Kepro®

Texas HHSC Dur Board Meeting

Prospective Prior Authorization Proposals

April 28, 2023

Proposed Clinical Prior Authorizations

- **Antimigraine Agents, Ergot Derivatives**
  - New criteria
- **Cytokine and CAM Antagonists**
  - Sotyktu (deucravacitinib) – new criteria
  - Rinvoq (upadacitinib) – criteria revision
  - Skyrizi (risankizumab-rzaa) – criteria revision
- **Erythropoiesis-Stimulating Agents**
  - Mircera (methoxy polyethylene glycol-epoetin beta) – new criteria
  - Reblozyl (luspatercept-aamt) – new criteria
- **Gattex (teduglutide)**
  - New criteria

These classes were recommended for review by the MCOs, Kepro and the Vendor Drug Program to ensure appropriate and safe utilization.

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Antimigraine Agents
Ergot Derivatives

Clinical Prior Authorization Proposal

Antimigraine Agents, Ergot Derivatives

- Included in this proposal:
  - Dihydroergotamine 1mg/mL injection
  - Dihydroergotamine nasal spray (includes Migranal 0.5mg/actuation and Trudhesa 0.725mg/actuation)
  - These agents are indicated for patients 18 years of age and older
  - Dosing:
    - Migranal: One spray into each nostril; repeat after 15 minutes (total of 4 sprays [2mg] per dose). The safety of doses greater than 3mg/24 hours and 4mg/7 days have not been evaluated. Note: once opened, the nasal spray should be discarded after 8 hours.
    - Trudhesa: One spray into each nostril (2 sprays per dose); may repeat if needed after ≥ 1 hour for a total of 4 sprays (2 doses). Patients should not use more than 2 doses/24 hours or 3 doses/7 days. Note: once opened, the nasal spray should be discarded after 8 hours.
    - Dihydroergotamine injection:
      - IM: 1mg as a single dose; may repeat hourly as needed
      - SQ: 1mg as a single dose; may repeat after ≥ 2 hours if needed
      - Max dose: 3mg/24 hours; 6mg/7 days
  - WAC Pricing*:
    - Migranal - $3823 for 8 - 4mg/mL vials
    - Dihydroergotamine nasal – varies, lowest WAC is $440 for 8 – 4mg/mL vials
    - Trudhesa - $893 for 4 – 4mg/mL vials
    - Dihydroergotamine injection – varies, lowest WAC is $663 for 10 – 1mg/mL vials

*Costs do not include any rebates that might be applicable

Dihydroergotamine, Migranal, Trudhesa. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2023 [cited 28 Apr 2023]. Available from www.micromedexsolutions.com.

Antimigraine Agents, Ergot Derivatives

- **Approval Criteria:**
  - Age ≥ 18 years
  - Diagnosis of migraine found in the last 730 days
  - Concurrent therapy with a contraindicated drug not found
  - History of a contraindicated diagnosis not found in the last 365 days
  - Request is for less than or equal to the maximum recommended quantity

Label Name	Maximum Quantity
DIHYDROERGOTAMINE 1 MG/ML AMP	24 mg/28 days
DIHYDROERGOTAMINE 4 MG/ML SPRY	32 mg/30 days
MIGRANAL NASAL SPRAY	32 mg/30 days (8 nasal devices)
TRUDHESA NASAL SPRAY	17.4 mg/28 days (Manufacturer recommends no more than 2 doses per 24 hours and no more than 3 doses per week, maximum quantity is 12 inhalers/28 days)

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Cytokine and CAM Antagonists

Clinical Prior Authorization Proposal

Sotyktu (deucravacitinib)

- Indicated for:
  - Treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
  - Dosing:
    - 6mg orally daily
  - WAC Pricing*:
    - $6164 for a 30-day supply

- Sotyktu is the first tyrosine kinase 2 (TYK2) inhibitor to be approved.
  - Sotyktu does not carry a black box warning like JAK inhibitors but has a general warning stating that it is not known whether TYK2 inhibition may be associated with the observed or potential reactions of JAK inhibition.

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Sotyktu. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2023 [cited 28 Apr 2023]. Available from www.micromedexsolutions.com.

Guidelines for the treatment of Plaque Psoriasis

AAD-NPF (2019)

- Mild psoriasis is defined as < 3% BSA involvement, moderate 3 to 10% and severe > 10%.
- Psoriasis Area Severity Index (PASI) is more specific, includes means to quantify extent and severity by looking at BSA and intensity of redness, scaling and plaque thickness.
  - Scores from 0 (no disease) to 72 (maximal disease)
- Management with biologics:
  - TNF inhibitors
  - IL-12/IL-23 inhibitors
  - IL-17 inhibitors
  - IL-23 inhibitors
  - JAK inhibitors
  - PDE4 inhibitors

Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. JAAD 2019;80(4):1029-1072.

Sotyktu (deucravacitinib)

- **Approval Criteria:**
  - Diagnosis of plaque psoriasis found in the last 730 days
  - Age ≥ 18 years
  - Client will not have concurrent therapy with a JAK inhibitor, biologic DMARD, or potent immunosuppressant
  - Client does not have a diagnosis of severe hepatic impairment in the last 365 days
  - Client does not have a history of serious active infection in the last 180 days
  - Requested dose is ≤ 1 tablet daily

Rinvoq (upadacitinib)

- Rinvoq is a JAK inhibitor indicated for:
  - Treatment of patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products or when use of those therapies is inadvisable.
  - Treatment of adult patients with moderately to severely active rheumatoid arthritis, active psoriatic arthritis, moderately to severely active ulcerative colitis, and ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers.
  - New indication recently added: treatment of adult patients with active non-radiographic axial spondylitis (nr-axSpA).
  - Dosing for nr-axSpA:
    - 15mg orally daily
  - WAC Pricing*:
    - $6125 for a 30-day supply

*Costs do not include any rebates that might be applicable

Rinvoq. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2023 [cited 28 Apr 2023]. Available from www.micromedexsolutions.com.

Skyrizi (risankizumab-rzaa)

- Skyrizi is an IL-23 antagonist indicated for:
  - Treatment of adult patients with moderate-to-severe plaque psoriasis and active psoriatic arthritis.
  - New indication recently added: treatment of adult patients with moderately to severely active Crohn's disease.
  - Dosing for Crohn's:
    - Maintenance dose: 180mg or 360mg SQ starting on week 12, and every 8 weeks thereafter
  - WAC Pricing*:
    - $19,735 for 180mg or 360mg injection

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Skyrizi. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2023 [cited 28 Apr 2023]. Available from www.micromedexsolutions.com.

Updated Approval Criteria

- **Rinvoq Revised Approval Criteria:**
  - Diagnosis of nr-axSpA found in the last 730 days

- **Skyrizi Revised Approval Criteria:**
  - Diagnosis of Crohn's found in the last 730 days

Erythropoiesis Stimulating Agents

Clinical Prior Authorization Revision Proposal

Mircera (methoxy polyethylene glycol-epoetin beta)

- Mircera is indicated for:
  - Treatment of anemia associated with chronic kidney disease (CKD) in:
    - Adult patients, regardless of dialysis status.
    - Pediatric patients ages 5 to 17 years on hemodialysis who are converting from another erythropoiesis stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA.
  - Dosing:
    - For adult patients with CKD: initial dose is 0.6 mcg/kg as a single IV dose or SQ every 2 weeks. Once hemoglobin is stabilized, Mircera can be given SQ every 2 weeks and titrated as needed.
    - Pediatric patients: PI contains information about converting the dose from a previous ESA. Mircera can then be given IV every 4 weeks.
  - WAC Pricing*:
    - 30 mcg/0.3 mL: $87
    - 200 mcg/0.3 mL: $577

*Costs do not include any rebates that might be applicable

Mircera. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2023 [cited 28 Apr 2023]. Available from www.micromedexsolutions.com.

Mircera (methoxy polyethylene glycol-epoetin beta)

- **Adult Approval Criteria:**
  - Diagnosis of CKD found in the last 730 days
  - Age ≥ 18 years
  - IF the client has a claim for an ESA in the last 90 days:
    - Client has a history of a complete blood count (CBC) in the last 90 days
    - Client has a history of ferritin and iron binding capacity (IBC) tests in the last 180 days
  - IF the client does not have a claim for an ESA in the last 90 days - approve

- **Pediatric Approval Criteria:**
  - Diagnosis of CKD found in the last 730 days
  - Age ≥ 5 years and < 18 years
  - Client is currently on dialysis
  - Client has a claim for an ESA other than Mircera in the last 60 days
  - Client has a history of a complete blood count (CBC) in the last 90 days
  - Client has a history of ferritin and iron binding capacity (IBC) tests in the last 180 days

Reblozyl (luspatercept-aamt)

- Reblozyl is indicated for:
  - Treatment of adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions.
  - Treatment of anemia in adult patients that have failed an ESA and required 2 or more RBC units over 8 weeks with a diagnosis of very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T).
  - Dosing:
    - Starting dose is 1 mg/kg SQ every 3 weeks.
  - WAC Pricing*:
    - $3725 – 25mg vial
    - $11,176 – 75mg vial

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Reblozyl. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2023 [cited 28 Apr 2023]. Available from www.micromedexsolutions.com.

Reblozyl (luspatercept-aamt)

- **Approval Criteria:**
  - Age ≥ 18 years
  - Diagnosis of beta thalassemia found in the last 730 days, OR diagnosis of MDS-RS or MDS/MPD-RS-T found in the last 365 days
  - Client has a history of a complete blood count (CBC) in the last 90 days
  - Client has a history of ferritin and iron binding capacity (IBC) tests in the last 180 days
  - Requested dose is ≤ 1.25 mg/kg every 3 weeks

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Gattex (teduglutide)

Clinical Prior Authorization Proposal

Gattex (teduglutide)

- Gattex is a GLP-2 analog indicated for:
  - Treatment of patients 1 year of age and older with short bowel syndrome (SBS) who are dependent on parenteral support.
  - Not recommended in pediatric patients weighing less than 10kg.
- Dosing:
  - 0.05 mg/kg SQ daily
  - For patients with severe renal impairment or end-stage renal disease, recommended dose is 0.025 mg/kg SQ daily
- WAC Pricing*:
  - $44,201 per kit (each kit contains 30 single-dose vials of teduglutide and necessary supplies)

*Costs do not include any rebates that might be applicable
*Gattex. *In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2023 [cited 28 Apr 2023]. Available from www.micromedexsolutions.com.*

Gattex (teduglutide)

- **Initial Approval Criteria:**
  - Client is ≥ 1 year of age
  - Client has a diagnosis of short bowel syndrome in the last 730 days
  - Client is currently dependent on parenteral support
  - If the client is ≥ 18 years of age, client has had a colonoscopy in the last 180 days; IF the client is ≥ 1 year and < 18 years, the client has had fecal occult blood testing in the last 180 days
  - Diagnosis of intestinal or stomal obstruction not found in the last 180 days
  - If a diagnosis of moderate to severe renal impairment or ESRD is found in the last 365 days, the requested dose is ≤ 0.025 mg/kg daily; IF the renal impairment diagnoses are not found, the requested dose is ≤ 0.05 mg/kg daily [Manual]
- **Renewal Criteria:**
  - Client is ≥ 1 year of age
  - Client has a diagnosis of short bowel syndrome in the last 730 days
  - Client is currently dependent on parenteral support
  - Client continues to receive clinical benefit from treatment [Manual]