. A preferred antispasmodic agent (dicyclomine or hyoscyamine).
 - b. A preferred antidiarrheal agent (loperamide).

If criteria for coverage are met, initial authorization will be given for 3 months to assess the response to treatment. Requests for continuation of therapy will require the following:

1. Patient has not developed any contraindications to therapy (defined above).
2. Patient has experienced a positive clinical response to therapy as demonstrated by at least one of the following:
 - a. Improvement in abdominal cramping or pain.

b. Improvement in stool frequency and consistency.

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

No recommendations were made to remove PA criteria during the 2016 state fiscal year.



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

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August 6, 2015

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

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, August 5, 2015. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Topical Corticosteroids, Ivacaftor (Kalydeco[®]), Idiopathic Pulmonary Fibrosis, Select Oncology Agents and Edoxaban (Savaysa[®]). The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments received from the medical/pharmacy associations in response to a June 10, 2015 letter that was sent to them detailing the proposed criteria for Topical Corticosteroids, Ivacaftor (Kalydeco[®]), Idiopathic Pulmonary Fibrosis, Oral Oncology agents, and Edoxaban (Savaysa[®]).

Topical Corticosteroids

Newly Proposed Prior Authorization Criteria

Prior authorization is required for non-preferred topical corticosteroids. Payment will be considered for patients when there is documentation of adequate trials and therapy failures with at least two preferred, chemically distinct, topical corticosteroid agents within the same potency class or a higher potency class in the past 12 months. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Ivacaftor (Kalydeco[®])

Proposed Prior Authorization Criteria (*changes italicized*)

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

1. Patient is 2 years of age or older; and

2. Has a diagnosis of cystic fibrosis with one of the following mutations in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, and *R117H* as detected by a FDA-cleared CF mutation test; and
3. Prescriber is a CF specialist or pulmonologist; and
4. *Baseline liver function tests (AST/ALT) and FEV₁, if age appropriate, are provided; and*
5. Patient does not have one of the following infections: *Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abscessus.*

If the criteria for coverage are met, an initial authorization will be given for 3 months.

Additional approvals will be granted for 6 months at a time if the following criteria are met:

1. *Adherence to ivacaftor therapy is confirmed; and*
2. *Response to therapy is documented by prescriber (e.g., improved FEV₁ from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and*
3. *Liver function tests (AST/ALT) are assessed every 3 months during the first year of treatment and annually thereafter.*

Idiopathic Pulmonary Fibrosis

Newly Proposed Prior Authorization Criteria

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

1. Patient is 40 years of age or older; and
2. Is prescribed by a pulmonologist; and
3. Patient has a diagnosis of idiopathic pulmonary fibrosis as confirmed by one of the following (attach documentation):
 - Findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP); or
 - A surgical lung biopsy demonstrating usual interstitial pneumonia (UIP); and
4. Prescriber has excluded other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity; and
5. Patient has documentation of pulmonary function tests within the prior 60 days with a forced vital capacity (FVC) $\geq 50\%$ predicted; and
6. Patient has a carbon monoxide diffusion capacity (%DLco) of $\geq 30\%$ predicted; and
7. Patient does not have hepatic impairment as defined below:
 - Nintedanib - Patient does not have moderate or severe hepatic impairment (Child Pugh B or C) or
 - Pifenidone - Patient does not have severe hepatic impairment (Child Pugh C); and
8. Patient does not have renal impairment as defined below:
 - Nintedanib - Patient does not have severe renal impairment (CrCl < 30 ml/min) or end-stage renal disease or
 - Pirfenidone – Patient does not have end-stage renal disease requiring dialysis; and
9. Patient is a nonsmoker or has been abstinent from smoking for at least six weeks.

If the criteria for coverage are met, initial requests will be given for 6 months. Additional

authorizations will be considered at 6 month intervals when the following criteria are met:

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

Edoxaban (Savaysa[®])

Newly Proposed Prior Authorization Criteria

Prior authorization is required for edoxaban (Savaysa[®]). Payment will be considered for patients when the following criteria are met:

1. Patient does not have a mechanical heart valve; and
2. Patient does not have moderate to severe mitral stenosis; and
3. Patient does not have active pathological bleeding; and
4. A recent creatinine clearance (CrCl) is provided and is within specified range listed below; and
5. Patient does not have moderate or severe hepatic impairment (Child-Pugh B or C); and
6. Patient has documentation of a previous trial and therapy failure with warfarin (TIA, stroke, or inability to maintain a therapeutic INR with a minimum 6 month trial); and
7. Patient has documentation of a previous trial and therapy failure with apixaban or rivaroxaban, where applicable.

Atrial Fibrillation

1. Patient has documentation of a diagnosis of non-valvular atrial fibrillation; with
2. Presence of at least one additional risk factor for stroke, with a CHADS₂ score ≥1; and
3. Patient does not have a creatinine clearance (CrCl) > 95 mL/min.
4. Requests will be considered for the following dosing:
 - a. 60mg once daily in patients with a CrCl of > 50 mL/min to ≤ 95 mL/min; or
 - b. 30mg once daily in patients with a CrCl of 15 to 50 mL/min

Treatment of Deep Vein Thrombosis or Pulmonary Embolism

1. Patient has documentation of a current deep vein thrombosis or pulmonary embolism; with
2. Documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin).
3. Requests will be considered for the following dosing:
 - a. 60mg once daily; or
 - b. 30mg once daily in patients with any of the following:
 - i. CrCl 15 mL/min to 50 mL/min
 - ii. Body weight ≤60 kg

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

The DUR Commission discussed the proposed prior authorization criteria for Select Oncology Agents in addition to reviewing written comments received on this topic. The DUR Commission made changes to the proposed prior authorization criteria and asked the criteria be sent out to the medical and pharmacy associations for their review and comment.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Topical Corticosteroids, Ivacaftor (Kalydeco[®]), Idiopathic Pulmonary Fibrosis, and Edoxaban (Savaysa[®]).

Sincerely,

A handwritten signature in black ink that reads "Paula Smith R.Ph." in a cursive script.

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

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



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

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October 8, 2015

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

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, October 7, 2015. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Topical Antifungals for Onychomycosis, Alpha-1 Proteinase Inhibitors, Lumacaftor/Ivacaftor (Orkambi™), Biologicals for Inflammatory Bowel Disease, Biologicals for Ankylosing Spondylitis, Biologicals for Plaque Psoriasis, and Select Oncology Agents. The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments received from the medical/pharmacy associations in response to an August 12, 2015 letter that was sent to them detailing the proposed criteria for Topical Antifungals for Onychomycosis, Alpha-1 Proteinase Inhibitors, Lumacaftor/Ivacaftor (Orkambi™), Biologicals for Inflammatory Bowel Disease, Biologicals for Ankylosing Spondylitis, Biologicals for Plaque Psoriasis, and Select Oncology Agents.

Topical Antifungals for Onychomycosis

Newly Proposed Prior Authorization Criteria

Jublia® (efinaconazole) and Kerydin® (tavaborole) will be considered when the following criteria are met:

1. Patient has a diagnosis of onychomycosis of the toenail(s) confirmed by a positive potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy (attach results) without dermatophytomas or lunula (matrix) involvement; and
2. Patient is 18 years of age or older; and
3. Patient has documentation of a complete trial and therapy failure or intolerance to oral terbinafine; and
4. Patient has documentation of a complete trial and therapy failure or intolerance to ciclopirox 8% topical solution; and
5. Patient is diabetic or immunosuppressed/immunocompromised.

If the criteria for coverage are met, a one-time authorization of 48 weeks will be given. Requests for reoccurrence of infection will not be considered.

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

Alpha₁-Proteinase Inhibitor Enzymes

Proposed Prior Authorization Criteria (changes italicized)

Prior authorization is required for Alpha₁-Proteinase Inhibitor enzymes. Payment for a non-preferred Alpha₁-Proteinase Inhibitor enzyme 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 for patients when the following is met:

1. Patient has a diagnosis of congenital alpha₁-antitrypsin (AAT) deficiency; *with a pretreatment serum concentration of AAT less than 11µM/L or*
 - *80mg/dl if measured by radial immunodiffusion, or*
 - *50mg/dl if measured by nephelometry; and*
2. *Patient has a high-risk AAT deficiency phenotype (PiZZ, PiZ (null), or PI (null)(null) or other phenotypes associated with serum AAT concentrations of less than 11µM/L, such as PiSZ or PiMZ); and*
3. *Patient has documented progressive panacinar emphysema with a documented rate of decline in forced expiratory volume in 1 second (FEV₁); and*
4. *Patient is 18 years of age or older; and*
5. *Patient is currently a non-smoker; and*
6. *Patient is currently on optimal supportive therapy for obstructive lung disease (inhaled bronchodilators, inhaled steroids); and*
7. *Medication will be administered in the member's home by home health or in a long-term care facility.*

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

1. *Evidence of clinical efficacy, as documented by:*
 - a. *An elevation of AAT levels (above protective threshold i.e., > 11µM/L); and*
 - b. *A reduction in rate of deterioration of lung function as measured by a decrease in the FEV₁ rate of decline; and*
2. *Patient continues to be a non-smoker; and*
3. *Patient continues supportive therapy for obstructive lung disease.*

Lumacaftor/Ivacaftor (Orkambi™)

Newly Proposed Prior Authorization Criteria

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

1. Patient is 12 years of age or older; and
2. Has a diagnosis of cystic fibrosis; and

3. Patient is homozygous for the *F508del* mutation in the *CFTR* gene as confirmed by a FDA-cleared CF mutation test; and
4. Baseline liver function tests (AST/ALT) and bilirubin levels are provided and
5. Baseline percent predicted forced expiratory volume (ppFEV₁) is provided and is greater than or equal to (\geq) 40; and
6. Prescriber is a CF specialist or pulmonologist; and
7. Patient does not have one of the following infections: *Burkholderia cenocepacia*, *Burkholderia dolosa*, or *Mycobacterium abscessus*.

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

1. Adherence to lumacaftor/ivacaftor therapy is confirmed; and
2. Response to therapy is documented by prescriber (e.g., improved ppFEV₁ from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and
3. Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter.

Biologicals for Inflammatory Bowel Disease

Proposed Prior Authorization Criteria (changes italicized)

Prior authorization is required for biologicals used for inflammatory bowel disease. Payment for non-preferred biologicals for inflammatory bowel disease will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred 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 biological 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 while patients with active TB will only be considered upon completion of TB treatment.*

Payment will be considered under the following conditions:

- Crohn's Disease – Payment will be considered following an inadequate response to two preferred conventional therapies including aminosalicylates (mesalamine, sulfasalazine), azathioprine/6-mercaptopurine, and/or methotrexate.
- Ulcerative colitis (moderate to severe) – Payment will be considered following an inadequate response to two preferred conventional therapies including aminosalicylates and azathioprine/6-mercaptopurine.

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

Biologicals for Ankylosing Spondylitis

Proposed Prior Authorization Criteria (changes italicized)

Prior authorization is required for biologicals used for ankylosing spondylitis. Payment for non-preferred biologicals for ankylosing spondylitis will be considered only for cases in

which there is documentation of previous trials and therapy failures with two preferred biological agents.

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 biological 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 while patients with active TB will only be considered upon completion of TB treatment.*

Payment will be considered following inadequate responses to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at maximum therapeutic doses, unless there are documented adverse responses or contraindications to NSAID use. These trials should be at least three months in duration. Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include sulfasalazine and methotrexate. *The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.*

Biologics for Plaque Psoriasis

Proposed Prior Authorization Criteria (changes italicized)

Prior authorization is required for biologics used for plaque psoriasis. Payment for non-preferred biologics for plaque psoriasis will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred 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 biological 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 while patients with active TB will only be considered upon completion of TB treatment.*

Payment will be considered following an inadequate response to phototherapy, systemic retinoids (oral acitretin), methotrexate, or cyclosporine. *The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.*

Select Oncology Agents

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for select oncology agents. Patient must have a diagnosis that is indicated in the FDA approved package insert or the use is for an indication supported by the compendia (including National Comprehensive Cancer Network (NCCN) compendium level of evidence 1, 2A, or 2B). The following must be submitted with the prior authorization request: copies of medical records (i.e. diagnostic evaluations and recent chart notes), location of treatment (provider office, facility, home health, etc.) if medication requested is not an oral agent, the original prescription, and the most recent copies of related laboratory results. If criteria for coverage are met, initial authorization will be given for three (3) months. Additional authorizations will be considered for up to six (6) month intervals when criteria for coverage are met. Updates on disease progression must be provided with each renewal request. If disease progression is noted, therapy will not be continued unless otherwise justified.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Topical Antifungals for Onychomycosis, Alpha-1 Proteinase Inhibitors, Lumacaftor/Ivacaftor (Orkambi™), Biologicals for Inflammatory Bowel Disease, Biologicals for Ankylosing Spondylitis, Biologicals for Plaque Psoriasis, and Select Oncology Agents.

Sincerely,

A handwritten signature in cursive script that reads "Paula Smith R.Ph.".

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

Cc: Erin Halverson, R.Ph., IME
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December 3, 2015

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

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, December 2, 2015. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Growth Hormone, Cholic Acid (Cholbam[®]), and Binge Eating Disorder Agents. The DUR Commission members also discussed implementing ProDUR edits; an age edit and quantity limit for desmopressin tablets and modifying the quantity limit for ondansetron tablets/ODT. The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments received from the medical/pharmacy associations in response to an October 8, 2015 letter that was sent to them detailing the proposed criteria for Growth Hormone, Cholic Acid (Cholbam[®]), and Binge Eating Disorder Agents.

Growth Hormone

Proposed Prior Authorization Criteria (*changes italicized*)

Prior authorization is required for therapy with growth hormones. Payment for non-preferred growth hormones will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. All of the following criteria must be met for approval for prescribing of growth hormones:

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

Prior authorization will be granted for 12-month periods per patient as needed.

The following FDA approved indications for Growth Hormone therapy are considered not medically necessary and requests will be denied: Idiopathic Short Stature (ISS) *and Small for Gestational Age (SGA)*.

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

Cholic Acid (Cholbam®)

Newly Proposed Prior Authorization Criteria (changes italicized)

Prior authorization is required for cholic acid (Cholbam). Payment will be considered under the following conditions:

1. Is prescribed by a hepatologist or pediatric gastroenterologist; and
2. Is prescribed for a diagnosis of bile acid synthesis disorder due to a single enzyme defect (SED) including:
 - 3-beta-hydroxy-delta-5C27-steroid oxidoreductase deficiency (3 β -HSD),
 - aldo-keto reductase 1D1 (AKR1D1),
 - alpha-methylacyl-CoA racemase deficiency (AMACR deficiency),
 - sterol 27-hydroxylase deficiency (cerebrotendinous xanthomatosis [CTX]),
 - cytochrome P450 7A1 (CYP7A1),
 - 25-hydroxylation pathway (Smith-Lemli-Opitz); OR
3. Is prescribed as an adjunctive treatment of a peroxisomal disorder (PD) in patients who exhibit manifestations of liver disease, steatorrhea, or complications from fat soluble vitamin absorption. Peroxisomal disorders include Zellweger syndrome (ZWS), neonatal adrenoleukodystrophy (NALD), or infantile refsum disease (IRD); and
4. Diagnosis is confirmed by mass spectrometry or other biochemical testing or genetic testing (attach results); and
5. Baseline liver function tests are taken prior to initiation of therapy (AST, ALT, GGT, ALP, total bilirubin, INR) and provided with request; and
6. Patient must have elevated serum aminotransferases (AST and ALT) with normal serum gamma glutamyltransferase (GTT); and
7. Patient is at least 3 weeks old.

When criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 12 months at a time requiring documentation of response to therapy by meeting two of the following criteria:

- Body weight has increased by 10% or is stable at $\geq 50^{\text{th}}$ percentile,
- Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) < 50 U/L or baseline levels reduced by 80%,
- Total bilirubin level reduced to $\leq 1\text{mg/dL}$.

Binge Eating Disorder Agents

Proposed Prior Authorization Criteria

Prior authorization (PA) is required for Vyvanse for the treatment of Binge Eating Disorder (BED). Prior to requesting PA, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program (PMP) website at <https://pmp.iowa.gov/IAPMPWebCenter/>. Payment will be considered under the following conditions:

1. Patient is 18 to 55 years of age; and
2. Patient meets the DSM-5 criteria for BED; and
3. Patient has documentation of moderate to severe BED, as defined by the number of binge eating episodes per week (number must be reported); and
4. Patient has documentation of non-pharmacologic therapies tried, such as cognitive-behavioral therapy or interpersonal therapy, for a recent 3 month period, that did not significantly reduce the number of binge eating episodes; and
5. Prescription is written by a psychiatrist or psychiatric nurse practitioner;
6. Patient has a BMI of 25 to 45; and
7. Patient does not have a personal history of cardiovascular disease; and
8. Patient has no history of substance abuse; and
9. Is not being prescribed for the treatment of obesity or weight loss; and
10. Doses above 70mg per day will not be considered.

Initial requests will be approved for 12 weeks when criteria for coverage are met. Requests for renewal must include documentation of a change from baseline at week 12 in the number of binge days per week.

DSM-5 Criteria

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

The DUR Commission also made the following ProDUR edit recommendations:

- Quantity Limits

Drug/Strength	Proposed Quantity Limit per 30 Days
Ondansetron 4mg & 8mg tablet	60 tablets
Ondansetron 4mg & 8mg ODT tablet	60 tablets
Desmopressin 0.1mg tablet	90 tablets
Desmopressin 0.2mg tablet	90 tablets

- Age Edit
 - Desmopressin 0.1mg & 0.2mg tablets – Payable for members 6 years of age or older

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Growth Hormone, Cholic Acid (Cholbam[®]), and Binge Eating Disorder Agents in addition to the ProDUR edits recommended for ondansetron tablets/ODT and desmopressin tablets.

Sincerely,



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

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



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April 8, 2016

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

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, April 6, 2016. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for PCSK9 Inhibitors, with quantity limits; Valsartan/Sacubitril (*Entresto*); Sodium Oxybate (*Xyrem*); and Non-Parenteral Vasopressin Derivatives of Posterior Pituitary Hormone Products. The DUR Commission also discussed and made recommendations to update the current Public Comment policy. The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments received from the medical/pharmacy associations in response to a December 7, 2015 letter that was sent to them detailing the proposed criteria for PCSK9 Inhibitors, with quantity limits; Valsartan/Sacubitril (*Entresto*); Sodium Oxybate (*Xyrem*); and Non-Parenteral Vasopressin Derivatives of Posterior Pituitary Hormone Products.

PCSK9 Inhibitors

Newly Proposed 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:

Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH)

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.

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 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.

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 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

Valsartan/Sacubitril (Entresto™)

Newly Proposed Prior Authorization Criteria

Prior authorization 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 18 years of age or older; and
2. Patient has a diagnosis of NYHA Functional Class II, III, or IV heart failure; and
3. Patient has a left ventricular ejection fraction (LVEF) \leq 40%; and
4. Patient has documentation of a previous trial and therapy failure or intolerance to an ACE inhibitor at a maximally tolerated dose; and

5. Patient has documentation of a previous trial and therapy failure or intolerance to an angiotensin II receptor blocker (ARB); and
6. 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); and
7. Will not be used in combination with an ACE inhibitor or ARB; and
8. Will not be used in combination with aliskiren (Tekturna) in diabetic patients; and
9. Patient does not have a history of angioedema associated with the use of ACE inhibitor or ARB therapy; and
10. Patient is not pregnant; and
11. Patient does not have severe hepatic impairment (Child Pugh Class C); and
12. Prescriber is a cardiologist or has consulted with a cardiologist (telephone consultation is acceptable).

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

If the criteria for coverage are met, initial authorization will be given for 3 months. Requests for continuation of therapy may be provided if prescriber documents adequate response to therapy.

Sodium Oxybate (Xyrem®)

Current Prior Authorization Criteria

Prior authorization is required for sodium oxybate (Xyrem®). Payment will be considered for patients 16 years of age or older under the following conditions:

1. A diagnosis of cataplexy associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trial and therapy failure with one of the following tricyclic antidepressants: clomipramine, imipramine, or protriptyline.
2. Patient is enrolled in the Xyrem® Success Program.
3. A diagnosis of excessive daytime sleepiness associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trials and therapy failures at a therapeutic dose with a preferred amphetamine and non-amphetamine stimulant.
4. Patient has been instructed to not drink alcohol when using Xyrem®.
5. Patients with and without a history of substance abuse have been counseled regarding the potential for abuse and dependence and will be closely monitored for signs of abuse and dependence.
6. Requests for patients with concurrent use of a sedative hypnotic or a semialdehyde dehydrogenase deficiency will not be considered.
7. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/> prior to requesting prior authorization.

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

Proposed Prior Authorization Criteria (*changes are italicized*)

Prior authorization is required for sodium oxybate (Xyrem®). Payment will be considered for patients 18 years of age or older under the following conditions:

1. A diagnosis of cataplexy associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trial and therapy failure with one of the following tricyclic antidepressants: clomipramine, imipramine, or protriptyline; *or*
2. A diagnosis of excessive daytime sleepiness associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trials and therapy failures at a therapeutic dose with a preferred amphetamine and non-amphetamine stimulant.
3. Patient is enrolled in the Xyrem® REMS Program.
4. Patient has been instructed to not drink alcohol when using Xyrem®.
5. Patients with and without a history of substance abuse have been counseled regarding the potential for abuse and dependence and will be closely monitored for signs of abuse and dependence.
6. Requests for patients with concurrent use of a sedative hypnotic or a semialdehyde dehydrogenase deficiency will not be considered.
7. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/> prior to requesting prior authorization.

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

Non-Parenteral Vasopressin Derivatives of Posterior Pituitary Hormone Products (Removal of PA criteria for nocturnal enuresis)

Current Prior Authorization Criteria

Prior authorization is required for non-parenteral vasopressin derivatives of posterior pituitary hormone products. Payment for preferred non-parenteral vasopressin derivatives of posterior pituitary hormone products will be authorized for the following diagnoses:

1. Diabetes Insipidus
2. Hemophilia A
3. Von Willebrand's disease

Payment for oral vasopressin derivatives of posterior pituitary hormone products used in the treatment of primary nocturnal enuresis will be authorized for patients who are six years of age or older for periods of six months. Approvals will be granted for subsequent six-month periods only after a drug-free interval to assess the need for continued therapy. Payment for non-preferred non-parenteral vasopressin derivatives will be authorized only for cases in which there is documentation of trial(s) and therapy failure with the preferred agent(s).

Proposed Prior Authorization Criteria (*changes italicized*)

Prior authorization is required for non-parenteral vasopressin derivatives of posterior pituitary hormone products. Payment for preferred non-parenteral vasopressin derivatives of posterior pituitary hormone products will be authorized for the following diagnoses:

1. Diabetes Insipidus
2. Hemophilia A
3. Von Willebrand's disease

Requests for desmopressin nasal spray for the treatment of nocturnal enuresis will not be considered. Payment for non-preferred non-parenteral vasopressin derivatives will be authorized only for cases in which there is documentation of trial(s) and therapy failure with

the preferred agent(s). *Please refer to the Selected Brand-Name Drugs prior authorization form if requesting a non-preferred brand-name product.*

The DUR Commission also discussed the current Public Comment policy which allows individuals attending the meeting the opportunity to address the Commission twice during the open portion of the meeting with a limit of 5 minutes or less for comment. The DUR Commission made a recommendation to decrease the number of public comment periods from two to one, with no change to the time limit.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for PCSK9 Inhibitors, with quantity limits; Valsartan/Sacubitril (*Entresto*); Sodium Oxybate (*Xyrem*); and Non-Parenteral Vasopressin Derivatives of Posterior Pituitary Hormone Products, in addition to the recommendation for Public Comment policy.

Sincerely,

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

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



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

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DUR Project Coordinator

June 2, 2016

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

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, June 1, 2016. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Long-Acting Opioids; Adalimumab (Humira) for Hidradenitis Suppurativa; Rifaximin (Xifaxan); Ivabradine (Corlanor); Deferasirox; and Eluxadoline (Viberzi). The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments received from the medical/pharmacy associations in response to a April 11, 2016 letter that was sent to them detailing the proposed criteria for Long-Acting Opioids; Adalimumab (Humira) for Hidradenitis Suppurativa; Rifaximin (Xifaxan); Ivabradine (Corlanor); Deferasirox; and Eluxadoline (Viberzi).

Long-Acting Opioids

Proposed Long-Acting Opioids Prior Authorization Criteria (*changes italicized*)

Prior authorization is required for all non-preferred long-acting *opioids*. Payment will be considered under the following conditions:

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

6. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/> and determine if use of a long-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization, and
7. Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids.
8. Requests for long-acting opioids will only be considered for FDA approved dosing intervals. As-needed (PRN) dosing will not be considered.

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

1. Patient has experienced improvement in pain control and level of functioning; and
2. Prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/> and has determined continued use of a long-acting opioid is appropriate for this member.

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

Adalimumab (Humira®) for Hidradenitis Suppurativa

Newly Proposed Prior Authorization Criteria

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

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

Payment will be considered under the following conditions:

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

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

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

Rifaximin (Xifaxan[®])

Newly Proposed Prior Authorization Criteria

Prior authorization is required for rifaximin. Only FDA approved dosing will be considered.

Payment will be considered under the following conditions:

1. A diagnosis of travelers' diarrhea:
 - a. Patient is 12 years of age or older; and
 - b. Patient has a diagnosis of travelers' diarrhea not complicated by fever or blood in the stool or diarrhea due to pathogens other than *Escherichia coli*; and
 - c. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with a preferred generic fluoroquinolone or azithromycin.
 - d. A maximum 3 day course of therapy (9 tablets) of the 200mg tablets per 30 days will be allowed.
2. A diagnosis of hepatic encephalopathy:
 - a. Patient is 18 years of age or older; and
 - b. Patient has a diagnosis of hepatic encephalopathy; and
 - c. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with lactulose.
3. A diagnosis of irritable bowel syndrome with diarrhea:
 - a. Patient is 18 years of age or older; and
 - b. Patient has a diagnosis of irritable bowel syndrome with diarrhea; and
 - c. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with a preferred antispasmodic agent (dicyclomine, hyoscyamine); and
 - d. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with amitriptyline and loperamide.
 - e. If criteria for coverage are met, a single 14-day course will be approved.
 - f. Subsequent requests will require documentation of recurrence of IBS-D symptoms. A minimum 10 week treatment-free period between courses is required.
 - g. A maximum of 3 treatment courses of rifaximin will be allowed per lifetime.

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

Ivabradine (Corlanor®)

Newly Proposed Prior Authorization Criteria

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

1. Patient is 18 years of age or older; and
2. Patient has a diagnosis of stable, symptomatic heart failure (NYHA Class II, III, or IV); and
3. Patient has documentation of a left ventricular ejection fraction $\leq 35\%$; and
4. Patient is in sinus rhythm with a resting heart rate of ≥ 70 beats per minute; and
5. Patient has documentation of blood pressure $\geq 90/50$ mmHg; and
6. Heart failure symptoms persist with maximally tolerated doses of at least one beta-blocker with proven mortality benefit in a heart failure clinical trial (e.g. carvedilol 50mg daily, metoprolol succinate 200mg daily, or bisoprolol 10mg daily), or patient has a documented intolerance or FDA labeled contraindication to beta-blockers; and
7. Patient has documentation of a trial and continued use with a preferred ACE inhibitor or preferred ARB at a maximally tolerated dose.

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

Deferasirox

Proposed Prior Authorization Criteria (*changes italicized*)

Prior authorization is required for deferasirox. *Requests will only be considered for FDA approved dosing.* Payment will be considered under the following conditions:

1. Patient does not have a serum creatinine greater than 2 times the age-appropriate upper limit of normal or creatinine clearance < 40 mL/min; and
2. Patient does not have a poor performance status; and
3. Patient does not have a high-risk myelodysplastic syndrome; and
4. Patient does not have advanced malignancies; and
5. Patient does not have a platelet count $< 50 \times 10^9$ /L.

Transfusional Iron Overload

Initiation of Therapy

1. Patient is 2 years of age or older; and
2. Patient has documentation of iron overload related to anemia (attach documentation); and
3. Patient has documentation of a recent history of frequent blood transfusions that has resulted in chronic iron overload; and
4. Serum ferritin is consistently > 1000 mcg/L (attach lab results dates within the past month).; and
5. Starting dose does not exceed: *Exjade - 20mg/kg/day OR Jadenu - 14mg/kg/day.* Calculate dose to the nearest whole tablet.
6. Initial requests will be considered for up to 3 months.

Continuation of Therapy

1. Serum ferritin has been measured within 30 days of continuation of therapy request (attach documentation); and

2. Ferritin levels are > 500mcg/L; and
3. Dose does not exceed: *Exjade* - 40mg/kg/day OR *Jadenu* - 28mg/kg/day.

Non-Transfusional Iron Overload

Initiation of Therapy

1. Patient is 10 years of age or older; and
2. Patient has documentation of iron overload related to anemia (attach documentation); and
3. Serum ferritin and liver iron concentration (LIC) has been measured within 30 days of initiation (attach lab results); and
4. Serum ferritin levels are > 300mcg/L; and
5. LIC are > 5mg Fe/g dw; and
6. Dose does not exceed: *Exjade* - 10mg/kg/day (if LIC is \leq 15mg Fe/g dw), or 20mg/kg/day (if LIC is > 15mg Fe/g dw); OR *Jadenu* - 7mg/kg/day (if LIC is \leq 15mg Fe/g dw), or 14mg/kg/day (if LIC is > 15mg Fe/g dw).
7. Initial authorization will be considered for up to 6 months.

Continuation of Therapy

1. Serum ferritin and LIC have been measured within 30 days of continuation of therapy request; and
2. Serum ferritin levels are \geq 300mcg/L; and
3. LIC is \geq 3mg Fe/g dw.
4. Dose does not exceed: *Exjade* - 10mg/kg/day (if LIC is 3 to 7 mg Fe/g dw) or 20mg/kg/day (if LIC is > 7mg Fe/g dw); OR *Jadenu* - 7mg/kg/day (if LIC is 3 to 7 mg Fe/g dw) or 14mg/kg/day (if LIC is > 7mg Fe/g dw).

Eluxadoline (Viberzi™)

Newly Proposed Prior Authorization Criteria

Prior authorization is required for eluxadoline. Only FDA approved dosing will be considered. Payment will be considered under the following conditions:

1. Patient is 18 years of age or older.
2. Patient has a diagnosis of irritable bowel syndrome with diarrhea (IBS-D).
3. Patient does not have any of the following contraindications to therapy:
 - a. Known or suspected biliary duct obstruction, or sphincter of Oddi disease/dysfunction.
 - b. Alcoholism, alcohol abuse, alcohol addiction, or consumption of more than 3 alcoholic beverages per day.
 - c. A history of pancreatitis or structural diseases of the pancreas (including known or suspected pancreatic duct obstruction).
 - d. Severe hepatic impairment (Child-Pugh Class C).
 - e. Severe constipation or sequelae from constipation.
 - f. Known or suspected mechanical gastrointestinal obstruction.
4. Patient has documentation of a previous trial and therapy failure at a therapeutic dose with both of the following:
 - a. A preferred antispasmodic agent (dicyclomine or hyoscyamine).
 - b. A preferred antidiarrheal agent (loperamide).

If criteria for coverage are met, initial authorization will be given for 3 months to assess the response to treatment. Requests for continuation of therapy will require the following:

1. Patient has not developed any contraindications to therapy (defined above).
2. Patient has experienced a positive clinical response to therapy as demonstrated by at least one of the following:
 - a. Improvement in abdominal cramping or pain.
 - b. Improvement in stool frequency and consistency.

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

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Long-Acting Opioids; Adalimumab (Humira) for Hidradenitis Suppurativa; Rifaximin (Xifaxan); Ivabradine (Corlanor); Deferasirox; and Eluxadoline (Viberzi).

Sincerely,

A handwritten signature in cursive script that reads "Paula Smith R.Ph.".

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

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

Appendix H

Prospective DUR

**Prospective DUR
SFY16**

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

- Quantity Limits

Drug/Strength	Proposed Quantity Limit per 30 Days
Ondansetron 4mg & 8mg tablet	60 tablets
Ondansetron 4mg & 8mg ODT tablet	60 tablets
Desmopressin 0.1mg tablet	90 tablets
Desmopressin 0.2mg tablet	90 tablets

- Age Edit

- Desmopressin 0.1mg & 0.2mg tablets – Payable for members 6 years of age or older

Appendix I
Meeting Minutes

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes August 5, 2015

Attendees:

Commission Members

Mark Graber, M.D., FACEP; Laurie Pestel, Pharm.D.; Larry Ambrosion, R.Ph.; Kellen Ludvigson, Pharm.D.; Brett Faine, Pharm.D.; Brian Couse, M.D.; Daniel Gillette, M.D.; and Susan Parker, Pharm.D.
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Staff

Pam Smith, R.Ph.

Guests

Jason Kessler, M.D., IME; Erin Halverson, R.Ph., IME; Gina Tiernan, Pharm.D., IME; Tina Valentino, Pharm.D., IME; and Melissa Biddle, IME.
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Welcome & Introductions

Mark Graber called the meeting to order at 9:37 a.m. at the Learning Resource Center in West Des Moines. The minutes from the June 3, 2015 meeting were reviewed. Brian Couse motioned to accept them, and Brett Faine seconded. All members were in favor. Members were asked to update their conflict of interest disclosure forms, and the Commission then proceeded to chairperson and vice-chairperson elections. Mark Graber nominated Brett Faine, who respectfully declined and then nominated Mark Graber to remain as chairperson. This was met with unanimous approval from the other members. Kellen Ludvigson then nominated Laurie Pestel to remain as vice-chairperson, and Larry Ambrosion seconded. All members were in favor. The recommendation letter sent to DHS after the last meeting was also reviewed, along with a summary of the Annual Federal Report for federal fiscal year ending 2014. Overall, the program produced \$138,853.65 in savings from patient-focused review, and \$482,262.85 from problem-focused studies, for a net savings of \$351,116.50 after administrative costs.

IME Updates

Almost 134,000 members are now enrolled in the Iowa Health and Wellness Plan. Eleven bids were submitted in response to the Medicaid Modernization managed care Request for Proposal (RFP). Awards are expected to be announced on or around August 17, 2015, with implementation still slated for January 1, 2016. This is the first meeting for new Commission member, Dr. Daniel Gillette. Pam Smith provided a quarterly report on the new Complex Pharmaceutical Oversight Program (CPOP), which brought \$476,274 in direct cost avoidance savings (State and Federal dollars extrapolated to the end of the state fiscal year) from 38 interventions in its second quarter of operation. Additionally, Gina Tiernan is now Clinical Pharmacy Manager at the IME, and this is her first meeting.

Prevalence Report Summary

Statistics from May through June 2015 were discussed, including: cost per user (\$343.09), number of total prescriptions dispensed (a decrease of 5.0% compared to the previous reporting period), average cost per prescription (\$68.42), and generic utilization (85.2%). The total paid amount decreased by 2.8% from the previous reporting period. There were 197,276 unique users, which is 6.2% less than the total for March and April. Lists of the top 20 therapeutic classes were provided. SSRIs had the highest prescription count, and Anticonvulsants came in second. The Hepatitis C category is quickly rising up the top therapeutic classes by paid amount report, currently in seventh place with \$2,567,268 in expenditures, an increase of 45.7% from the previous reporting period. The top 100 drugs were also reviewed. The ten most expensive medications were: Abilify, Vyvanse, methylphenidate hcl er, Harvoni, Lantus, Focalin XR, Advate, Novoseven RT, Strattera, and Spiriva Handihaler. Pam Smith also reviewed the top drugs for other insurance carriers, as had been requested at the previous meeting.

Case Studies

Pam Smith presented 4 case studies. Recommendations by commissioners from these four examples resulted in annualized total savings of \$8,333.50 pre-rebate (state and federal).

Public Comment #1

Name	Representing	Drug/Topic
Lee Ding	Genentech	Esbriet
Nancy Bell	Pfizer	NOACs (DOACs)
Tyrone McBayne	Baxalta	Glassia and Aralast
Larry Lanier	National Patient Advocate Foundation	Prior Authorizations
Kori Hack	Novartis	Cosentyx
Jennifer Stofel	Janssen	Stelara
Peter Zoob	Vertex	Orkambi
Betty Johnston	National Patient Advocate Foundation (volunteer)	Prior Authorizations

Focus Studies

Short-Acting Opioid Overutilization: This was a follow-up discussion. Nine of the 33 members identified changed therapy, for an annualized cost savings of \$1,876.16 (state and federal, pre-rebate) as a result of the 109 surveys sent out to prescribers and pharmacies. A total of 38 (34.86%) of those surveys were returned.

Metoclopramide Utilization: Gastroparesis and chemotherapy regimens were removed from the results as requested at the June meeting, which left 103 members identified as taking oral metoclopramide for greater than 90 days

without a medical reason, when therapy should not exceed 12 weeks. Letters will be sent to the providers of these 103 members to ask if the medication can be discontinued.

Modafinil Utilization: Letters will be sent to the providers of the members under 21 years of age taking modafinil for ADHD to ask if the patient has had adequate trials and therapy failures with methylphenidate and/or amphetamine agents prior to the use of modafinil, and if not, if the patient would be a candidate to use a different preferred stimulant. In the future, the quantity limit on the 400mg dose may also be lowered.

Duplicate Antidepressants: Letters will be sent to the providers of the members taking 4 or more antidepressants concurrently, as well those of members taking 2 or more medications from the same drug class and those taking both an SSRI and SNRI. Pam Smith will pull doses on the TCAs, and serotonergic drugs, and pull up the old data from the previous study to compare.

Public Comment #2

Name	Representing	Drug/Topic
Doug Struyk	American Cancer Society Cancer Action Network	Oncology PA Criteria

Prior Authorization

Topical Antifungals for Onychomycosis: The Commission reviewed the prior authorization criteria as follows:

Jublia[®] (efinaconazole) and Kerydin[®] (tavaborole) will be considered when the following criteria are met:

1. *Patient has a diagnosis of onychomycosis of the toenail(s) confirmed by a positive potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy (attach results) without dermatophytomas or lunula (matrix) involvement; and*
2. *Patient is 18 years of age or older; and*
3. *Patient has documentation of a complete trial and therapy failure or intolerance to oral terbinafine; and*
4. *Patient has documentation of a complete trial and therapy failure or intolerance to ciclopirox 8% topical solution; and*
5. *Patient is diabetic or immunosuppressed/immunocompromised.*

If the criteria for coverage are met, a one-time authorization of 48 weeks will be given. Requests for reoccurrence of infection will not be considered.

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 amended, and Brian Couse seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Alpha-1 Proteinase Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Alpha₁-Proteinase Inhibitor enzymes. Payment for a non-preferred Alpha₁-Proteinase Inhibitor enzyme 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 for patients when the following is met:

1. *Patient has a diagnosis of congenital alpha₁-antitrypsin (AAT) deficiency; with a pretreatment serum concentration of AAT less than 11µM/L or
 - 80mg/dl if measured by radial immunodiffusion, or
 - 50mg/dl if measured by nephelometry; and*
2. *Patient has a high-risk AAT deficiency phenotype (PiZZ, PiZ (null), or PI (null)(null) or other phenotypes associated with serum AAT concentrations of less than 11µM/L, such as PiSZ or PiMZ); and*
3. *Patient has documented progressive panacinar emphysema with a documented rate of decline in forced expiratory volume in 1 second (FEV₁); and*
4. *Patient is 18 years of age or older; and*
5. *Patient is currently a non-smoker; and*
6. *Patient is currently on optimal supportive therapy for obstructive lung disease (inhaled bronchodilators, inhaled steroids); and*
7. *Medication will be administered in the member's home by home health or in a long-term care facility.*

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

1. *Evidence of clinical efficacy, as documented by:
 - a) *An elevation of AAT levels (above protective threshold i.e., > 11µM/L); and*
 - b) *A reduction in rate of deterioration of lung function as measured by a decrease in the FEV₁ rate of decline; and**
2. *Patient continues to be a non-smoker; and*
3. *Patient continues supportive therapy for obstructive lung disease.*

Brett Faine motioned to accept the criteria as amended, and Brian Couse seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

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

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

- 1. Patient is 12 years of age or older; and*
- 2. Has a diagnosis of cystic fibrosis; and*
- 3. Patient is homozygous for the F508del mutation in the CFTR gene as confirmed by a FDA-cleared CF mutation test; and*
- 4. Baseline liver function tests (AST/ALT) and bilirubin levels are provided and*
- 5. Baseline percent predicted forced expiratory volume (ppFEV₁) is provided and is greater than or equal to (\geq) 40; and*
- 6. Prescriber is a CF specialist or pulmonologist; and*
- 7. Patient does not have one of the following infections: Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abscessus.*

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

- 1. Adherence to lumacaftor/ivacaftor therapy is confirmed; and*
- 2. Response to therapy is documented by prescriber (e.g., improved ppFEV₁ from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and*
- 3. Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter.*

Brett Faine motioned to accept the criteria, and Larry Ambrosion seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Biologicals for Ankylosing Spondylitis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for ankylosing spondylitis. Payment for non-preferred biologicals for ankylosing spondylitis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents.

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 biological 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 while patients with active TB will only be considered upon completion of TB treatment.*

Payment will be considered following inadequate responses to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at maximum therapeutic doses, unless there are documented adverse responses or contraindications to NSAID use. These trials should be at least three months in duration. Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include sulfasalazine and methotrexate. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Brett Faine motioned to accept the criteria as modified (for all three Biologicals categories), and Larry Ambrosion seconded. The decision was unanimous. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Biologicals for Inflammatory Bowel Disease: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for inflammatory bowel disease. Payment for non-preferred biologicals for inflammatory bowel disease will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred 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 biological 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 while patients with active TB will only be considered upon completion of TB treatment.*

Payment will be considered under the following conditions:

- *Crohn's Disease – Payment will be considered following an inadequate response to two preferred conventional therapies including*

aminosalicylates (mesalamine, sulfasalazine), azathioprine/6-mercaptopurine, and/or methotrexate.

- *Ulcerative colitis (moderate to severe) – Payment will be considered following an inadequate response to two preferred conventional therapies including aminosalicylates and azathioprine/6-mercaptopurine.*

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

Brett Faine motioned to accept the criteria as modified (for all three Biologicals categories), and Larry Ambrosion seconded. The decision was unanimous. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Biologicals for Plaque Psoriasis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for plaque psoriasis. Payment for non-preferred biologicals for plaque psoriasis will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred 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 biological 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 while patients with active TB will only be considered upon completion of TB treatment.*

Payment will be considered following an inadequate response to phototherapy, systemic retinoids (oral isotretinoin), methotrexate, or cyclosporine. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Brett Faine motioned to accept the criteria as modified (for all three Biologicals categories), and Larry Ambrosion seconded. The decision was unanimous. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Topical Corticosteroids: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for non-preferred topical corticosteroids. Payment will be considered for patients when there is documentation of adequate trials and therapy failures with at least two preferred, chemically distinct, topical

corticosteroid agents within the same potency class or a higher potency class in the past 12 months. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

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

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

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

- 8. Patient is 2 years of age or older; and*
- 9. Has a diagnosis of cystic fibrosis with one of the following mutations in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, and R117H as detected by a FDA-cleared CF mutation test; and*
- 10. Prescriber is a CF specialist or pulmonologist; and*
- 11. Baseline liver function tests (AST/ALT) and FEV1, if age appropriate, are provided; and*
- 12. Patient does not have one of the following infections: Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abscessus.*

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

- 4. Adherence to ivacaftor therapy is confirmed; and*
- 5. Response to therapy is documented by prescriber (e.g., improved FEV1 from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and*
- 6. Liver function tests (AST/ALT) are assessed every 3 months during the first year of treatment and annually thereafter.*

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

Idiopathic Pulmonary Fibrosis: The Commission reviewed the prior authorization criteria as follows:

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

- 1. Patient is 40 years of age or older; and*
- 2. Is prescribed by a pulmonologist; and*
- 3. Patient has a diagnosis of idiopathic pulmonary fibrosis as confirmed by one of the following (attach documentation):*

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

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

- a) Adherence to pirfenidone (Esbriet[®]) and nintedanib (Ofev[®]) is confirmed; and
- b) Patient is tolerating treatment defined as improvement or maintenance of disease ($< 10\%$ decline in percent predicted FVC or $< 200\text{ mL}$ decrease in FVC); and
- c) Documentation is provided that the patient has remained tobacco-free; and
- d) Patient is tolerating treatment; and
- e) ALT, AST, and bilirubin are assessed periodically during therapy.

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

Edoxaban (Savaysa): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for edoxaban (Savaysa[®]). Payment will be considered for patients when the following criteria are met:

1. Patient does not have a mechanical heart valve; and

2. *Patient does not have moderate to severe mitral stenosis; and*
3. *Patient does not have active pathological bleeding; and*
4. *A recent creatinine clearance (CrCl) is provided and is within specified range listed below; and*
5. *Patient does not have moderate or severe hepatic impairment (Child-Pugh B or C).*
6. *Patient has documentation of a previous trial and therapy failure with warfarin (TIA, stroke, or inability to maintain a therapeutic INR with a minimum 6 month trial); and*
7. *Patient has documentation of a previous trial and therapy failure with apixaban or rivaroxaban, where applicable.*

Atrial Fibrillation

1. *Patient has documentation of a diagnosis of non-valvular atrial fibrillation; with*
2. *Presence of at least one additional risk factor for stroke, with a CHADS₂ score ≥ 1 ; and*
3. *Patient does not have a creatinine clearance (CrCl) > 95 mL/min.*
4. *Requests will be considered for the following dosing:*
 - a) *60mg once daily in patients with a CrCl of > 50 mL/min to ≤ 95 mL/min; or*
 - b) *30mg once daily in patients with a CrCl of 15 to 50 mL/min*

Treatment of Deep Vein Thrombosis or Pulmonary Embolism

1. *Patient has documentation of a current deep vein thrombosis or pulmonary embolism; with*
2. *Documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin).*
3. *Requests will be considered for the following dosing:*
 - a. *60mg once daily; or*
 - b. *30mg once daily in patients with any of the following:*
 - i. *CrCl 15 mL/min to 50 mL/min*
 - ii. *Body weight ≤ 60 kg*

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

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration. The P&T Committee will also be reviewing the NOACs at their November meeting, and there may be additional recommended changes after their review.

Select Oncology Agents: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for select oncology agents. Patient must have a diagnosis that is indicated in the FDA approved package insert or the use is for an indication supported by the compendia (including National Comprehensive Cancer Network (NCCN) compendium level of evidence 1, 2A, or 2B). The following must be submitted with the prior authorization request: copies of medical records (i.e. diagnostic evaluations and recent chart notes), location of treatment (provider office, facility, home health, etc.) if medication requested is not an oral agent, the original prescription, and the most recent copies of related laboratory results. If criteria for coverage are met, initial authorization will be given for three (3) months. Additional authorizations will be considered for up to six (6) month intervals when criteria for coverage are met. Updates on disease progression must be provided with each renewal request. If disease progression is noted, therapy will not be continued unless otherwise justified.

After a lengthy discussion, Kellen Ludvigson motioned to accept the criteria as amended, and Daniel Gillette seconded. The decision was unanimous. Due to changes in the recommended criteria, the PA criteria will be sent to the medical/pharmacy associations for their comment and brought back to the next DUR meeting.

Miscellaneous

DUR Digest: The Commission members reviewed the draft for DUR Digest Volume 27, Number 3. Dr. Gillette will review his introductory paragraph and let Pam Smith know of any requested changes.

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

A unanimous roll call vote was made at 12:26 to adjourn the meeting and move to closed session (motion by Kellen Ludvigson, second by Daniel Gillette).

The next meeting will be held at 9:30 a.m. on Wednesday, October 7, 2015, at the Learning Resource Center in West Des Moines.

Iowa Medicaid Drug Utilization Review Commission **Meeting Minutes October 7, 2015**

Attendees:

Commission Members

Mark Graber, M.D., FACEP; Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Kellen Ludvigson, Pharm.D.; Jason Wilbur, M.D.; Brian Couse, M.D.; Daniel Gillette, M.D.; and Susan Parker, Pharm.D.
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Staff

Pam Smith, R.Ph.

Guests

Jason Kessler, M.D., IME; Erin Halverson, R.Ph., IME; Gina Tiernan, Pharm.D., IME; and Melissa Biddle, IME.

Welcome & Introductions

Mark Graber called the meeting to order at 9:35 a.m. at the Learning Resource Center in West Des Moines. The minutes from the August 5, 2015 meeting were reviewed. Brian Couse motioned to accept them, and Kellen Ludvigson seconded. All members were in favor. The recommendation letter sent to DHS after the last meeting was also reviewed, along with the letter from the P&T Committee requesting that the DUR Commission develop prior authorization criteria for Cholbam.

IME Updates

On August 17, 2015, four managed care organizations (MCOs) were selected from the 11 bids submitted in response to the Medicaid Modernization managed care Request for Proposal (RFP): Amerigroup Iowa, Inc.; AmeriHealth Caritas Iowa, Inc.; UnitedHealthcare Plan of the River Valley, Inc.; and WellCare of Iowa, Inc. Contracts will be signed soon. An Iowa Health Link Tool Kit is available for providers on the Medicaid Modernization web site. Provider training sessions are also scheduled, with implementation still slated for January 1, 2016. Providers can enroll with any or all of the MCOs and should contact the MCOs about enrollment; Informational Letter 1539 contains their contact information.

Prevalence Report Summary

Statistics from July through August 2015 were discussed, including: cost per user (\$356.41), number of total prescriptions dispensed (an increase of 1.0% compared to the previous reporting period), average cost per prescription (\$69.39), and generic utilization (85.3%). The total paid amount increased by 2.5% from the previous reporting period. There were 193,048 unique users, which is 1.5% less than the total for May and June 2015. Lists of the top 20 therapeutic classes were provided. SSRIs had the highest prescription count, and Anticonvulsants came in second. The Hepatitis C category is quickly rising on the top therapeutic classes by paid amount report, currently in fifth place with \$2,818,490 in expenditures, an increase of 9.8% from the

previous reporting period. The top 100 drugs were also reviewed. The ten most expensive medications were: Abilify, Vyvanse, methylphenidate hcl er, Harvoni, Lantus, Humalog, Focalin XR, Advate, Strattera, and Spiriva Handihaler.

Case Studies

Pam Smith presented 4 case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of \$1,107.65 pre-rebate (state and federal).

Public Comment

Name	Representing	Drug/Topic
Matt Lewis	Amgen	PCSK9 Inhibitors, Repatha
Rick Melbye	Sanofi	Praluent
Tyrone McBayne	Baxalta	Glassia and Aralast
Shelley Baugh	Celgene	Otezla

Pam Smith also clarified the Oncology Agents prior authorization criteria, as there had been multiple written public comments received regarding the criteria implementation. The criteria will only apply to outpatient services, including home health, and does not include steps through other preferred agents. It is merely clinical criteria, based on the medication labels, and all medications subject to PA use the same PA form. The IME Pharmacy department is required to process all requests within 24 hours once received.

Focus Studies

Short-Acting Opioid Overutilization (Four or More Doses per Day): This was a follow-up discussion. Three-hundred sixty-seven (367) of the 1,990 members identified changed therapy, for an annualized cost savings of \$93,607.04 (state and federal, pre-rebate) as a result of the 6,352 surveys sent out to prescribers and pharmacies. A total of 2,343 (36.89%) surveys were returned.

Duplicate Inhaled Corticosteroids: Letters will be sent to the providers of the members identified as using concurrent inhaled corticosteroids pointing out the use of more than one inhaled corticosteroid is not supported in guidelines and can increase the risk of adverse drug events and asking if one could be discontinued.

Duplicate Long-Acting Beta-2 Agonists: Letters will be sent to the providers of the members identified as using concurrent LABAs pointing out the use of more than one LABA is not supported in guidelines and can increase the risk of adverse drug events and asking if one could be discontinued. Only twelve members were identified as having 60 days or more of therapy with two or more LABAs.

Public Comment

Name	Representing	Drug/Topic
Peter Zoob	Vertex	Orkambi

Prior Authorization

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

PA Category	Recommended Changes
Anti-Acne	Will be updated once acne guidelines are updated.
Antiemetic-5HT3 Receptor Agonists/Substance P Neurokinin Agents	Increase the quantity limit on ondansetron.
Apixaban (Eliquis)	Update to CHA ₂ DS ₂ – Vasc score
Biologic Immunomodulators	Will be updated once guidelines are updated.
Daibigatran (Pradaxa)	Update to CHA ₂ DS ₂ – Vasc score
Erythropoiesis Stimulating Agents	CHF thresholds
Ketorolac	Verify not taking oral agents. Total combined duration should not exceed 5 days.
Non-Parenteral Vasopressin Derivatives of Posterior Pituitary Hormone Products	Remove prior authorization requirement and add a quantity limit of 90 per 30 days.
Pulmonary Arterial Hypertension Agents	Review to establish more specific criteria.
Rivaroxaban (Xarelto)	Update to CHA ₂ DS ₂ – Vasc score
Repository Corticotropin Injection (Acthar HP)	Sabril has also been approved for infantile spasms and is more cost effective, possibly require trial.
Thrombopoietin Receptor Agents	Review, possibly change ribavirin therapy requirement.
Topical Retinoids	Will be updated once acne guidelines are updated.
Roflumilast (Daliresp)	Require both a beta-agonist and anticholinergic prior to oral.
Zontivity	Possibly require trials of other anti-platelet agents first.

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

Prior authorization is required for therapy with growth hormones. Payment for non-preferred growth hormones will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. All of the following criteria must be met for approval for prescribing of growth hormones:

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

6. *Epiphyses open.*

Prior authorization will be granted for 12-month periods per patient as needed.

The following FDA approved indications for Growth Hormone therapy are considered not medically necessary and requests will be denied: Idiopathic Short Stature (ISS) and Small for Gestational Age (SGA).

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

The Commission members voted, by a show of hands, 4 to 3 in favor of excluding coverage for treatment of SGA as is not medically necessary or is considered cosmetic. Brian Couse then motioned to accept the criteria as amended, and Daniel Gillette and Jason Wilbur both seconded. Mark Graber was opposed, but the motion passed. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

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

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. *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 lipid profile is provided; AND*
5. *Documented abstinence from tobacco for the previous 90 days is provided; AND*
6. *Is prescribed by a lipidologist or cardiologist.*
7. *The 72-hour emergency supply rule does not apply to PCSK9 Inhibitors.*
8. *Prescriber and dispensing pharmacy has educated 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. *Is prescribed for one of the following diagnoses:*

Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH)

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 maximally tolerated dose of two or more statins (at least one of which must be either atorvastatin or rosuvastatin), PLUS ezetimibe (Zetia) 10mg daily PLUS at least one other concurrently administered lipid lowering agent.

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 maximally tolerated dose of two or more statins (at least one of which must be either atorvastatin or rosuvastatin) PLUS ezetimibe (Zetia) 10mg daily.

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 maximally tolerated dose of atorvastatin or rosuvastatin (or other preferred high-dose statin if patient cannot take atorvastatin or rosuvastatin) PLUS ezetimibe (Zetia) 10mg daily PLUS at least one other concurrently administered lipid lowering agent.

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

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.*

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*

Pam Smith will revise the criteria, incorporating suggested changes, and bring it back to the next meeting for further review. The baseline and current numbers need to be clarified, with current regimen provided, and goal defined, with member counseled about weight loss and smoking cessation.

Cholic Acid (Cholbam): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for cholic acid (Cholbam). Payment will be considered under the following conditions:

1. *Is prescribed by a hepatologist or pediatric gastroenterologist; and*
2. *Is prescribed for a diagnosis of bile acid synthesis disorder due to a single enzyme defect (SED) including:*
 - *3-beta-hydroxy-delta-5C27-steroid oxidoreductase deficiency (3β-HSD),*
 - *aldo-keto reductase 1D1 (AKR1D1),*
 - *alpha-methylacyl-CoA racemase deficiency (AMACR deficiency),*
 - *sterol 27-hydroxylase deficiency (cerebrotendinous xanthomatosis [CTX]),*
 - *cytochrome P450 7A1 (CYP7A1),*
 - *25-hydroxylation pathway (Smith-Lemli-Opitz); OR*
3. *Is prescribed as an adjunctive treatment of a peroxisomal disorder (PD) in patients who exhibit manifestations of liver disease, steatorrhea, or complications from fat soluble vitamin absorption. Peroxisomal disorders include Zellweger syndrome (ZWS), neonatal adrenoleukodystrophy (NALD), or infantile refsum disease (IRD); and*

4. *Diagnosis is confirmed by mass spectrometry or other biochemical testing or genetic testing (attach results); and*
5. *Baseline liver function tests are taken prior to initiation of therapy (AST, ALT, GGT, ALP, total bilirubin, INR) and provided with request; and*
6. *Patient must have elevated serum aminotransferases (AST and ALT) with normal serum gamma glutamyltransferase (GTT); and*
7. *Patient is at least 3 weeks old.*

When criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 12 months at a time requiring documentation of response to therapy by meeting two the following criteria:

- *Body weight has increased by 10% or is stable at $\geq 50^{\text{th}}$ percentile,*
- *Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) < 50 U/L or baseline levels reduced by 80%,*
- *Total bilirubin level reduced to $\leq 1\text{mg/dL}$.*

Kellen Ludvigson motioned to accept the criteria, and Jason Wilbur and Larry Ambrosion seconded simultaneously. The decision was unanimous. Dr. Graber suggested also checking to see if the member is on an enzyme inducer, and Pam Smith said that could be checked internally by IME staff. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

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

Prior authorization (PA) is required for Vyvanse for the treatment of Binge Eating Disorder (BED). Prior to requesting PA, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program (PMP) website at <https://pmp.iowa.gov/IAPMPWebCenter/>. Payment will be considered under the following conditions:

1. *Patient is 18 to 55 years of age; and*
2. *Patient meets the DSM-5 criteria for BED; and*
3. *Patient has documentation of moderate to severe BED, as defined by the number of binge eating episodes per week (number must be reported); and*
4. *Patient has documentation of non-pharmacologic therapies tried, such as cognitive-behavioral therapy or interpersonal therapy, for a recent 3 month period, that did not significantly reduce the number of binge eating episodes; and*
5. *Prescription is written by a psychiatrist or psychiatric nurse practitioner;*
6. *Patient has a BMI of 25 to 45; and*
7. *Patient does not have a personal history of cardiovascular disease; and*
8. *Patient has no history of substance abuse; and*
9. *Is not being prescribed for the treatment of obesity or weight loss; and*
10. *Doses above 70mg per day will not be considered.*

Initial requests will be approved for 12 weeks when criteria for coverage are met. Requests for renewal must include documentation of a change from baseline at week 12 in the number of binge days per week.

Jason Wilbur motioned to accept the criteria, and Kellen Ludvigson seconded. The decision was unanimous. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Topical Antifungals for Onychomycosis: The Commission reviewed the prior authorization criteria as follows:

Jublia[®] (efinaconazole) and Kerydin[®] (tavaborole) will be considered when the following criteria are met:

- 1. Patient has a diagnosis of onychomycosis of the toenail(s) confirmed by a positive potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy (attach results) without dermatophytomas or lunula (matrix) involvement; and*
- 2. Patient is 18 years of age or older; and*
- 3. Patient has documentation of a complete trial and therapy failure or intolerance to oral terbinafine; and*
- 4. Patient has documentation of a complete trial and therapy failure or intolerance to ciclopirox 8% topical solution; and*
- 5. Patient is diabetic or immunosuppressed/immunocompromised.*

If the criteria for coverage are met, a one-time authorization of 48 weeks will be given. Requests for reoccurrence of infection will not be considered.

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

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

Alpha-1 Proteinase Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Alpha₁-Proteinase Inhibitor enzymes. Payment for a non-preferred Alpha₁-Proteinase Inhibitor enzyme 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 for patients when the following is met:

- 1. Patient has a diagnosis of congenital alpha₁-antitrypsin (AAT) deficiency; with a pretreatment serum concentration of AAT less than 11µM/L or
 - 80mg/dl if measured by radial immunodiffusion, or*
 - 50mg/dl if measured by nephelometry; and**
- 2. Patient has a high-risk AAT deficiency phenotype (PiZZ, PiZ (null), or PI (null)(null) or other phenotypes associated with serum AAT concentrations of less than 11µM/L, such as PiSZ or PiMZ); and*
- 3. Patient has documented progressive panacinar emphysema with a documented rate of decline in forced expiratory volume in 1 second (FEV₁); and*

4. Patient is 18 years of age or older; and
5. Patient is currently a non-smoker; and
6. Patient is currently on optimal supportive therapy for obstructive lung disease (inhaled bronchodilators, inhaled steroids); and
7. Medication will be administered in the member's home by home health or in a long-term care facility.

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

1. Evidence of clinical efficacy, as documented by:
 - a) An elevation of AAT levels (above protective threshold i.e., $> 11\mu\text{M/L}$); and
 - b) A reduction in rate of deterioration of lung function as measured by a decrease in the FEV₁ rate of decline; and
2. Patient continues to be a non-smoker; and
3. Patient continues supportive therapy for obstructive lung disease.

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

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

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

1. Patient is 12 years of age or older; and
2. Has a diagnosis of cystic fibrosis; and
3. Patient is homozygous for the F508del mutation in the CFTR gene as confirmed by a FDA-cleared CF mutation test; and
4. Baseline liver function tests (AST/ALT) and bilirubin levels are provided and
5. Baseline percent predicted forced expiratory volume (ppFEV₁) is provided and is greater than or equal to (\geq) 40; and
6. Prescriber is a CF specialist or pulmonologist; and
7. Patient does not have one of the following infections: *Burkholderia cenocepacia*, *Burkholderia dolosa*, or *Mycobacterium abscessus*.

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

1. Adherence to lumacaftor/ivacaftor therapy is confirmed; and
2. Response to therapy is documented by prescriber (e.g., improved ppFEV₁ from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and
3. Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter.

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

Biologicals for Ankylosing Spondylitis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for ankylosing spondylitis. Payment for non-preferred biologicals for ankylosing spondylitis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents.

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 biological 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 while patients with active TB will only be considered upon completion of TB treatment.*

Payment will be considered following inadequate responses to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at maximum therapeutic doses, unless there are documented adverse responses or contraindications to NSAID use. These trials should be at least three months in duration. Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include sulfasalazine and methotrexate. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

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

Biologicals for Inflammatory Bowel Disease: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for inflammatory bowel disease. Payment for non-preferred biologicals for inflammatory bowel disease will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred 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 biological 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 while patients with active TB will only be considered upon completion of TB treatment.*

Payment will be considered under the following conditions:

- *Crohn's Disease – Payment will be considered following an inadequate response to two preferred conventional therapies including aminosalicylates (mesalamine, sulfasalazine), azathioprine/6-mercaptopurine, and/or methotrexate.*
- *Ulcerative colitis (moderate to severe) – Payment will be considered following an inadequate response to two preferred conventional therapies including aminosalicylates and azathioprine/6-mercaptopurine.*

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

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

Biologicals for Plaque Psoriasis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for plaque psoriasis. Payment for non-preferred biologicals for plaque psoriasis will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred 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 biological 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 while patients with active TB will only be considered upon completion of TB treatment.*

Payment will be considered following an inadequate response to phototherapy, systemic retinoids (oral isotretinoin), methotrexate, or cyclosporine. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

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

Select Oncology Agents: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for select oncology agents. Patient must have a diagnosis that is indicated in the FDA approved package insert or the use is for an indication supported by the compendia (including National Comprehensive Cancer Network (NCCN) compendium level of evidence 1, 2A, or 2B). The following must be submitted with the prior authorization request: copies of medical records (i.e. diagnostic evaluations and recent chart notes), location of treatment (provider office, facility, home health, etc.) if medication requested is not an oral agent, the original prescription, and the most recent copies of related laboratory results. If criteria for coverage are met, initial authorization will be given for three (3) months. Additional authorizations will be considered for up to six (6) month intervals when criteria for coverage are met. Updates on disease progression must be provided with each renewal request. If disease progression is noted, therapy will not be continued unless otherwise justified.

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 reviewed the draft for DUR Digest Volume 28, Number 1. No changes were recommended and the DUR Digest will be posted to the DUR website.

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

A unanimous roll call vote was made at 11:48 to adjourn the meeting and move to closed session (motion by Daniel Gillette, second by Brian Couse).

The next meeting will be held at 9:30 a.m. on Wednesday, December 2, 2015, at the Learning Resource Center in West Des Moines.

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes December 2, 2015

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Kellen Ludvigson, Pharm.D.; Jason Wilbur, M.D.; Brian Couse, M.D.; Daniel Gillette, M.D.; Brett Faine, Pharm.D.; and Susan Parker, Pharm.D.

Staff
Pam Smith, R.Ph.

Guests
Chuck Wadle, D.O., Magellan; Jason Kessler, M.D., IME; Erin Halverson, R.Ph., IME; and Melissa Biddle, IME.

Welcome & Introductions

Mark Graber called the meeting to order at 9:34 a.m. at the Learning Resource Center in West Des Moines. The minutes from the October 7, 2015 meeting were reviewed. Jason Wilbur motioned to accept them, and Kellen Ludvigson seconded. All members were in favor. The recommendation letter sent to DHS after the last meeting was also reviewed.

IME Updates

The IME is progressing toward Medicaid Modernization managed care, set to take effect on January 1, 2016. An Iowa Health Link Tool Kit is available for providers on the Medicaid Modernization web site. Provider training sessions are also scheduled. Providers can enroll with any or all of the MCOs and should contact the MCOs about enrollment; Informational Letter 1539 contains their contact information. Member MCO assignment has begun; they have received letters advising them how to choose their MCO if they don't wish to be assigned one. They will have 90 days after January 1st to change their MCO for any reason. Chuck Wadle was presented with a certificate of appreciation and letter thanking him for his service to the Commission, as this was his last meeting in his current advisory capacity for Magellan.

Prevalence Report Summary

Statistics from September through October 2015 were discussed, including: cost per user (\$338.02), number of total prescriptions dispensed (an increase of 6.6% compared to the previous reporting period), average cost per prescription (\$67.53), and generic utilization (85.5%). The total paid amount increased by 3.7% from the previous reporting period. There were 209,464 unique users, which is 9.1% more than the total for July and August. Lists of the top 20 therapeutic classes were provided. SSRIs had the highest prescription count, and Anticonvulsants came in second. The top 100 drugs were also reviewed. The ten most expensive medications were: Vyvanse, Abilify,

methylphenidate hcl er, Lantus, Focalin XR, Humalog, Advate, Harvoni, Strattera, and Advair Diskus.

Case Studies

Pam Smith presented 4 case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of \$11,483.94 pre-rebate (state and federal).

Public Comment

Name	Representing	Drug/Topic
Nikki Moon	Abbvie	Humira
Biran Patel	Novo Nordisk	Norditropin
Kori Hack	Novartis	Entresto
Nancy Bell	Pfizer	Methadone
Matt Lewis	Amgen	Repatha

Focus Studies

Duplicate Benzodiazepines: This was a follow-up discussion. A total of 189 of the 291 members identified changed therapy, for an annualized cost savings of \$28,615.80 (state and federal, pre-rebate) as a result of the 673 surveys sent out to prescribers and pharmacies. A total of 242 (35.96%) of those surveys were returned.

Niacin plus Statin: This was a follow-up discussion. A total of 39 of the 73 members identified changed therapy, for an annualized cost savings of \$74,522.52 (state and federal, pre-rebate) as a result of the 164 surveys sent out to prescribers and pharmacies. A total of 57 (34.76%) of those surveys were returned.

Duplicate Antipsychotics in Children: This was a follow-up discussion. A total of 132 of the 220 members identified changed therapy, for an annualized cost savings of \$73,883.80 (state and federal, pre-rebate) as a result of the 621 surveys sent out to prescribers and pharmacies. A total of 266 (42.83%) of those surveys were returned.

Duplicate Antipsychotics in Adults: This was a follow-up discussion. A total of 386 of the 666 members identified changed therapy, for an annualized cost savings of \$6,043,534.51 (state and federal, pre-rebate) as a result of the 1,935 surveys sent out to prescribers and pharmacies. A total of 744 (38.45%) of those surveys were returned.

Methadone Utilization: A group of US senators sent a letter to CMS asking that state Medicaid programs look into this. The Commission wants to look into members using methadone in combination with other narcotics (including tramadol), and contact the methadone clinics if concurrent claims are found. Methadone will remain preferred for now, but PA criteria for Long-Acting Narcotics will be reviewed at the next meeting, along with the possibility of a limit of 40mg per day should the medication remain preferred. A report of dispensed quantities (excluding United Community Services' opioid dependence usage) will also be evaluated at the next meeting. Methadone

dosing will be featured in an upcoming DUR Digest article.

Focus Studies

ProDUR Edits: Tramadol Utilization in Members under 18 Years of Age: Diagnoses and number of prescribers will be investigated, with results brought back to the next meeting.

Public Comment

There were no additional comments.

Prior Authorization

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

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:*

Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH)

- 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 \leq 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.

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 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 or rosuvastatin), PLUS ezetimibe (Zetia) 10mg daily, PLUS cholestyramine daily.*

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 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 or 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*

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

Brian Couse motioned to accept the criteria as amended, and Larry Ambrosion seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

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

Prior authorization 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 18 years of age or older; and
2. Patient has a diagnosis of NYHA Functional Class II, III, or IV heart failure; and
3. Patient has a left ventricular ejection fraction (LVEF) $\leq 40\%$; and
4. Patient has documentation of a previous trial and therapy failure or intolerance to an ACE inhibitor at a maximally tolerated dose; and
5. Patient has documentation of a previous trial and therapy failure or intolerance to an angiotensin II receptor blocker (ARB); and
6. 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); and
7. Will not be used in combination with an ACE inhibitor or ARB; and

8. *Will not be used in combination with aliskiren (Tekturna) in diabetic patients; and*
9. *Patient does not have a history of angioedema associated with the use of ACE inhibitor or ARB therapy; and*
10. *Patient is not pregnant; and*
11. *Patient does not have severe hepatic impairment (Child Pugh Class C); and*
12. *Prescriber is a cardiologist or has consulted with a cardiologist (telephone consultation is acceptable).*

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

If the criteria for coverage are met, initial authorization will be given for 3 months. Requests for continuation of therapy may be provided if prescriber documents adequate response to therapy.

Jason Wilbur motioned to accept the criteria above, and Daniel Gillette seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Adalimumab (Humira): The Commission reviewed the prior authorization criteria as follows:

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

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

Payment will be considered under the following conditions:

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

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

Mark Graber suggested that trials on Augmentin and/or an oral cephalosporin be required for stage 2 disease as per the Johns Hopkins Antibiotic Guide. Initial requests will be approved for 3 months, with additional authorization granted upon documentation of response to therapy. Clinical response needs to be defined and addressed in the criteria. Pam Smith will revise and bring this back to the next meeting.

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

Prior authorization is required for sodium oxybate (Xyrem®). Payment will be considered for patients 18 years of age or older under the following conditions:

- 1. A diagnosis of cataplexy associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trial and therapy failure with one of the following tricyclic antidepressants: clomipramine, imipramine, or protriptyline; or*
- 2. A diagnosis of excessive daytime sleepiness associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trials and therapy failures at a therapeutic dose with a preferred amphetamine and non-amphetamine stimulant.*
- 3. Patient is enrolled in the Xyrem® REMS Program.*
- 4. Patient has been instructed to not drink alcohol when using Xyrem®.*
- 5. Patients with and without a history of substance abuse have been counseled regarding the potential for abuse and dependence and will be closely monitored for signs of abuse and dependence.*
- 6. Requests for patients with concurrent use of a sedative hypnotic or a semialdehyde dehydrogenase deficiency will not be considered.*
- 7. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/> prior to requesting prior authorization.*

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

Larry Ambrosion motioned to accept the criteria above, and Brett Faine seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Antiemetic-5HT3 Receptor Agonists/Substance P Neurokinin Agents: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for preferred Antiemetic-5HT3 Receptor Antagonists/Substance P Neurokinin medications for quantities exceeding the following

dosage limits per month. Payment for Antiemetic-5HT3 Receptor Antagonists/Substance P Neurokinin Agents beyond this limit will be considered on an individual basis after review of submitted documentation.

Prior authorization will be required for all non-preferred Antiemetic-5HT3 Receptor Antagonists/Substance P Neurokinin medications beginning the first day of therapy. Payment for non-preferred medications will be authorized only for cases in which there is documentation of previous trial(s) and therapy failure with a preferred agent in this class. Note: Aprepitant (Emend) will only be payable when used in combination with other antiemetic agents (5-HT3 medication and dexamethasone) for patients receiving highly emetogenic cancer chemotherapy.

Kellen Ludvigson motioned to implement a quantity limit of 60 per 30 days on oral ondansetron tablets only, and Brian Couse seconded. All members were in favor. No changes were made to the existing PA criteria.

Non-Parenteral Vasopressin Derivatives of Posterior Pituitary Hormone Products:

The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for non-parenteral vasopressin derivatives of posterior pituitary hormone products. Payment for preferred non-parenteral vasopressin derivatives of posterior pituitary hormone products will be authorized for the following diagnoses:

- 1. Diabetes Insipidus*
- 2. Hemophilia A*
- 3. Von Willebrand's disease*

Requests for desmopressin nasal spray for the treatment of nocturnal enuresis will not be considered. Payment for non-preferred non-parenteral vasopressin derivatives will be authorized only for cases in which there is documentation of trial(s) and therapy failure with the preferred agent(s). Please refer to the Selected Brand-Name Drugs prior authorization form if requesting a non-preferred brand-name product.

Daniel Gillette motioned to accept the criteria above, and Brian Couse and Larry Ambroson both seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

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

Prior authorization is required for therapy with growth hormones. Payment for non-preferred growth hormones will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. All of the following criteria must be met for approval for prescribing of growth hormones:

- 1. Standard deviation of 2.0 or more below mean height for chronological age.*
- 2. No intracranial lesion or tumor diagnosed by MRI.*
- 3. Growth rate below five centimeters per year.*

4. Failure of any two stimuli tests to raise the serum growth hormone level above ten nanograms per milliliter. Stimuli testing will not be required for the following diagnoses: Turners Syndrome, chronic renal failure, and HIV/AIDS.
5. Annual bone age testing is required for the diagnosis of Growth Hormone Deficiency. A bone age 14 to 15 years or less in females and 15 to 16 years or less in males is required.
6. Epiphyses open.

Prior authorization will be granted for 12-month periods per patient as needed.

The following FDA approved indications for Growth Hormone therapy are considered not medically necessary and requests will be denied: Idiopathic Short Stature (ISS) and Small for Gestational Age (SGA).

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

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

Cholic Acid (Cholbam): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for cholic acid (Cholbam). Payment will be considered under the following conditions:

1. *Is prescribed by a hepatologist or pediatric gastroenterologist; and*
2. *Is prescribed for a diagnosis of bile acid synthesis disorder due to a single enzyme defect (SED) including:*
 - *3-beta-hydroxy-delta-5C27-steroid oxidoreductase deficiency (3 β -HSD),*
 - *aldo-keto reductase 1D1 (AKR1D1),*
 - *alpha-methylacyl-CoA racemase deficiency (AMACR deficiency),*
 - *sterol 27-hydroxylase deficiency (cerebrotendinous xanthomatosis [CTX]),*
 - *cytochrome P450 7A1 (CYP7A1),*
 - *25-hydroxylation pathway (Smith-Lemli-Opitz); OR*
3. *Is prescribed as an adjunctive treatment of a peroxisomal disorder (PD) in patients who exhibit manifestations of liver disease, steatorrhea, or complications from fat soluble vitamin absorption. Peroxisomal disorders include Zellweger syndrome (ZWS), neonatal adrenoleukodystrophy (NALD), or infantile refsum disease (IRD); and*
4. *Diagnosis is confirmed by mass spectrometry or other biochemical testing or genetic testing (attach results); and*

5. Baseline liver function tests are taken prior to initiation of therapy (AST, ALT, GGT, ALP, total bilirubin, INR) and provided with request; and
6. Patient must have elevated serum aminotransferases (AST and ALT) with normal serum gamma glutamyltransferase (GTT); and
7. Patient is at least 3 weeks old.

When criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 12 months at a time requiring documentation of response to therapy by meeting two the following criteria:

- *Body weight has increased by 10% or is stable at $\geq 50^{\text{th}}$ percentile,*
- *Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) < 50 U/L or baseline levels reduced by 80%,*
- *Total bilirubin level reduced to $\leq 1\text{mg/dL}$.*

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

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

Prior authorization (PA) is required for Vyvanse for the treatment of Binge Eating Disorder (BED). Prior to requesting PA, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program (PMP) website at <https://pmp.iowa.gov/IAPMPWebCenter/>. Payment will be considered under the following conditions:

1. *Patient is 18 to 55 years of age; and*
2. *Patient meets the DSM-5 criteria for BED; and*
3. *Patient has documentation of moderate to severe BED, as defined by the number of binge eating episodes per week (number must be reported); and*
4. *Patient has documentation of non-pharmacologic therapies tried, such as cognitive-behavioral therapy or interpersonal therapy, for a recent 3 month period, that did not significantly reduce the number of binge eating episodes; and*
5. *Prescription is written by a psychiatrist or psychiatric nurse practitioner;*
6. *Patient has a BMI of 25 to 45; and*
7. *Patient does not have a personal history of cardiovascular disease; and*
8. *Patient has no history of substance abuse; and*
9. *Is not being prescribed for the treatment of obesity or weight loss; and*
10. *Doses above 70mg per day will not be considered.*

Initial requests will be approved for 12 weeks when criteria for coverage are met. Requests for renewal must include documentation of a change from baseline at week 12 in the number of binge days per week.

Prior to the formal recommendation of clinical prior authorization criteria going to the Department of Human Services, the DUR Commission is interested in the opinions of the members of your organization. Any comments regarding the proposed prior authorization criteria may be forwarded to me and will be shared with the DUR Commission members. My

contact information is listed below. Please have comments/feedback submitted to me on or before October 30, 2015.

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 reviewed the draft for DUR Digest Volume 28, Number 2. No changes/updates were recommended. It will be brought back to the next DUR meeting for a second review.

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

A unanimous roll call vote was made at 11:31 to adjourn the meeting and move to closed session (motion by Larry Ambrosion, second by Jason Wilbur).

The next meeting will be held at 9:30 a.m. on Wednesday, February 3, 2016, at the Learning Resource Center in West Des Moines.

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes April 6, 2016

Attendees:

Commission Members

Mark Graber, M.D., FACEP; Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Brian Couse, M.D.; Daniel Gillette, M.D.; Brett Faine, Pharm.D.; and Susan Parker, Pharm.D.

Staff

Pam Smith, R.Ph.

Guests

C. David Smith, M.D., IME; Erin Halverson, R.Ph., IME; Gina Tiernan, R.Ph., IME; Melissa Biddle, IME; Sandy Pranger, R.Ph., Amerigroup; and Jennifer Schonhorst, Pharm.D., AmeriHealth Caritas.

Welcome & Introductions

Mark Graber called the meeting to order at 9:40 a.m. at the Iowa Medicaid Enterprise in Des Moines. The minutes from the December 2, 2015 meeting were reviewed. Daniel Gillette motioned to accept them, and Brian Couse seconded. All members were in favor. The recommendation letter sent to DHS after the last meeting, and the Public Comment Policy were also reviewed. The members decided to eliminate the second public comment period, but leave the existing five minute time limit per speaker/manufacturer (motion by Daniel Gillette and Brett Faine, second by Brian Couse). Additionally, these items relevant to Medicaid were discussed: 1) CMS Medicaid Drug Rebate Program Notice, Release Number 172 (regarding coverage of Hepatitis C agents); 2) A letter from the United States Senate on high-priced drugs; and 3) The CDC guideline for prescribing opioids for chronic pain. Erin Halverson will request numbers to see how many Hepatitis C patients with fibrosis stage 2 would qualify for treatment, and bring results back to a future meeting.

IME Pharmacy Update

Medicaid Modernization Managed Care took effect on April 1, 2016; numerous informational letters have gone out regarding the change. Informational letters with MC after the number signify they apply to managed care, and those without the MC apply to fee-for-service. An Iowa Health Link Tool Kit is available for providers on the Medicaid Modernization web site. The legislative session is still ongoing, but there hasn't been much legislation thus far that specifically speaks to the pharmacy program, other than the managed care initiative. Various bills involving overdose treatments are in process. Senate File 2218, which deals with possession and administration of emergency rescue drugs by first responders, is expected to be signed by the Governor. CMS has finally released their outpatient covered drug rule for Medicaid, which finalizes the reimbursement provisions for Actual Acquisition Cost (AAC), professional dispensing fee, 340B entities, Indian Health Services, and a variety of other topics, with many of the changes expected to be incorporated into the State Plan by April of 2017. Informational

letters will be going out in with regards to these changes as they are implemented. The new CMS survey related to the annual report focuses heavily on methadone (specifically limiting usage to morphine sulfate equivalents), opioids, antipsychotics in children, and opioids used in combination with benzodiazepines. The American Academy of Dermatology has released new guidelines, so the Anti-Acne Prior Authorization criteria can now be reviewed and revised, most likely at the June meeting.

Prevalence Report Summary

Statistics from January through February 2016 were discussed, including: cost per user (\$340.88), number of total prescriptions dispensed (an increase of 3.5% compared to the previous reporting period), average cost per prescription (\$69.98), and generic utilization (86.5%). The total paid amount increased by 5.2% from the previous reporting period. There were 216,585 unique users, which is 5.6% more than the total for November and December. Lists of the top 20 therapeutic classes were provided. SSRIs had the highest prescription count, and Anticonvulsants came in second. The top 100 drugs were also reviewed. The ten most expensive medications were: Vyvanse, Abilify, methylphenidate hcl er, Lantus, Focalin XR, Harvoni, Humalog, Advate, Strattera, and Synagis.

Case Studies

Pam Smith presented 4 case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of \$529.02 pre-rebate (state and federal). Results from 4 previous case studies, with a total savings of \$625.76 (state and federal), were also provided as the February meeting was cancelled.

Public Comment

Name	Representing	Drug/Topic
Rick Fiscella	Allergen	IBS Treatments (Viberzi)
Mai Duong	Novartis	Entresto
Jarod Downing	Purdue Pharma	Butrans
Christina Soltwedel	Amgen	Repatha
Ryan Flugge	Novo Nordisk	Victoza
Biran Patel	Novo Nordisk	SGA Eliminated from Coverage (Norditropin)
Nikki Moon	Abbvie	Humira
Donald Hillebrand	Center for Liver Disease at UnityPoint	Hepatitis C Therapy
Mike Ketcher	Merck	Zepatier
Maurice Landers	Salix	Xifaxan

Focus Studies

Duplicate Benzodiazepines: This was a follow-up discussion. A total of 428 of the 574 members identified changed therapy, for an annualized cost savings of \$288,762.84 (state and federal, pre-rebate) as a result of the 2,318 surveys sent out to prescribers and pharmacies. A total of 959 (41.37%) surveys were returned.

High Dose Amphetamine IR: This was a follow-up discussion. A total of 25 of the 67 members identified changed therapy, for an annualized cost savings of \$88,524.48 (state and federal, pre-rebate) as a result of the 135 surveys sent out to prescribers and pharmacies. A total of 53 (39.26%) surveys were returned.

High Dose Methylphenidate IR: This was a follow-up discussion. Six (6) of the 25 members identified changed therapy, for an annualized cost savings of \$14,154.00 (state and federal, pre-rebate) as a result of the 51 surveys sent out to prescribers and pharmacies. A total of 20 (39.22%) surveys were returned.

Anxiolytic Benzodiazepine Use without an SSRI or SNRI: This was a follow-up discussion. A total of 25 of the 989 members identified changed therapy, for an annualized cost savings of \$45,197.16 (state and federal, pre-rebate) as a result of the 2,984 surveys sent out to prescribers and pharmacies. A total of 1191 (39.91%) surveys were returned.

Methadone Utilization: Congress sent a letter to CMS asking that state Medicaid programs look into this. Methadone will remain preferred for now, but the Commission agreed that a quantity limit would make sense. This limit could possibly just apply to the tablets to leave the solution more available to the clinics that use it for opioid dependence. A limit of 40mg per day was suggested, but Pam Smith will look at what other states are doing, and at morphine equivalent quantity limits prior to an official vote and implementation. She will also investigate number of deaths from overdose and the associated diagnoses involved.

ProDUR Edits

Tramadol Utilization in Members under 18 Years of Age: The data will be run again on the March claims, to see if the FDA warning has made an impact, with results brought back to the next meeting.

Public Comment

Name	Representing	Drug/Topic
Nancy Bell	Pfizer	DUR Public Comment Policy

Prior Authorization

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

Prior authorization is required for all non-preferred long-acting opioids. Payment will be considered under the following conditions:

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

3. *Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants)*
4. *There is documentation of previous trials and therapy failures with one preferred long-acting opioid at a maximally tolerated dose, and*
5. *A signed chronic opioid therapy management plan between the prescriber and patient must be included with the prior authorization, and*
6. *The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/> and determine if use of a long-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization, and*
7. *Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids.*
8. *Requests for long-acting opioids will only be considered for FDA approved dosing. As-needed (PRN) dosing will not be considered.*

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

1. *Patient has experienced improvement in pain control and level of functioning; and*
2. *Prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/> and has determined continued use of a long-acting opioid is appropriate for this member.*

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

Brian Couse motioned to accept the criteria, and Brett Faine seconded. The decision was unanimous. The Commission is also interested in adding quantity limits based on morphine sulfate equivalents in the future. Additionally, the P&T Committee will be reviewing this category at their April 21, 2016 meeting. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Adalimumab (Humira): The Commission reviewed the prior authorization criteria as follows:

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

1. *Be screened for hepatitis B and C. Patients with active hepatitis B will not be considered for coverage; and*
2. *Have not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biologic agent; and*

3. *Not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and*
4. *Be screened for latent TB infection. Patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment.*

Payment will be considered under the following conditions:

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

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

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

Larry Ambroson motioned to accept the updated criteria, and Daniel Gillette seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Rifaximin (Xifaxan): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for rifaximin. Only FDA approved dosing will be considered. Payment will be considered under the following conditions:

1. *A diagnosis of travelers' diarrhea*
 - a. *Patient is 12 years of age or older; and*
 - b. *Patient has a diagnosis of travelers' diarrhea not complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli; and*
 - c. *Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with a preferred generic fluoroquinolone or azithromycin.*
 - d. *A maximum 3 day course of therapy (9 tablets) of the 200mg tablets per 30 days will be allowed.*
2. *A diagnosis of hepatic encephalopathy*

- a. Patient is 18 years of age or older; and
 - b. Patient has a diagnosis of hepatic encephalopathy; and
 - c. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with lactulose.
3. A diagnosis of irritable bowel syndrome with diarrhea
- a. Patient is 18 years of age or older; and
 - b. Patient has a diagnosis of irritable bowel syndrome with diarrhea; and
 - c. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with a preferred antispasmodic agent (dicyclomine, hyoscyamine); and
 - d. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with amitriptyline and loperamide.
 - e. If criteria for coverage are met, a single 14-day course will be approved.
 - f. Subsequent requests will require documentation of recurrence of IBS-D symptoms. A minimum 10 week treatment-free period between courses is required.
 - g. A maximum of 3 treatment courses of rifaximin will be allowed per lifetime.

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

Brett Faine motioned to accept the updated criteria, and Daniel Gillette seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

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

Payment will be considered under the following conditions:

- 1. Patient is 18 years of age or older; and
- 2. Patient has a diagnosis of stable, symptomatic heart failure (NYHA Class II, III, or IV); and
- 3. Patient has documentation of a left ventricular ejection fraction $\leq 35\%$; and
- 4. Patient is in sinus rhythm with a resting heart rate of ≥ 70 beats per minute; and
- 5. Patient has documentation of blood pressure $\geq 90/50$ mmHg; and
- 6. Heart failure symptoms persist with maximally tolerated doses of at least one beta-blocker with proven mortality benefit in a heart failure clinical trial (e.g. carvedilol 50mg daily, metoprolol succinate 200mg daily, or bisoprolol 10mg daily), or patient has a documented intolerance or FDA labeled contraindication to beta-blockers; and
- 7. Patient has documentation of a trial and continued use with a preferred ACE inhibitor or preferred ARB at a maximally tolerated dose.

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

Brett Faine and Larry Ambroson both motioned to accept the updated criteria, and Brian Couse seconded. All members were in favor. This medication will also be reviewed by the P&T Committee at their April 21, 2016 meeting. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

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

Prior authorization is required for deferasirox. Requests will only be considered for FDA approved dosing. Payment will be considered under the following conditions:

- 1. Patient does not have a serum creatinine greater than 2 times the age-appropriate upper limit of normal or creatinine clearance < 40mL/min; and*
- 2. Patient does not have a poor performance status; and*
- 3. Patient does not have a high-risk myelodysplastic syndrome; and*
- 4. Patient does not have advanced malignancies; and*
- 5. Patient does not have a platelet count < 50 x 10⁹/L.*

Transfusional Iron Overload

Initiation of Therapy

- 1. Patient is 2 years of age or older; and*
- 2. Patient has documentation of iron overload related to anemia (attach documentation); and*
- 3. Patient has documentation of a recent history of frequent blood transfusions that has resulted in chronic iron overload; and*
- 4. Serum ferritin is consistently > 1000mcg/L (attach lab results dates within the past month); and*
- 5. Starting dose does not exceed: Exjade - 20mg/kg/day OR Jadenu - 14mg/kg/day. Calculate dose to the nearest whole tablet.*
- 6. Initial requests will be considered for up to 3 months.*

Continuation of Therapy

- 1. Serum ferritin has been measured within 30 days of continuation of therapy request (attach documentation); and*
- 2. Ferritin levels are > 500mcg/L; and*
- 3. Dose does not exceed: Exjade - 40mg/kg/day OR Jadenu - 28mg/kg/day.*

Non-Transfusional Iron Overload

Initiation of Therapy

- 1. Patient is 10 years of age or older; and*
- 2. Patient has documentation of iron overload related to anemia (attach documentation); and*
- 3. Serum ferritin and liver iron concentration (LIC) has been measured within 30 days of initiation (attach lab results); and*
- 4. Serum ferritin levels are > 300mcg/L; and*

5. LIC are $> 5\text{mg Fe/g dw}$; and
6. Dose does not exceed: Exjade - 10mg/kg/day (if LIC is $\leq 15\text{mg Fe/g dw}$), or 20mg/kg/day (if LIC is $> 15\text{mg Fe/g dw}$); OR Jadenu - 7mg/kg/day (if LIC is $\leq 15\text{mg Fe/g dw}$), or 14mg/kg/day (if LIC is $> 15\text{mg Fe/g dw}$).
7. Initial authorization will be considered for up to 6 months.

Continuation of Therapy

1. Serum ferritin and LIC have been measured within 30 days of continuation of therapy request; and
2. Serum ferritin levels are $\geq 300\text{mcg/L}$; and
3. LIC is $\geq 3\text{mg Fe/g dw}$.
4. Dose does not exceed: Exjade - 10mg/kg/day (if LIC is 3 to 7 mg Fe/g dw) or 20mg/kg/day (if LIC is $> 7\text{mg Fe/g dw}$); OR Jadenu - 7mg/kg/day (if LIC is 3 to 7 mg Fe/g dw) or 14mg/kg/day (if LIC is $> 7\text{mg Fe/g dw}$).

Brian Couse motioned to accept the updated criteria, and Larry Ambrosion seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Eluxadoline (Viberzi): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for eluxadoline. Only FDA approved dosing will be considered. Payment will be considered under the following conditions:

1. Patient is 18 years of age or older
2. Patient has a diagnosis of irritable bowel syndrome with diarrhea (IBS-D)
3. Patient does not have any of the following contraindications to therapy:
 - a. Known or suspected biliary duct obstruction, or sphincter of Oddi disease/dysfunction
 - b. Alcoholism, alcohol abuse, alcohol addiction, or consumption of more than 3 alcoholic beverages per day
 - c. A history of pancreatitis or structural diseases of the pancreas (including known or suspected pancreatic duct obstruction)
 - d. Severe hepatic impairment (Child-Pugh Class C)
 - e. Severe constipation or sequelae from constipation
 - f. Known or suspected mechanical gastrointestinal obstruction
4. Patient has documentation of a previous trial and therapy failure at a therapeutic dose with both of the following:
 - a. A preferred antispasmodic agent (dicyclomine or hyoscyamine)
 - b. A preferred antidiarrheal agent (loperamide)

If criteria for coverage are met, initial authorization will be given for 3 months to assess the response to treatment. Requests for continuation of therapy will require the following:

1. *Patient has not developed any contraindications to therapy (defined above)*
2. *Patient has experienced a positive clinical response to therapy as demonstrated by at least one of the following:*
 - a. *Improvement in abdominal cramping or pain*
 - b. *Improvement in stool frequency and consistency.*

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

Brian Couse motioned to accept the updated criteria, and Brett Faine seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Mepolizumab (Nucala): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for mepolizumab (Nucala). Requests will not be considered with concurrent use of omalizumab. Payment will be considered under the following conditions:

1. *Patient is 12 years of age or older; and*
2. *Patient has a diagnosis of severe asthma with an eosinophilic phenotype; and*
3. *Patient has a pretreatment blood eosinophil count of ≥ 150 cells per mcL within the previous 6 weeks or blood eosinophils of ≥ 300 cells per mcL within 12 months prior to initiation of therapy; and*
4. *Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (long-acting beta2-agonist [LABA] and leukotriene receptor antagonist [LTRA]) for a minimum of 3 consecutive months, with or without oral corticosteroids. Patient must be compliant with therapy, based on pharmacy claims; and*
5. *Patient has a history of two (2) or more exacerbations in the previous year despite regular use of high-dose ICS plus an additional controller medication (LABA or LTRA); and*
6. *A pretreatment forced expiratory volume in 1 second (FEV₁) <80% predicted; and*
7. *Prescriber is an allergist, immunologist, or pulmonologist; and*
8. *Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility.*

If criteria for coverage are met, an initial authorization will be given for 3 months to assess the need for continued therapy. Requests for continuation of therapy will be based on continued medical necessity and will be considered if one or more of the following criteria are met:

1. *Patient continues to receive therapy with both an ICS and a controller medication (LABA or LTRA); and*
2. *Patient has experienced a reduction in asthma signs and symptoms including wheezing, chest tightness, coughing, shortness of breath, or*

3. *Patient has experienced a decrease in administration of rescue medication (albuterol); or*
4. *Patient has experienced a decrease in exacerbation frequency; or*
5. *Patient has experienced an increase in predicted FEV₁ from the pretreatment baseline.*

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

Brian Couse motioned to accept the updated criteria, and Brett Faine seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Smoking Cessation Therapy: No changes were made to the existing criteria. Pam Smith just clarified that members with MCO eligibility would not need to enroll with Quitline Iowa, as the MCOs have their own smoking cessation programs. However, members who continue in the fee-for-service (FFS) program will need to continue submitting prior authorization forms to the Quitline Iowa fax number.

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

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:*

Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH)

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 > 290 mg/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.*

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 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 or rosuvastatin), PLUS ezetimibe (Zetia) 10mg daily, PLUS cholestyramine daily.*

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

1. *Total cholesterol and LDL-C > 600 mg/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 or 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*

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

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

Prior authorization 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 18 years of age or older; and*
2. *Patient has a diagnosis of NYHA Functional Class II, III, or IV heart failure; and*

3. *Patient has a left ventricular ejection fraction (LVEF) \leq 40%; and*
4. *Patient has documentation of a previous trial and therapy failure or intolerance to an ACE inhibitor at a maximally tolerated dose; and*
5. *Patient has documentation of a previous trial and therapy failure or intolerance to an angiotensin II receptor blocker (ARB); and*
6. *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); and*
7. *Will not be used in combination with an ACE inhibitor or ARB; and*
8. *Will not be used in combination with aliskiren (Tekturna) in diabetic patients; and*
9. *Patient does not have a history of angioedema associated with the use of ACE inhibitor or ARB therapy; and*
10. *Patient is not pregnant; and*
11. *Patient does not have severe hepatic impairment (Child Pugh Class C); and*
12. *Prescriber is a cardiologist or has consulted with a cardiologist (telephone consultation is acceptable).*

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

If the criteria for coverage are met, initial authorization will be given for 3 months. Requests for continuation of therapy may be provided if prescriber documents adequate response to therapy.

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

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

Prior authorization is required for sodium oxybate (Xyrem[®]). Payment will be considered for patients 18 years of age or older under the following conditions:

1. *A diagnosis of cataplexy associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trial and therapy failure with one of the following tricyclic antidepressants: clomipramine, imipramine, or protriptyline; or*
2. *A diagnosis of excessive daytime sleepiness associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trials and therapy failures at a therapeutic dose with a preferred amphetamine and non-amphetamine stimulant.*
3. *Patient is enrolled in the Xyrem[®] REMS Program.*
4. *Patient has been instructed to not drink alcohol when using Xyrem[®].*
5. *Patients with and without a history of substance abuse have been counseled regarding the potential for abuse and dependence and will be closely monitored for signs of abuse and dependence.*

6. *Requests for patients with concurrent use of a sedative hypnotic or a semialdehyde dehydrogenase deficiency will not be considered.*
7. *The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/> prior to requesting prior authorization.*

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

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

Antiemetic-5HT3 Receptor Agonists/Substance P Neurokinin Agents: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for preferred Antiemetic-5HT3 Receptor Antagonists/Substance P Neurokinin medications for quantities exceeding the following dosage limits per month. Payment for Antiemetic-5HT3 Receptor Antagonists/Substance P Neurokinin Agents beyond this limit will be considered on an individual basis after review of submitted documentation.

Prior authorization will be required for all non-preferred Antiemetic-5HT3 Receptor Antagonists/Substance P Neurokinin medications beginning the first day of therapy. Payment for non-preferred medications will be authorized only for cases in which there is documentation of previous trial(s) and therapy failure with a preferred agent in this class. Note: Aprepitant (Emend) will only be payable when used in combination with other antiemetic agents (5-HT3 medication and dexamethasone) for patients receiving highly emetogenic cancer chemotherapy.

As this was the second review of these criteria, no motion was necessary. A quantity limit of 60 per 30 days will also be implemented on oral ondansetron. The recommendation will be sent to the Department for consideration.

Non-Parenteral Vasopressin Derivatives of Posterior Pituitary Hormone Products: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for non-parenteral vasopressin derivatives of posterior pituitary hormone products. Payment for preferred non-parenteral vasopressin derivatives of posterior pituitary hormone products will be authorized for the following diagnoses:

1. *Diabetes Insipidus*
2. *Hemophilia A*
3. *Von Willebrand's disease*

Requests for desmopressin nasal spray for the treatment of nocturnal enuresis will not be considered. Payment for non-preferred non-parenteral vasopressin derivatives will be authorized only for cases in which there is documentation of trial(s) and therapy failure with the preferred agent(s). Please refer to the Selected Brand-Name Drugs prior authorization form if requesting a non-preferred brand-name product.

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 reviewed the drafts for DUR Digest Volume 28, Number 2 (second review) and DUR Digest Volume 28, Number 3 (first review). DUR Digest Volume 28, Number 2 will be posted to the DUR website.

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

A unanimous roll call vote was made at 12:04 to adjourn the meeting. (motion by Larry Ambroson, second by Daniel Gillette).

The next meeting will be held at 9:30 a.m. on Wednesday, June 1, 2016, at the Learning Resource Center in West Des Moines.

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes June 1, 2016

Attendees:

Commission Members

Mark Graber, M.D., FACEP; Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Brian Couse, M.D.; Daniel Gillette, M.D.; Brett Faine, Pharm.D.; Jason Wilbur, M.D.; Kellen Ludvigson, Pharm.D.; and Susan Parker, Pharm.D.

Staff

Pam Smith, R.Ph.

Guests

C. David Smith, M.D., IME; Erin Halverson, R.Ph., IME; Melissa Biddle, IME; Sandy Pranger, R.Ph., Amerigroup; Jennifer Schonhorst, Pharm.D., AmeriHealth Caritas; and Karrie Hansotia, United Healthcare Plan of the River Valley.

Welcome & Introductions

Mark Graber called the meeting to order at 9:32 a.m. at the Learning Resource Center in West Des Moines. The minutes from the April 6, 2015 meeting were reviewed. Larry Ambroson motioned to accept them, and Daniel Gillette seconded. All members were in favor. The DUR recommendation letter sent to DHS after the last meeting and a letter from the P&T Committee to the DUR Commission regarding prior authorization criteria for Nucala were also reviewed.

IME Pharmacy Update

Susan Parker encouraged those that hadn't already signed up for the Iowa Medicaid Newsletter to do so, as these bi-monthly newsletters contain much useful information regarding managed care and fee for service issues. Pam Smith reviewed her findings on how other states were attempting to control opioid abuse.

Prevalence Report Summary

Statistics from March through April 2016 were discussed, including: cost per user (\$238.48), number of total prescriptions dispensed (a decrease of 43.9% compared to the previous reporting period), average cost per prescription (\$70.54), and generic utilization (86.3%). The total paid amount decreased by 43.5% from the previous reporting period. There were 174,211 unique users, which is 19.2% less than the total for January and February. This is the first prevalence report since the switch to managed care on April 1, 2016, which accounts for the significant changes. Lists of the top 20 therapeutic classes were provided. SSRIs had the highest prescription count, and Anticonvulsants came in second. The top 100 drugs were also reviewed. The ten most expensive medications were: Vyvanse, Abilify, methylphenidate hcl er, Harvoni, Lantus, Focalin XR, Humalog, Strattera, Latuda, and Advate.

Case Studies

Pam Smith presented 4 case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of \$1,043.41 pre-rebate (state and federal).

Public Comment

Name	Representing	Drug/Topic
Nancy Bell	Pfizer	Anticoagulants
Julie McDavid	Boehringer-Ingelheim	Pradaxa
Jennifer Stofel	Janssen	Xarelto

Focus Studies

Members Exceeding Proposed Benzodiazepine Quantity Limits: This was a follow-up discussion. Ninety-one (91) of the 213 members identified changed therapy, for an annualized cost savings of \$11,404.20 (state and federal, pre-rebate) as a result of the 431 surveys sent out to prescribers and pharmacies. A total of 176 (40.84%) surveys were returned.

Duplicate Beta-Blockers: This was a follow-up discussion. Seventeen (17) of the 34 members identified changed therapy, for an annualized cost savings of \$5,364.12 (state and federal, pre-rebate) as a result of the 104 surveys sent out to prescribers and pharmacies. A total of 44 (42.31%) surveys were returned.

Vimpat Dose Greater than 400mg: This was a follow-up discussion. Two of the 19 members identified changed therapy, for an annualized cost savings of \$4,707.23 (state and federal, pre-rebate) as a result of the 46 surveys sent out to prescribers and pharmacies. A total of 23 (50.00%) surveys were returned.

Anticholinergics with Second Generation Antipsychotics: This was a follow-up discussion. A total of 183 of the 724 members identified changed therapy, for an annualized cost savings of \$24,517.72 (state and federal, pre-rebate) as a result of the 1,745 surveys sent out to prescribers and pharmacies. A total of 607 (34.79%) surveys were returned.

Methadone Utilization: Following a letter from Congress to CMS asking that state Medicaid programs look into this, it was discussed at the prior DUR meeting in April. Pam Smith then researched how other states were responding, and reported her findings, along with the possible conversion ratio issues involved with implementing morphine equivalent quantity limits. Jason Wilbur motioned to recommend that the P&T Committee make methadone non-preferred, and Brian Couse seconded. Brett Faine opposed, but all of the other members were in favor, so the motion passed. A check box to note usage for opioid dependence will be added to the prior authorization form. Quantity limits were discussed again, but none will be implemented at this time.

ProDUR Edits

Tramadol Utilization in Members under 18 Years of Age: An age edit was recommended to restrict usage to members 18 years of age and older due to issues with slowed breathing in children (motion by Brett Faine, second by Jason Wilbur, unanimous decision).

Prior Authorization

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

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 for moderate to severe acne.*
- 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.

Jason Wilbur motioned to accept the criteria as modified, and Kellen Ludvigson seconded. The decision was unanimous. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

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

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

1. Patient does not have a mechanical heart valve; and
2. Patient does not have active bleeding; and
3. For a diagnosis of atrial fibrillation or stroke prevention, patient has the presence of at least one additional risk factor for stroke, with a CHA₂DS₂-VASc score ≥ 1 ; and
4. A recent creatinine clearance (CrCl) is provided; and
5. A recent Child-Pugh score is provided; and
6. Patient's current body weight is provided; and
7. Patient has documentation of a trial and therapy failure at a therapeutic dose with at least two preferred NOACs.
8. For requests for edoxaban, documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin).

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

In addition to the above PA criteria the DUR Commission made the recommendation to implement the following ProDUR quantity limits on rivaroxaban (Xarelto):

- 10mg tablet – 30 tablets per 30 days
- 15mg tablets – allow twice daily dosing for 21 days followed by once daily dosing
- 20mg tablets – 30 tablets per 30 days

Brett Faine motioned to accept the amended criteria, along with the proposed quantity limits, and Brian Couse seconded. The decision was unanimous. The decision was unanimous. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Patiromer (Veltassa): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for non-preferred potassium binders. Payment will be considered under the following conditions:

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

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

Brian Couse motioned to accept the criteria, and Jason Wilbur seconded. The decision was unanimous. The decision was unanimous. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

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

Prior authorization is required for all non-preferred long-acting opioids. Payment will be considered under the following conditions:

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

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

- 1. Patient has experienced improvement in pain control and level of functioning; and*
- 2. Prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/> and has determined continued use of a long-acting opioid is appropriate for this member.*

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

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

Adalimumab (Humira): The Commission reviewed the prior authorization criteria as follows:

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

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

Payment will be considered under the following conditions:

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

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

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

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

Rifaximin (Xifaxan): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for rifaximin. Only FDA approved dosing will be considered. Payment will be considered under the following conditions:

- 1. A diagnosis of travelers' diarrhea*
 - a. Patient is 12 years of age or older; and*
 - b. Patient has a diagnosis of travelers' diarrhea not complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli; and*

- c. *Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with a preferred generic fluoroquinolone or azithromycin.*
- d. *A maximum 3 day course of therapy (9 tablets) of the 200mg tablets per 30 days will be allowed.*
- 2. *A diagnosis of hepatic encephalopathy*
 - a. *Patient is 18 years of age or older; and*
 - b. *Patient has a diagnosis of hepatic encephalopathy; and*
 - c. *Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with lactulose.*
- 3. *A diagnosis of irritable bowel syndrome with diarrhea*
 - a. *Patient is 18 years of age or older; and*
 - b. *Patient has a diagnosis of irritable bowel syndrome with diarrhea; and*
 - c. *Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with a preferred antispasmodic agent (dicyclomine, hyoscyamine); and*
 - d. *Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with amitriptyline and loperamide.*
 - e. *If criteria for coverage are met, a single 14-day course will be approved.*
 - f. *Subsequent requests will require documentation of recurrence of IBS-D symptoms. A minimum 10 week treatment-free period between courses is required.*
 - g. *A maximum of 3 treatment courses of rifaximin will be allowed per lifetime.*

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

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

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

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

- 1. *Patient is 18 years of age or older; and*
- 2. *Patient has a diagnosis of stable, symptomatic heart failure (NYHA Class II, III, or IV); and*
- 3. *Patient has documentation of a left ventricular ejection fraction $\leq 35\%$; and*
- 4. *Patient is in sinus rhythm with a resting heart rate of ≥ 70 beats per minute; and*
- 5. *Patient has documentation of blood pressure $\geq 90/50$ mmHg; and*
- 6. *Heart failure symptoms persist with maximally tolerated doses of at least one beta-blocker with proven mortality benefit in a heart failure clinical trial (e.g. carvedilol*

- 50mg daily, metoprolol succinate 200mg daily, or bisoprolol 10mg daily), or patient has a documented intolerance or FDA labeled contraindication to beta-blockers; and
7. Patient has documentation of a trial and continued use with a preferred ACE inhibitor or preferred ARB at a maximally tolerated dose.

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

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

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

Prior authorization is required for deferasirox. Requests will only be considered for FDA approved dosing. Payment will be considered under the following conditions:

1. Patient does not have a serum creatinine greater than 2 times the age-appropriate upper limit of normal or creatinine clearance < 40mL/min; and
2. Patient does not have a poor performance status; and
3. Patient does not have a high-risk myelodysplastic syndrome; and
4. Patient does not have advanced malignancies; and
5. Patient does not have a platelet count < 50 x 10⁹/L.

Transfusional Iron Overload

Initiation of Therapy

1. Patient is 2 years of age or older; and
2. Patient has documentation of iron overload related to anemia (attach documentation); and
3. Patient has documentation of a recent history of frequent blood transfusions that has resulted in chronic iron overload; and
4. Serum ferritin is consistently > 1000mcg/L (attach lab results dates within the past month); and
5. Starting dose does not exceed: Exjade - 20mg/kg/day OR Jadenu - 14mg/kg/day. Calculate dose to the nearest whole tablet.
6. Initial requests will be considered for up to 3 months.

Continuation of Therapy

1. Serum ferritin has been measured within 30 days of continuation of therapy request (attach documentation); and
2. Ferritin levels are > 500mcg/L; and
3. Dose does not exceed: Exjade - 40mg/kg/day OR Jadenu - 28mg/kg/day.

Non-Transfusional Iron Overload

Initiation of Therapy

1. Patient is 10 years of age or older; and
2. Patient has documentation of iron overload related to anemia (attach documentation); and
3. Serum ferritin and liver iron concentration (LIC) has been measured within 30 days of initiation (attach lab results); and

4. Serum ferritin levels are > 300mcg/L; and
5. LIC are > 5mg Fe/g dw; and
6. Dose does not exceed: Exjade - 10mg/kg/day (if LIC is \leq 15mg Fe/g dw), or 20mg/kg/day (if LIC is > 15mg Fe/g dw); OR Jadenu - 7mg/kg/day (if LIC is \leq 15mg Fe/g dw), or 14mg/kg/day (if LIC is > 15mg Fe/g dw).
7. Initial authorization will be considered for up to 6 months.

Continuation of Therapy

1. Serum ferritin and LIC have been measured within 30 days of continuation of therapy request; and
2. Serum ferritin levels are \geq 300mcg/L; and
3. LIC is \geq 3mg Fe/g dw.
4. Dose does not exceed: Exjade - 10mg/kg/day (if LIC is 3 to 7 mg Fe/g dw) or 20mg/kg/day (if LIC is > 7mg Fe/g dw); OR Jadenu - 7mg/kg/day (if LIC is 3 to 7 mg Fe/g dw) or 14mg/kg/day (if LIC is > 7mg Fe/g dw).

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

Eluxadoline (Viberzi): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for eluxadoline. Only FDA approved dosing will be considered. Payment will be considered under the following conditions:

1. Patient is 18 years of age or older
2. Patient has a diagnosis of irritable bowel syndrome with diarrhea (IBS-D)
3. Patient does not have any of the following contraindications to therapy:
 - a. Known or suspected biliary duct obstruction, or sphincter of Oddi disease/dysfunction
 - b. Alcoholism, alcohol abuse, alcohol addiction, or consumption of more than 3 alcoholic beverages per day
 - c. A history of pancreatitis or structural diseases of the pancreas (including known or suspected pancreatic duct obstruction)
 - d. Severe hepatic impairment (Child-Pugh Class C)
 - e. Severe constipation or sequelae from constipation
 - f. Known or suspected mechanical gastrointestinal obstruction
4. Patient has documentation of a previous trial and therapy failure at a therapeutic dose with both of the following:
 - a. A preferred antispasmodic agent (dicyclomine or hyoscyamine)
 - b. A preferred antidiarrheal agent (loperamide)

If criteria for coverage are met, initial authorization will be given for 3 months to assess the response to treatment. Requests for continuation of therapy will require the following:

1. Patient has not developed any contraindications to therapy (defined above)

2. *Patient has experienced a positive clinical response to therapy as demonstrated by at least one of the following:*
 - a. *Improvement in abdominal cramping or pain*
 - b. *Improvement in stool frequency and consistency.*

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

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

Mepolizumab (Nucala): The Commission reviewed the prior authorization criteria and made changes as follows:

Prior authorization is required for mepolizumab (Nucala). Requests will not be considered with concurrent use of omalizumab. Payment will be considered under the following conditions:

1. *Patient is 12 years of age or older; and*
2. *Patient has a diagnosis of severe asthma with an eosinophilic phenotype; and*
3. *Patient has a pretreatment blood eosinophil count of ≥ 150 cells per mcL within the previous 6 weeks or blood eosinophils of ≥ 300 cells per mcL within 12 months prior to initiation of therapy; and*
4. *Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (long-acting beta2-agonist [LABA] and leukotriene receptor antagonist [LTRA]) for a minimum of 3 consecutive months, with or without oral corticosteroids. Patient must be compliant with therapy, based on pharmacy claims; and*
5. *Patient has a history of two (2) or more exacerbations in the previous year despite regular use of high-dose ICS plus an LABA and LTRA; and*
6. *A pretreatment forced expiratory volume in 1 second (FEV₁) <80% predicted; and*
7. *Prescriber is an allergist, immunologist, or pulmonologist; and*
8. *Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility.*

If criteria for coverage are met, an initial authorization will be given for 3 months to assess the need for continued therapy. Requests for continuation of therapy will be based on continued medical necessity and will be considered if one or more of the following criteria are met:

1. *Patient continues to receive therapy with an ICS, LABA and LTRA; and*
2. *Patient has experienced a reduction in asthma signs and symptoms including wheezing, chest tightness, coughing, shortness of breath, or*
3. *Patient has experienced a decrease in administration of rescue medication (albuterol); or*
4. *Patient has experienced a decrease in exacerbation frequency; or*
5. *Patient has experienced an increase in predicted FEV₁ from the pretreatment baseline.*

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

Brett Faine motioned to accept the updated criteria, and Larry Ambroson and Daniel Gillette both seconded simultaneously. All members were in favor. Since the criteria was changed, the newly recommended criteria will be sent to the medical/pharmacy associations for their comment and brought back to the next DUR meeting.

Miscellaneous

DUR Digest: The Commission members reviewed the draft for DUR Digest Volume 28, Number 3. As this was the second review, it will be posted to the DUR website.

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

At 10:58, Jason Wilbur motioned to adjourn the meeting and Kellen Ludvigson seconded. (No closed session was needed due to lack of profile review post MCO transition.)

The next meeting will be held at 9:30 a.m. on Wednesday, August 3, 2016, at the Learning Resource Center in West Des Moines.

Appendix J
Mental Health Advisory Group

Mental Health Advisory Group

The Iowa Medicaid Drug Utilization Review Mental Health Advisory Group (MHAG), formerly known as the Mental Health Work Group, was established in SFY08. It is currently comprised of two members of the Drug Utilization Review Commission (psychiatrist and pharmacist), several pediatric and adolescent psychiatrists, an adult psychiatrist, a psychiatric pharmacist, a pediatrician and a psychiatrist from Magellan Health Services.

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

The original goal of the MHWG was to address issues that developed specific to the pediatric and adolescent psychiatrists within the State of Iowa when mental health drug consolidation edits were implemented in October, 2007. Since then, the DUR Commission has made the decision to refer other mental health issues that impact the entire mental health population of Iowa Medicaid, regardless of the members' age.

The MHAG did not meet in SFY16 as the DUR Commission did not request a topic be referred to the MHAG.

Appendix K
Recommendations to the P&T

P & T Recommendations SFY16

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 was one recommendation made to the P&T Committee.



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

100 Army Post Road – Des Moines, IA 50315 □ (515) 974-3131 □ Fax 1-866-626-0216

Brett Faine, Pharm.D.
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Jason Wilbur, M. D.

Professional Staff:

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DUR Project Coordinator

June 3, 2016

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

Dear Susan:

At the request of the DUR Commission members, I am forwarding the following referral to the Pharmaceutical and Therapeutics (P&T) Committee members for further consideration.

The DUR Commission reviewed clinical information regarding methadone at multiple meetings and most recently at their June 1, 2016 meeting.

According to the Centers for Disease Control and Prevention (CDC), deaths due to prescription opioid pain medication overdose in the United States have more than quadrupled from 1999 to 2011. Of the total drug overdose deaths in 2013, 37% were associated with prescription opioid analgesics. Though all prescription opioids can contribute to unintentional overdose and death, methadone accounts for a disproportionate share of opioid related overdoses and deaths. The CDC estimates that 30% of prescription opioid related drug overdose deaths in 2009 involved methadone prescriptions for pain. In order to reduce prescription opioid related harms, the Department of Health and Human Services has encouraged states to consider additional steps to reduce the misuse of methadone prescribed for pain relief, including removing methadone for pain (outside of end of life care) from their preferred drug lists.

Based on the above information, the DUR Commission requests the P&T Committee consider making methadone non-preferred on the Preferred Drug List (PDL), thus limiting its use for the treatment of pain to only those patients for whom treatment with other opioid medications is ineffective.

Thank you in advance for consideration of moving methadone to non-preferred status on the PDL.

Sincerely,

Paula Smith R.Ph.

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

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

Appendix L

Useful Links

Iowa Drug Utilization Review (DUR) Commission Useful Links

DUR Website

<http://iadur.org/>

DUR Newsletters

<http://iadur.org/newsletters>

Prevalence Reports

To view prevalence reports, visit the link below under Packets. Each packet included the bi-monthly prevalence report reviewed by the DUR Commission.

<http://iadur.org/agendas>