Tremfya (guselkumab) injection, for intravenous use

Policy Number: MC/PC 045
Effective Date: June 1, 2025

Instructions for Use

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Related Policies

- N/A

Coverage Rationale

This policy is applicable to Tremfya (guselkumab) injection, for intravenous use. Tremfya (guselkumab) injection, for self-administered subcutaneous injection is obtained under the pharmacy benefit.

Crohn's Disease (CD)

For initial coverage of Tremfya (guselkumab) intravenous injection for Crohn's Disease (CD), the following will be required:

- Diagnosis of moderately to severely active Crohn's disease (CD) **and**
- One of the following:
  - Frequent diarrhea and abdominal pain
  - At least 10% weight loss
  - Complications such as obstruction, fever, abdominal mass
  - Abnormal lab values (e.g., C-reactive protein [CRP])
  - CD Activity Index (CDAI) greater than 220 **and**
- Will be administered as an intravenous induction dose **and**
- Prescribed by or in consultation with a gastroenterologist

Ulcerative Colitis (UC)

For initial coverage of Tremfya (guselkumab) intravenous injection for Ulcerative Colitis (UC), the following will be required:

- Diagnosis of moderately to severely active ulcerative colitis (UC) **and**
- One of the following:
  - Greater than 6 stools per day
  - Frequent blood in the stools
  - Frequent urgency
  - Presence of ulcers

    - Abnormal lab values (e.g., hemoglobin, erythrocyte sedimentation rate, C-reactive protein)
    - Dependent on, or refractory to, corticosteroids **and**
- Will be administered as an intravenous induction dose **and**
- Prescribed by or in consultation with a gastroenterologist

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.

HCPCS Code	Description
J1628	guselkumab, for intravenous injection, 1 mg

ICD-10 Code	Description
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
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

ICD-10 Code	Description
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 (guselkumab) is an interleukin (IL)-23 antagonist. Guselkumab (human immunoglobulin G (IgG)1 λ monoclonal antibody) selectively binds to the p19 subunit of IL-23 cytokine and inhibits its interaction with the IL-23 receptor. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses. Guselkumab inhibits the release of pro-inflammatory cytokines and chemokines.

Clinical Evidence

Crohn's Disease (CD)
The approval of guselkumab for Crohn's Disease was based on three randomized, placebo-controlled, double-blind, treat-through studies that enrolled adult patients with moderately to severely active CD who had a history of inadequate response, loss of response, or intolerance to oral corticosteroids, immunomodulators, and/or biologic therapy (eg, tumor necrosis factor [TNF] antagonists or vedolizumab). In the GALAXI 2 and GALAXI 3 studies, 361 patients and 360 patients, respectively, were randomized to receive intravenous (IV) guselkumab at weeks 0, 4, and 8 or placebo for induction therapy. The combined clinical remission and endoscopic response at week 12 in GALAXI 2 was 20% in the

guselkumab group vs. 3% in the placebo group (treatment difference 17%; 95% CI: 11, 23; p < 0.001). The combined clinical remission and endoscopic response at week 12 in GALAXI 3 was 21% in the guselkumab group vs. 3% in the placebo group (treatment difference 18%; 95% CI: 12, 24; p < 0.001) (Tremfya prescribing information 2025).

Maintenance results at 48 weeks for GALAXI 2 (n = 508) and GALAXI 3 (n = 513) demonstrated superiority vs. placebo in achievement of the coprimary endpoints of clinical response at week 12 plus clinical remission at week 48, and clinical response at week 12 plus endoscopic response at week 48 (p < 0.001 for all comparisons). In a pooled analysis of both trials at week 48, both maintenance doses of subcutaneous (SC) guselkumab 100 mg every 8 weeks and 200 mg every 4 weeks demonstrated superiority vs. ustekinumab 6 mg/kg IV for 1 dose, followed by 90 mg SC every 8 weeks for endoscopic response at 48 weeks (47.9% and 52.7% vs. 37.1%), endoscopic remission (33.2% and 37.2% vs. 24.7%), and clinical remission plus endoscopic response (41.6% and 47.3% vs. 33.7%) (Panaccione et al 2024).

The GRAVITI trial evaluated the efficacy and safety of SC induction followed by SC maintenance of guselkumab in 347 patients. Patients were randomized to receive SC Tremfya at weeks 0, 4, and 8 followed by SC Tremfya every 8 weeks (with the first dose given at week 16); SC Tremfya at weeks 0, 4, and 8 followed by SC guselkumab every 4 weeks (with the first dose given at week 12); or placebo. The coprimary endpoints were clinical remission at week 12 and endoscopic response at week 12 vs. placebo. The guselkumab dosing was identical through week 12, so patients in both guselkumab groups were combined for the analysis at week 12. Clinical remission at week 12 was 56.1% in the Tremfya groups vs. 21.4% in the placebo group (treatment difference: 34.9%; 95% CI: 25.1, 44.6; p < 0.001). The endoscopic response at week 12 was 41.3% in the guselkumab groups vs. 21.4% in the placebo group (treatment difference: 19.9%; 95% CI: 10.2, 29.6; p < 0.001). Maintenance of clinical remission and endoscopic remission was statistically higher than placebo with both guselkumab dosing regimens at weeks 24 and 48 (p < 0.001 for all comparisons). The most common adverse reactions (≥ 3%) with guselkumab in CD were respiratory tract infections, abdominal pain, injection site reactions, headache, fatigue, arthralgia, diarrhea, and gastroenteritis (Hart et al 2025, Tremfya prescribing information 2025).

Ulcerative Colitis (UC)
The efficacy of Tremfya (guselkumab) for induction of UC was demonstrated in the QUASAR Phase 2b induction study, where guselkumab resulted in significantly higher clinical response rates at week 12 in patients with moderately to severely active UC: 61.4% (200 mg, n = 101) and 60.7% (400 mg, n = 107) vs. 27.6% for placebo (n = 105; both p < 0.001) (Peyrin-Biroulet et al 2023). In the Phase 3 QUASAR maintenance trial, among patients who achieved a clinical response after induction, those receiving guselkumab 100 mg every 8 weeks and 200 mg every 4 weeks had higher clinical remission rates at week 44 (45.2% and 50.0%, respectively) compared to placebo (18.9%), with similar improvements observed in corticosteroid-free remission and endoscopic improvement (Rubin et al 2025, Tremfya prescribing information 2025).

A systematic review and network meta-analysis of 35 trials was conducted on the management of moderate-to-severe UC (Ananthakrishnan et al 2024). In biologically naïve patients, evidence supports clinically important benefit with infliximab, ozanimod, risankizumab, and guselkumab over adalimumab and mirikizumab for achieving remission with induction therapy. Risankizumab and ozanimod ranked highest for induction of clinical remission, followed by guselkumab. When JAK inhibitors were included as first-line therapy (of note, this is not recommended per FDA labeling), upadacitinib was more effective compared to other agents except ozanimod and risankizumab. In patients with prior biologic exposure, upadacitinib, tofacitinib, and ustekinumab ranked highest for achieving remission.

Place in therapy

Crohn's Disease
Of note, Tremfya (guselkumab) was approved for Crohn's Disease in 2025, therefore, guidelines have not been updated to inform a place in therapy.

The 2018 American College of Gastroenterology (ACG) guideline for the management of Crohn's disease listed TNF inhibitors as an option for disease that is resistant to corticosteroids, severely active disease, perianal fistulizing disease, and maintenance of remission (Lichtenstein et al 2018). The guideline made a conditional recommendation that in high-risk patients, anti-TNF agents should be started within 4 weeks of surgery in order to prevent postoperative Crohn's disease recurrence.

The 2021 American Gastroenterological Association (AGA) guideline on the medical management of moderate to severe CD strongly recommends the use of biologic monotherapy over thiopurine monotherapy for the induction of remission in adult outpatients and recommends TNF inhibitors or ustekinumab over no treatment for induction and maintenance of remission. In patients who are naïve to biologic drugs, infliximab, adalimumab, or ustekinumab are recommended over certolizumab pegol for the induction of remission and vedolizumab is suggested over certolizumab pegol. In patients who never responded to TNF inhibitors, the use of ustekinumab is recommended and the use of vedolizumab is suggested over no treatment for the induction of remission. In patients who previously responded to infliximab, the use of adalimumab or ustekinumab is recommended and the use of vedolizumab is suggested over no treatment for the induction of remission (Feuerstein et al 2021).

The 2024 ECCO guideline on medical treatment in CD recommends the use of infliximab, adalimumab, ustekinumab, risankizumab, vedolizumab, and upadacitinib to induce remission and maintenance of remission in patients with moderate-to-severe CD (Gordon et al 2024). Other immunomodulator-related recommendations within the guideline include:

- Recommending combination therapy with infliximab and thiopurines when starting infliximab as induction therapy in patients with moderate-to-severe CD and recommending combination therapy for a minimum of 6 to 12 months.
- Suggesting against the combination of adalimumab and thiopurines over adalimumab alone to achieve clinical remission and response.
- Suggesting certolizumab can be used as induction therapy and maintenance therapy in moderate-to-severe CD.
- Suggesting adalimumab or ustekinumab are equally effective as induction and maintenance therapy in biologic-naïve patients with moderate-to-severe CD.

Ulcerative Colitis (UC)

A 2019 guideline from the American College of Gastroenterology (ACG) recommends 5-ASA therapy for induction of remission in mildly active UC, and budesonide, systemic corticosteroids, TNF inhibitor therapy (adalimumab, golimumab, or infliximab), vedolizumab, and tofacitinib for induction of remission in moderately to severely active disease. Vedolizumab and tofacitinib are recommended for induction of remission in patients who have failed previous TNF inhibitor therapy. For maintenance of remission in patients with previously mildly active disease, 5-ASA therapy is recommended, and in patients with previously moderately to severely active disease, continuation of TNF inhibitor therapy, vedolizumab, or tofacitinib is recommended after induction of remission with these agents (Rubin et al 2019).

For adult outpatients with moderate to severe UC, an American Gastroenterological Association (AGA) living guideline was last updated in 2024, and recommends using infliximab, golimumab, vedolizumab, tofacitinib, upadacitinib, ustekinumab, ozanimod, etrasimod, risankizumab, and *guselkumab* over no treatment and suggests use of adalimumab, filgotinib (not approved in the U.S.) or mirikizumab over no treatment (Singh et al 2024). Biosimilars of infliximab, adalimumab, and ustekinumab are considered equivalent to the reference drug. Subcutaneous formulations of infliximab and vedolizumab have comparable efficacy to the intravenous maintenance doses. In patients with severe disease, extended induction regimens up to 16 weeks or dose escalation may be beneficial for certain agents. In patients with moderate to severe UC naïve to advanced therapies, the AGA suggests using a higher-efficacy medication (infliximab, vedolizumab, ozanimod, etrasimod, upadacitinib, risankizumab, *guselkumab*) or an intermediate-efficacy medication (golimumab, ustekinumab, tofacitinib, filgotinib, mirikizumab), instead of a lower-efficacy medication (adalimumab). In patients who are biologic-experienced (particularly TNF antagonist-experienced), the AGA suggests using a higher-efficacy medication (eg, tofacitinib, upadacitinib, and ustekinumab), or an intermediate-efficacy

medication (eg, filgotinib, mirikizumab, risankizumab, and *guselkumab*) rather than a lower-efficacy medication (eg, adalimumab, vedolizumab, ozanimod, and etrasimod). JAK inhibitors may be associated with higher risk of major adverse cardiovascular events and cancer than TNF antagonists in older adults with cardiovascular risk factors. JAK inhibitors are recommended in those with failure or intolerance to TNF antagonists. Vedolizumab and anti-IL therapies may be associated with a lower infection risk than TNF antagonists and may be preferred in those at risk of immunosuppression-related infections or malignancies. JAK inhibitors and S1P receptor modulators should be avoided in women of childrearing age contemplating pregnancy.

The European Crohn's and Colitis Organisation (ECCO) recommends thiopurines for maintenance of remission in patients with steroid-dependent UC who are intolerant of 5-ASA. Remission can be induced with TNF inhibitors, vedolizumab, tofacitinib, or ustekinumab in patients with moderate to severe disease that has not responded to conventional therapy. Remission can be maintained with the same biologic agent that was used for induction therapy (Raine et al 2022).

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 (guselkumab) 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

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Policy History/Revision Information

Date	Summary of Changes
5/15/2025	Approved by OptumRx P&T Committee

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting 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, please check the member specific benefit plan document and any applicable federal or state mandates. The insurance 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.

OptumRx may also use tools developed by third parties to assist us in administering health benefits. OptumRx 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.

Archived Policy Versions (Internal Only)

Effective Date	Policy Number	Policy Title
mm/dd/yyyy – mm/dd/yyyy	######	Title of Policy Hyperlinked to KL or Other Internal Location

Nondiscrimination & Language Access Policy

Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:
Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If *you* need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If *you* believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If *you* need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help *you*.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1-800-332-6501 (TTY: 711).

Arabic تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف1-800-332-6501(رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: _यान द_: य_द आप ि हंदी बोलते ह_ तो आपके ि लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-6501 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1-800-332-6501 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文， 您可以免費獲得語言援助服務。請 致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).

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