Clinical Policy: Tildrakizumab-asmn (Ilumya)
Reference Number: CP.PHAR.386
Effective Date: 05.01.18
Last Review Date: 05.19
Line of Business: Medicaid, HIM-Medical Benefit

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Tildrakizumab-asmn (Ilumya™) is an interleukin-23 (IL-23) blocker.

FDA Approved Indication(s)
Ilumya is indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Ilumya is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Plaque Psoriasis (must meet all):
       1. Diagnosis of PsO;
       2. Prescribed by or in consultation with a dermatologist or rheumatologist;
       3. Age ≥ 18 years;
       4. Member meets one of the following (a or b):
          a. Failure of a trial of ≥ 3 consecutive months of methotrexate (MTX) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
          b. If intolerance or contraindication to MTX (see Appendix D), failure of a trial of ≥ 3 consecutive months of cyclosporine or acitretin at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
       5. Failure of etanercept (Enbrel® is preferred) and adalimumab (Humira® is preferred), each used for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced; *Prior authorization is required for etanercept and adalimumab
       6. Dose does not exceed 100 mg at weeks 0 and 4, followed by maintenance dose of 100 mg every 12 weeks.

Approval duration: 6 months

*Revision Log*
B. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid and HIM-Medical Benefit.

II. Continued Therapy
A. Plaque Psoriasis (must meet all):
   1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   2. Member is responding positively to therapy;
   3. If request is for a dose increase, new dose does not exceed 100 mg every 12 weeks.
   Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):
   1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
   2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid and HIM-Medical Benefit.

III. Diagnoses/Indications for which coverage is NOT authorized:
A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid and HIM-Medical Benefit or evidence of coverage documents.

IV. Appendices/General Information
   Appendix A: Abbreviation/Acronym Key
   FDA: Food and Drug Administration
   IL-23: interleukin-23
   MTX: methotrexate
   PsO: plaque psoriasis

   Appendix B: Therapeutic Alternatives
   This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>acitretin (Soriatane®)</td>
<td>PsO 25 or 50 mg PO daily</td>
<td>50 mg/day</td>
</tr>
<tr>
<td>cyclosporine (Sandimmune®, Neoral®)</td>
<td>PsO 2.5 – 4 mg/kg/day PO divided BID</td>
<td>4 mg/kg/day</td>
</tr>
<tr>
<td>methotrexate (Rheumatrex®)</td>
<td>PsO 10 – 25 mg/week PO or 2.5 mg PO Q12 hr for 3 doses/week</td>
<td>30 mg/week</td>
</tr>
</tbody>
</table>
### CLINICAL POLICY

#### Tildrakizumab-asmn

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Enbrel® (etanercept)</strong></td>
<td>PsO</td>
<td>50 mg/week</td>
</tr>
<tr>
<td><strong>Initial dose:</strong></td>
<td>50 mg SC twice weekly for 3 months</td>
<td></td>
</tr>
<tr>
<td>Maintenance dose:</td>
<td>50 mg SC once weekly</td>
<td></td>
</tr>
<tr>
<td><strong>Humira® (adalimumab)</strong></td>
<td>PsO</td>
<td>40 mg every other week</td>
</tr>
<tr>
<td><strong>Initial dose:</strong></td>
<td>80 mg SC</td>
<td></td>
</tr>
<tr>
<td>Maintenance dose:</td>
<td>40 mg SC every other week starting one</td>
<td></td>
</tr>
<tr>
<td></td>
<td>week after initial dose</td>
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</tbody>
</table>

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

**Appendix C: Contraindications/Boxed Warnings**
- Contraindication(s): Serious hypersensitivity reaction to tildrakizumab or to any of the excipients
- Boxed warning(s): none reported

**Appendix D: General Information**
- Definition of failure of MTX or DMARDs
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.

**V. Dosage and Administration**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PsO</strong></td>
<td>Initial dose: 100 mg SC at weeks 0 and 4</td>
<td>100 mg every 12 weeks</td>
</tr>
<tr>
<td></td>
<td>Maintenance dose: 100 mg SC every 12 weeks</td>
<td></td>
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<tr>
<td></td>
<td>Ilumya should only be administered by a healthcare professional.</td>
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</tr>
</tbody>
</table>

**VI. Product Availability**
- Single-dose prefilled syringe: 100 mg/1 mL
VII. References


<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy created</td>
<td>05.01.18</td>
<td>08.18</td>
</tr>
<tr>
<td>2Q 2019 annual review: no significant changes; added HIM-Medical Benefit; references reviewed and updated.</td>
<td>02.26.19</td>
<td>05.19</td>
</tr>
</tbody>
</table>

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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