IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
1305 East Walnut – Des Moines, IA 50309 □ (515) 974-3131 □ Fax 1-866-626-0216

Brett Faine, Pharm.D.
Melissa Klotz, Pharm.D.
Jason Kruse, D.O
Kellen Ludvigson, Pharm.D.
Susan Parker, R.Ph., Pharm.D.
Jason Wilbur, M. D.
Charles Wadle, D.O.
John Ellis, Pharm.D.
Lisa Todd, Pharm.D.

Professional Staff: Pam Smith, R.Ph.
DUR Project Coordinator

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Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
1305 East Walnut
Des Moines, Iowa 50309

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, August 4, 2021. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Proton Pump Inhibitors; Initial Days' Supply Limit Override; Mannitol Inhalation Powder (Bronchitol); Vesicular Monoamine Transporter (VMAT) 2 Inhibitors; and removal of PA criteria for Valsartan/Sacubitril (Entresto). In addition, the DUR Commission discussed ProDUR quantity limits for valsartan/sacubitril (Entresto); budesonide/formoterol (Symbicort); and mometasone/formoterol (Dulera). The following recommendations have been made by the DUR Commission:

Comments were received and reviewed from the medical/pharmacy associations in response to a May 11, 2021 letter that was sent to them detailing the proposed criteria for Proton Pump Inhibitors; Initial Days' Supply Limit Override; Mannitol Inhalation Powder (Bronchitol); Vesicular Monoamine Transporter (VMAT) 2 Inhibitors; removal of PA criteria for Valsartan/Sacubitril (Entresto); and the ProDUR quantity limits for valsartan/sacubitril (Entresto); budesonide/formoterol (Symbicort); and mometasone/formoterol (Dulera).

Proton Pump Inhibitors

Current Clinical Prior Authorization Criteria
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.

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
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*, Erosive esophagitis, or Peptic stricture* (Please fax a copy of the scope results with the initial request)*; or*
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)*; or*
4. Recurrent peptic ulcer disease*; or*
5. Gastroesophageal reflux disease will be considered after documentation of a therapeutic trial and therapy failure with *the requested PPI at maximal dose within the established quantity limit of one unit per day.* ~~concomitant use of once daily PPI dosing and a bedtime dose of a histamine H2-receptor antagonist~~. ~~Upon failure of combination therapy, subsequent~~ ~~r~~*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 *dose reduction* ~~retrial of~~ *to* 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*; or*
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.

Initial Days' Supply Limit Override

Newly Proposed Prior Authorization Criteria
Requests for medications exceeding the initial days' supply limit require prior authorization. Payment will be considered under the following conditions:

1. Diagnosis is provided; and
2. Medical rationale for exceeding the initial days' supply limit is provided; and
3. Requests for opioids exceeding the 7 day initial supply limit will be considered:

a. For patients with active cancer, patients experiencing acute sickle cell crises, end-of-life/palliative care, or on an individual case-by-case basis based on medical necessity documentation provided; and
b. Request must meet all other opioid requirements (quantity limits, morphine milligram equivalents (MME), and the preferred drug list (PDL). If requests do not comply with these requirements, separate, additional, prior authorization is required. Please reference and use the following prior authorization (PA) forms at www.iowamedicaidpdl.com where appropriate:
    i. Quantity Limit Override Form (exceeds established quantity limit)
    ii. High Dose Opioid PA Form (exceeds established MME limit)
    iii. Short-Acting Opioids PA Form (non-preferred short-acting opioids)
    iv. Long-Acting Opioids PA Form (non-preferred long-acting opioids); or

4. Requests for non-opioid drugs subject to the initial days' supply limit will be considered on an individual case-by-case basis, based on medical necessity documentation provided.

Mannitol Inhalation Powder (Bronchitol)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for mannitol inhalation powder (Bronchitol). Payment will be considered when the following criteria are met:

1. Patient has a diagnosis of cystic fibrosis; and
2. Patient meets the FDA approved age; and
3. Prescriber is a cystic fibrosis specialist or pulmonologist; and
4. Documentation is provided that patient has successfully completed the Bronchitol tolerance test (BTT); and
5. Patient will pre-medicate with a short-acting bronchodilator; and
6. Dose does not exceed the FDA approved dose.

If the criteria for coverage are met, an initial authorization will be given for 6 months. Additional approvals will be granted if the following criteria are met:

1. Adherence to mannitol inhalation powder (Bronchitol) therapy is confirmed; and
2. Patient has demonstrated improvement or stability of disease symptoms, such as improvement in FEV_1, decrease in pulmonary exacerbations, decrease in hospitalizations, or improved quality of life.

Vesicular Monoamine Transporter (VMAT) 2 Inhibitors

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for VMAT 2 inhibitors. Payment for non-preferred agents will be considered only for cases in which there is documentation of previous trial and therapy failure with a preferred agent (when applicable, based on diagnosis). Payment will be considered under the following conditions:

Tardive Dyskinesia (Ingrezza or Austedo)

1. Patient meets the FDA approved age; and
2. Patient has a diagnosis of tardive dyskinesia (TD) based on the presence of ALL of the following:
    a. Involuntary athetoid or choreiform movements
    b. Documentation or claims history of current or prior chronic use (≥ 3 months or 1 month in patients ≥ 60 years old) of a dopamine receptor blocking agent

(e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.)
    c. Symptoms lasting longer than 4-8 weeks; and
3. Prescribed by or in consultation with a neurologist or psychiatrist; and
4. Prescriber has evaluated the patient's current medications for consideration of a dose reduction, withdrawal, or change of the dopamine receptor blocking agent causing the TD; and
5. Documentation of baseline AIMS (Abnormal Involuntary Movement Scale) Score (attach AIMS); and
6. For Ingrezza:
    a. Will not be used concurrently with MAO inhibitors (e.g., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine, etc.) or strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, phenobarbital, rifampin and related agents, St. John's wort, etc.); and
    b. Will not be used concurrently with other vesicular monoamine transporter 2 (VMAT2) inhibitors; and
    c. Is prescribed within the FDA approved dosing; or
7. For Austedo:
    a. Patient is not suicidal, or does not have untreated/inadequately treated depression;
    b. Patient does not have hepatic impairment;
    c. Will not be used concurrently with MAO inhibitors, reserpine, or other VMAT2 inhibitors; and
    d. Patients that are taking a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) or are poor CYP2D6 metabolizers, the daily dose does not exceed 36mg per day (18mg twice daily); and
    e. Is prescribed within the FDA approved dosing.

If criteria for coverage are met, initial requests will be given for 3 months. Continuation of therapy will be considered when the following criteria are met:

1. Patient continues to meet the criteria for initial approval; and
2. Documentation of improvement in TD symptoms as evidenced by a reduction of AIMS score from baseline (attach current AIMS).

<u>Chorea associated with Huntington's disease</u> (Austedo or tetrabenazine)

1. Patient meets the FDA approved age; and
2. Patient has a diagnosis of Huntington's disease with chorea symptoms; and
3. Prescribed by or in consultation with a neurologist or psychiatrist; and
4. Is prescribed within the FDA approved dosing; and
5. Patient is not suicidal, or does not have untreated or inadequately treated depression; and
6. Patient does not have hepatic impairment; and
7. Patient does not have concurrent therapy with MAO inhibitors, reserpine, or other VMAT2 inhibitors; and
8. For tetrabenazine, patients requiring doses above 50mg per day have been tested and genotyped for the drug metabolizing enzyme CYP2D6 to determine if they are a poor metabolizer or extensive metabolizer; and
9. In patients that are taking a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) or are poor CYP2D6 metabolizers, the daily dose does not exceed the following:
    a. Austedo - 36mg per day (18mg single dose) or
    b. Tetrabenazine – 50mg per day (25mg single dose)

If criteria for coverage are met, initial requests will be given for 3 months. Continuation of therapy will be considered when the following criteria are met:

1. Patient continues to meet the criteria for initial approval; and
2. Documentation of improvement in chorea symptoms is provided.

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization (PA) is required for VMAT 2 inhibitors. Payment for non-preferred agents will be considered only for cases in which there is documentation of previous trial and therapy failure with a preferred agent (when applicable, based on diagnosis). Payment will be considered under the following conditions:
Tardive Dyskinesia (Ingrezza or Austedo)

1. Patient meets the FDA approved age; and
2. Patient has a diagnosis of tardive dyskinesia (TD) based on the presence of ALL of the following:
    a. Involuntary athetoid or choreiform movements
    b. Documentation or claims history of current or prior chronic use (≥ 3 months or 1 month in patients ≥ 60 years old) of a dopamine receptor blocking agent (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.)
    c. Symptoms lasting longer than 4-8 weeks; and
3. Prescribed by or in consultation with a neurologist or psychiatrist; and
4. Prescriber has evaluated the patient's current medications for consideration of a dose reduction, withdrawal, or change of the dopamine receptor blocking agent causing the TD; and
5. Documentation of baseline AIMS (Abnormal Involuntary Movement Scale) Score (attach AIMS); and
6. For Ingrezza:
    a. Will not be used concurrently with MAO inhibitors (e.g., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine, etc.) or strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, phenobarbital, rifampin and related agents, St. John's wort, etc.); and
    b. Will not be used concurrently with other vesicular monoamine transporter 2 (VMAT2) inhibitors; and
    c. Is prescribed within the FDA approved dosing; or
7. For Austedo:
    ~~a. Patient is not suicidal, or does not have untreated/inadequately treated depression;~~
    b. Patient does not have hepatic impairment;
    c. Will not be used concurrently with MAO inhibitors, reserpine, or other VMAT2 inhibitors; and
    d. Patients that are taking a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) or are poor CYP2D6 metabolizers, the daily dose does not exceed 36mg per day (18mg twice daily); and
    e. Is prescribed within the FDA approved dosing.

If criteria for coverage are met, initial requests will be given for 3 months. Continuation of therapy will be considered when the following criteria are met:

1. Patient continues to meet the criteria for initial approval; and
2. Documentation of improvement in TD symptoms as evidenced by a reduction of AIMS score from baseline (attach current AIMS).

Chorea associated with Huntington's disease (Austedo or tetrabenazine)

1. Patient meets the FDA approved age; and

2. Patient has a diagnosis of Huntington's disease with chorea symptoms; and
3. Prescribed by or in consultation with a neurologist or psychiatrist; and
4. Is prescribed within the FDA approved dosing; and
5. Patient is not suicidal, or does not have untreated or inadequately treated depression; and
6. Patient does not have hepatic impairment; and
7. Patient does not have concurrent therapy with MAO inhibitors, reserpine, or other VMAT2 inhibitors; and
8. For tetrabenazine, patients requiring doses above 50mg per day have been tested and genotyped for the drug metabolizing enzyme CYP2D6 to determine if they are a poor metabolizer or extensive metabolizer; and
9. In patients that are taking a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) or are poor CYP2D6 metabolizers, the daily dose does not exceed the following:
    a. Austedo - 36mg per day (18mg single dose) or
    b. Tetrabenazine – 50mg per day (25mg single dose)

If criteria for coverage are met, initial requests will be given for 3 months. Continuation of therapy will be considered when the following criteria are met:

1. Patient continues to meet the criteria for initial approval; and
2. Documentation of improvement in chorea symptoms is provided.

Valsartan/Sacubitril (Entresto)

The DUR Commission reviewed information regarding a newly expanded indication for valsartan/sacubitril (Entesto), to reduce the risk of cardiovascular death and hospitalization for heart failure. The DUR Commission also reviewed The 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment. Guideline-directed therapy for heart failure with reduced ejection fraction (HFrEF) includes angiotensin-converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs) as initial treatment, with an ARNI being preferred regardless of prior treatment with an ACEI or ARB. After review of the new information and discussion, the DUR Commission determined removal of PA criteria would be in the best interest of Iowa Medicaid members given the proven efficacy of valsartan/sacubitril (Entresto) in the treatment of heart failure.

Current Clinical Prior Authorization – ***Recommendation to Remove Criteria***

Prior authorization (PA) 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 within the FDA labeled age for indication; and
2. Patient has a diagnosis of NYHA Functional Class II, III, or IV heart failure; and
    a. Patient has a left ventricular ejection fraction (LVEF) ≤40%; and
    b. Patient is currently tolerating treatment with an ACE inhibitor or angiotensin ll receptor blocker (ARB) at a therapeutic dose, where replacement with valsartan/sacubitril is recommended to further reduce morbidity and mortality; and
    c. 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); or

3. Pediatric patient has a diagnosis of symptomatic heart failure (NYHA/Ross Class ll to lV) due to systemic left ventricular systolic dysfunction with documentation of a left ventricular ejection fraction ≤40%; and
4. Will not be used in combination with an ACE inhibitor or ARB; and
5. Will not be used in combination with aliskiren (Tekturna) in diabetic patients; and
6. Patient does not have a history of angioedema associated with the use of ACE inhibitor or ARB therapy; and
7. Patient is not pregnant; and
8. Patient does not have severe hepatic impairment (Child Pugh Class C); and

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

ProDUR Edit(s)

The DUR Commission recommends implementing the following ProDUR quantity limits:

Drug Product	**Proposed Quantity Limit per 30 Days**
Entresto 24 mg-26 mg	60 tablets
Entresto 49 mg-51 mg	60 tablets
Entresto 97 mg-103 mg	60 tablets
Symbicort	240 inhalations (2 inhalers)
Dulera	240 inhalations (2 inhalers)

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Proton Pump Inhibitors; Initial Days' Supply Limit Override; Mannitol Inhalation Powder (Bronchitol); Vesicular Monoamine Transporter (VMAT) 2 Inhibitors; removal of PA criteria for Valsartan/Sacubitril (Entresto); and ProDUR quantity limits for valsartan/sacubitril (Entresto); budesonide/formoterol (Symbicort); and mometasone/formoterol (Dulera).

Sincerely,

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Erin Halverson, R.Ph, IME
Gina Kuebler, R.Ph, IME