IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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Susan L. Parker, R.Ph, Pharm.D.
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Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, November 4, 2020. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Acute Migraine Treatments; Pirfenidone (Esbriet)/Nintedanib (Ofev); Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors; and Peanut Allergen Powder (Palforzia). Additionally, the DUR Commission members recommended several ProDUR quantity limits. The following recommendations have been made by the DUR Commission:

Comments were received and reviewed from the medical/pharmacy associations in response to an August 7, 2020 letter that was sent to them detailing the proposed criteria for Acute Migraine Treatments; Pirfenidone (Esbriet)/Nintedanib (Ofev); Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors; and Peanut Allergen Powder (Palforzia); in addition to the proposed ProDUR quantity limits.

Acute Migraine Treatments (formerly Serotonin 5-HT-1-Receptor Agonists)

Current Clinical Prior Authorization Criteria
Prior authorization (PA) is required for preferred serotonin 5-HT1-receptor agonists for quantities exceeding 12 unit doses of tablets, syringes or sprays per 30 days. Payment for serotonin 5-HT1-receptor agonists beyond this limit will be considered on an individual basis after review of submitted documentation. PA will be required for all non-preferred serotonin 5-HT1-receptor agonists as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. Payment for non-preferred serotonin 5-HT1-receptor agonists will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred agents. Requests for non-preferred combination products may only be considered after documented separate trials and therapy failures with the individual ingredients. For consideration, the following information must be supplied:

1. The diagnosis requiring therapy.

2. Documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications.

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)

*No ~~P~~p*rior authorization (PA) *is required for preferred acute migraine treatments, as indicated on the Preferred Drug List (PDL). PA* is required for ~~preferred~~ *acute migraine treatments* ~~serotonin 5-HT1-receptor agonists~~ *under the following conditions:*

1. *A diagnosis of acute migraine; and*
2. *Patient meets the FDA approved age for requested agent; and*
3. *For preferred acute migraine treatments where PA is required, as indicated on the PDL, documentation of previous trials and therapy failures with two preferred agents that do not require PA; and/or*
4. ~~Payment f~~*F*or *non*-preferred *acute migraine treatments,* ~~serotonin 5-HT1-receptor agonists will be authorized only for cases in which there is~~ documentation of previous trials and therapy failures with two preferred agents *that do not require PA. Requests for non-preferred CGRP inhibitors will also require documentation of a trial and therapy failure with a preferred CGRP inhibitor; and/or*
5. *~~f~~F*or quantities exceeding *the established quantity limit for each agent,* ~~12 unit doses of tablets, syringes or sprays per 30 days. Payment for serotonin 5-HT1-receptor agonists beyond *this* limit will be considered on an individual basis after review of submitted~~ documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications*; and/or*
6. ~~Requests *f~~F*or *non*-preferred combination products*,* ~~may only be considered after~~ document*ation~~ed~~ of* separate trials and therapy failures with the individual ingredients*, in addition to the above criteria for preferred or non-preferred acute migraine treatments requiring PA*.

~~PA will be required for all non-preferred serotonin 5-HT1-receptor agonists as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. For consideration, the following information must be supplied:~~

1. ~~The diagnosis requiring therapy.~~
2. ~~Documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications.~~

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

Pirfenidone (Esbriet)/Nintedanib (Ofev) (formerly Idiopathic Pulmonary Fibrosis)

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for pirfenidone (Esbriet) and nintedanib (Ofev). Dosing outside of the FDA approved dosing will not be considered. Concomitant use of pirfenidone and nintedanib will not be considered. Payment will be considered for patients when the following criteria are met:

1. Patient is 40 years of age or older; and
2. Is prescribed by a pulmonologist; and
3. Patient has a diagnosis of idiopathic pulmonary fibrosis as confirmed by one of the following (attach documentation):
    a. Findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP); or
    b. A surgical lung biopsy demonstrating usual interstitial pneumonia (UIP); and

4. Prescriber has excluded other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity; and
5. Patient has documentation of pulmonary function tests within the prior 60 days with a forced vital capacity (FVC) ≥50% predicted; and
6. Patient has a carbon monoxide diffusion capacity (%DLco) of ≥30% predicted; and
7. Patient does not have hepatic impairment as defined below:
    a. Nintedanib - Patient does not have moderate or severe hepatic impairment (Child Pugh B or C) or
    b. Pirfenidone - Patient does not have severe hepatic impairment (Child Pugh C); and
8. Patient does not have renal impairment as defined below:
    a. Nintedanib - Patient does not have severe renal impairment (CrCl <30ml/min) or end-stage renal disease or
    b. Pirfenidone – Patient does not have end-stage renal disease requiring dialysis; and
9. Patient is a nonsmoker or has been abstinent from smoking for at least six weeks.

If the criteria for coverage are met, initial requests will be given for 6 months. Additional authorizations will be considered at 6 month intervals when the following criteria are met:

1. Adherence to pirfenidone (Esbriet) and nintedanib (Ofev) is confirmed; and
2. Patient is tolerating treatment defined as improvement or maintenance of disease (<10% decline in percent predicted FVC or < 200 mL decrease in FVC); and
3. Documentation is provided that the patient has remained tobacco-free; and
4. ALT, AST, and bilirubin are assessed periodically during therapy

<u>Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)</u>
Prior authorization (PA) is required for pirfenidone (Esbriet) and nintedanib (Ofev). Dosing outside of the FDA approved dosing will not be considered. Concomitant use of pirfenidone and nintedanib will not be considered. Payment will be considered for patients when the following criteria are met:

1. Patient *meets the FDA approved age* ~~is 40 years of age or older~~; and
2. Is prescribed by a pulmonologist; and
3. Patient does not have hepatic impairment as defined below:
    a. Nintedanib - Patient does not have moderate or severe hepatic impairment (Child Pugh B or C) or
    b. Pirfenidone - Patient does not have severe hepatic impairment (Child Pugh C); and
4. Patient does not have renal impairment as defined below:
    a. Nintedanib - Patient does not have severe renal impairment (CrCl <30ml/min) or end-stage renal disease or
    b. Pirfenidone – Patient does not have end-stage renal disease requiring dialysis; and
5. Patient ~~is~~ *does not utilize non-prescribed inhalants, such as vaping or other inhaled tobacco products, prior to initiating therapy and has been instructed to avoid tobacco products while using pirfenidone or nintedanib* ~~a nonsmoker or has been abstinent from smoking for at least six weeks~~*, and*~~.~~
6. Patient has a diagnosis of idiopathic pulmonary fibrosis *(nintedanib or pirfenidone)* as confirmed by one of the following (attach documentation):
    a. Findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP); or

b. A surgical lung biopsy demonstrating usual interstitial pneumonia (UIP); and
c. Prescriber has excluded other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity; and
d. Patient has documentation of pulmonary function tests within the prior 60 days with a forced vital capacity (FVC) ≥50% predicted; and
e. Patient has a carbon monoxide diffusion capacity (%DLco) of ≥30% predicted; ~~and~~ *or*

7. *Patient has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (nintedanib)as confirmed by the following (attach documentation:*
   a. *Documentation of a chest high resolution computed tomography (HRCT) scan showing fibrosis affecting ≥ 10% of the lungs; and*
   b. *Patient has documented pulmonary function tests within the prior 60 days showing FVC ≥ 40% predicted; and*
   c. *Patient has a carbon monoxide diffusion capacity (%DLco) of ≥ 30-89% predicted; or*
8. *Patient has a diagnosis of chronic fibrosing interstitial lung disease with a progressive phenotype (nintedanib) as confirmed by the following (attach documentation):*
   a. *Documentation of a chest high resolution computed tomography (HRCT) scan showing fibrosis affecting ≥ 10% of the lungs; and*
   b. *Patient has documented pulmonary function tests within the prior 60 days showing FVC ≥ 45% predicted; and*
   c. *Patient has a carbon monoxide diffusion capacity (%DLco) of ≥ 30-79% predicted; and*
   d. *Patient has at least one sign of clinical progression for interstitial lung disease within the last 24 months despite standard treatment with an agent other than nintedanib or pirfenidone:*
      i. *A relative decline in the FVC of at least 10% predicted; or*
      ii. *A relative decline in the FVC of 5-9% predicted combined with at least one of the following:*
         1. *Worsening respiratory symptoms; or*
         2. *Increased extent of fibrosis on HRCT; or*
      iii. *Worsening of respiratory symptoms and an increased extent of fibrotic changes on HRCT only.*

If the criteria for coverage are met, initial requests will be given for 6 months. Additional authorizations will be considered at 6 month intervals when the following criteria are met:

1. Adherence to pirfenidone (Esbriet) ~~and~~ *or* nintedanib (Ofev) is confirmed; and
2. *Documentation of a positive response to therapy, defined as meeting at least one of the following:* ~~Patient is tolerating treatment defined as improvement or maintenance of disease (<10% decline in percent predicted FVC or < 200 mL decrease in FVC)~~;
   a. *Rate of lung function decline slowed; or*
   b. *Improved or no worsening of symptoms of cough or shortness of breath;* and
3. Documentation is provided that the patient has remained tobacco-free; and
4. ALT, AST, and bilirubin are assessed periodically during therapy.

Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for adenosine triphosphate-citrate lyase (ACL) inhibitors. Payment will be considered under the following conditions:

1. Patient meets the FDA approved age; and
2. Documentation of adherence to prescribed lipid lowering medications (including a maximally tolerated statin), prior to ACL inhibitor therapy, for the previous 90 days is provided (further defined below, by diagnosis); and
3. Documentation is provided that medication will be used in combination with a maximally tolerated statin; and
4. A baseline and current lipid profile is provided. Baseline lipid profile is defined as a lipid profile obtained prior to pharmacologic therapy; and
5. Patient will continue to follow an appropriate low fat diet; and
6. Is prescribed by or in consultation with a lipidologist, cardiologist, or endocrinologist; and
7. If patient is taking in combination with:
    a. Simvastatin, dose does not exceed 20mg per day; or
    b. Pravastatin, dose does not exceed 40 mg per day; and
8. Concurrent use with a PCSK9 inhibitor will not be considered; and
9. Goal is defined as a 50% reduction in untreated baseline LDL-C; and
10. Is prescribed for one of the following diagnoses:
    a. Heterozygous Familial Hypercholesterolemia (HeFH):
        i. Documentation is provided verifying diagnosis (attach documentation/results), as evidenced by:
            1. Clinical manifestations of HeFH (e.g. tendon xanthomas, cutaneous xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma); or
            2. Confirmation of diagnosis by gene or receptor testing; and
        ii. Documentation of untreated LDL-C ≥ 190 mg-dL; and
        iii. Patient is unable to reach LDL-C goal with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (must include atorvastatin and rosuvastatin), PLUS ezetimibe 10mg daily; or
    b. Clinical Atherosclerotic Cardiovascular Disease (ASCVD):
        i. History of MI, angina, coronary or other arterial revascularization, stroke, TIA, or PVD of atherosclerotic origin; and
        ii. Patient is unable to reach LDL-C goal with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (must include atorvastatin and rosuvastatin), PLUS ezetimibe 10mg daily.

If criteria for coverage are met, requests will be approved for 3 months. Additional authorizations will be considered at yearly intervals under the following conditions:

a. Patient continues therapy with a maximally tolerated statin dose and remains at goal; and
b. Patient continues to follow an appropriate low fat diet; and
c. Documentation of LDL reduction is provided.

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

Peanut Allergen Powder-dnfp (Palforzia)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for Peanut (*Arachis hypogaea*) Allergen Powder-dnfp (Palforzia). Payment will be considered under the following conditions:

1. Patient has a confirmed diagnosis of peanut allergy, as documented by a skin prick test to peanut ≥ 3 mm compared to control or a peanut-specific serum IgE ≥ 0.35 kUA/L (kilos of allergen-specific units per liter); and
2. Patient is 4 to 17 years of age at initiation of therapy or 4 years of age and older for continued up-dosing and maintenance therapy; and
3. Prescribed by or in consultation with an allergist or immunologist; and
4. Patient has access to injectable epinephrine; and
5. Will be used in conjunction with a peanut-avoidant diet; and
6. Patient does not have any of the following:
    a. Uncontrolled asthma; and/or
    b. A history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease; and
7. Patient will adhere to the complex up-dosing schedule that requires frequent visits to the administering healthcare facility; and
8. The initial dose escalation and the first dose of each new up-dosing level is administered under the supervision of a health care professional in a health care setting with the ability to manage potentially severe allergic reactions, including anaphylaxis. Initial dose escalation and the first dose of all up-dosing levels is not to be billed to the Iowa Medicaid outpatient pharmacy program as the initial dose escalation is administered in the provider office and should be billed via the medical benefit and the first dose of all up-dosing levels is provided via the Office Dose Kit; and
9. Follows FDA approved dosing; and
10. PA is required for all up-dosing dose levels (dose level 1 through 11); and
11. Maintenance dosing will be considered with documentation patient has successfully completed all dose levels of up-dosing.

ProDUR Edits

The DUR Commission recommends the following ProDUR quantity limits:

Drug Product	Quantity	Days Supply
Baclofen 5mg tablet	120	30
Baclofen 10mg tablet	120	30
Baclofen 20mg tablet	120	30
Nurtec ODT	15	30
Reyvow 50mg tablet	8	30
Reyvow 100mg tablet	8	30
Ubrelvy 50mg tablet	16	30
Ubrelvy 100mg tablet	16	30

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Acute Migraine Treatments; Pirfenidone (Esbriet)/Nintedanib (Ofev); Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors; and Peanut Allergen Powder (Palforzia); in addition to the proposed ProDUR quantity limits.

Sincerely,

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Iowa Medicaid Enterprise

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