IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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October 8, 2015

Susan L. Parker, R.Ph., Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
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Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, October 7, 2015. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Topical Antifungals for Onychomycosis, Alpha-1 Proteinase Inhibitors, Lumacaftor/Ivacaftor (Orkambi™), Biologicals for Inflammatory Bowel Disease, Biologicals for Ankylosing Spondylitis, Biologicals for Plaque Psoriasis, and Select Oncology Agents. 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 August 12, 2015 letter that was sent to them detailing the proposed criteria for Topical Antifungals for Onychomycosis, Alpha-1 Proteinase Inhibitors, Lumacaftor/Ivacaftor (Orkambi™), Biologicals for Inflammatory Bowel Disease, Biologicals for Ankylosing Spondylitis, Biologicals for Plaque Psoriasis, and Select Oncology Agents.

Topical Antifungals for Onychomycosis

Newly Proposed Prior Authorization Criteria

Jublia® (efinaconazole) and Kerydin® (tavaborole) will be considered when the following criteria are met:

1. Patient has a diagnosis of onychomycosis of the toenail(s) confirmed by a positive potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy (attach results) without dermatophytomas or lunula (matrix) involvement; and
2. Patient is 18 years of age or older; and
3. Patient has documentation of a complete trial and therapy failure or intolerance to oral terbinafine; and
4. Patient has documentation of a complete trial and therapy failure or intolerance to ciclopirox 8% topical solution; and
5. Patient is diabetic or immunosuppressed/immunocompromised.

If the criteria for coverage are met, a one-time authorization of 48 weeks will be given. Requests for reoccurrence of infection will not be considered.

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

Alpha$_1$-Proteinase Inhibitor Enzymes

Proposed Prior Authorization Criteria (changes italicized)
Prior authorization is required for Alpha$_1$-Proteinase Inhibitor enzymes. Payment for a non-preferred Alpha$_1$-Proteinase Inhibitor enzyme will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. Payment will be considered for patients when the following is met:

1. Patient has a diagnosis of congenital alpha$_1$-antitrypsin (AAT) deficiency; *with a pretreatment serum concentration of AAT less than 11µM/L or*
    - *80mg/dl if measured by radial immunodiffusion, or*
    - *50mg/dl if measured by nephelometry; and*
2. *Patient has a high-risk AAT deficiency phenotype (PiZZ, PiZ (null), or PI (null)(null) or other phenotypes associated with serum AAT concentrations of less than 11µM/L, such as PiSZ or PiMZ); and*
3. *Patient has documented progressive* panacinar emphysema *with a documented rate of decline in forced expiratory volume in 1 second (FEV_1); and*
4. *Patient is 18 years of age or older; and*
5. *Patient is currently a non-smoker; and*
6. *Patient is currently on optimal supportive therapy for obstructive lung disease (inhaled bronchodilators, inhaled steroids); and*
7. *Medication will be administered in the member's home by home health or in a long-term care facility.*

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. *Evidence of clinical efficacy, as documented by:*
    a. *An elevation of AAT levels (above protective threshold i.e., > 11µM/L); and*
    b. *A reduction in rate of deterioration of lung function as measured by a decrease in the FEV_1 rate of decline; and*
2. *Patient continues to be a non-smoker; and*
3. *Patient continues supportive therapy for obstructive lung disease.*

Lumacaftor/Ivacaftor (Orkambi™)

Newly Proposed Prior Authorization Criteria
Prior authorization is required for Orkambi™ (lumacaftor/ivacaftor). Dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator will not be considered. Payment will be considered for patients when the following criteria are met:

1. Patient is 1*2* years of age or older; and
2. Has a diagnosis of cystic fibrosis; and

3. Patient is homozygous for the *F508del* mutation in the *CFTR* gene as confirmed by a FDA-cleared CF mutation test; and
4. Baseline liver function tests (AST/ALT) and bilirubin levels are provided and
5. Baseline percent predicted forced expiratory volume ($ppFEV_1$) is provided and is greater than or equal to (≥) 40; and
6. Prescriber is a CF specialist or pulmonologist; and
7. Patient does not have one of the following infections: *Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abcessus.*

If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met:

1. Adherence to lumacaftor/ivacaftor therapy is confirmed; and
2. Response to therapy is documented by prescriber (e.g., improved $ppFEV_1$ from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and
3. Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter.

Biologicals for Inflammatory Bowel Disease

Proposed Prior Authorization Criteria (changes italicized)

Prior authorization is required for biologicals used for inflammatory bowel disease. Payment for non-preferred biologicals for inflammatory bowel disease will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. *Patients initiating therapy with a biological agent must:*

1. *Be screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and*
2. *Have not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and*
3. *Not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and*
4. *Be screened for latent TB infection. Patients with latent TB will only be considered after one month of TB treatment while patients with active TB will only be considered upon completion of TB treatment.*

Payment will be considered under the following conditions:

- Crohn's Disease – Payment will be considered following an inadequate response to two preferred conventional therapies including aminosalicylates (mesalamine, sulfasalazine), azathioprine/6-mercaptopurine, and/or methotrexate.
- Ulcerative colitis (moderate to severe) – Payment will be considered following an inadequate response to two preferred conventional therapies including aminosalicylates and azathioprine/6-mercaptopurine.

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

Biologicals for Ankylosing Spondylitis

Proposed Prior Authorization Criteria (changes italicized)

Prior authorization is required for biologicals used for ankylosing spondylitis. Payment for non-preferred biologicals for ankylosing spondylitis will be considered only for cases in

which there is documentation of previous trials and therapy failures with two preferred biological agents.
Patients initiating therapy with a biological agent must:

1. *Be screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and*
2. *Have not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and*
3. *Not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and*
4. *Be screened for latent TB infection. Patients with latent TB will only be considered after one month of TB treatment while patients with active TB will only be considered upon completion of TB treatment.*

Payment will be considered following inadequate responses to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at maximum therapeutic doses, unless there are documented adverse responses or contraindications to NSAID use. These trials should be at least three months in duration. Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include sulfasalazine and methotrexate. *The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.*

Biologicals for Plaque Psoriasis

Proposed Prior Authorization Criteria (changes italicized)
Prior authorization is required for biologicals used for plaque psoriasis. Payment for non-preferred biologicals for plaque psoriasis will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. *Patients initiating therapy with a biological agent must:*

1. *Be screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and*
2. *Have not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and*
3. *Not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and*
4. *Be screened for latent TB infection. Patients with latent TB will only be considered after one month of TB treatment while patients with active TB will only be considered upon completion of TB treatment.*

Payment will be considered following an inadequate response to phototherapy, systemic retinoids (oral acitretin), methotrexate, or cyclosporine. *The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.*

Select Oncology Agents

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for select oncology agents. Patient must have a diagnosis that is indicated in the FDA approved package insert or the use is for an indication supported by the compendia (including National Comprehensive Cancer Network (NCCN) compendium level of evidence 1, 2A, or 2B). The following must be submitted with the prior authorization request: copies of medical records (i.e. diagnostic evaluations and recent chart notes), location of treatment (provider office, facility, home health, etc.) if medication requested is not an oral agent, the original prescription, and the most recent copies of related laboratory results. If criteria for coverage are met, initial authorization will be given for three (3) months. Additional authorizations will be considered for up to six (6) month intervals when criteria for coverage are met. Updates on disease progression must be provided with each renewal request. If disease progression is noted, therapy will not be continued unless otherwise justified.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Topical Antifungals for Onychomycosis, Alpha-1 Proteinase Inhibitors, Lumacaftor/Ivacaftor (Orkambi™), Biologicals for Inflammatory Bowel Disease, Biologicals for Ankylosing Spondylitis, Biologicals for Plaque Psoriasis, and Select Oncology Agents.

Sincerely,

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