

Montana Healthcare Programs Physicians Administered Drug Coverage Interim Criteria

TREMFYA® (guselkumab)

I. Medication Description

Tremfya® is an interleukin-23 antagonist indicated for the treatment of:

- Active psoriatic arthritis in adults
- Moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy

II. Position Statement

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

III. Initial Coverage Criteria

Active Psoriatic Arthritis

Member must meet all the following criteria:

- Member must be 18 years of age or older.
- Member must have a diagnosis of psoriatic arthritis.
- Must be prescribed by or in consult with an appropriate specialist (rheumatologist).
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Must have a trial and inadequate response or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List.
- Prescriber attests to the following:
 - The member has been screened for tuberculosis (TB) prior to initiating treatment.
 - The provider will monitor for active infection.
- Provider attests member will not use Tremfya® concomitantly with other biologics.

Moderate to Severe Plague Psoriasis

Member must meet all the following criteria:

- Member must be 18 years of age or older.
- Member must have a diagnosis of moderate to severe plaque psoriasis.
- Must be prescribed by or in consult with an appropriate specialist (dermatologist/rheumatologist).
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Must have a trial and inadequate response or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List.
- Prescriber attests to the following:
 - The member has been screened for TB prior to initiating treatment.

- o The provider will monitor for active infection.
- Provider attests member will not use Tremfya® concomitantly with other biologics.

IV. Renewal Coverage Criteria

Member must meet all the following criteria:

- Member has documentation of positive clinical response to therapy (reduction in the frequency and/or severity of symptoms and exacerbations).
- Annual specialist consult provided if prescriber not a specialist.
- Provider attests member will not use Tremfya® concomitantly with other biologics.

V. Quantity Limitations

- Dosing is the same for moderate to severe plaque psoriasis and active psoriatic arthritis
 - o 100mg subcutaneous injection at Week 0, Week 4 and every 8 weeks thereafter

VI. Coverage Duration

- Initial approval: 4 doses (weeks 0, 4, 12 and 20). Update required prior to dose at 28 weeks.
- Renewal approval duration for all: 1 year