



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

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Dear Abby:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, November 1, 2023. At this meeting, the DUR Commission members discussed new or updated PA criteria for Antidepressants; Deucravacitinib (Sotyktu); Tezepelumab (Tezspire); and Janus Kinase Inhibitors. In addition, the DUR Commission discussed ProDUR quantity limits for Auvelity, Sotyktu, Nayzilam, Tezspire, and Valtoco, as well as a ProDUR age edit for Auvelity. The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to an August 3, 2023 letter that was sent to them detailing: the new or updated PA criteria for Antidepressants, Deucravacitinib (Sotyktu), Tezepelumab (Tezspire), and Janus Kinase Inhibitors; the proposed ProDUR quantity limits for Auvelity, Sotyktu, Nayzilam, Tezspire, and Valtoco; as well as the proposed ProDUR age edit for Auvelity.

Antidepressants

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for non-preferred antidepressants subject to clinical criteria. Requests for doses above the manufacturer recommended dose will not be considered. Payment will be considered for patients when the following criteria are met:

1. The patient has a diagnosis of Major Depressive Disorder (MDD) and is 18 years of age or older; and
2. Documentation of a previous trial and therapy failure at a therapeutic dose with two preferred generic SSRIs; and
3. Documentation of a previous trial and therapy failure at a therapeutic dose with one preferred generic SNRI; and
4. Documentation of a previous trial and therapy failure at a therapeutic dose with one non-SSRI/SNRI generic antidepressant

5. If the request is for an isomer, prodrug or metabolite of a medication indicated for MDD, one of the trials must be with the preferred parent drug of the same chemical entity that resulted in a partial response with a documented intolerance.

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 italicized/highlighted or stricken)

Prior authorization (PA) is required for non-preferred antidepressants subject to clinical criteria. ~~Requests for doses above the manufacturer recommended dose will not be considered.~~ Payment will be considered *when patient has an FDA approved or compendia indication for the requested drug for patients* when the following criteria are met:

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*
2. ~~The patient has a diagnosis of Major Depressive Disorder (MDD) and is 18 years of age or older; and~~
3. Documentation of a previous trial and therapy failure at a therapeutic dose with two preferred generic SSRIs; and
4. Documentation of a previous trial and therapy failure at a therapeutic dose with one preferred generic SNRI; and
5. Documentation of a previous trial and therapy failure at a therapeutic dose with one non-SSRI/SNRI generic antidepressant; *and*
6. *Documentation of a previous trial and therapy failure at a therapeutic dose with vilazodone; and*
7. *Documentation of a previous trial and therapy failure at a therapeutic dose with vortioxetine; and*
8. *Documentation of a previous trial and therapy failure at a therapeutic dose with an antidepressant plus adjunct; and*
9. *If the request is for dextromethorphan and bupropion extended-release tablet (Auvelity), one of the trials must include a previous trial and inadequate response at a therapeutic dose with an extended-release bupropion agent; and*
10. If the request is for an isomer, prodrug or metabolite of a *the requested* medication indicated ~~for MDD~~, one of the trials must be with the preferred parent drug of the same chemical entity that resulted in a partial response with a documented intolerance.

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

Deucravacitinib (Sotyktu)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for deucravacitinib (Sotyktu). Payment will be considered when patient has an FDA approved or compendia indication for the requested drug when the following criteria are met:

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
2. Patient has a diagnosis of plaque psoriasis; and
 - a. Documentation of a trial and inadequate response to phototherapy, systemic retinoids, methotrexate, or cyclosporine is provided; and

- b. Documentation of a trial and inadequate response to the preferred adalimumab agent; and
- c. Will not be combined with any of the following systemic agents: biologic DMARD, Janus kinase inhibitor, phosphodiesterase 4 (PDE4) inhibitor, or potent immunosuppressant.

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

Tezepelumab-ekko (Tezspire) Prefilled Pen

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for tezepelumab-ekko (Tezspire) prefilled pen. Requests for tezepelumab-ekko (Tezspire) single dose vial or prefilled syringe will not be considered through the pharmacy benefit. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

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
2. Patient has a diagnosis of severe asthma; and
 - a. Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g., long-acting beta2 agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and
 - b. Patient must have one of the following, in addition to the regular maintenance medications defined above:
 - i. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment in the previous 12 months, or
 - ii. One or more asthma exacerbations resulting in hospitalization in the previous 12 months; and
 - c. This medication will be used as an add-on maintenance treatment; and
 - d. Patient/caregiver will administer medication in patient's home; and
 - e. Is not prescribed in combination with other biologics indicated for asthma.

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Requests for continuation of therapy will require documentation of a positive response to therapy.

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

Janus Kinase Inhibitors

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for Janus kinase (JAK) inhibitors. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug, excluding requests for the FDA approved

indication of alopecia areata, vitiligo, or other excluded medical use(s), as defined in Section 1927(d)(2) of the Social Security Act, State Plan, and Rules when the following conditions are met:

1. Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, biological therapies, or potent immunosuppressants (azathioprine or cyclosporine); and
2. 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
3. Patient has a diagnosis of:
 - a. Moderate to severe rheumatoid arthritis (baricitinib, tofacitinib, upadacitinib); with
 - i. A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate; and
 - ii. A documented trial and inadequate response to one preferred TNF inhibitor; OR
 - b. Psoriatic arthritis (tofacitinib, upadacitinib); with
 - i. A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
 - ii. Documented trial and therapy failure with one preferred TNF inhibitor used for psoriatic arthritis; OR
 - c. Moderately to severely active ulcerative colitis (tofacitinib, upadacitinib); with
 - i. A documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and
 - ii. A documented trial and inadequate response with a preferred TNF inhibitor; and
 - iii. If requested dose is for tofacitinib 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit; OR
 - d. Polyarticular Course Juvenile Idiopathic Arthritis (tofacitinib); with
 - i. A documented trial and inadequate response to intraarticular glucocorticoid injections; and
 - ii. A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
 - iii. A documented trial and inadequate response with a preferred TNF inhibitor; OR
 - e. Axial spondyloarthritis conditions (e.g., ankylosing spondylitis or nonradiographic axial spondyloarthritis) (tofacitinib, upadacitinib); with
 - i. A documented trial and inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at a maximally tolerated dose for a minimum of at least one month; and
 - ii. A documented trial and inadequate response with at least one preferred TNF inhibitor; OR
 - f. Atopic dermatitis; with
 - i. Documentation patient has failed to respond to good skin care and regular use of emollients; and
 - ii. A documented adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and

- iii. A documented trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
- iv. For mild to moderate atopic dermatitis (ruxolitinib)
 - a. A documented trial and therapy failure with crisaborole; and
 - b. Affected area is less than 20% of body surface area (BSA); and
 - c. Patient has been instructed to use no more than 60 grams of topical ruxolitinib per week; or
- v. For moderate to severe atopic dermatitis (abrocitinib, upadacitinib):
 - a. A documented trial and therapy failure with cyclosporine or azathioprine; and
 - b. Requests for upadacitinib for pediatric patients 12 to less than 18 years of age must include the patient's weight in kg.

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 Janus kinase (JAK) inhibitors. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug, excluding requests for the FDA approved indication of alopecia areata, vitiligo, or other excluded medical use(s), as defined in Section 1927(d)(2) of the Social Security Act, State Plan, and Rules when the following conditions are met:

- 1. Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, biological therapies, or potent immunosuppressants (azathioprine or cyclosporine); and
- 2. 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
- 3. Patient has a diagnosis of:
 - a. Moderate to severe rheumatoid arthritis (baricitinib, tofacitinib, upadacitinib); with
 - i. A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate; and
 - ii. A documented trial and inadequate response to one preferred TNF inhibitor; OR
 - b. Psoriatic arthritis (tofacitinib, upadacitinib); with
 - i. A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
 - ii. Documented trial and therapy failure with one preferred TNF inhibitor used for psoriatic arthritis; OR
 - c. Moderately to severely active ulcerative colitis (tofacitinib, upadacitinib); with
 - i. A documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and
 - ii. A documented trial and inadequate response with a preferred TNF inhibitor; and
 - iii. If requested dose is for tofacitinib 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit; OR
 - d. *Moderately to severely active Crohn's disease (upadacitinib); with*

- i. A documented trial and inadequate response to two preferred conventional therapies including aminosalicylates (sulfasalazine), azathioprine/6-mercaptopurine, and/or methotrexate; and
 - ii. A documented trial and inadequate response with a preferred TNF inhibitor; OR
- e. Polyarticular Course Juvenile Idiopathic Arthritis (tofacitinib); with
 - i. A documented trial and inadequate response to intraarticular glucocorticoid injections; and
 - ii. A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
 - iii. A documented trial and inadequate response with a preferred TNF inhibitor; OR
- f. Axial spondyloarthritis conditions (e.g., ankylosing spondylitis or nonradiographic axial spondyloarthritis) (tofacitinib, upadacitinib); with
 - i. A documented trial and inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at a maximally tolerated dose for a minimum of at least one month; and
 - ii. A documented trial and inadequate response with at least one preferred TNF inhibitor; OR
- g. Atopic dermatitis; with
 - i. Documentation patient has failed to respond to good skin care and regular use of emollients; and
 - ii. A documented adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
 - iii. A documented trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
 - iv. For mild to moderate atopic dermatitis (ruxolitinib)
 - a. A documented trial and therapy failure with crisaborole; and
 - b. Affected area is less than 20% of body surface area (BSA); and
 - c. Patient has been instructed to use no more than 60 grams of topical ruxolitinib per week; or
 - v. For moderate to severe atopic dermatitis (abrocitinib, upadacitinib):
 - a. A documented trial and therapy failure with cyclosporine or azathioprine; and
 - b. Requests for upadacitinib for pediatric patients 12 to less than 18 years of age must include the patient's weight in kg.

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

Proposed ProDUR Quantity Limits

Drug Product	Quantity	Days Supply
Auvelity (dextromethorphan & bupropion ER) 45 mg/105 mg	60	30
Sotyktu (deucravacitinib) 6 mg	30	30
Nayzilam (midazolam) 5 mg	5 boxes (10 nasal spray units)	30
Tezspire (tezepelumab-ekko) 210 mg	1 prefilled pen	28
Valtoco (diazepam) 5 mg, 10 mg	5 cartons (10 blister packs)	30
Valtoco (diazepam) 15 mg, 20 mg	10 cartons (20 blister packs)	30

Proposed ProDUR Age Edit

The DUR Commission also discussed and recommended a ProDUR age edit for Auvelity (dextromethorphan and bupropion) extended-release tablet for members 18 years of age and older.

Thank you in advance for the Department’s consideration of accepting the DUR Commission’s recommendations for Antidepressants, Deucravacitinib (Sotyktu), Tezepelumab (Tezspire), and Janus Kinase Inhibitors; the proposed ProDUR quantity limits for Auvelity, Sotyktu, Nayzilam, Tezspire, and Valtoco; as well as the proposed ProDUR age edit for Auvelity.

Sincerely,



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