Reference number(s)
6653-A

Standard Medicare Part B Management Tremfya Intravenous (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	Dosage Form
Tremfya	guselkumab	intravenous (IV)

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[1]

- Treatment of moderately to severely active ulcerative colitis (UC) in adults.
- Treatment of moderately to severely active Crohn's disease (CD) 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.

- Treatment of moderate to severe plaque psoriasis (PsO) in adults who are candidates for phototherapy or systemic therapy.
- Treatment of active psoriatic arthritis (PsA) in adults.

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

Coverage Criteria

Ulcerative colitis (UC)[1,2]

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

Crohn's disease (CD)[1,2]

Authorization of 12 months may be granted for treatment of moderately to severely active Crohn's disease.

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 Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis
- ACG Clinical Guideline: Management of Crohn's Disease in Adults
- AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease

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.

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References

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3. Self-Administered Drug Exclusion List: (A52571) Version R28. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed March 25, 2025.
4. Self-Administered Drug Exclusion List: (A53032) Version R40. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed March 25, 2025.
5. Self-Administered Drug Exclusion List: (A53033) Version R41. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed March 25, 2025.
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9. Self-Administered Drug Exclusion List: (A53066) Version R46. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. March 25, 2025.
10. Self-Administered Drug Exclusion List: Medical Policy Article (A53022) Version R38. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed March 25, 2025.

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