Clinical Policy: Guselkumab (Tremfya)
Reference Number: CP.PHAR.364
Effective Date: 08.29.17
Last Review Date: 05.19
Line of Business: Medicaid

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

Description
Guselkumab (Tremfya®) is an interleukin-23 (IL-23) blocker.

FDA Approved Indication(s)
Tremfya 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 Tremfya 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 ≥ 3 consecutive month trial 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 ≥ 3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
      5. Failure of a ≥ 3 consecutive month trial of Taltz®, unless contraindicated or clinically significant adverse effects are experienced;
         *Prior authorization is required for Taltz
      6. Dose does not exceed 100 mg at weeks 0 and 4, followed by maintenance dose of 100 mg every 8 weeks.

Approval duration: 6 months
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.

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 8 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.

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 policy – CP.PMN.53 for Medicaid 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 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>
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<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>
**Drug Name** | **Dosing Regimen** | **Dose Limit/Maximum Dose**
--- | --- | ---
Taltz® (ixekizumab) | **PsO**
Initial dose: 160 mg (two 80 mg injections) SC at week 0, then 80 mg SC at weeks 2, 4, 6, 8, 10, and 12
Maintenance dose: 80 mg SC every 4 weeks | 80 mg every 4 weeks

*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
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>
</table>
| PsO | Initial dose: 100 mg SC at weeks 0 and 4
   Maintenance dose: 100 mg SC every 8 weeks | 100 mg every 8 weeks |

VI. Product Availability
Single-dose prefilled syringe: 100 mg/mL

VII. References


Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>C9029</td>
<td>Injection, guselkumab, 1 mg</td>
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Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>08.29.17</td>
<td>11.17</td>
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<tr>
<td>02.27.18</td>
<td>05.18</td>
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<td>09.04.18</td>
<td>11.18</td>
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<tr>
<td>02.26.19</td>
<td>05.19</td>
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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.
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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**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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