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 though 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 antispasmotic 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 ≤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 ≥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 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 > 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 ≤ 15mg Fe/g dw), or 20mg/kg/day (if LIC is > 15mg Fe/g dw); OR Jadenu - 7mg/kg/day (if LIC is ≤ 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 ≥ 300mcg/L; and*
3. *LIC is ≥ 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).*

Brian Couse motioned to accept the updated criteria, and Larry Ambroson 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 (FEV_1) <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 FEV_1 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:*

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

1. *Total cholesterol > 290mg/dL or LDL-C > 190mg/dL; AND*

a. *Presence of tendon xanthomas; OR*
b. *In first or second degree relative, one of the following:*
    i. *Documented tendon xanthomas; or*
    ii. *MI at age ≤60 years; or*
    iii. *Total cholesterol > 290mg/dL; OR*
c. *Confirmation of diagnosis by gene or receptor testing (attach results); AND*

2. *Unable to reach goal LDL-C with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (including atorvastatin and rosuvastatin), PLUS ezetimibe (Zetia) 10mg daily PLUS cholestyramine daily.*

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 medially 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) ≤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.