IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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Date: February 10, 2015

To: Iowa Medical/Pharmacy Associations

From: Pamela Smith, R.Ph., DUR Project Coordinator

RE: **DUR Recommendation to the Department of Human Services**

The members of the Iowa Medicaid Drug Utilization Review Commission met on February 4, 2015 and voted in favor of making the following recommendations to the Department of Human Services regarding clinical prior authorization criteria. You are receiving this letter because the DUR Commission is interested in the opinions of the members of your organization on this issue.

Apixaban (Eliquis)

Current Prior Authorization Criteria
Prior authorization is required for apixaban (Eliquis®). Payment will be considered under the following conditions:

1. Patient does not have a mechanical prosthetic heart valve; and
2. Patient does not have active pathological bleeding; and
3. Patient has a diagnosis of non-valvular atrial fibrillation; with
4. Documentation of a previous trial and therapy failure with warfarin (TIA, stroke, or inability to maintain a therapeutic INR with a minimum 6 month trial); and
5. Presence of at least one additional risk factor for stroke, with a CHADS2 score ≥ 1; OR
6. For patients requiring deep vein thrombosis (DVT) prophylaxis undergoing hip or knee replacement. Requests will be considered when the patient has contraindications to use of the preferred agent(s).
7. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Proposed Prior Authorization Criteria (changes italicized)
Prior authorization is required for apixaban (Eliquis®). Payment will be considered under the following conditions:

1. Patient does not have a mechanical prosthetic heart valve; and
2. Patient does not have active pathological bleeding.

Atrial Fibrillation

- Patient has a diagnosis of non-valvular atrial fibrillation; with

- Documentation of a previous trial and therapy failure with warfarin (TIA, stroke, or inability to maintain a therapeutic INR with a minimum 6 month trial); and
- Presence of at least one additional risk factor for stroke, with a CHADS2 score ≥ 1.
- *Requests will be considered for the following dosing:*
    - *5mg twice daily; or*
    - *2.5mg twice daily in patients with any two (2) of the following:*
        - *Age ≥80 years*
        - *Body weight ≤60 kg*
        - *Serum creatinine ≥1.5 mg/dL.*

Treatment and Prevention of DVT or PE

- *Patient has documentation of a previous trial and therapy failure with warfarin (TIA, stroke, or inability to maintain a therapeutic INR with a minimum 6 month trial).*
- *Requests will be considered for the following dosing:*
    - *Initial Treatment of DVT or PE: 10mg twice daily for 7 days, followed by 5mg twice daily up to 12 months of treatment.*
    - *Prevention of DVT or PE following initial therapy with standard anticoagulation therapy for 6 to 12 months of treatment for DVT or PE: 2.5mg twice daily*

Prophylaxis of DVT following hip or knee replacement surgery

- Requests will be considered when the patient has contraindications to use of the preferred agent(s).
- *Requests will be considered for the following dosing:*
    - *Hip replacement: 2.5mg twice daily for up to 35 days following hip replacement; or*
    - *Knee replacement: 2.5mg twice daily for up to 12 days after knee replacement.*

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

Thrombopoietin Receptor Agonists

Current Prior Authorization Criteria

Payment for a preferred thrombopoietin receptor agonist will only be considered for cases in which there is a diagnosis of chronic immune thrombocytopenic purpura (ITP) including documentation of an insufficient response to a corticosteroid, an immunoglobulin, or the patient has undergone a splenectomy.

Payment for eltrombopag (Promacta®) for the treatment of chronic hepatitis C associated thrombocytopenia will only be considered to allow for initiation and/or maintenance of interferon-based therapy with ribavirin when the patient has a baseline platelet count less then 75 x 10^9/L. Requests will not be considered under the following conditions:

1. Patient taking direct acting antiviral agents for the treatment of chronic hepatitis C genotype 1 infection in addition to interferon based therapy with ribavirin.

2. Patients with decompensated liver disease with a Child-Pugh score > 6 (Class B & C).
3. Patients with a history of ascites.
4. Patients with hepatic encephalopathy.

Payment for a non-preferred thrombopoietin receptor agonist will be considered following documentation of a recent trial and therapy failure with a preferred thrombopoietin receptor agonist unless such a trial would be medically contraindicated.

Proposed Prior Authorization Criteria (changes italicized)
Payment for a preferred thrombopoietin receptor agonist will only be considered for cases in which there is a diagnosis of chronic immune thrombocytopenic purpura (ITP) including documentation of an insufficient response to a corticosteroid, an immunoglobulin, or the patient has undergone a splenectomy.

Payment for eltrombopag (Promacta®) for the treatment of chronic hepatitis C associated thrombocytopenia will only be considered to allow for initiation and/or maintenance of interferon-based therapy with ribavirin when the patient has a baseline platelet count less then 75 x 10^9/L. Requests will not be considered under the following conditions:

1. Patients taking direct acting antiviral agents for the treatment of chronic hepatitis C infection in addition to interferon based therapy with ribavirin.
2. *Patients taking direct acting antiviral agents used without interferon for treatment of chronic hepatitis C infection.*
3. Patients with decompensated liver disease with a Child-Pugh score > 6 (Class B & C).
4. Patients with a history of ascites.
5. Patients with hepatic encephalopathy.

Payment for eltrombopag (Promacta®) for the treatment of severe aplastic anemia will only be considered under the following conditions:

1. *Patient has documentation of an insufficient response or intolerance to at least one prior immunosuppressive therapy; and*
2. *Patient has a platelet count less than or equal 30 X 10^9/L.*
3. *If criteria for coverage are met, initial authorization will be given for 16 weeks. Documentation of hematologic response after 16 weeks of therapy will be required for further consideration.*

Payment for a non-preferred thrombopoietin receptor agonist will be considered following documentation of a recent trial and therapy failure with a preferred thrombopoietin receptor agonist unless such a trial would be medically contraindicated.

Testosterone Products

Current Prior Authorization Criteria
Prior authorization is required for testosterone products. Payment for non-preferred testosterone products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred agents. Requests for symptoms of sexual dysfunction, erectile dysfunction and infertility will not be considered. Payment for a diagnosis of hypogonadism (testosterone deficiency) will be considered under the following conditions:

1. Patient is male and 18 years of age or older (or 12 years of age and older for testosterone cypionate); and
2. Patient has two (2) morning pre-treatment testosterone levels below the lower limit of the normal testosterone reference range of the individual laboratory used (Please attach lab results); and
3. Patient has at least one of the signs and symptoms specific to androgen deficiency
    - Incomplete or delayed sexual development
    - Breast discomfort, gynecomastia
    - Loss of body hair, reduction in shaving frequency
    - Very small (<5mL) or shrinking testes
    - Hot flushes, sweats
    - Height loss, low trauma fracture, low bone mineral density; and
4. Patient does not have:
    - Breast or prostate cancer
    - Palpable prostate nodule or prostate-specific antigen (PSA) > 4ng/mL
    - Hematocrit > 50%
    - Untreated severe obstructive sleep apnea
    - Severe lower urinary tract symptoms
    - Uncontrolled or poorly controlled heart failure

If criteria for coverage are met, initial authorization will be given for 3 months. Requests for continuation of therapy will require the following:

1. An updated testosterone level (Please attach lab result); and
2. Documentation of how the patient's specific symptoms have responded to therapy; and
3. Documentation the patient has not experienced a hematocrit > 54% or an increase in PSA > 1.4ng/mL in the past 12 months.

Requests for FDA approved indications other than hypogonadism will not be subject to prior authorization criteria with adequate documentation of diagnosis.
The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

<u>Proposed Prior Authorization Criteria (changes italicized)</u>
Prior authorization is required for testosterone products. *Payment will be considered with documentation of a specific testicular or hypothalamic/pituitary disease (primary hypogonadism or hypogonadotropic hypogonadism) that results in classic hypogonadism. Requests for FDA approved indications other than hypogonadism will not be subject to prior authorization criteria with adequate documentation of diagnosis.*
Payment for non-preferred testosterone products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred agents. Requests for erectile dysfunction, infertility, and *age-related hypogonadism* will not be considered. Payment will be considered under the following conditions:

1. Patient is male and 18 years of age or older (or 12 years of age and older for testosterone cypionate); and
2. Patient has two (2) morning pre-treatment testosterone levels below the lower limit of the normal testosterone reference range of the individual laboratory used (Please attach lab results); and

3. *Patient has primary hypogonadism or hypogonadotropic hypogonadism (further defined below):*
    - *Primary hypogonadism (congenital or acquired) caused by testicular failure due to one of the following:*
        - *Cryptorchidism*
        - *Bilateral torsion*
        - *Orchitis*
        - *Vanishing testes syndrome,*
        - *Orchiectomy*
        - *Klinefelter's syndrome,*
        - *Chemotherapy*
        - *Toxic damage from alcohol or heavy metals*
    - *Hypogonadotropic hypogonadism*
        - *Idiopathic gonadotropin or luteinizing hormone-releasing (LHRH) deficiency*
        - *Pituitary-hypothalamic injury from tumors, trauma, or radiation*
4. Patient does not have:
    - Breast or prostate cancer
    - Palpable prostate nodule or prostate-specific antigen (PSA) > 4ng/mL
    - Hematocrit > 50%
    - Untreated severe obstructive sleep apnea
    - Severe lower urinary tract symptoms
    - Uncontrolled or poorly controlled heart failure

Requests for continuation of therapy will require the following:
1. An updated testosterone level (Please attach lab result); and
2. Documentation the patient has not experienced a hematocrit > 54% or an increase in PSA > 1.4ng/mL in the past 12 months.

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

Apremilast (Otezla)

Current Prior Authorization Criteria
Prior authorization is required for apremilast (Otezla®). Payment will be considered under the following conditions:
1. Patient is 18 years of age or older; and
2. Patient has a diagnosis of active psoriatic arthritis (≥ 3 swollen joints and ≥ 3 tender joints); and
3. Prescribed by a rheumatologist or a dermatologist; and
4. Patient does not have severe renal impairment (CrCl < 30mL/min); and
5. Patient has documentation of a trial and inadequate response to therapy with the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
6. Patient has documentation of trials and therapy failures with two preferred biological agents used for psoriatic arthritis.

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

Proposed Prior Authorization Criteria (changes italicized)
Prior authorization is required for apremilast (Otezla®). Payment will be considered under the following conditions:

1. Patient is 18 years of age or older; and
2. Patient has a diagnosis of active psoriatic arthritis (≥ 3 swollen joints and ≥ 3 tender joints); *or*
3. *Patient has a diagnosis of moderate to severe plaque psoriasis; and*
4. Prescribed by a rheumatologist or a dermatologist; and
5. Patient does not have severe renal impairment (CrCl < 30mL/min).~~; and~~

Psoriatic Arthritis

- Patient has documentation of a trial and inadequate response to therapy with the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
- Patient has documentation of trials and therapy failures with two preferred biological agents used for psoriatic arthritis.

Plaque Psoriasis

- *Patient has documentation of a trial and inadequate response to phototherapy, systemic retinoids, methotrexate, or cyclosporine; and*
- *Patient has documentation of trials and therapy failures with two preferred biological agents.*

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

The DUR Commission also discussed implementing the following ProDUR quantity limits per 30 days:

Drug	Proposed Quantity Limit Per 30 Days	Current Quantity Limit Per 30 Days
Adderall 12.5mg tablet	90	120
Adderall 20mg tablet	90	120
Alprazolam IR tablet (all strengths)	120	150
Clonazepam tablet (all strengths)	120	150
Concerta 18mg tablet	30	60
Concerta 27mg tablet	30	60
Concerta 54mg tablet	30	60
Focalin IR tablet (all strengths)	60	None
Focalin XR 5mg	30	60
Focalin XR 10mg	30	60
Focalin XR 15mg	30	90
Focalin XR 20mg	30	60
Focalin XR 25mg	30	60
Focalin XR 30mg	30	60
Lorazepam tablet (all strengths)	120	150
Ritalin IR (all strengths)	90	None

The DUR Commission recently re-reviewed their recommendation on ProDUR edits for Antipsychotics initially made in April 2012. Specifically, the Commission recommendation was to:

1. Implement an age edit on risperidone for members less than five (5) years of age and an age edit on all other antipsychotics for members less than six (6) years of age; and
2. Apply a duplicate therapy edit to all antipsychotics for members under 18 years of age initially, with the same edit being applied to members 18 years of age and older in a second phase.

Additionally, the Mental Health Advisory Group (MHAG) reviewed the proposed ProDUR edits on Antipsychotics. After reviewing comments from the MHAG, the DUR Commission felt it would be appropriate to proceed with implementation of the ProDUR edits as initially recommended.

Prior to the formal recommendation of clinical prior authorization criteria going to the Department of Human Services, the DUR Commission is interested in the opinions of the members of your organization. Any comments regarding the proposed prior authorization criteria may be forwarded to me and will be shared with the DUR Commission members. My contact information is listed below. Please have comments/feedback submitted to me on or before March 2, 2015.

Sincerely,

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