Tremfya® (Guselkumab)

Policy Number: 2026D0134D
Effective Date: May 1, 2026

➲ Instructions for Use

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Related Commercial/Individual Exchange Policies

- Maximum Dosage and Frequency
- Provider Administered Drugs – Site of Care (for Commercial Only)
- Self-Administered Medications (for Commercial Only)
- Self-Administered Medications (for Exchange Only)

Community Plan Policy

- Tremfya® (Guselkumab)

Application

UnitedHealthcare Commercial

This Medical Drug Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Drug Policy applies to Individual Exchange benefit plans.

Coverage Rationale

➲ See Benefit Considerations

This policy refers to Tremfya (guselkumab) injection for intravenous use. Tremfya (guselkumab) for self-administered subcutaneous injection is obtained under the pharmacy benefit, unless otherwise specified in the member's specific benefit plan documents. Exception: For members enrolled in UnitedHealthcare of California plans with a delegated provider group conducting the prior authorization review, the self-administered Tremfya may be obtained under the medical benefit.

Ulcerative Colitis (UC)

Tremfya is proven for the treatment of ulcerative colitis when all of the following criteria are met:

- Diagnosis of moderately to severely active ulcerative colitis; **and**
- Tremfya is to be administered as three intravenous induction doses; **and**
- Tremfya induction dosing is in accordance with the U.S FDA labeled dosing for UC; **and**
- Patient is not receiving Tremfya in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Entyvio (vedolizumab), Olumiant (baricitinib), Omvoh (mirikizumab-mrkz), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Xeljanz (tofacitinib)] for treatment of the same indication; **and**
- Authorization will be issued for 3 induction doses

Tremfya is medically necessary for the treatment of ulcerative colitis when all of the following criteria are met:

- Diagnosis of moderately to severely active ulcerative colitis; **and**
- **One** of the following:

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- Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine); **or**
- Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of ulcerative colitis [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Xeljanz (tofacitinib)]

and

- Tremfya is to be administered as three intravenous induction doses; **and**
- Tremfya induction dosing is in accordance with the U.S. FDA labeled dosing for UC; **and**
- Patient is not receiving Tremfya in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Entyvio (vedolizumab), Olumiant (baricitinib), Omvoh (mirikizumab-mrkz), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Xeljanz (tofacitinib)] for treatment of the same indication; **and**
- Prescribed by or in consultation with a gastroenterologist; **and**
- Authorization will be issued for 3 induction doses

Crohn's Disease (CD)

Tremfya is proven for the treatment of Crohn's disease (CD) when all of the following criteria are met:

- Diagnosis of moderately to severely active Crohn's disease; **and**
- Tremfya is to be administered as three intravenous induction doses; **and**
- Tremfya induction dosing is in accordance with the United States Food and Drug Administration (FDA) labeled dosing for CD; **and**
- Patient is not receiving Tremfya in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), ustekinumab] for treatment of the same indication; **and**
- Authorization will be issued for 3 induction doses

Tremfya is medically necessary for the treatment of Crohn's disease (CD) when all of the following criteria are met:

- Diagnosis of moderately to severely active Crohn's disease; **and**
- One of the following:
  - History of failure to **one** of the following conventional therapies at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced:
    - Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
    - 6-mercaptopurine (Purinethol)
    - Azathioprine (Imuran)
    - Methotrexate (Rheumatrex, Trexall)

    or
  - Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of Crohn's disease [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), ustekinumab]

  and
- Tremfya is to be administered as three intravenous induction doses; **and**
- Tremfya induction dosing is in accordance with the United States Food and Drug Administration (FDA) labeled dosing for CD; **and**
- Patient is not receiving Tremfya in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), ustekinumab] for treatment of the same indication; **and**
- Prescribed by or in consultation with a gastroenterologist; **and**
- Authorization will be issued for 3 induction doses

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other policies and guidelines may apply.

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HCPCS Code	Description
J1628	Injection, guselkumab, 1 mg

National Drug Code	How Supplied
57894-0650-02	200 mg/ 20 mL vial

Diagnosis Code	Description
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complications
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.019	Ulcerative (chronic) pancolitis with unspecified complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess

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Diagnosis Code	Description
K51.218	Ulcerative (chronic) proctitis with other complication
K51.219	Ulcerative (chronic) proctitis with unspecified complications
K51.30	Ulcerative (chronic) recto sigmoiditis without complications
K51.311	Ulcerative (chronic) recto sigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) recto sigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) recto sigmoiditis with fistula
K51.314	Ulcerative (chronic) recto sigmoiditis with abscess
K51.318	Ulcerative (chronic) recto sigmoiditis with other complication
K51.319	Ulcerative (chronic) recto sigmoiditis with unspecified complications
K51.40	Inflammatory polyps of colon without complications
K51.411	Inflammatory polyps of colon with rectal bleeding
K51.412	Inflammatory polyps of colon with intestinal obstruction
K51.413	Inflammatory polyps of colon with fistula
K51.414	Inflammatory polyps of colon with abscess
K51.418	Inflammatory polyps of colon with other complication
K51.419	Inflammatory polyps of colon with unspecified complications
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.519	Left sided colitis with unspecified complications
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with intestinal obstruction
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.818	Other ulcerative colitis with other complication
K51.819	Other ulcerative colitis with unspecified complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
K51.919	Ulcerative colitis, unspecified with unspecified complications
K52.1	Toxic gastroenteritis and colitis

Background

Tremfya is a human monoclonal IgG1λ antibody that selectively binds to the p19 subunit of interleukin 23 (IL-23) and inhibits its interaction with the IL-23 receptor. IL-23 is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Tremfya inhibits the release of proinflammatory cytokines and chemokines.

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Benefit Considerations

Some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions for this service. Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances when certain conditions are met. Where such mandates apply, they supersede language in the benefit document or in the medical or drug policy.

Clinical Evidence

Proven

Ulcerative Colitis

Induction Trial: UC1

In the 12-week induction study (UC1; NCT04033445), 701 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. Disease activity was assessed by the modified Mayo score (mMS), 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. Enrolled subjects with a mMS between 5 and 9 and an ES of 2 or 3 were classified as having moderately to severely active ulcerative colitis. Subjects with inadequate response, loss of response, or intolerance to corticosteroids, immunomodulators (azathioprine, 6-mercaptopurine), biologic therapy (TNF blockers, vedolizumab), and/or Janus kinase (JAK) inhibitors were enrolled.

At baseline in UC1, the median mMS was 7, 64% of subjects had severely active disease (mMS ≥ 7), and 68% of subjects had an ES of 3. In UC1, 49% of subjects had previously failed (inadequate response, loss of response, or intolerance) treatment with at least one biologic therapy and/or JAK inhibitor, 48% were biologic and JAK inhibitor naïve, and 3% had previously received but not failed a biologic or JAK inhibitor. The median age was 39 years (ranging from 18 to 79 years); 43% were female; and 72% identified as White, 21% as Asian, 1% as Black or African American, < 1% as American Indian or Alaskan Native, and < 1% as multiple racial groups.

Enrolled subjects were permitted to use stable doses of oral aminosalicylates, immunomodulators (azathioprine, 6-mercaptopurine, methotrexate), and/or oral corticosteroids (up to 20 mg/day prednisone or equivalent). At baseline, 72% of subjects were receiving aminosalicylates, 21% of subjects were receiving immunomodulators, and 43% of subjects were receiving corticosteroids. Concomitant biologic therapies or JAK inhibitors were not permitted.

In UC1, the primary endpoint was clinical remission at Week 12 as defined by the mMS. Secondary endpoints at Week 12 included endoscopic improvement, clinical response, and histologic endoscopic mucosal improvement. Clinical remission was achieved in 23% of patients with Tremfya vs. 8% with placebo (treatment difference 15%, 95% CI: 10, 20; $p < 0.001$).

Maintenance Trial: UC2

The maintenance trial (UC2) evaluated 568 subjects who received one of two intravenous Tremfya induction regimens, including the recommended 200 mg regimen, for 12 weeks in Studies UC1 or UC3 (induction dose-finding study) and demonstrated clinical response per mMS after 12 weeks. Subjects were rerandomized 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.

In UC2, 42% of subjects had failed (inadequate response, loss of response, or intolerance) treatment with one or more biologics or JAK inhibitors.

The primary endpoint 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. Clinical remission was achieved in 45% of patients with Tremfya 100 mg, 50% with Tremfya 200 mg, and 19% with placebo. Treatment difference vs. placebo was 25% (95% CI: 16, 34; $p < 0.001$) for Tremfya 100 mg and 30% (95% CI: 21, 38; $p < 0.001$) for Tremfya 200 mg.

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U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Tremfya is an interleukin-23 antagonist indicated for the treatment of adult patients with:
- Moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
- Active psoriatic arthritis
- Moderately to severely active ulcerative colitis
- Moderately to severely active Crohn's disease

References

1. Tremfya [package insert]. Horsham, PA: Janssen Biotech Inc.; September 2025.
2. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020 Jan 13.
3. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol. 2019 Mar;114(3):384-413.Yese.

Policy History/Revision Information

Date	Summary of Changes
08/01/2026	**Related Individual Exchange Policies** • Updated reference link to the Medical Benefit Drug Policy titled *Maximum Dosage and Frequency*

05/01/2026	**Template Update**
	• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans
	• Added *Application* section to indicate this policy applies to:
	  ○ UnitedHealthcare Commercial benefit plans
	  ○ Individual Exchange benefit plans
	Coverage Rationale
	• Revised coverage criteria; replaced criterion requiring:
	  ○ "The patient is not receiving Tremfya in combination with another targeted immunomodulator" with "the patient is not receiving Tremfya in combination with another *systemic* targeted immunomodulator *for treatment of the same indication*"
	  ○ "The patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis/Crohn's disease" with "the patient has been previously treated with a *systemic* targeted immunomodulator FDA-approved for the treatment of ulcerative colitis/Crohn's disease"
	Supporting Information
	• Updated *References* section to reflect the most current information
	• Archived previous policy versions 2025D0134C and IEXD00134.02

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

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UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

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