# Medical Policy Bulletin

**Title:**
Guselkumab (Tremfya®) Injection for Intravenous Use
**Policy #:**
MA08.179a

**The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.**

**When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.**

**This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.**

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## Policy

**Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.**

**The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.**

**In the absence of coverage criteria from applicable Medicare statutes, regulations, NCDs, LCDs, CMS manuals, or other Medicare coverage documents, this policy uses internal coverage criteria developed by the Company in consideration of peer-reviewed medical literature, clinical practice guidelines, and/or regulatory status.**

**MEDICALLY NECESSARY**

Guselkumab (Tremfya) for intravenous (IV) infusion is considered medically necessary and, therefore, covered for the treatment of individuals with moderate-to-severe active ulcerative colitis AND crohn's disease when ALL of the following criteria listed below are met:

**ULCERATIVE COLITIS/CROHN'S DISEASE**

- The individual is at least 18 years of age.
- There is documentation of inadequate response, lost response, or intolerance to a trial of one or more conventional therapies : (e.g., immunomodulators, dependence of corticosteroids, biologics)
- No concurrent use with any other biologic therapy (i.e., tumor necrosis factor antagonists)
- Prescribed by or in consultation with a gastroenterologist
- Dosing and frequency: IV infusion will be used as an induction dose, followed by maintenance dosing with subcutaneous (SC) injection
    - Induction: IV: 200 mg on weeks 0, 4, and 8 followed by maintenance (Tremfya SC)

Note: The duration of guselkumab (Tremfya) IV infusion is limited to three doses.

**EXPERIMENTAL/INVESTIGATIONAL**

All other uses for guselkumab (Tremfya) injection for IV use are considered experimental/investigational and,

therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

**REQUIRED DOCUMENTATION**

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

When coverage of guselkumab (Tremfya) injection for IV use is requested outside of the Dosing and Frequency Requirements listed in this policy, the prescribing professional provider must supply documentation (i.e., published peer-reviewed literature) to the Company that supports this request.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

**BILLING REQUIREMENTS**

For drugs that have more than one method of administration, application of the JA modifier is required to indicate the route of administration.

- To report the IV route of administration, append the following modifier: JA Administered Intravenously

Inclusion of a code in this policy does not imply reimbursement. Eligibility, benefits, limitations, exclusions, utilization management/referral requirements, provider contracts, and Company policies apply.

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## Guidelines

**BENEFIT APPLICATION**

Subject to the applicable Evidence of Coverage, guselkumab (Tremfya) injection for intravenous use is covered under the medical benefits of the Company's Medicare Advantage products when the medical necessity criteria and Dosing and Frequency Requirements listed in this medical policy are met.

For Medicare Advantage members, certain drugs are available through either the member's medical benefit (Part B benefit) or pharmacy benefit (Part D benefit), depending on how the drug is prescribed, dispensed, or administered. This medical policy only addresses instances when guselkumab (Tremfya) injection for intravenous use is covered under a member's medical benefit (Part B benefit). It does not address instances when guselkumab (Tremfya) injection for intravenous use is covered under a member's pharmacy benefit (Part D benefit).

Guselkumab (Tremfya) injection for *subcutaneous* use is not covered under the medical benefits for most of the Company's products. Guselkumab (Tremfya) injection for *subcutaneous* use may be covered under a member's pharmacy benefit, if applicable.

**US FOOD AND DRUG ADMINISTRATION (FDA) STATUS**

Initial FDA approval for guselkumab (Tremfya) injection for intravenous (IV) use was granted on September 11, 2024, for induction treatment of ulcerative colitis in adults with moderate to severe active disease. Guselkumab (Tremfya) injection for subcutaneous use was approved by the FDA in July 2017. Supplemental IV approval for the treatment of adults with moderately to severely active Crohn’s disease (CD) was granted on March 20, 2025.

PEDIATRIC USE
The safety and effectiveness of guselkumab (Tremfya) injection for intravenous use in pediatric individuals younger than 18 years of age have not been established.

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## Description

**GUSELKUMAB (TREMFYA)**

Guselkumab (Tremfya) injection for intravenous use is a fully-human, dual-acting monoclonal antibody that blocks IL-23 while also binding to CD64, a receptor on cells that produce IL-23. IL-23 is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Guselkumab inhibits the release of proinflammatory cytokines and chemokines.
Guselkumab (Tremfya) is available in two forms: injection for intravenous use and injection for subcutaneous use. The lowest effective dosage should be used to maintain therapeutic response.

Inflammatory bowel disease (IBD) is a chronic inflammatory disorder of the gastrointestinal tract of unknown etiology. IBD has two major categories: ulcerative colitis (UC) and crohn's disease (CD).

**ULCERATIVE COLITIS (UC)**

The most common symptoms in UC are diarrhea, rectal bleeding, urgency to have bowel movements, abdominal cramps, pain, fever, and weight loss. UC primarily causes inflammation of the mucosal lining and is generally limited to the colon and rectum. The treatment of UC is focused on stopping the inflammation and preventing flare-ups. The type of treatment depends on the type and severity of symptoms. Mild symptoms may respond to an antidiarrheal medicine such as loperamide (e.g., Imodium). Treatment for individuals who may be having mild-to-moderate symptoms include aminosalicylates and antibiotics, whereas individuals with severe symptoms may be treated with:

- Immunomodulators/DMARDs (e.g., azathioprine, 6-mercaptopurine, methotrexate)
- Demonstrated dependence on corticosteroids (e.g., budesonide [Entocort EC], prednisone, hydrocortisone, methylprednisolone)
- Tumor necrosis factor (TNF) blocker (e.g., adalimumab Humira®)
- Biologics for the treatment of UC (e.g., ustekinumab (Stelara), risankizumab (Skyrizi), Golimumab (Simponi®)
- JAK Inhibitors (e.g., tofacitinib [Xeljanz], Upadacitinib [Rinvoq])
- Sphingosine 1-Phosphate (S1P) Receptor Modulator (e.g., Zeposia, Velsipity)

DMARDs can be subdivided into the traditional small-molecular-mass, chemically synthesized non-biologic DMARDs (such as, but not limited to, methotrexate, sulfasalazine, azathioprine, leflunomide, hydroxychloroquine sulfate, and cyclosporine) and biologic DMARDs. Examples of biologic DMARDs include, but are not limited to, infliximab (Remicade), etanercept (Enbrel), adalimumab (Humira), anakinra (Kineret), golimumab (Simponi, Simponi Aria), tocilizumab (Actemra), and rituximab (Rituxan).

The American Gastroenterological Association (2020) and the American College of Gastroenterology (2019) have clinical practice guidelines on the management of moderate to severe UC and make recommendations for the use of biologics for induction and maintenance of remission in adults. Generally TNF inhibitors, Entyvio® (vedolizumab intravenous infusion/subcutaneous injection), Stelara® (ustekinumab intravenous infusion/subcutaneous injection), or Xeljanz®/Xeljanz® XR (tofacitinib tablets, tofacitinib extended-release tablets) are recommended for induction treatment of moderate to severe disease (strong recommendations, moderate quality of evidence).

**CROHN'S DISEASE (CD)**

CD is characterized by inflammation in the digestive tract, anywhere from the mouth to anus, but most commonly in the small intestine and the beginning of the large intestine. Individuals may experience flares, when symptoms are present, followed by periods of remission, lasting weeks to years, where the symptoms disappear. The symptoms usually start slowly and can get worse over time. Common symptoms are diarrhea, abdominal pain and cramping, and weight loss. Outside of the GI tract, symptoms can include joint pain or arthritis, painful skin rashes or bumps, eye irritation, the development of kidney stones, inflammation of the lungs that can lead to difficulty breathing, or inflammation of the liver and bile ducts that can cause primary sclerosis cholangitis. It is estimated that 1 million individuals in the US have CD. CD is more common in individuals between the ages of 13 to 30, have a family member with IBD, smoke cigarettes, or are of Jewish descent. Complications of CD can include anemia, osteoporosis or osteopenia, delayed growth and development, or malnutrition. Serious complications can include intestinal obstruction, the formation of fistulas, or the development of abscesses, anal fissures, or ulcers anywhere along the GI tract. Individuals with CD are also more likely to develop colorectal cancer (CRC). There is no cure for CD, so the goal of treatment is to maintain remission. Treatments may include medication with or without surgery.

Commonly used medications for the treatment of CD are similar to those used for UC, and can include corticosteroids, immunosuppressants, and biologics. However, not all medications that treat UC can also be used to treat CD, for example:

- Immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate)
- Demonstrated dependence on corticosteroids (e.g., budesonide [Entocort EC], prednisone, hydrocortisone, methylprednisolone)
- Tumor necrosis factor (TNF) blocker (e.g., adalimumab Humira®)
- Biologics for the treatment of CD (e.g., ustekinumab (Stelara), risankizumab (Skyrizi))

**PEER-REVIEWED LITERATURE**

SUMMARY
The UC approval for Guselkumab (Tremfya) for IV use is based on data from the phase 2b/3 QUASAR study (ClinicalTrials.gov Identifier: NCT04033445), which evaluated the safety and efficacy of guselkumab, an interleukin-23 antagonist, in patients with moderately to severe active UC who had an inadequate response, loss of response, or intolerance to corticosteroids, immunomodulators, biologic therapy, and/or Janus kinase inhibitors. During the 12-week induction study, participants were randomly assigned to receive guselkumab 200 mg (n=421) or placebo (n=280) by intravenous (IV) infusion at week 0, week 4, and week 8. The primary endpoint was clinical remission per modified Mayo Score, defined as stool frequency subscore of no more than 1 and not greater than baseline, rectal bleeding subscore of 0 and endoscopic subscore of no more than 1 without friability at week 12. Results showed 23% of participants treated with guselkumab achieved clinical remission at week 12 compared with 8% of participants who received placebo (treatment difference, 15% [95% CI, 10-20]; *P* <.001). Moreover, 27% of guselkumab-treated participants achieved endoscopic improvement at week 12 compared with 11% of participants on placebo (*P* <.001). The most common adverse reaction reported was respiratory tract infection.

The expanded approval for CD was supported by data from the Phase 3 GALAXI and GRAVITI studies. In the GALAXI 2 and GALAXI 3 studies, patients who received 200 mg of Tremfya IV at Weeks 0, 4, and 8 showed statistically significantly higher rates of clinical remission and endoscopic response at Week 12 than patients who received placebo. Additionally, Tremfya demonstrated superiority to J&J's Stelara (ustekinumab) across all pooled secondary endoscopic endpoints. Of the randomized patients, 52% had previously failed at least one biologic therapy. In the GRAVITI study, Tremfya 400 mg SC at Weeks 0, 4, and 8 met the co-primary endpoints of clinical remission and endoscopic response at Week 12 versus placebo.

**OFF-LABEL INDICATIONS**

There may be additional indications contained in the Policy section of this document due to evaluation of criteria highlighted in the Company's off-label policy, and/or review of clinical guidelines issued by leading professional organizations and government entities.

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## References


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## Coding

**Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.**

**The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.**

**In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.**

**The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.**

### CPT Procedure Code Number(s)
N/A

### ICD - 10 Procedure Code Number(s)
N/A

### ICD - 10 Diagnosis Code Number(s)
Report the most appropriate diagnosis code in support of medically necessary criteria as listed in the policy.

### HCPCS Level II Code Number(s)
J1628 Injection, guselkumab, 1 mg

### Revenue Code Number(s)
N/A

**To report the intravenous route of administration, append the following modifier:**

JA Administered Intravenously

## Policy History

**Revisions From 08.179a:**

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| 09/16/2025 | This version of the policy will become effective 09/16/2025.<br><br>The following new policy has been developed to communicate the Company's coverage criteria for guselkumab (Tremfya) for intravenous use. |

Version Effective Date:
09/16/2025
Version Issued Date:
09/16/2025
Version Reissued Date:
N/A