IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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December 7, 2017

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

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, December 6, 2017. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Biologicals for Ankylosing Spondylitis; Biologicals for Arthritis; Biologicals for Inflammatory Bowel Disease; Biologicals for Plaque Psoriasis; Tramadol or Codeine in Members Under 18 Years of Age; and Sacubitril/Valsartan (Entresto). The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments that were received from the medical/pharmacy associations in response to an October 11, 2017 letter that was sent to them detailing the proposed criteria for Biologicals for Ankylosing Spondylitis; Biologicals for Arthritis; Biologicals for Inflammatory Bowel Disease; Biologicals for Plaque Psoriasis; Tramadol or Codeine in Members Under 18 Years of Age; and Sacubitril/Valsartan (Entresto).

Biologicals for Ankylosing Spondylitis

Proposed Clinical Prior Authorization Criteria (changes highlighted, italicized, or stricken)
Prior authorization is required for biologicals used for ankylosing spondylitis. *Request must adhere to all FDA approved labeling.* 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. *Payment will be considered under the following conditions* ~~Patients initiating therapy with a biological agent must~~:

- ~~Payment will be considered following~~ *Patient has documentation of an* inadequate response~~s~~ 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; *and*

- 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; *and*
- ~~Be~~ *Patient has been* screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; *and*
- ~~Be~~ *Patient has been* screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; *and*

In addition to the above:
Requests for TNF Inhibitors:

- ~~Have~~ *Patient has* 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*
- *Patient does* ~~N~~*n*ot have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or lV and with an ejection fraction of 50% or less.

Requests for Interleukins:

- *Medication will not be given concurrently with live vaccines.*

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

Biologicals for Arthritis

Proposed Clinical Prior Authorization Criteria (changes highlighted, italicized, or stricken)
Prior authorization is required for biologicals used for arthritis. *Request must adhere to all FDA approved labeling.* Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. *Payment will be considered under the following conditions* ~~Patients initiating therapy with a biological agent must~~:

- ~~Be~~ *Patient has been* screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; *and*
- ~~Be~~ *Patient has been* screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage*; and*
- *Patient has* a diagnosis of rheumatoid arthritis (RA):
  A trial and inadequate response to two preferred disease modifying antirheumatic drugs (DMARD) used concurrently. The combination must include methotrexate plus another preferred oral DMARD (hydroxychloroquine, sulfasalazine, leflunomide, or minocycline). Upon an unsuccessful methotrexate trial in patients with established RA, the combination trial with a second DMARD may be overridden if there is evidence of severe disease documented by radiographic erosions*; or*
- *Patient has* a diagnosis of moderate to severe psoriatic arthritis:
  A trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); *or*
- *Patient has* a diagnosis of moderate to severe juvenile idiopathic arthritis:

A trial and inadequate response to intraarticular glucocorticoid injections and the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); *and*

In addition to the above:
Requests for TNF Inhibitors:

- ~~Have~~ *Patient has* 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*
- *Patient does* ~~N~~*n*ot have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or lV and with an ejection fraction of 50% or less.

Requests for Interleukins:

- *Medication will not be given concurrently with live vaccines.*

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

Biologicals for Inflammatory Bowel Disease

Proposed Clinical Prior Authorization Criteria (changes highlighted, italicized, or stricken)
Prior authorization is required for biologicals used for inflammatory bowel disease. *Request must adhere to all FDA approved labeling.* 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. *Payment will be considered under the following conditions* ~~Patients initiating therapy with a biological agent must~~:

- ~~Be~~ *Patient has been* screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; *and*
- ~~Be~~ *Patient has been* screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage*; and*
- *Patient has a diagnosis of* Crohn's Disease – Payment will be considered following an inadequate response to two preferred conventional therapy including aminosalicylates (mesalamine, sulfasalazine), azathioprine/6-mercaptopurine, and/or methotrexate; or
- *Patient has a diagnosis of* Ulcerative Colitis (moderate to severe) – Payment will be considered following an inadequate response to two preferred conventional therapies including aminosalicylates and azathioprine/6-mercaptopurine*; and*

In addition to the above:
Requests for TNF Inhibitors:

- ~~Have~~ *Patient has* 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*
- *Patient does* ~~N~~*n*ot have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or lV and with an ejection fraction of 50% or less.

Requests for Interleukins:

- *Medication will not be given concurrently with live vaccines.*

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 Clinical Prior Authorization Criteria (changes highlighted, italicized, or stricken)
Prior authorization is required for biologicals used for plaque psoriasis. *Request must adhere to all FDA approved labeling.* Payment for non-preferred biologicals for plaque psoriasis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. *Payment will be considered under the following conditions* ~~Patients initiating therapy with a biological agent must~~:

- ~~Payment will be considered following~~ *Patient has documentation of* an inadequate response to phototherapy, systemic retinoids (oral isotretinoin), methotrexate, or cyclosporine; and
- ~~Be~~ *Patient has been* screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; *and*
- ~~Be~~ *Patient has been* screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and

In addition to the above:
Requests for TNF Inhibitors:

- ~~Have~~ *Patient has* 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
- *Patient does* ~~N~~not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or lV and with an ejection fraction of 50% or less.

Requests for Interleukins:

- *Medication will not be given concurrently with live vaccines.*

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

Age Edit Override – Codeine or Tramadol

Newly Proposed Prior Authorization Criteria
An age edit override for codeine or tramadol is required for patients under 18 years of age. Payment will be considered under the following conditions:

1. Member is 12 years of age or older; and
2. Medication is not being prescribed to treat pain after surgery following tonsil and/or adenoid procedure for members 12 to18 years of age; and
3. If member is between 12 and 18 years of age, member is not obese (BMI greater than 30kg/m2), does not have obstructive sleep apnea, or severe lung disease.

Sacubitril/Valsartan (Entresto)

Proposed Clinical Prior Authorization Criteria (changes highlighted, italicized, or stricken)
Prior authorization 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 18 years of age or older; and
2. Patient has a diagnosis of NYHA Functional Class II, III, or IV heart failure; and
3. Patient has a left ventricular ejection fraction (LVEF) ≤40%; and
4. Patient *is currently tolerating treatment with an ACE inhibitor or angiotensin II receptor blocker (ARB) at a therapeutic dose, where replacement with valsartan/sacubitril is recommended to further reduce morbidity and mortality* ~~previous trial and therapy failure or intolerance to an ACE inhibitor at a maximally tolerated dose~~; and
5. ~~Patient has documentation of a previous trial and therapy failure or intolerance to an angiotensin II receptor blocker (ARB); and~~
6. 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); and
7. Will not be used in combination with an ACE inhibitor or ARB; and
8. Will not be used in combination with aliskiren (Tekturna) in diabetic patients; and
9. Patient does not have a history of angioedema associated with the use of ACE inhibitor or ARB therapy; and
10. Patient is not pregnant; and
11. Patient does not have severe hepatic impairment (Child Pugh Class C); and
12. Prescriber is a cardiologist or has consulted with a cardiologist (telephone consultation is acceptable).

The required trial(s) may be overridden when documented evidence is provided that the use of these agent(s) would be medically contraindicated.

~~If the criteria for coverage are met, initial authorization will be given for 3 months. Requests for continuation of therapy may be provided if prescriber documents adequate response to therapy.~~

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Biologicals for Ankylosing Spondylitis; Biologicals for Arthritis; Biologicals for Inflammatory Bowel Disease; Biologicals for Plaque Psoriasis; Tramadol or Codeine in Members Under 18 Years of Age; and Sacubitril/Valsartan (Entresto).

Sincerely,

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

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