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 though 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:*

<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*

  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 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.

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.

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 Ambroson 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 (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 ≥50th percentile,*
- *Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) < 50 U/L or baseline levels reduced by 80%,*
- *Total bilirubin level reduced to ≤1mg/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 Ccommission 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 Ambroson, 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.