IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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June 3, 2015

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Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, June 3, 2015. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Hepatitis C Agents; CNS Stimulants and Atomoxetine; Dextromethorphan/Quinidine (Nuedexta®); Chronic Pain Syndromes; and Sedative/Hypnotics – Non-Benzodiazepines. The Commission also received feedback from the Mental Health Advisory Group (MHAG) regarding proposed quantity limits for stimulant medications and the ProDUR edits on antipsychotics in children. The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments received from the medical/pharmacy associations in response to an April 7, 2015 letter that was sent to them detailing the proposed criteria for Hepatitis C Agents; CNS Stimulants and Atomoxetine; Dextromethorphan/Quinidine (Nuedexta®); Chronic Pain Syndromes; and Sedative/Hypnotics – Non-Benzodiazepines.

Hepatitis C Agents

Proposed Prior Authorization Criteria (*changes italicized*)
Prior authorization is required for *hepatitis C treatments*. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

1. Patient is 18 years of age or older *and has a diagnosis of chronic hepatitis C*; and
2. *Patient has had testing for hepatitis C virus (HCV) genotype; and*
3. *Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment*; and
4. Viral load will be submitted by prescriber 12 weeks after the completion of therapy; and
5. Patient has advanced liver disease corresponding to a Metavir score of 3 or

greater fibrosis as confirmed by one of the following:
- Liver biopsy confirming a Metavir score ≥ F3; or
- Transient elastography (FibroScan) score ≥ 9.5kPa; or
- FibroSURE (FibroTest) score ≥ 0.58; or
- APRI score > 1.5; or
- Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension); or
- Physical findings or clinical evidence consistent with cirrhosis; *or*
- *Patients at highest risk for severe complications: organ transplant, type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis), proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis.*

6. Patient's prior treatment history is provided (treatment naïve or *treatment experienced*; and
7. If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and
8. Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test; and
9. *Patient does not have severe renal impairment (creatinine clearance <30ml/min) or end stage renal disease requiring hemodialysis; and*
10. *HCV treatment is prescribed by a digestive disease, liver disease, or infectious disease provider practice; and*.
11. For patients on a regimen containing ribavirin, the following must be documented on the PA form:
    a) Patient is not a pregnant female or a male with a pregnant female partner; and
    b) Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and
    c) Monthly pregnancy tests *will be* performed during treatment; and
12. *Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the HCV medication.*
13. *Documentation is provided for patients who are ineligible to receive interferon or ribavirin.*
14. Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved.
15. If patient is recently eligible for Iowa Medicaid, and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on established length of therapy for the particular treatment (defined below).
16. Lost or stolen medication replacement requests will not be authorized.
17. The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.

CNS Stimulants and Atomoxetine

Proposed Prior Authorization Criteria (*changes italicized*)
Prior authorization (PA) is required for *CNS stimulants and Atomoxetine* for patients 21 years of age or older. *Prior to requesting prior authorization for any covered diagnosis, the prescriber must review the patient's use of controlled substances on the Iowa*

Prescription Monitoring Program website at https://pmp.iowa.gov/IAPMPWebCenter/. Payment for CNS stimulants and Atomoxetine will be considered under the following conditions:

1. Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-*5* criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV). Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more *current* environments (social, academic, or occupational). *Documentation of a recent clinical visit that confirms the patient continues to require medication to treat the symptoms of ADD/ADHD will be required for renewals or patients newly eligible that are established on medication to treat ADD/ADHD.*
2. Narcolepsy with diagnosis confirmed with a recent sleep study (ESS, MSLT, PSG).
3. Excessive sleepiness from obstructive sleep apnea/hypopnea syndrome (OSAHS) with documentation of non-pharmacological therapies tried (weight loss, position therapy, CPAP at maximum titration, BiPAP at maximum titration or surgery) and results from a recent sleep study (ESS, MSLT, PSG) with the diagnosis confirmed by a sleep specialist.
4. *Binge Eating Disorder (Vyvanse only)*
    - *Patient is 18 to 55 years of age; and*
    - *Patient meets the DSM-5 criteria for Binge Eating Disorder; and*
    - *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*
    - *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*
    - *Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with topiramate and fluvoxamine*
    - *Prescription is written by a psychiatrist or psychiatric nurse practitioner; and*
    - *Patient has a BMI of 25 to 45; and*
    - *Patient does not have personal history of cardiovascular disease; and*
    - *Patient has no history of substance abuse; and*
    - *Is not being prescribed for the treatment of obesity or weight loss; and*
    - *Doses above 70mg per day will not be considered.*
    - *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.*

    <u>DSM-5 Criteria</u>

    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

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. *If a non-preferred long-acting medication is requested, a trial *with* the preferred immediate release and extended release product of the same chemical entity *(methylphenidate class) or chemically related agent (amphetamine class)* is required.

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

Dextromethorphan/Quinidine (Nuedexta)

Proposed Prior Authorization Criteria (*changes italicized*)
Prior authorization is required for Nuedexta®. Payment will be considered under the following conditions:

1. Patients must have a diagnosis of pseudobulbar affect (PBA) secondary to *a neurological condition*.
2. A trial and therapy failure at a therapeutic dose with amitriptyline or an SSRI; *and*
3. *Patient has documentation of a current EKG (within the past 3 months) without QT prolongation.*
4. Initial authorizations will be approved for 12 weeks with a baseline Center for Neurologic Studies Lability Scale (CNS-LS) questionnaire.
5. Subsequent prior authorizations will be considered at 6 month intervals with documented efficacy as seen in an improvement in the CNS-LS questionnaire.

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

Chronic Pain Syndromes

Proposed Prior Authorization Criteria (*changes italicized*)
A prior authorization is required for pregabalin (Lyrica®) and milnacipran (Savella™). *These drugs will be considered for their FDA indication(s) and other conditions as listed*

in the compendia. Requests for doses above the manufacturer recommended dose will not be considered. For patients with a chronic pain diagnosis who are currently taking opioids, as seen in pharmacy claims, a plan to decrease and/or discontinue the opioid(s) must be provided with the initial request. Initial authorization will be given for three (3) months. There must be a significant decrease in opioid use or discontinuation of opioid(s) after the initial three (3) month authorization for further approval consideration. Additional prior authorizations will be considered with documentation of a continued decrease in opioid utilization. Payment will be considered under the following conditions:

1. A diagnosis of **fibromyalgia** (Lyrica® and Savella™)
    a. A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following *preferred generic agents*: tricyclic antidepressant or SNRI, **WITH**
    b. Documented non-pharmacologic therapies (cognitive behavior therapies, exercise, etc.).
2. A diagnosis of **postherpetic neuralgia** (Lyrica®)

    A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, topical lidocaine, or valproate.
3. A diagnosis of **diabetic peripheral neuropathy** (Lyrica®)

    A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, *duloxetine* or topical lidocaine.
4. A diagnosis of **partial onset seizures**, as adjunct therapy (Lyrica®)

Sedative/Hypnotics Non-Benzodiazepines

Proposed Prior Authorization Criteria (*changes italicized*)

Preferred agents are available without prior authorization (PA). *Requests for doses above the manufacturer recommended dose will not be considered.* Prior authorization is required for all non-preferred non-benzodiazepine sedative/hypnotics. Payment for non-preferred non-benzodiazepine sedative/hypnotics will be authorized only for cases in which there is documentation of previous trial*s* and therapy failure*s* with, *at a minimum*, *three (3)* preferred agents. Payment for non-preferred non-benzodiazepine sedative/hypnotics will be considered when the following criteria are met:

1. A diagnosis of insomnia*; and*
2. Medications with a side effect of insomnia (i.e. stimulants) are decreased in dose, changed to a short acting product, and/or discontinued; *and*
3. Enforcement of good sleep hygiene is documented; and
4. All medical, neurological, and psychiatric disease states causing chronic insomnia are being adequately treated with appropriate medication at therapeutic doses.
5. *In addition to the above criteria, requests for suvorexant (Belsomra) will require documentation of a trial and therapy failure with at least one non-preferred agent, other than suvorexant, prior to consideration of coverage.*
6. *Non-preferred alternative delivery systems will only be considered for cases in which the use of the alternative delivery system is medically necessary and there is a previous trial and therapy failure with a preferred alternative delivery system if available.*

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

Additionally, the DUR Commission received feedback from the MHAG regarding the proposed quantity limits on select CNS stimulants and proposed prior authorization criteria for CNS stimulants and atomoxetine. The DUR took the recommendation of the MHAG to keep the quantity limit for Concerta 54mg (brand and generic) at the current quantity limit of 60 tablets per 30 days, as literature supports the use of this dose. The DUR also clarified the requirement for prescribers to check the Iowa PMP website, and recommended it should apply to quantity limit override requests as well. Below are the recommended quantity limits on select CNS stimulants:

Drug (applies to brand and generic)	**Proposed Quantity Limit**	**Current Quantity Limit**
Adderall IR 12.5mg	90	120
Adderall IR 20mg	90	120
Concerta 18mg	30	60
Concerta 27mg	30	60
Focalin IR 2.5mg	60	None
Focalin IR 5mg	60	None
Focalin IR 10mg	60	None
Focalin XR 5mg	30	60
Focalin XR 10mg	30	60
Focalin XR 15mg	30	90
Focalin XR 20mg	30	60
Focalin XR 25mg	30	60
Focalin XR 30mg	30	60
Ritalin IR 5mg	90	None
Ritalin IR 10mg	90	None
Ritalin IR 20mg	90	None

The DUR Commission also received feedback from the MHAG regarding the ProDUR edits on Antipsychotics in children. While they appreciate the comments from the MHAG, they feel no changes to the initial recommendations are needed.

Finally, the DUR Commission made the recommendation in February to implement a quantity limit of 120 units per 30 days for all strengths of alprazolam, clonazepam, and lorazepam after letters were mailed to prescribers of members identified as exceeding the recommended quantity limit. The data was refreshed to use current claims data and letters were mailed at the end of February.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Hepatitis C Agents; CNS Stimulants and Atomoxetine; Dextromethorphan/Quinidine (Nuedexta®); Chronic Pain Syndromes; and Sedative/Hypnotics – Non-Benzodiazepines and quantity limits for CNS stimulants and benzodiazepines

Sincerely,

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