ALASKA MEDICAID
Prior Authorization Criteria

Tremfya®
(guselkumab)

FDA INDICATIONS AND USAGE[1]

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

- moderate to severe plaques psoriasis who are candidates for systemic therapy or phototherapy
- active psoriatic arthritis
- moderately to severely active ulcerative colitis

APPROVAL CRITERIA[1,2,3]

1. Initial Authorization Request must include:
   - Monitoring plan
   - Previous therapies trialed and the nature of the failure
   - Complete medication regimen
   - Confirmation patient is **not** receiving concurrent phototherapy
   - Requested dosing which conforms to an FDA approved regimen based on indication

   Plaque psoriasis (PsO)
   1. Patient meets FDA labeled age; **AND**
   2. Has moderate to severe Ps; **AND**
   3. Has a Psoriasis Area and Severity Index (PASI) score ≥ 12 (or equivalent); **AND**
   4. Has tried and failed a TNF blocker and at least one other therapy to include at least one topical agent.

   Psoriatic Arthritis (PsA)
   1. Patient meets FDA labeled age; **AND**
   2. Has active PsA; **AND**
   3. Has a Health Assessment Questionnaire-Disability Index (HAQ-DI) score ≥ 2 (or equivalent); **AND**
   4. Has tried and failed a TNF blocker and at least one other therapy.

   Ulcerative Colitis (UC)
   1. Patient meets FDA labeled age; **AND**
   2. Has moderate to severely active UC; **AND**
   3. Baseline Mayo score (or equivalent) has been submitted; **AND**
   4. Has tried and failed a TNF blocker and at least one other therapy (e.g. azathioprine, cyclosporine, mesalamine, etc.).

DENIAL CRITERIA[1]

1. Known hypersensitivity to guselkumab or any of its excipients.
2. Current active severe infection.
3. Concurrent therapy with another biologic agent.
4. Concurrent phototherapy.

CAUTIONS[1]

1. Patients should be evaluated for tuberculosis (TB) prior to initiating guselkumab. Guselkumab should not be initiated in a patient with an active TB infection.
2. Patients should not receive live vaccines while being treated with guselkumab.
3. Serious hypersensitivity reactions, including anaphylaxis, have been reported
4. Tremfya may increase the risk of infection. If a clinically significant infection develops while being treated with guselkumab, discontinue until the infection resolves.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months

REFERENCES / FOOTNOTES:

1. Tremfya (guselkumab [prescribing information]. Horsham, PA: Janssen Biotech; September 2024
2. The Efficacy and Safety of Guselkumab as Maintenance Therapy in Patients With Moderately to Severely Active Ulcerative Colitis: Results From the Phase 3 QUASAR Maintenance Study. Gastroenterol Hepatol (N Y). 2024 Jul;20(7 Suppl 6):8-9. PMID: 39193118; PMCID: PMC11345979.
3. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4: Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol. 2009;61:451-485.