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Texas HHSC Dur Board Meeting

Prospective Prior Authorization Proposals

January 20, 2023

Proposed Clinical Prior Authorizations

- **Antiseizure Agents**
  - Ztalmy (ganaxolone) – new criteria
- **ADD/ADHD Agents**
  - Non-stimulant agents – criteria revision
- **Cytokine and CAM Antagonists**
  - Olumiant (baricitinib) – new criteria for alopecia areata
- **Multiple Sclerosis Agents**
  - Tascenso ODT (fingolimod) – new criteria
- **Opioid/Benzodiazepine/Muscle Relaxant Combinations**
  - Revised criteria
- **Topical Immunomodulators**
  - Opzelura (ruxolitinib) – new criteria for nonsegmental vitiligo

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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Antiseizure Agents
Ztalmy (ganaxolone)

Clinical Prior Authorization Proposal

Ztalmy (ganaxolone)

- Indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 deficiency disorder (CDD).
  - For patients 2 years of age and older.
  - Dosing:
    - Patients ≤ 28kg: starting dose is 6mg/kg TID (18mg/kg/day) and the maximum dose is 21mg/kg TID (63mg/kg/day).
    - Patients > 28kg: starting dose is 150mg TID (450mg/day) and the maximum dose is 600mg TID (1800mg/day).
  - Supplied as on oral suspension: 50mg/mL (110mL bottle).
  - Each bottle should be discarded 30 days after first opening.
  - WAC Pricing*:
    - One 110mL bottle: $2425
    - Max adult dose: $24,250/month
    - Max dose for patients ≤ 28kg: $2425/month

*Costs do not include any rebates that might be applicable

Ztalmy. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2023 [cited 20 Jan 2023]. Available from www.micromedexsolutions.com.

Ztalmy (ganaxolone)

- **Approval Criteria:**
  - Age ≥ 2 years
  - Diagnosis of CDD found in the last 730 days
  - Requested dose ≤ 1800 mg/day

- **Renewal Criteria:**
  - Client is currently stable on therapy with Ztalmy

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ADD/ADHD Agents
Non-Stimulant Agents

Clinical Prior Authorization Revision Proposal

ADD/ADHD Agents (Atomoxetine)

- **Current Approval Criteria:**
  - Age and dosing check

- **Revised Approval Criteria will add/update the steps below:**
  - Atomoxetine:
    - If diagnosis of bipolar disorder is found in the last 365 days, client is currently on a mood stabilizer
    - No diagnosis of suicidal ideation or suicide attempt found in the last 180 days
    - No history of therapy with an MAO inhibitor in the last 14 days
    - No history of severe cardiovascular disease, pheochromocytoma, or narrow angle glaucoma found in the last 365 days

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Cytokine and CAM Antagonists
Olumiant (baricitinib)

Clinical Prior Authorization Revision Proposal

Olumiant (baricitinib)

- Olumiant is a JAK inhibitor with an indication recently added for alopecia areata (currently approved for treatment of rheumatoid arthritis and COVID-19).
  - Dosing:
    - For clients 18 years and older: 2 mg once daily, may be increased to 4 mg daily if the response to treatment is not adequate.
  - WAC Pricing*:
    - 1mg/2 mg tablets: $2497/month
    - 4 mg tablets: $4994/month

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Olumiant. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2023 [cited 20 Jan 2023]. Available from www.micromedexsolutions.com.

Guidelines for the treatment of Alopecia Areata

UpToDate (2022)

- Assess severity
  - Less than 50% hair loss: intralesional corticosteroid injections (preferred) or topical corticosteroids. If satisfactory response, treatment can be stopped or tapered.
  - More than 50% hair loss, or poor response with intralesional corticosteroid injections or topical corticosteroids: oral JAK inhibitor or topical immunotherapy. If satisfactory response, continue JAK inhibitor and taper topical immunotherapy to lowest frequency necessary to maintain response.
  - If poor response to JAK inhibitor or topical immunotherapy: trial of alternative JAK inhibitor, dupilumab, oral immunosuppressants, sulfasalazine, or topical anthralin.

Messenger AG, Alopecia areata: Management. 2022. Ofori AO, ed. UpToDate. Waltham, MA: UpToDate Inc. (Accessed January 3, 2023).

Olumiant (baricitinib)

- **Current Approval Criteria:**
  - Age ≥ 18 years
  - Diagnosis of rheumatoid arthritis found in the last 730 days
  - Claim for a TNF-blocker found in the last 180 days
  - No claim for a JAK inhibitor, biologic DMARD or potent immunosuppressant found in the last 30 days
  - No claim for an OAT3 inhibitor found in the last 90 days
  - No diagnosis found in the last 180 days that indicates increased risk of GI perforation, thrombosis, or malignancy
  - No diagnosis of severe renal or hepatic impairment found in the last 365 days
  - No history of serious active infection found in the last 180 days
  - Requested dose is less than or equal to 1 tablet daily
- **Revised Approval Criteria will add/update the steps below:**
  - Diagnosis of alopecia areata found in the last 730 days

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Multiple Sclerosis Agents
Tascenso ODT (fingolimod)

Clinical Prior Authorization Proposal

Tascenso ODT (fingolimod)

- Tascenso ODT:
  - Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome (CIS), relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older, weighing less than or equal to 40 kg.
- Dosing:
  - 0.25 mg orally once daily
- WAC Pricing*:
  - $9741/month

*Costs do not include any rebates that might be applicable

Tascenso ODT. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2023 [cited 20 Jan 2023]. Available from www.micromedexsolutions.com.

Tascenso ODT (fingolimod)

- **Approval Criteria:**
  - Client is ≥ 10 years of age
  - Client has a diagnosis of MS found in the last 730 days
  - Client will not have concurrent therapy with another fingolimod product
  - Diagnosis of MI, unstable angina, stroke, TIA, decompensated heart failure, or class III/IV heart failure not found in the last 180 days
  - History of Mobitz type II second-degree, third-degree AV block, sick sinus syndrome or sino-atrial block not found in the last 180 days, OR the client has a functioning pacemaker
  - History of therapy with class Ia or class III anti-arrhythmic drugs not found in the last 90 days
  - Requested dose ≤ 1 tablet/day

Opioid/Benzodiazepine/Muscle Relaxant Combinations

Clinical Prior Authorization Revision Proposal

Opioid/Benzodiazepine/Muscle Relaxant Combinations

- Current approval criteria:
  - Edit #1: must have a 14-day overlap of an opiate, a benzodiazepine and a muscle relaxant in the last 35 days
  - Edit #2: must have a 14-day overlap of an opiate and a benzodiazepine in the last 35 days
  - Edit #3: must have a 14-day overlap of a benzodiazepine and a muscle relaxant in the last 35 days

- Requested criteria revision:
  - Update to a 7-day overlap in the last 35 days

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Topical Immunomodulators
Opzelura (ruxolitinib)

Clinical Prior Authorization
Revision Proposal

Opzelura (ruxolitinib)

- Opzelura is a topical JAK inhibitor with a new indication added for treatment of nonsegmental vitiligo (currently approved for treatment of mild to moderate atopic dermatitis).
  - Dosing:
    - For clients 12 years and older: apply a thin layer twice daily to affected areas of up to 10% body surface area. Do not use more than one 60gm tube per week or one 100gm tube per 2 weeks.
  - WAC Pricing*:
    - 60gm tube: $1950
    - 240gm (max amount per month): $7800

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Opzelura. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2023 [cited 20 Jan 2023]. Available from www.micromedexsolutions.com.

Guidelines for the treatment of Nonsegmental Vitiligo

UpToDate (2022)

- Assess severity
  - To stabilize rapidly progressive nonsegmental vitiligo: suggest oral glucocorticoids and/or narrowband UVB as first-line therapy.
  - Patients with stable vitiligo affecting < 10% body surface area (BSA):
    - Mid- to high-potency topical corticosteroids (TCS) or topical calcineurin inhibitors (TCI) are recommended as first-line therapy.
    - Topical ruxolitinib is a therapeutic option for patients who do not respond to TCS or TCI and may be alternative first-line therapy in appropriate patients.
  - Patients with disseminated disease:
    - Topical therapies may be impractical and may be best treated with narrowband UVB.
  - Recalcitrant disease:
    - Therapeutic options may include targeted phototherapy, psoralen plus UVA photochemotherapy and surgical options.
  - Vitiligo involving 10 to 40% BSA: narrowband UVB is recommended as first-line therapy. TCS or TCI may intermittently used in combination.
  - Vitiligo involving > 40% BSA: narrowband UVB is recommended as first-line therapy.

Grimes PE. Vitiligo: Management and Prognosis. 2022. Corona R, ed. UpToDate. Waltham, MA: UpToDate Inc. (Accessed January 3, 2023).

Opzelura (ruxolitinib)

- **Current Approval Criteria:**
  - Age ≥ 12 years
  - Claim for a topical steroid found in the last 365 days, OR claim for crisaborole, pimecrolimus or tacrolimus found in the last 90 days
  - Diagnosis of atopic dermatitis found in the last 730 days
  - No history of serious active infection found in the last 180 days
  - Client will not have concurrent therapy with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants
  - No claim for a strong CYP3A4 inhibitor found in the last 90 days
  - Requested quantity is ≤ 60 gm/week or 240 gm/month
  - If client has prior therapy with ruxolitinib, there is ≤ 56 days in the last 200 days
- **Revised Approval Criteria will add/update the steps below:**
  - Diagnosis of nonsegmental vitiligo in the last 730 days