Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes August 7, 2019

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; Jason Wilbur, M.D. Chuck Wadle, D.O.; and Susan Parker, Pharm.D.
Staff
Pam Smith, R.Ph.
Guests
Erin Halverson, R.Ph., IME; Melissa Biddle, IME; and Sandy Pranger, R.Ph., Amerigroup.

Welcome & Introductions

Chairperson Brett Faine called the meeting to order at 9:33 a.m. in Capitol Room 116 in Des Moines. The minutes from the May 1, 2019 meeting were reviewed. Jason Wilbur motioned to accept them, and Jason Kruse seconded. All members were in favor. The recommendation letter sent to DHS after the last meeting was also reviewed. Members were asked to complete their annual conflict of interest disclosures. Jason Wilbur motioned to retain Brett Faine as chairperson and Kellen Ludvigson as vice-chairperson. Mark Graber seconded, and all members in attendance were in favor. Following up from previous meetings, Pam Smith announced that CMS had finally provided guidance on H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act. The associated required edits and/or Pro-DUR or retrospective initiatives will likely result in some additional DUR reviews in the future, though DHS will do what is required to meet the given deadlines and then potentially strengthen the criteria through DUR input down the line, given the time constraints and length of time between DUR meetings.

IME Pharmacy Update

House File 623 removed prior authorization requirements for Medication Assisted Treatment (MAT); DHS is currently in the process of creating rules to allow at least one form of MAT medication without PA, effective February 1, 2020. Susan Parker suggested Retro DUR actions to control these medications due to the process needed to follow the State Plan Amendment for opioids. There is still an opening for a pharmacist on the DUR Commission, hopefully filled by the November meeting. DHS is in the process of reviewing applications and conducting interviews.

MCO Prevalence Report Summary and Updates

Amerigroup: Sandy Pranger provided an overview for Amerigroup's statistics from March 2019 through May 2019, including: a breakdown of utilization by age and gender, top 100 pharmacies by prescription count, top 100 pharmacies by paid amount, top 100 prescribing providers by prescription count, and top 100 prescribing providers by paid

amount. The Bi-Monthly Statistics report reflected that expenditures totaled $57,404,281, a 12.5% increase from the total for December through February. Similar to previous reports, the top 5 therapeutics classes by paid amount were: ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; Antidiabetics; Antipsychotics/Antimanic Agents; Antiasthmatic and Bronchodilator Agents; and Analgesics – Anti-Inflammatory. The following were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Antihypertensives, and Ulcer Drugs/Antispasmodics/ Anticholinergics. Vyvanse was the most expensive medication, followed by Concerta, Humira Pen, Latuda, and Humalog. Omeprazole had the highest prescription count, followed by: levothyroxine sodium, lisinopril, atorvastatin calcium, and sertraline hcl.

United Healthcare Community Plan: Commission members were provided written summaries that included United's statistics from March 2019 through May 2019, and were encouraged to contact Pam Smith with any questions, now that United Healthcare is no longer a contracted managed care organization for Iowa Medicaid.

Fee-for-Service Prevalence Report Summary

Pam Smith provided an overview of fee-for-service statistics from March 2019 through May 2019, including: total amount paid ($3,098,407), cost per user ($293.49), and number of total prescriptions dispensed (46,830). There were 10,557 unique users, which is 7.8% more than the total for December through February. The top 5 therapeutics classes by paid amount were: Anticonvulsants; Anti-Inflammatories, Non-NSAID; Antipsychotics – Atypicals; Diabetic – Insulin Penfills; and Antiretroviral Combinations. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Beta-Lactams/Clavulanate Combos; and Narcotics – Miscellaneous. The top 100 drugs were also reviewed, by paid amount and prescription count. The ten most expensive medications were: Vyvanse, Concerta, Epclusa, Humira Pen, Biktarvy, Tamiflu, Humalog, Invega Systenna, Novolog Flexpen, and ProAir HFA. The five drugs with the highest prescription count were: amoxicillin, sertraline hcl, lisinopril, gabapentin, and trazodone hcl.

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 $154,673,364 was spent in total for 292,611 unique users who had 2,045,840 prescriptions.

Public Comment

In addition to the written public comments provided to Commission members as part of their meeting materials, they heard oral public comment from the speakers listed below. Also, in response to the written comment regarding Zyvox, Brett Faine requested that the criteria for that be brought back to the next meeting for review.

Name	Representing	Drug/Topic
Maggie Murphy	Teva	Ajovy
Tammy Sova	Biogen	Tecfidera

Christina Brandmejer	Amgen	CGRP Inhibitors
Joseph Cirrincione	Otsuka	Abilify MyCite
Kevin Duhrkopf	Sanofi Genzyme	Dupixent
Kerri Hoernemann	Novartis	Mayzent

ProDUR Edits

Gabapentin Quantity Limit: To reduce the risk of misuse and abuse of both gabapentin and pregabalin, a recommendation was made to implement ProDUR quantity limits based on maximum recommended daily doses in addition to programming for both gabapentin and pregabalin based on maximum milligrams per day across all the different strengths of each drug. Jason Wilbur made the motion to accept the recommendation, and Jason Kruse seconded. The decision was unanimous. Mark Graber also suggested using this for a possible retrospective DUR study. FFS and MCOs will run numbers to see how many members are utilizing gabapentin and pregabalin concurrently and bring the results back as requested to a future meeting.

Initial Seven Day Opioid Supply Limit: At the May meeting, the Commission recommended a POS hard edit that could be overridden with DUR codes should be implemented, with a 60-day look-back on member claims. 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.

Retrospective DUR Proposals

Overutilization of Short-Acting Beta$_2$-Agonist Inhalers in Patients with Asthma: FFS and MCOs will run numbers to see how many members have gotten 3,4,5, or 6+ canisters within a six-month time frame. Current quantity limits allow 3 albuterol inhalers per month. Mark Graber suggested a retrospective study to identify members using both canisters and nebulizer solutions, and he also asked if data could be run to see how many members were on controller medications. Jason Kruse requested that those with multiple providers be flagged. Data will be brought back to a future meeting.

CNS Stimulant Therapy without Indication: FFS and MCOs will run numbers to identify members with no diagnosis codes in their histories, breaking them into groups under 21 years of age and 21 and older, and looking back at 12 months of medical claims (to catch the diagnosis codes) and 2 months of pharmacy claims (to identify the stimulants). Prior authorization including diagnosis code is already required for adults. Melissa Klotz suggested that summer months be avoided for the pharmacy claim histories, as children often skip taking stimulants during summer break. Data will be brought back to a future meeting.

The Commission took a short break; open session resumed at 11:03.

Prior Authorization

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

For patients initiating therapy with a preferred oral medication, a manual prior

authorization 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. *Patient meets the FDA approved age; and*
3. *Request is for FDA approved dosing; and*
4. *A previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis.*
5. *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.

For patients initiating therapy with fingolimod (Gilenya):

1. *Patient does not have a recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization or Class lll/lV heart failure; and*
2. *Patient does not have a history or presence of Mobitz Type ll 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a pacemaker; and*
3. *Patient does not have a baseline QTc interval ≥ 500ms; and*
4. *Patient is not being treated with Class Ia or Class lll anti-arrhythmic drugs.*

For patients initiating therapy with teriflunomide (Aubagio):

1. *Patient does not have severe hepatic impairment; and*
2. *A negative pregnancy test for females of childbearing age; and*
3. *Use of a reliable form of contraception for females of childbearing age; and*
4. *Patient is not taking leflunomide.*

For patients initiating therapy with dimethyl fumarate (Tecfidera):

1. *Patient does not have a low lymphocyte count as documented by a recent (within 6 months) CBC prior to initiating therapy; and*
2. *Upon renewal, documentation of an updated CBC.*

For patients initiating therapy with cladribine (Mavenclad):

1. *Patient's current weight is provided; and*
2. *Patient does not have a current malignancy and patient is up to date on all age appropriate malignancy screening; and*
3. *Pregnancy has been excluded in females of reproductive potential; and*

4. *Women and men of reproductive potential must use effective contraception during treatment and for 6 months after the last dose in each treatment course; and*
5. *Women must not intend to breastfeed while being treated and for 10 days after the last dose; and*
6. *Patient does not have HIV infection; and*
7. *Patient does not have active chronic infection (e.g. hepatitis or tuberculosis); and*
8. *No more than two yearly treatment courses (i.e. two treatment courses consisting of two treatment cycles) will be considered.*

For patients initiating therapy on siponimod (Mayzent):

1. *Patient does not have a CYP2C9*3/*3 genotype; and*
2. *Patient does not have a recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure; and*
3. *Patient does not have a presence of Mobitz Type II 2nd degree, 3rd degree AV block or sick sinus syndrome, unless the patient has a functioning pacemaker.*

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

Ospemifene (Osphena): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for ospemifene (Osphena). Requests for a diagnosis of moderate to severe dyspareunia are considered not medically necessary and will be denied. Payment will be considered under the following conditions:

1. *Patient is a post-menopausal woman with a diagnosis of moderate to severe vaginal dryness due to vulvar and vaginal atrophy; and*
2. *Patient has documentation of an adequate trial and therapy failure with a preferred vaginal estrogen agent; and*
3. *Patient does not have any contraindications to ospemifene as listed in the FDA approved label; and*
4. *Will not be used with estrogens, estrogen agonist/antagonists, fluconazole, or rifampin; and*
5. *Patient does not have severe hepatic impairment (Child-Pugh Class C); and*
6. *Patient will be evaluated periodically as clinically appropriate to determine if treatment is still necessary as ospemifene should be used for the shortest duration consistent with treatment goals and risks for the individual woman; and*
7. *Dose does not exceed the FDA approved dose.*

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

Initial requests will be approved for 3 months. Additional prior authorizations will be considered upon documentation of clinical response to therapy.

Kellen Ludvigson motioned to accept the criteria as amended, and Melissa Klotz seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion. Additionally, Pam Smith will look into whether any over-the-counter products are rebate eligible, and if trials of those could be required if so.

Abilify MyCite: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for aripiprazole tablets with sensor (Abilify MyCite). Payment will be considered under the following conditions:

1. *Patient has a diagnosis of Schizophrenia, Bipolar I Disorder, or Major Depressive Disorder; and*
2. *Patient meets the FDA approved age for use of the Abilify MyCite device; and*
3. *Dosing follows the FDA approved dose for the submitted diagnosis; and*
4. *Documentation of patient adherence to generic aripiprazole tablets is less than 80% within the past 6 months (prescriber must provide documentation of the previous 6 months' worth of pharmacy claims for aripiprazole documenting non-adherence); and*
5. *Documentation all the following strategies to improve patient adherence have been tried without success:*
    a. *Utilization of a pill box*
    b. *Utilization of a reminder device (e.g. alarm, application, or text reminder)*
    c. *Involving family members or friends to assist*
    d. *Coordinating timing of dose with dosing of another daily medication; and*
6. *Documentation of a trial and intolerance to the long-acting injectable Abilify Maintena; and*
7. *Prescriber agrees to track and document adherence of Abilify MyCite through the web-based portal for health care providers and transition member to generic aripiprazole tablets after a maximum of 4 months use of Abilify MyCite. Initial approvals will be given for one month. Prescriber must review member adherence in the web-based portal and document adherence for additional consideration. If non-adherence continues, prescriber must document a plan to improve adherence. If adherence is improved, consideration to switch member to generic aripiprazole tablets*

must be considered. Note, the ability of the Abilify MyCite to improve patient compliance has not been established.

8. *Requests will not be considered for patients in long-term care facilities.*
9. *A once per lifetime approval will be allowed.*

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

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

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

Prior authorization is required for CGRP Inhibitors. Payment will be considered for a FDA approved or compendia indicated diagnosis under the following conditions:

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

5. *For Episodic Cluster Headache, patient has documentation of*
    a. *A previous trial and therapy failure at an adequate dose with glucocorticoids (prednisone 30mg per day or dexamethasone 8mg BID) started promptly at the start of a cluster period. Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamine, lidocaine) at least once daily for at least two days per week after the first full week of adequately dosed steroid therapy; and*
    b. *A previous trial and therapy failure at an adequate dose of verapamil for at least 3 weeks (total daily dose of 480 mg to 960 mg). Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamines, lidocaine) at least once daily for at least two days per week after three weeks of adequately dosed verapamil therapy.*
6. *The requested dose does not exceed the maximum FDA labeled dose for the submitted diagnosis; and*
7. *Lost, stolen, or destroyed medication replacement requests will not be authorized.*

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

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

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

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

Prior authorization is required for non-preferred benzodiazepines. Payment for non-preferred benzodiazepines will be authorized in cases with documentation of previous trial and therapy failure with two preferred products. If a long-acting medication is requested, one of the therapeutic trials must include the immediate release form of the requested benzodiazepine. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determine if the use of a benzodiazepine is appropriate for this member.

Prior authorization will be approved for up to 12 months for documented:

1. *Generalized anxiety disorder.*

2. *Panic attack with or without agoraphobia.*
3. *Seizure.*
4. *Non-progressive motor disorder.*
5. *Dystonia.*

Prior authorization requests will be approved for up to a three-month period for all other diagnoses related to the use of benzodiazepines.

For patients taking concurrent opioids, the prescriber must document the following:

1. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
2. *Documentation as to why concurrent use is medically necessary is provided; and*
3. *A plan to taper the opioid or benzodiazepine is provided, if appropriate.*

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

Chuck Wadle questioned if psychiatric therapy should be added as a requirement, but ultimately, 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.

Lupron Depot – Adult: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Lupron Depot (leuprolide acetate). Payment will be considered for patients under the following conditions:

1. *Patient meets the FDA approved age; and*
2. *Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and*
3. *Patient has a diagnosis of endometriosis for which concurrent therapy with a preferred NSAID and at least one preferred 3 month continuous course of hormonal contraceptive has failed; or*
4. *Patient has a diagnosis of uterine leiomyomata with anemia (hematocrit < 30 g/dL or hemoglobin < 10 g/dL) that did not respond to treatment with at least a one month trial of iron and is to be used preoperatively; or*
5. *Patient has a diagnosis of advanced prostate cancer.*

Therapy will be limited as follows:

1. *Endometriosis – initial 6 month approval. If symptoms of endometriosis recur after the first course of therapy, a second course of therapy with concomitant norethindrone acetate 5 mg daily will be considered. Retreatment is not recommended for longer than one additional 6 month course.*
2. *Uterine leiomyomata – 3 month approval.*

3. *Advanced prostate cancer – initial 6 month approval. Renewal requests must document suppression of testosterone levels towards a castrate level of < 50 ng/dL (attach lab).*

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.

Dupilumab (Dupixent): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient is within the FDA labeled age for indication; and*
2. *Patient has a diagnosis of moderate-to-severe atopic dermatitis; and*
    a. *Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and*
    b. *Patient has failed to respond to good skin care and regular use of emollients; and*
    c. *Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*
    d. *Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
    e. *Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and*
    f. *Patient will continue with skin care regimen and regular use of emollients; or*
3. *Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) OR with oral corticosteroid dependent asthma; and*
    a. *Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and*
    b. *Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted; and*
    c. *Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g. long acting $beta_2$ agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and*
    d. *Patient must have one of the following, in addition to the regular maintenance medications defined above:*
        i. *Two (2) or more exacerbations in the previous year or*
        ii. *Require daily oral corticosteroids for at least 3 days; and*
4. *Dose does not exceed the FDA approved dosing for indication.*

If criteria for coverage are met, initial authorization will be given for 16 weeks to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy.

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.

Cannabidiol (Epidiolex): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient meets the FDA approved age; and*
2. *Baseline serum transaminases (ALT and AST) and total bilirubin levels have been obtained prior to initiating therapy (attach results); and*
3. *A diagnosis of Lennox-Gastaut syndrome with documentation of an adequate trial and inadequate response with at least two concomitant antiepileptic drugs (AEDs) from the following:*
    a. *Valproic acid,*
    b. *Lamotrigine,*
    c. *Topiramate,*
    d. *Felbamate,*
    e. *Rufinamide,*
    f. *Clobazam, or*
4. *A diagnosis of Dravet syndrome with documentation of an adequate trial and inadequate response with at least two concomitant AEDs from the following:*
    a. *Clobazam,*
    b. *Valproic acid,*
    c. *Levetiracetam,*
    d. *Topiramate, and*
5. *Is prescribed by or in consultation with a neurologist; and*
6. *The total daily dose does not exceed 20mg/kg/day.*

If criteria for coverage are met, initial requests will be approved for 3 months. Additional prior authorization requests will be considered when the following criteria are met:

1. *Documentation of clinical response to therapy (i.e. reduction in the frequency of seizures); and*
2. *The total daily dose does not exceed 20mg/kg/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.

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

Prior authorization (PA) is required for therapy with growth hormones. Requests will only be considered for FDA approved dosing. 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. 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). Payment will be considered under the following conditions:

Children with Growth Hormone Deficiency

1. *Standard deviation of 2.0 or more below mean height for chronological age; and*
2. *No expanding intracranial lesion or tumor diagnosed by MRI; and*
3. *Growth rate below five centimeters per year; and*
4. *Failure of any two stimuli tests to raise the serum growth hormone level above ten nanograms per milliliter; and*
5. *Annual bone age testing is required. A Bone age 14 to 15 years or less in females and 15 to 16 years or less in males is required; and*
6. *Epiphyses open.*

Pediatric Chronic Kidney Disease

1. *Is prescribed by or in consultation with a nephrologist; and*
2. *Standard deviation of 2.0 or more below mean height for chronological age; and*
3. *No expanding intracranial lesion or tumor diagnosed by MRI; and*
4. *Growth rate below five centimeters per year; and*
5. *Bone age of 14-15 years or less in females and 15-16 years or less in males; and*
6. *Epiphyses open.*

Turner's Syndrome

1. *Chromosomal abnormality showing Turners syndrome; and*
2. *Prescribed by or in consultation with an endocrinologist; and*
3. *Standard deviation of 2.0 or more below mean height for chronological age; and*
4. *No expanding intracranial lesion or tumor diagnosed by MRI; and*
5. *Growth rate below five centimeters per year; and*
6. *Bone age of 14-15 years or less in females and 15-16 years or less in*

males; and
7. *Epiphyses open.*

Prader Willi Syndrome
1. *Diagnosis is confirmed by appropriate genetic testing (attach results); and*
2. *Prescribed by or in consultation with an endocrinologist; and*
3. *Bone age of 14-15 years or less in females and 15-16 years or less in males; and*
4. *Epiphyses open.*

Noonan Syndrome
1. *Diagnosis is confirmed by the appropriate genetic testing (attach results); and*
2. *Prescribed by or in consultation with an endocrinologist; and*
3. *Standard deviation of 2.0 or more below mean height for chronological age; and*
4. *Bone age of 14-15 years or less in females and 15-16 years or less in males; and*
5. *Epiphyses open.*

SHOX (Short Stature Homeobox)
1. *Diagnosis is confirmed by the appropriate genetic testing (attach results); and*
2. *Prescribed by or in consultation with an endocrinologist; and*
3. *Bone age of 14-15 years or less in females and 15-16 years or less in males; and*
4. *Epiphyses open.*

Adults with Growth Hormone Deficiency
1. *Patients who were growth hormone deficient during childhood (childhood onset) and who have a continued deficiency; or*
2. *Patients who have growth hormone deficiency (adult onset) as a result of pituitary or hypothalamic disease (e.g., panhypopituitarism, pituitary adenoma, trauma, cranial irradiation, pituitary surgery); and*
3. *Failure of at least one growth hormone stimulation test as an adult with a peak growth hormone value of ≤5 mcg/L after stimulation.*

Adults with AIDS Wasting/Cachexia
1. *Greater than 10% of baseline weight loss over 12 months that cannot be explained by a concurrent illness other than HIV infection; and*
2. *Patient is currently being treated with antiviral agents; and*
3. *Patient has documentation of a previous trial and therapy failure with an appetite stimulant (i.e. dronabinol or megestrol).*

Short Bowel Syndrome

*If the request is for **Zorbtive**® [somatropin (rDNA origin) for injection] approval will be granted in patients receiving specialized nutritional support. Zorbtive® therapy should be used in conjunction with optimal management of Short Bowel Syndrome. PA will be considered for a maximum of 4 weeks.*

If the criteria for coverage is met, initial requests will be given for 12-months, unless otherwise stated above. Additional prior authorizations will be considered upon documentation of clinical response to therapy and patient continues to meet the criteria for the submitted diagnosis.

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

Miscellaneous

DUR Digest: The Commission members conducted the initial review of the draft DUR Digest Volume 32, Number 1.

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

At 11:55, Chuck Wadle motioned to adjourn, and Jason Kruse seconded. All in attendance agreed.

The next meeting will be held at 9:30 a.m. on Wednesday, November 6, 2019, at the Iowa State Capitol, Room 116.