Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes March 3, 2021

Attendees:

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

Welcome & Introductions

In Brett Faine's absence, vice-chairperson Kellen Ludvigson called the meeting to order at 9:31 a.m. This meeting was purely virtual and done through WebEx teleconference due to COVID-19. The minutes from the November 19, 2020 meeting were reviewed. Jason Kruse motioned to accept them, and Melissa Klotz seconded. All members were in favor. The recommendation letter sent to DHS after the last DUR meeting was also reviewed, along with a recommendation letter from the P&T Committee to the DUR Commission requesting development of prior authorization (PA) criteria for Evrysdi and Fintepla. Pam Smith provided an overview of additions to the SUPPORT Act Final Rule related to opioid standards, which will be discussed at future meetings.

IME Pharmacy Update

There is still an opening for a doctor on the DUR Commission, as Mark Graber reached the end of his 3 allowable terms, but the search has been on hold due to COVID-19.

Prevalence Report Summaries

Amerigroup*:* Lisa Todd provided an overview for Amerigroup's statistics from September 2020 through November 2020, including: total paid amount ($99,126,320); unique users (152,661); total prescriptions (1,102,276); generic prescriptions (982,700 totaling $19,719,158); brand prescriptions (119,576 totaling $79,407,162). The breakdown of utilization by age shows that ages 19-64 continue to have the highest utilization. The top 100 pharmacies by prescription count had 4 Walgreens locations and the University of Iowa Ambulatory Care Pharmacy making up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Caremark Kansas Specialty, CVS Specialty, Hy-Vee Pharmacy Solutions, and Nucara Specialty. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Antiasthmatic and Bronchodilator Agents; Analgesics – Anti-Imflammatory; and ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents,

Anticonvulsants, Antihypertensives, and ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants. Humira (CF) Pen was the most expensive medication, followed by Vyvanse, Latuda, Vraylar, and Ozempic. Omeprazole had the highest prescription count, followed by: sertraline hcl, trazodone hcl, atorvastatin calcium, and gabapentin.

Iowa Total Care: Emily Rogers spoke and provided written summaries that included ITC's statistics from September through November 2020, including: total paid amount ($63,672,027.61); total prescriptions (761,226); and unique users (109,718). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy, Broadlawns Outpatient Pharmacy, and 3 Walgreens locations made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Nucara Specialty, Unity Point at Home, Hy-Vee Pharmacy Solutions, and CVS. The top 5 therapeutic classes by paid amount were: Insulin; Sympathomimetics; Antiretrovirals; Anti-TNF-alpha-Monoclonal Antibodies; and Antipsychotics - Misc. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Sympathomimetics; Proton-Pump Inhibitors; and HMG CoA Reductase Inhibitors. The most expensive drugs were Humira Pen, Vyvanse, Vraylar, Trikafta, and Invega Sustenna, while omeprazole, albuterol, sertraline, atorvastatin, and Lisinopril had the top 5 prescription counts.

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from September 2020 through November 2020, including: total amount paid ($2,240,412), unique users (3,710); cost per user ($603.88), number of total prescriptions dispensed (21,985); and percent generic (88.7%). The top 5 therapeutic classes by paid amount were: Anticonvulsants; Antipsychotics – Atypicals; Anti-Inflammatories, Non-NSAID; Muscular Dystrophy Agents; and Antiretroviral Combinations. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Antihypertensives - Central; and GI – Proton Pump Inhibitors. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Fintepla, Evrysdi, Humira Pen, Vyvanse, and Biktarvy. The five drugs with the highest prescription counts were: trazodone hcl, clonidine hcl, omeprazole, sertraline hcl, and albuterol.

Comparative Prevalence Report Summary

Pam Smith also created a report that compared the FFS stats with those from each MCO. Its side-by-side statistics showed that $165,038,760 was spent in total for 264,089 unique users who had 1,885,487 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Humira and Vyvanse were the two most expensive drugs for the MCO plans. Humira was in third place for FFS, but Fintepla and Evrysdi had the top 2 spots. The top 25 drugs by prescription count were also similar across FFS and both MCO plans. When all three plans were combined, Scott Murray had the overall highest prescription count at 5,873. All three complete prevalence reports and the comparative summary can be found in the finalized meeting packet posted at https://iadur.org/sites/default/files/ghs-files//03-03-21-dur-meeting-packet-final.pdf.

Public Comment

In addition to the written public comments provided to Commission members, posted in the finalized meeting packet at: https://iadur.org/sites/default/files/ghs-files//03-03-21-dur-meeting-packet-final.pdf, they heard oral public comment from the speakers listed below.

Name	Representing	Drug/Topic
Jeremy Whalen	Genentech	Evrysdi & Enspryng
Holly Budlong	AbbVie	Elagolix
Tami Sova	Biogen	Vumerity
Kevin Duhrkopf	Sanofi Genzyme	Aubagio
Joseph Dang	Novartis	Kesimpta

Retrospective DUR Data Presentations

Concurrent Use of an SSRI and SNRI: Educational letters will be sent to providers regarding members identified as having concurrent claims for an SNRI and SSRI, alerting providers to the therapeutic duplication and increased risk of serious adverse effects, the lack of evidence of an increased therapeutic benefit with the use of these medications concurrently, and asking if one agent could be discontinued. The presented data will appear appear in a future DUR Digest.

Duplicate Therapy – Two Unique Opioids: Educational letters will be sent to providers regarding members identified as having 2 long-acting opioids, alerting providers to the therapeutic duplication and asking if one could be discontinued. Educational letters will also be sent to providers regarding members identified as having 2 short-acting opioids, alerting providers to the therapeutic duplication and asking if one could be discontinued and/or asking if the patient's chronic pain would be better controlled with a preferred long-acting opioid. Letters will be held until data from January through March 2021 is available.

Duplicate Therapy – Skeletal Muscle Relaxants: Educational letters will be sent to providers regarding members identified as having two or more chemically distinct muscle relaxants, with at least a 45 day overlap, in their pharmacy claims, alerting the provider(s) to the therapeutic duplication and increased risk of adverse effects, and asking if one agent could be discontinued. The DUR Commission will then re-evaluate the data trends to decide if additional steps, such as a ProDUR duplicate therapy edit, need to be implemented. This will also appear as a DUR Digest article.

Concurrent Use of Gabapentinoid and Opioid: Educational letters will be sent to providers regarding members identified as having concurrent therapy with an opioid and gabapentinoid in their pharmacy claims, alerting the provider(s) to the increased risk of adverse effects and asking if one agent could be discontinued.

Concurrent Opioids and Benzodiazepines: Data will be re-run, for a 90 day period with a 45 day overlap showing concurrent use of an opioid and benzodiazepine. Updated results will be brought back to the next meeting. Members with claims for naloxone within that group will also be reported.

Retrospective DUR Proposals

Duplicate Therapy – Benzodiazepines: The Commission would like to move forward with the recommendation to review data for members with two or more chemically distinct benzodiazepines, with at least 60 days overlap, over a 3 month period. Dr. Wilbur suggested also looking at non-sedative hypnotic benzodiazepines, like zolpidem and eszopiclone.

Single Ingredient Buprenorphine: Data will be run to look at members with a claim for single ingredient buprenorphine tablets, broken out by gender, then looking further at female patients and reviewing medical claims for a pregnancy diagnosis.

Commission Recommendations for Retrospective DUR Agenda Topics

There were no additional topic suggestions.

The Commission took a short break and open session resumed at 11:36. A roll call was conducted to ensure a quorum.

Prior Authorization

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

Binge Eating Disorder (Vyvanse only)

a. *Patient is 18 to 55 years of age; and*
b. *Patient meets DSM-5 criteria for Binge Eating Disorder (BED); and*
c. *Patient has documentation of moderate to severe BED, as defined by the number of binge eating episodes per week (number of episodes must be reported); and*
d. *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*
e. *Prescription is written by a psychiatrist, psychiatric nurse practitioner, or psychiatric physician assistant; and*
f. *Patient has a BMI of 25 to 45; and*
g. *Patient does not have a history of cardiovascular disease; and*
h. *Patient has no history of substance abuse; and*
i. *Is not being prescribed for the treatment of obesity or weight loss; and*
j. *Doses above 70mg per day will not be considered.*
k. *Initial requests will be approved for 12 weeks.*

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

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

Moderate to Severe BED

Based on the number of binge eating episodes per week:

Moderate - 4 to 7
Severe – 8 to 13
Extreme – 14 or more

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

IL-5 Antagonists: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for IL-5 antagonists. Requests will not be considered with concurrent use with another monoclonal antibody. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions:

1. *Is requested for an FDA approved or compendia indicated diagnosis; and*
2. *Patient meets the FDA approved or compendia indicated age and dose for submitted diagnosis; and*
3. *Patient has a diagnosis of severe asthma with an eosinophilic phenotype, and*
    a. *Patient has a pretreatment blood eosinophil count of ≥ 150 cells/mcL within the previous 6 weeks or blood eosinophils ≥ 300 cells/mcL within 12 months prior to initiation of therapy; and*
    b. *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

   c. *Patient has a history of two (2) or more exacerbations in the previous year despite regular use of high-dose ICS plus a LABA and LTRA; and*
   d. *A pretreatment forced expiratory volume in 1 second (FEV_1) < 80% predicted in adults and < 90% in adolescents; or*

4. *Patient has a diagnosis of eosinophilic granulomatosis with polyangiitis, and*
   a. *Patient has documentation of an adequate trial and therapy failure with systemic glucocorticoids; and*
   b. *One of the following:*
      i. *Eosinophil count >1000 cells/mcL; or*
      ii. *Eosinophil count > 10% of the total leukocyte count; or*
5. *Patient has a diagnosis of hypereosinophilic syndrome (HES); and*
   a. *Patient has been diagnosed with HES for ≥ 6 months prior to starting treatment; and*
   b. *Documentation that non-hematologic secondary causes of HES have been ruled out; and*
   c. *Documentation patient does not have FIP1L1-PDGFR□ kinase-positive HES; and*
   d. *Documentation of ≥ 2 HES flares within the previous 12 months while on stable HES therapy (e.g., chronic or episodic oral corticosteroids, immunosuppressive, or cytotoxic therapy); and*
   e. *Patient has a blood eosinophil count ≥ 1,000 cells/mcL; and*
   f. *Medication will be used in combination with stable doses of at least one other HES therapy; and*
6. *Prescribed by or in consultation with an allergist, hematologist, immunologist, pulmonologist, or rheumatologist.*

If criteria for coverage are met, an initial authorization will be given for 3 months for a diagnosis of severe asthma with an eosinophilic phenotype and eosinophilic granulomatosis with polyangiitis or 6 months for a diagnosis of hypereosinophilic syndrome to assess the need for continued therapy. Requests for continuation of therapy will be based on continued medical necessity and will be considered when the following criteria are met:

Severe Asthma with an Eosinophilic Phenotype:

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 FEV_1 from the pretreatment baseline.*

Eosinophilic Granulomatosis with Polyangiitis:

1. *Patient has demonstrated a positive clinical response to therapy (increase in remission time).*

Hypereosinophilic Syndrome:

1. *Patient has demonstrated a positive clinical response to therapy (improvement of symptoms and/or reduction in the number of flares); and*
2. *Medication continues to be used in combination with stable doses of at least one other HES therapy.*

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

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

Isotretinoin (Oral): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for oral isotretinoin therapy. Payment for non-preferred oral isotretinoin products will be authorized only for cases in which there is documentation of trial(s) and therapy failure with a preferred agent(s). Payment will be considered for preferred oral isotretinoin products for moderate to severe acne under the following conditions:

1. *There are documented trials and therapy failures of systemic antibiotic therapy and topical vitamin A derivative (tretinoin or adapalene) therapy. Documented trials and therapy failures of systemic antibiotic therapy and topical vitamin A derivative therapy are not required for approval for treatment of acne conglobata; and*
2. *Prescriber attests patient has enrolled in and meets all requirements of the iPLEDGE program.*

Initial authorization will be granted for up to 24 weeks. A minimum of 8 weeks without therapy is required to consider subsequent authorizations.

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

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

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

For patients initiating therapy with a preferred oral multiple sclerosis agent, a manual prior authorization (PA) is not required if a preferred injectable interferon or non-

interferon agent is found in the member's pharmacy claims history in the previous 12 months. If a preferred injectable agent is not found in the member's pharmacy claims, documentation of the following must be provided:

1. *A diagnosis of relapsing forms of multiple sclerosis; and*
2. *Request must adhere to all FDA approved labeling, including indication, age, dosing, contraindications, and warnings and precautions; and*
3. *Documentation of a previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis.*

Requests for a non-preferred oral multiple sclerosis agent must document a previous trial and therapy failure with a preferred oral multiple sclerosis agent.

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

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

Nonsteroidal Anti-Inflammatory Drugs: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for all non-preferred nonsteroidal anti-inflammatory drugs (NSAIDs). Payment for a non-preferred NSAID will be considered under the following conditions:

1. *Documentation of previous trials and therapy failures with at least three preferred NSAIDs; and*
2. *Requests for a non-preferred extended release NSAID must document previous trials and therapy failures with three preferred NSAIDs, one of which must be the preferred immediate release NSAID of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance.*

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

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

Proton Pump Inhibitors: The Commission discussed prior authorization criteria as follows and discussed next steps:

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

Requests for PPIs exceeding one unit per day will be considered for the following

diagnoses with additional documentation regarding the medical necessity:

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

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

Criteria under #5 will be simplified, possibly to allow for failure on once-daily dosing at maximum daily dose, and potentially requiring higher once-a-day dosing prior to letting them go to twice daily. Pam Smith will look at current guidelines, and bring adjusted proposed criteria back to the next meeting.

Alpha$_2$ Agonists, Extended Release: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for extended-release alpha$_2$ agonists. Payment will be considered for patients when the following is met:

1. *The patient has a diagnosis of ADHD and is between 6 and 17 years of age; and*
2. *Previous trial with the preferred immediate release product of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance; and*
3. *Previous trial and therapy failure at a therapeutic dose with one preferred amphetamine and one preferred non-amphetamine stimulant.*

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 remove the criteria as recommended, but keep the ProDUR age edit, and Chuck Wadle seconded. All members were in favor. A claim for a preferred alpha$_2$ agonist, extended release, will adjudicate when the member is between 6 and 17 years of age (and meets already established quantity limits); requests for a non-preferred

agent will require prior authorization. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Elagolix/Estradiol/Norethindrone Acetate (Oriahnn): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for elagolix containing drugs. Payment will be considered for patients when the following is met:

1. *Pregnancy has been ruled out; and*
2. *Patient does not have osteoporosis; and*
3. *Patient does not have severe hepatic impairment; and*
4. *Patient is not taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g. cyclosporine and gemfibrozil); and*
5. *Requests for elagolix (Orilissa) will be considered under the following conditions:*
    a. *Patient has a diagnosis of moderate to severe pain associated with endometriosis; and*
    b. *Patient has documentation of a previous trial and therapy failure with at least one preferred oral NSAID and at least one preferred 3-month course of a continuous hormonal contraceptive taken concurrently; and*
    c. *Patient has documentation of a previous trial and therapy failure with a preferred GnRH agonist.*
    d. *Initial requests will be considered for 3 months. Additional requests will be considered upon documentation of improvement of symptoms.*
    e. *Requests will be considered for a maximum of 24 months for the 150mg dose and six (6) months for the 200mg dose; or*
6. *Requests for elagolix, estradiol, and norethindrone acetate; elagolix (Oriahnn) will be considered under the following conditions:*
    a. *Patient is premenopausal; and*
    b. *Patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); and*
    c. *Patient has documentation of a previous trial and therapy failure with at least one preferred 3-month course of a continuous hormonal contraceptive; and*
    d. *Patient has documentation of a previous trial and therapy failure with tranexamic acid.*
    e. *Initial requests will be considered for 6 months. Additional requests will be considered upon documentation of improvement of symptoms.*
    f. *Requests will be considered for a maximum of 24 months treatment.*

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

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

Select Anticonvulsants: The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient meets the FDA approved age for submitted diagnosis and drug; and*
2. *Patient has an FDA approved or compendia indicated diagnosis, for requested drug, of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex, with documentation of an adequate trial and inadequate response with at least two preferred concomitant antiepileptic drugs (AEDs), if available; and*
3. *Is prescribed by or in consultation with a neurologist; and*
4. *Patient's current weight is provided; and*
5. *Follows FDA approved dosing for indication and drug. The total daily dose does not exceed the following:*
    a. *Cannabidiol*
        i. *Lennox-Gastaut syndrome or Dravet syndrome: 20 mg/kg/day; or*
        ii. *Tuberous sclerosis complex: 25 mg/kg/day; or*
    b. *Fenfluramine*
        i. *With concomitant stiripentol (plus clobazam): 0.4 mg/kg/d with a maximum of 17 mg per day; or*
        ii. *Without concomitant stiripentol: 0.7 mg/kg/day with a maximum of 26 mg per day; or*
    c. *Stiripentol*
        i. *Prescribed concomitantly with clobazam; and*
        ii. *50 mg/kg/day with a maximum of 3,000 mg/day.*

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

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

Risdiplam (Evrysdi): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient has a diagnosis of spinal muscular atrophy (SMA); and*
2. *Patient meets the FDA approved age for diagnosis; and*
3. *Dosing follows FDA approved dose for age and weight; and*
4. *A negative pregnancy test for females of reproductive potential prior to initiating treatment; and*

5. *Female patients of reproductive potential have been advised to use effective contraception during treatment and for at least 1 month after last dose and male patients of reproductive potential have been counseled on the potential effects on fertility; and*
6. *Patient does not have impaired liver function; and*
7. *Will not be prescribed concomitantly with other SMA treatments, such as Spinraza (nusinersen), Zolgensma (onasemnogene abeparvovec), or any other new products that are approved by the FDA and released; and*
8. *Documentation of previous SMA therapies and response to therapy is provided; and*
    a. *For patients currently on Spinraza, documentation Spinraza will be discontinued is provided, including date of last dose, and the appropriate interval based on the dosing frequency of the other drug has been met (i.e. 4 months from the last dose when on maintenance therapy); or*
    b. *For patients treated with Zolgensma, requests will not be considered; and*
9. *Is prescribed by or in consultation with a neurologist; and*
10. *Pharmacy will educate the member, or member's caregiver, on the storage and administration of Evrysdi, as replacements for improper storage or use will not be authorized.*

If the criteria for coverage are met, requests will be approved for 1 year. Requests for continuation of therapy will require documentation of a positive response to therapy including stabilization or improved function unless intercurrent event (fracture, illness, other) affects functional testing.

Jason Kruse motioned to accept the criteria as amended, and Jason Wilbur seconded. All members were in favor. As additional changes had been recommended during this second review, these criteria will be reviewed again at the next meeting prior to the recommendation being sent to the Department for consideration.

Satralizumab-mwge (Enspryng): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD); and*
2. *Patient is anti-aquaporin 4 (AQP4) seropositive (attach documentation); and*
3. *Patient meets the FDA approved age and dosing; and*
4. *Patient has a history of at least 1 relapse in the previous 12 months prior to initiation of therapy; and*
5. *Patient has been tested for tuberculosis prior to the initiation of therapy and does not have active or untreated latent tuberculosis; and*

6. *Patient has been tested for hepatitis B virus (HBV) prior to the initiation of therapy and confirmed negative for active HBV; and*
7. *Prescribed by a neurologist.*

If criteria for coverage are met, initial requests will be given for 1 year. Additional authorizations will be considered upon documentation of clinical response to therapy (i.e. a reduction in the frequency of relapse).

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

Miscellaneous

DUR Digest: The Commission members conducted the second review of the draft DUR Digest Volume 33, Number 1. Typos showing the word serious as serous will be corrected before posting.

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

At 12:36, Jason Kruse motioned to adjourn, and Chuck Wadle seconded. All in attendance agreed.

The next scheduled meeting is set for May 5, 2021, and will be a virtual meeting.