IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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August 8, 2024

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Dear Abby:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, August 7, 2024. At this meeting, the DUR Commission members discussed updated prior authorization (PA) criteria for Antidiabetic Non-Insulin Agents; Biologicals for Axial Spondyloarthritis; and Biologics for Plaque Psoriasis. The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to a May 3, 2024 letter that was sent to them detailing the updated PA criteria for Antidiabetic Non-Insulin Agents; Biologicals for Axial Spondyloarthritis; and Biologics for Plaque Psoriasis.

Anti-Diabetic Non-Insulin Agents

Current Clinical Prior Authorization

Prior authorization (PA) is required for preferred anti-diabetic, non-insulin agents subject to clinical criteria. Payment will be considered under the following conditions:

1. Patient has an FDA approved or compendia indicated diagnosis, and
2. Patient meets the FDA approved or compendia indicated age, and
3. For the treatment of Type 2 Diabetes Mellitus, the patient has not achieved HgbA1C goals after a minimum three month trial with metformin at maximally tolerated dose.
4. Requests for non-preferred anti-diabetic, non-insulin agents subject to clinical criteria, will be authorized only for cases in which there is documentation of previous trials and therapy failures with a preferred drug in the same class. Requests for a non-preferred agent for the treatment of Type 2 Diabetes Mellitus must document previous trials and therapy failures with metformin, a preferred DPP-4 Inhibitor or DPP-4 Inhibitor Combination, a preferred Incretin Mimetic, and a preferred SGLT2 Inhibitor at maximally tolerated doses.

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

Requests for weight loss are not a covered diagnosis of use and will be denied.

Initial authorizations will be approved for six months. Additional PAs will be considered on an individual basis after review of medical necessity and documented continued improvement in symptoms (such as HgbA1C for Type 2 Diabetes).

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized and/or stricken)
Prior authorization (PA) is required for *select* preferred anti-diabetic, non-insulin agents subject to clinical criteria. Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and* ~~Patient has an FDA approved or compendia indicated diagnosis, and~~
2. ~~Patient meets the FDA approved or compendia indicated age, and~~
3. For the treatment of Type 2 Diabetes Mellitus, *a current A1C is provided; and* ~~the patient has not achieved HgbA1C goals after a minimum three month trial with metformin at maximally tolerated dose.~~
4. Requests for non-preferred antidiabetic, non-insulin agents subject to clinical criteria, will be authorized only for cases in which there is documentation of previous trials and therapy failures with a preferred drug in the same class. *Additionally,* ~~R~~ *r*equests for a non-preferred agent for the treatment of Type 2 Diabetes Mellitus must document previous trials and therapy failures with *at least 3 preferred agents from 3 different drug classes* ~~metformin, a preferred DPP-4 Inhibitor or DPP-4 Inhibitor Combination, a preferred Incretin Mimetic, and a preferred SGLT2 Inhibitor~~ at maximally tolerated doses.

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

Requests for weight loss are not a covered diagnosis of use and will be denied.

~~Initial authorizations will be approved for six months. Additional PAs will be considered on an individual basis after review of medical necessity and documented continued improvement in symptoms (such as HgbA1C for Type 2 Diabetes).~~

Biologicals for Axial Spondyloarthritis

Current Clinical Prior Authorization
Prior authorization (PA) is required for biologicals used for axial spondyloarthritis conditions. Payment will be considered under the following conditions:

1. Patient has a diagnosis of:
    a. ankylosing spondylitis (AS) or
    b. nonradiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; and
2. The requested dose does not exceed the maximum FDA labeled or compendia recommended dose for the submitted diagnosis; and
3. Patient has been screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and
4. 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
5. Patient has documentation of an inadequate response 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 one month in duration; and
6. 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
7. Requests for non-preferred biologicals for axial spondyloarthritis conditions will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents that are FDA approved or compendia indicated for the submitted diagnosis, when applicable.

In addition to the above:
Requests for TNF Inhibitors:
1. 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
2. Patient does 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:
1. 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.

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized and/or stricken)
Prior authorization (PA) is required for biologicals used for axial spondyloarthritis conditions. *Request must adhere to all approved labeling for requested drug and indication, including age, dosing, contraindications, warnings & precautions, drug interactions, and use in specific populations.* Payment will be considered under the following conditions:
1. Patient has a diagnosis of:
    a. ankylosing spondylitis (AS) or
    b. nonradiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; and
~~2. The requested dose does not exceed the maximum FDA labeled or compendia recommended dose for the submitted diagnosis; and~~
~~3. Patient has been screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and~~
~~4. 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~~
5. Patient has documentation of an inadequate response 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 one month in duration; and
6. 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

7. Requests for non-preferred biologicals for axial spondyloarthritis conditions will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents that are FDA approved or compendia indicated for the submitted diagnosis, when applicable.

~~In addition to the above:~~
~~Requests for TNF Inhibitors:~~
1. ~~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~~
2. ~~Patient does 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:~~
1. ~~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

Current Clinical Prior Authorization Criteria
Prior authorization (PA) 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:
1. Patient has been screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and
2. 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
3. Patient has documentation of an inadequate response to phototherapy, systemic retinoids (oral isotretinoin), methotrexate, or cyclosporine; and

In addition to the above:
Requests for TNF Inhibitors:
1. 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
2. Patient does 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:
1. 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.

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized and/or stricken)
Prior authorization (PA) is required for biologicals used for plaque psoriasis. Request must adhere to all FDA approved labeling *for requested drug and indication, including age, dosing, contraindications, warnings & precautions, drug interactions, and use in specific populations*. 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:

1. ~~Patient has been screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and~~
2. ~~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~~
3. *Patient has a diagnosis of moderate to severe plaque psoriasis; and*
4. Patient has documentation of an inadequate response to phototherapy, systemic retinoids, methotrexate, or cyclosporine~~; and~~

~~In addition to the above:~~

~~Requests for TNF Inhibitors:~~

1. ~~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~~
2. ~~Patient does 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:~~

1. ~~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.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for Antidiabetic Non-Insulin Agents; Biologicals for Axial Spondyloarthritis; and Biologics for Plaque Psoriasis.

Sincerely,

Pamela Smith R.Ph.

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Iowa Medicaid

Cc: Erin Halverson, R.Ph, Iowa Medicaid
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