

Standard Medicare Part B Management Tremfya IV

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tremfya IV	guselkumab

Indications

FDA-approved Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, the member has no exclusions to the prescribed therapy, and the drug or biological is usually not self-administered. The criteria outlined in this policy is only applicable to drugs not usually self-administered and are furnished incident to a physician's service. Requests for drugs on a region's self-administered drug list are not covered. Members enrolled in Medicare Part D may seek coverage under their Medicare Part D plan.

FDA-approved Indications

For the treatment of moderately to severely active ulcerative colitis (UC) in adults.

- The following indications are FDA-approved but the drug approved to treat the indication is usually self-administered and thus not covered by this policy.
 - For the treatment of moderate to severe plaque psoriasis (PsO) in adults who are candidates for phototherapy or systemic therapy.
 - For the treatment of active psoriatic arthritis (PsA) in adults.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

Reference number(s)
6653-A

Documentation

The following documentation must be available, upon request, for all submissions:

Ulcerative colitis (UC)

For continuation requests: Chart notes or medical record documentation supporting benefit of therapy.

Coverage Criteria

Ulcerative colitis (UC)

Authorization of 12 months may be granted for treatment of moderately to severely active ulcerative colitis.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Ulcerative colitis (UC)

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with Tremfya.
- Tremfya is being used to treat an indication listed in the coverage criteria section.
- The member is receiving benefit from therapy.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Tremfya.
- The available compendium
 - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
 - Micromedex DrugDex
 - American Hospital Formulary Service- Drug Information (AHFS-DI)
 - Lexi-Drugs
 - Clinical Pharmacology
- 2019 ACG Clinical Guideline: Ulcerative Colitis in Adults
- AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis

Reference number(s)
6653-A

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Tremfya are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

References

1. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2024.
2. Self-Administered Drug Exclusion List: and Biologicals Excluded from Coverage- Medical Policy Article (A52527) Version RX. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed September 19, 2024.
3. Self-Administered Drug Exclusion List: (A52571). Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed September 19, 2024.
4. Self-Administered Drug Exclusion List: (A53032). Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed September 19, 2024.
5. Self-Administered Drug Exclusion List: (A53033). Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed September 19, 2024.
6. Self-Administered Drug Exclusion List: Medical Policy Article (A53021). Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed September 19, 2024.
7. Self-Administered Drug Exclusion List: (SAD List) (A52800). Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed September 19, 2024.
8. Self-Administered Drug Exclusion List: (A53127). Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed September 19, 2024.
9. Self-Administered Drug Exclusion List: (A53066). Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed September 19, 2024.
10. Self-Administered Drug Exclusion List: Medical Policy Article (A53022). Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed September 19, 2024.