guselkumab (Tremfya™) intravenous

Medicare Advantage Medical Policy #MA-141
Original Effective Date: 01/01/2026
Current Effective Date: 01/01/2026

Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Per the Self-Administered Drug list as defined by the Medicare Administrative Contractor for the Health Plan, subcutaneous guselkumab (Tremfya™) is eligible for coverage under Part D only and not targeted by this policy.

Ulcerative Colitis

Based on review of available data, the Health Plan may consider intravenous guselkumab (Tremfya™) for the treatment of moderately to severely active ulcerative colitis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for intravenous guselkumab (Tremfya) will be considered when all of the following criteria are met:

- Patient has a diagnosis of moderately to severely active ulcerative colitis; AND
- Patient is 18 years of age or older; AND
- Patient has failed or become intolerant to treatment with traditional immunomodulators (e.g., azathioprine, 6-mercaptopurine) or corticosteroids; AND
- Tremfya is NOT being used concurrently with other biologic products such as infliximab (Remicade®‡, biosimilars), adalimumab (Humira, biosimilars), or vedolizumab (Entyvio®)‡ for the treatment of moderately to severely active ulcerative colitis; AND
- Patient has negative tuberculosis (TB) test (e.g. purified protein derivative [PPD], blood test) prior to treatment; AND
- The requested dosage does not exceed 200 mg at week 0, week 4, and week 8.

Crohn's Disease

Based on review of available data, the Health Plan may consider intravenous guselkumab (Tremfya) for the treatment of moderately to severely active Crohn's disease to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for intravenous guselkumab (Tremfya) will be considered when all of the following criteria are met:

Initial

- Patient has a diagnosis of moderately to severely active Crohn's disease; AND

- Patient is 18 years of age or older; AND
- Patient has failed or become intolerant to treatment with traditional immunomodulators (e.g., azathioprine, 6-mercaptopurine) or corticosteroids OR the patient has failed or become intolerant to a tumor necrosis factor (TNF) blocker or another biologic for the treatment of Crohn's disease such as infliximab (Remicade, biosimilars), adalimumab (Humira, biosimilars), or vedolizumab (Entyvio); AND
- Tremfya is NOT being used concurrently with other biologic products such as infliximab (Remicade, biosimilars), adalimumab (Humira, biosimilars), or vedolizumab (Entyvio) for the treatment of moderately to severely active Crohn's disease; AND
- Patient has negative TB test (e.g. purified protein derivative [PPD], blood test) prior to treatment; AND
- The requested dosage does not exceed 200 mg at week 0, week 4, and week 8.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Health Plan considers the use of intravenous guselkumab (Tremfya) when any of the following criteria for their respective disease state listed below (and denoted in the patient selection criteria above) are not met to be **not medically necessary**:**

- For ulcerative colitis:
  - Patient has failed or become intolerant to treatment with traditional immunomodulators (e.g., azathioprine, 6-mercaptopurine) or corticosteroids
- For Crohn's disease:
  - Patient has failed or become intolerant to treatment with traditional immunomodulators (e.g., azathioprine, 6-mercaptopurine) or corticosteroids OR the patient has failed or become intolerant to a tumor necrosis factor (TNF) blocker or another biologic for the treatment of Crohn's disease

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan considers the use of intravenous guselkumab (Tremfya) when patient selection criteria are not met (with the exception of those denoted as **not medically necessary****) to be **investigational.***

Background/Overview

Tremfya is an interleukin-23 (IL-23) blocker indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy, for the treatment of adults with active psoriatic arthritis, for the treatment of adults with moderately to severely active ulcerative colitis, and for the treatment of adults with moderately to severely active Crohn's disease. IL-23 is a naturally occurring cytokine that is involved in normal inflammatory and immune

responses. Tremfya inhibits the release of pro-inflammatory cytokines and chemokines. Tremfya is supplied as 100 mg in a single-dose prefilled syringe, single dose prefilled pen, or a single dose patient-controlled injector and as 200 mg in a single-dose prefilled pen, single-dose prefilled syringe, or single-dose vial. Tremfya is dosed at 100 mg at weeks 0 and 4 and every 8 weeks thereafter for plaque psoriasis and psoriatic arthritis. For ulcerative colitis, an induction dose of 200 mg administered by intravenous infusion at week 0, week 4, and week 8, and a maintenance dose of 100 mg administered by subcutaneous injection beginning at week 16 and every 8 weeks thereafter or 200 mg administered by subcutaneous injection at week 12 and every 4 weeks thereafter is recommended. The recommended induction dose for Crohn's disease is 200 mg administered by intravenous infusion at weeks 0, 4, and 8 or 400 mg administered by subcutaneous injection at weeks 0, 4, and 8. The maintenance dose for Crohn's disease is 100 mg administered by subcutaneous injection at week 16 and every 8 weeks thereafter, or 200 mg given by subcutaneous injection at week 12 and every 4 weeks thereafter. For ulcerative colitis and Crohn's disease maintenance dosing, the lowest effective recommended dosage should be used to maintain therapeutic response.

Ulcerative Colitis
Ulcerative colitis is a chronic, episodic, inflammatory disease of the large intestine and rectum characterized by bloody diarrhea. This disease usually begins in the rectal area and may eventually extend through the entire large intestine. Repeated episodes of inflammation lead to thickening of the wall of the intestine and rectum with scar tissue. Death of colon tissue or sepsis may occur with severe disease. The goals of treatment are to control the acute attacks, prevent recurrent attacks and promote healing of the colon. Hospitalization is often required for severe attacks. Typically, first line treatments such as corticosteroids, 6-mercaptopurine and azathioprine are used to treat this condition.

Crohn's Disease
Crohn's disease is a chronic autoimmune disease that can affect any part of the gastrointestinal tract but most commonly occurs in the ileum. As a result of the immune attack, the intestinal wall becomes thick, and deep ulcers may form. In addition to the bowel abnormalities, Crohn's disease can also affect other organs in the body. Typically, first line treatments such as corticosteroids, 6-MP and azathioprine are used to treat this condition.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Tremfya is an interleukin-23 blocker approved in July of 2017 for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. In July of 2020, Tremfya was approved for the treatment of adult patients with active psoriatic arthritis. Tremfya gained approval for the treatment of adult patients with moderately to severely active ulcerative colitis in September of 2024. In March of 2025, Tremfya was approved for the treatment of adult patients with moderately to severely active Crohn's disease.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Ulcerative Colitis

The safety and efficacy of Tremfya were assessed in 2 studies, an induction and maintenance study. In the induction trial, UC1, subjects with moderately to severely active ulcerative colitis were randomized 3:2 to receive either Tremfya 200 mg or placebo by intravenous infusion at week 0, week 4, and week 8. The primary endpoint was clinical remission at week 12 defined by the modified Mayo Score (mMS). The mMS is a 3-component Mayo score (0-9) which consists of the following subscores (0 to 3 for each subscore): stool frequency (SFS), rectal bleeding (RBS), and findings on centrally reviewed endoscopy (ES). An ES of 2 was defined by marked erythema, lack of vascular pattern, friability, and/or erosions; an ES of 3 was defined by spontaneous bleeding and ulceration. The primary endpoint in UC1 was achieved by 23% of patients in the Tremfya treatment group compared to 8% of patients in the placebo treatment group. In the maintenance trial, UC2, subjects who demonstrated a clinical response to Tremfya IV induction dosing were re-randomized to receive a subcutaneous maintenance regimen of either Tremfya 100 mg every 8 weeks, Tremfya 200 mg every 4 weeks, or placebo for up to an additional 44 weeks. The primary endpoint for UC2 was clinical remission at week 44 defined by mMS. Secondary endpoints included corticosteroid-free clinical remission, endoscopic improvement, histologic endoscopic mucosal improvement, all at week 44 and maintenance of clinical remission at week 44 in subjects who achieved clinical remission 12 weeks after intravenous Tremfya induction treatment. In UC2, 45% of patients receiving Tremfya 100 mg every 8 weeks, 50% of patients receiving Tremfya 200 mg every 4 weeks, and 19% of patients receiving placebo all met the primary endpoint of clinical remission at week 44.

Crohn's Disease

The efficacy and safety of Tremfya were assessed in three randomized, double-blind, placebo-controlled trials that enrolled adult subjects with moderately to severely active Crohn's disease who had a history of inadequate response, loss of response, or intolerance to oral corticosteroids, immunomodulators (azathioprine, 6-mercaptopurine, methotrexate), and/or biologic therapy (TNF blockers or vedolizumab). Moderately to severely active Crohn's disease was defined as a Crohn's Disease Activity Index (CDAI) score of ≥ 220 and a Simple Endoscopic Score for Crohn's Disease (SES-CD) of ≥ 6 (or ≥ 4 for subjects with isolated ileal disease). In CD1 and CD2, subjects were randomized to receive intravenous Tremfya 200 mg at weeks 0, 4, and 8 or placebo. The co-primary endpoints were clinical remission at week 12, defined as CDAI score < 150, and endoscopic response, defined as > 50% improvement from baseline in SES-CD score. In CD1 and CD2, 47% of subjects receiving Tremfya achieved clinical remission compared to 20% and 15%, respectively, of those receiving placebo. 36% of subjects receiving Tremfya in CD1 and 34% of subjects receiving Tremfya in CD2 had an endoscopic response compared to 9% of subjects receiving placebo in CD1

and 13% of subjects receiving placebo in CD2. In CD3, subjects were randomized to receive subcutaneous Tremfya 400 mg at weeks 0, 4, and 8 followed by subcutaneous Tremfya 100 mg every 8 weeks, subcutaneous Tremfya 400 mg at weeks 0, 4, and 8 followed by subcutaneous Tremfya 200 mg every 4 weeks, or placebo. In CD3, the coprimary endpoints were clinical remission at week 12 and endoscopic response at week 12 compared to placebo. In CD3, 56% of subjects receiving Tremfya achieved clinical remission compared to 22% of subjects receiving placebo. In CD3, 34% of subjects receiving Tremfya had an endoscopic response compared to 15% of those receiving placebo.

References

1. Tremfya [package insert]. Janssen Biotech, Inc. Horsham, Pennsylvania. Updated March 2025.

Policy History

Original Effective Date: 01/01/2026
Current Effective Date: 01/01/2026
09/16//2025 UM Committee review and approval. New policy.
Next Scheduled Review Date: 09/2026

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of the Health Plan Medical Policy Coverage Guidelines is with the Health Plan and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in the Health Plan Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of the Health Plan Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No code
HCPCS	J1628
ICD-10 Diagnosis	All Related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

Medicare Advantage Members

Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-bene-help.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.