IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

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June 9, 2017

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, June 7, 2017. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for GLP-1 Agonist/Basal Insulin Combinations; Calcifediol; (Rayaldee); Lesinurad (Zurampic); and Sapropterin (Kuvan). Additionally, the DUR Commission members made a recommendation to implement ProDUR quantity limits on Lovenox (enoxaparin) and Fragmin (dalteparin). The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to an April 11, 2017 letter that was sent to them detailing the proposed criteria for GLP-1 Agonist/Basal Insulin Combinations; Calciferdiol; (Rayaldee); Lesinurad (Zurampic); and Sapropterin (Kuvan), as well as the proposed ProDUR quantity limits on Lovenox (enoxaparin) and Fragmin (dalteparin).

GLP-1 Agonist/Basal Insulin Combinations

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for GLP-1 agonist receptor/basal insulin combination products. Payment will be considered for patients when the following criteria are met:

1. A diagnosis of type 2 diabetes mellitus; and
2. Patient is 18 years of age or older; and
3. The patient has not achieved HgbA1C goals after a minimum three-month trial with metformin at a maximally tolerated dose, unless evidence is provided that use of this agent would be medically contraindicated; and

4. Documentation of an adequate trial and inadequate response with at least one preferred GLP-1 receptor agonist and one preferred long-acting insulin agent concurrently; and
5. Will not be used concurrently with prandial insulin; and
6. Clinical rational is provided as to why the patient cannot use a preferred GLP-1 receptor agonist and a preferred long-acting insulin agent concurrently; and
7. Medication will be discontinued and alternative antidiabetic products will be used if patients require a daily dosage of:
    a. Soliqua below 15 units or over 60 units, or
    b. Xultophy persistently below 16 units or over 50 units.

Calcifediol (Rayaldee)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for calcifediol (Rayaldee). Initial requests will be considered for patients when the following criteria are met:

1. Patient is 18 years of age or older; and
2. Patient is being treated for secondary hyperparathyroidism associated with a diagnosis of stage 3 or stage 4 chronic kidney disease (CKD) as documented by a current glomerular filtration rate (GFR); and
3. Patient is not on dialysis; and
4. Patient has a serum total 25-hydroxyvitamin D level less than 30 ng/mL and a serum corrected total calcium below 9.8 mg/dL within the past 3 months; and
5. Patient has documentation of a previous trial and therapy failure at a therapeutic dose with a preferred vitamin D analog for a minimum of 3 months.
6. Initial requests will be considered for a dose of 30 mcg once daily for 3 months.

Continuation of therapy will be considered when the following criteria are met:

1. Patient continues to need to be treated for secondary hyperparathyroidism associated with a diagnosis of stage 3 or stage 4 chronic kidney disease (CKD) documented by a current glomerular filtration rate (GFR); and
2. Patient has a serum total 25-hydroxyvitamin D level between 30 and 100 ng/mL, a serum corrected total calcium below 9.8 mg/dL, and a serum phosphorus below 5.5 mg/dL.

Lesinurad (Zurampic)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for lesinurad (Zurampic). Requests for doses above the FDA approved dose will not be considered. Requests 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 hyperuricemia associated with gout; and

3. Patient has not achieved target serum uric acid levels or patient remains symptomatic with a maximally tolerated dose of a xanthine oxidase inhibitor (allopurinol or febuxostat) for at least 3 months; and
4. Patient has documentation of a previous trial and therapy failure with probenecid in combination with a xanthine oxidase inhibitor; and
5. Patient has an estimated creatinine clearance (eCrCl) > 45 mL/min; and
6. Documentation is provided lesinurad will be used in combination with a xanthine oxidase inhibitor.
    a. If taking allopurinol, dose should be ≥300 mg per day (or ≥200 mg per day in patients with an eCrCl < 60 mL/min); and
7. Patient does not have a contraindication to therapy including any of the following:
    a. Severe renal impairment (eCrCl <30 mL/min),
    b. End stage renal disease,
    c. Kidney transplant recipient,
    d. On dialysis,
    e. Tumor lysis syndrome, or
    f. Lesch-Nyhan syndrome.

If criteria for coverage are met, initial requests will be given for 6 months. Continuation of therapy will be considered when the following criteria are met:

1. Patient continues to take medication in combination with a xanthine oxidase inhibitor.
    a. If allopurinol, dose should be ≥300 mg per day (or ≥200 mg per day in patients with an eCrCl < 60 mL/min)
2. Patient has an eCrCl > 45 mL/min; and
3. Patient does not have a contraindication to therapy including any of the following:
    a. Severe renal impairment (eCrCl <30 mL/min),
    b. End stage renal disease,
    c. Kidney transplant recipient,
    d. On dialysis,
    e. Tumor lysis syndrome, or
    f. Lesch-Nyhan syndrome.
4. Documentation of a positive clinical response to lesinurad.

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

Sapropterin (Kuvan)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for sapropterin (Kuvan). Requests for doses above the FDA approved dose will not be considered. Initial requests will be considered for patients when the following criteria are met:

1. Patient has a diagnosis of phenylketonuria (PKU); and
2. Patient is on a phenylalanine (Phe) restricted diet prior to therapy and will continue throughout therapy; and

3. Patient has a baseline blood Phe level ≥360 micromol/L while following a Phe restricted diet, obtained within 2 weeks of initiation of sapropterin therapy (attach lab results); and
4. Patient's current weight is provided; and
5. Request is for an FDA approved starting dose (10mg/kg/day for patients 1 month to 6 years and 10-20mg/kg/day for patients 7 years and older); and
6. Blood Phe levels will be measured after 1 week of therapy and at least one other time during the first month of therapy.

Initial requests will be considered for 1 month to assess response to therapy.
Continuation of therapy will be considered when the following criteria are met:

1. Patient's current weight is provided; and
2. Patient continues on a Phe restricted diet; and
3. For patients initiated at a dose of 10mg/kg/day and the blood Phe level did not decrease from baseline, dose may be increased to 20mg/kg/day. Approval will be given for 1 month to assess response to therapy.
4. For patients initiated at a dose of 20mg/kg/per day or those increased to this dose after 1 month of therapy at 10mg/kg/day, an updated blood Phe level must be provided documenting response to therapy, defined as at least a 30% reduction in blood Phe level. If blood Phe level does not decrease after 1 month at 20mg/kg/day, the patient is considered a non-responder and no further requests will be approved.
5. Maintenance dose requests will be considered for patients that have responded to therapy, based on the above criteria, at 6 month intervals. Documentation of compliance to diet and updated blood Phe levels documenting continued response to therapy are required for further consideration.

Additionally, the DUR Commission made a recommendation to implement ProDUR quantity limits on the following agents (applies to brand and generic):

Drug	**Proposed Quantity Limit per 30 Days**
Fragmin 2,500 u/0.2 mL; Fragmin 5,000 u/0.2 mL	12 mL
Fragmin 7,500 u/0.3 mL	18 mL
Fragmin 10,000 u/mL; Fragmin 25,000 u/mL	60 mL
Fragmin 12,500 u/0.5 mL	30 mL
Fragmin 15,000 u/0.6 mL	36 mL
Fragmin 18,000 u/0.72 mL	43.2 mL
Lovenox 30 mg/0.3 mL	18 mL
Lovenox 40 mg/0.4 mL	24 mL
Lovenox 60 mg/0.6 mL	36 mL
Lovenox 80 mg/0.8 mL; Lovenox 120 mg/0.8 mL	48 mL
Lovenox 100 mg/mL Lovenox 150 mg/mL	60 mL
Lovenox 300 mg/3mL	180 mL

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for GLP-1 Agonist/Basal Insulin Combinations; Calciferdiol; (Rayaldee); Lesinurad (Zurampic); and Sapropterin (Kuvan); and ProDUR quantity limits on Lovenox (enoxaparin) and Fragmin (dalteparin).

Sincerely,

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