Corporate Medical Policy: Guselkumab (Tremfya®) **"Notification"** **POLICY EFFECTIVE JULY 1, 2026**

Restricted Product(s):

- guselkumab (Tremfya®) intravenous infusion and subcutaneous injection for administration by a healthcare professional

FDA Approved Use:

- For the treatment of adults and pediatric patients 6 years of age and older who also weigh at least 40 kg with moderate-to-severe plaque psoriasis and who are candidates for systemic therapy or phototherapy
- For the treatment of adults and pediatric patients 6 years of age and older who also weigh at least 40 kg with active psoriatic arthritis
- For the treatment of adults with moderately to severely active ulcerative colitis
- For the treatment of adults with moderately to severely active Crohn's disease

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

1. The patient has a diagnosis of moderate to severe **plaque psoriasis (PS)**; **AND**
    a. The patient is 6 years of age or older; **AND**
    b. The patient weighs at least 40 kg; **AND**
    c. The patient has tried and had an inadequate response to ONE conventional agent (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, phototherapy [e.g., PUVA and UVB], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS for at least 3-months **[medical record documentation required]**; **OR**
    d. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PS **[medical record documentation required]**; **OR**
    e. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PS **[medical record documentation required]**; **OR**
    f. The patient has severe active PS (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **[medical record documentation required]**; **OR**
    g. The patient has concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [e.g., joint deformities, vision loss], highly active disease that causes major impairment in quality of life, active PsA at many sites [including dactylitis, enthesitis], function-limiting PsA at few sites, rapidly progressive) **[medical record documentation required]**; **OR**

h. The patient is currently established on a biologic or systemic immunomodulator agent that is FDA approved for the treatment of PS (excluding sample use) **[medical record documentation required]**; **AND**
    i. The patient has had positive clinical benefit (e.g., improvement in signs and symptoms, reduction in disease severity, etc.) from use of the biologic or systemic immunomodulator agent **[medical record documentation required]**; **OR**

2. The patient has a diagnosis of active **psoriatic arthritis (PsA)**; **AND**
    a. The patient is 6 years of age or older; **AND**
    b. The patient weighs at least 40 kg; **AND**
    c. The patient has tried and had an inadequate response to ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA for at least 3-months **[medical record documentation required]**; **OR**
    d. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PsA **[medical record documentation required]**; **OR**
    e. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **[medical record documentation required]**; **OR**
    f. The patient has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [e.g., joint deformities, vision loss], highly active disease that causes major impairment in quality of life, active PsA at many sites [including dactylitis, enthesitis], function-limiting PsA at few sites, rapidly progressive) **[medical record documentation required]**; **OR**
    g. The patient has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **[medical record documentation required]**; **OR**
    h. The patient is currently established on a biologic or systemic immunomodulator agent that is FDA approved for the treatment of PsA (excluding sample use) **[medical record documentation required]**; **AND**
        i. The patient has had positive clinical benefit (e.g., improvement in signs and symptoms, reduction in disease severity, etc.) from use of the biologic or systemic immunomodulator agent **[medical record documentation required]**; **OR**

3. The patient has a diagnosis of moderately to severely active **ulcerative colitis (UC)**; **AND**
    a. The patient is 18 years of age or older; **AND**
    b. The patient has moderately to severely active disease, as evidenced by ONE of the following:
        i. The patient has BOTH of the following:
            1. Symptoms consistent with active UC (e.g., increased stool frequency, rectal bleeding, bowel urgency, nocturnal symptoms, abdominal pain and/or cramping, extraintestinal manifestations, significant weight loss, etc.) **[medical record documentation required]**; **AND**

2. Evidence of active inflammation or high-risk disease, confirmed by ONE of the following **[medical record documentation required]**:
    a. Moderate to severe disease activity on a lower gastrointestinal endoscopy using a validated endoscopic assessment tool (e.g., Mayo Endoscopic Subscore [MES], Ulcerative Colitis Endoscopic Index of Severity [UCEIS] or equivalent); **OR**
    b. Evidence of active inflammatory disease on intestinal ultrasound (IUS), including findings consistent with active colitis (e.g., increased bowel wall thickness, hyperemia); **OR**
    c. Biomarker evidence indicative of inflammation (e.g., elevated fecal calprotectin [FC], elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate [ESR], low serum albumin); **OR**
    d. Presence of at least one poor prognostic factor (e.g., age younger than 40 years at diagnosis, extensive colitis, hospitalization for colitis) **[medical record documentation required]**; **OR**

ii. Corticosteroid-dependence, or refractory to oral corticosteroids **[medical record documentation required]**; **OR**

c. The patient is currently established on a biologic or systemic immunomodulator agent that is FDA approved for the treatment of UC (excluding sample use) **[medical record documentation required]**; **AND**
    i. The patient has had positive clinical benefit (e.g., improvement in signs and symptoms, reduction in disease severity, etc.) from use of the biologic or systemic immunomodulator agent **[medical record documentation required]**; **OR**

4. The patient has a diagnosis of moderately to severely active **Crohn's disease (CD)**; **AND**
    a. The patient is 18 years of age or older; **AND**
    b. The patient has moderately to severely active disease, as evidenced by ONE of the following:
        i. The patient has BOTH of the following:
            1. Symptoms consistent with active CD (e.g., diarrhea, abdominal pain, significant weight loss, fatigue, fever, anemia, vitamin or mineral deficiencies, intermittent nausea or vomiting, etc.) **[medical record documentation required]**; **AND**
            2. Evidence of active inflammation, confirmed by ONE of the following **[medical record documentation required]**:
                a. Active inflammatory disease on cross-sectional imaging (MRE, CTE), intestinal ultrasound, or pelvic MRI for perianal disease (e.g., bowel wall thickening, ulceration, hyperenhancement, fistula, abscess); **OR**
                b. Biomarker evidence indicative of inflammation (e.g., elevated fecal calprotectin [FC], elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate [ESR], low serum albumin); **OR**
        ii. Significant extent of disease or upper GI involvement identified on radiographic or endoscopic assessment (e.g., large or deep mucosal lesions, fistulas or perianal abscesses, intestinal strictures, extensive disease [ileal involvement >40 cm or pancolitis], prior bowel resection, etc.) **[medical record documentation required]**; **OR**

iii. Corticosteroid-dependence, or refractory to oral corticosteroids **[medical record documentation required]**; **OR**

c. The patient is currently established on a biologic or systemic immunomodulator agent that is FDA approved for the treatment of CD (excluding sample use) **[medical record documentation required]**; **AND**

i. The patient has had positive clinical benefit (e.g., improvement in signs and symptoms, reduction in disease severity, etc.) from use of the biologic or systemic immunomodulator agent **[medical record documentation required]**; **AND**

5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist for PS; rheumatologist for PsA; gastroenterologist for CD, UC) or has consulted with a specialist in the area of the patient's diagnosis; **AND**
6. The patient will NOT be using guselkumab (Tremfya®) in combination with another biologic immunomodulator agent or Otezla® or Zeposia®; **AND**
7. The patient does NOT have any FDA labeled contraindications to guselkumab (Tremfya®); **AND**
8. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB; **AND**
9. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**
10. For requests for injection or infusion administration of the requested medication in an **inpatient or outpatient hospital setting,** Site of Care Criteria applies (outlined below)*

Duration of Approval: 365 days (1 year)

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
guselkumab (Tremfya®) intravenous (IV) infusion, subcutaneous (SC) injection	PS in patients ≥ 6 years old who weigh at least 40 kg PsA in patients ≥ 6 years old who weigh at least 40 kg UC in patients ≥ 18 years old CD in patients ≥ 18 years old	**PS**: 100 mg SC at weeks 0 and 4, then every 8 weeks thereafter **PsA**: 100 mg SC at weeks 0 and 4, then every 8 weeks thereafter **UC:** • Induction: 200 mg IV at weeks 0, 4, and 8; OR 400 mg SC at weeks 0, 4, and 8	J1628	**PS**: 800 **PsA**: 800 **UC:** 3,200 **CD**: 3,200

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
		• Maintenance: 100 mg SC at week 16 and then every 8 weeks thereafter; OR 200 mg SC at week 12 and then every 4 weeks thereafter. Use the lowest effective recommended dosage to maintain therapeutic response. **CD**: • Induction: 200 mg IV at weeks 0, 4, and 8; OR 400 mg SC at weeks 0, 4, and 8 • Maintenance: 100 mg SC at week 16 and then every 8 weeks thereafter; OR 200 mg SC at week 12 and then every 4 weeks thereafter. Use the lowest effective recommended dosage to maintain therapeutic response.		

***Maximum units allowed for duration of approval**

***Site of Care Medical Necessity Criteria**

1. For requests for injection or infusion administration in an **inpatient setting**, the injection or infusion may be given if the above medical necessity criteria are met AND the inpatient admission is NOT for the sole purpose of administering the injection or infusion; **OR**
2. For requests for injection or infusion administration in an **outpatient hospital setting**, the injection or infusion may be given if the above medical necessity criteria are met AND ONE of the following must be met:
    a. History of a severe adverse event following the injection or infusion of the requested medication (i.e., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure); **OR**
    b. Conditions that cause an increased risk for severe adverse event (i.e., unstable renal function, cardiopulmonary conditions, unstable vascular access); **OR**
    c. History of mild adverse events that have not been successfully managed through mild pre-medication (e.g., diphenhydramine, acetaminophen, steroids, fluids, etc.); **OR**

   d. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity; **OR**
   e. New to therapy, defined as initial injection or infusion OR less than 3 months since initial injection or infusion; **OR**
   f. Re-initiation of therapy, defined as ONE of the following:
      i. First injection or infusion after 6 months of no injections or infusions for drugs with an approved dosing interval less than 6 months duration; **OR**
      ii. First injection or infusion after at least a 1-month gap in therapy outside of the approved dosing interval for drugs requiring every 6 months dosing duration; **OR**
   g. Requirement of a change in the requested restricted product formulation; **AND**
3. If the Site of Care Medical Necessity Criteria in #1 or #2 above are not met, the injection or infusion will be administered in a **home-based infusion** or physician office setting with or without supervision by a certified healthcare professional.

References: all information referenced is from FDA package insert unless otherwise noted below.

1. Blauvelt A, Papp KA, Griffiths CE, et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the continuous treatment of patients with moderate to severe psoriasis: results from the phase III, double-blinded, placebo- and active comparator-controlled VOYAGE 1 trial. *J Am Acad Dermatol*. 2017; 76(3):405-417.
2. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. *J Am Acad Dermatol*. 2019;81(3):775-804.
3. Langley RG, Tsai TF, Flavin S, et al. Efficacy and safety of guselkumab in patients with psoriasis who have an inadequate response to ustekinumab: results of the randomized, double-blind, phase 3 NAVIGATE trial. *Br J Dermatol*. 2018;178(1):114-123.
4. Lichtenstein GR, Loftus EV Jr, Isaacs KL, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol.* 2025;120(6):1225-1264.
5. Menter A, Strober BE, Kaplan DH, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072.
6. Reich K, Armstrong AW, Foley P, et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the treatment of patients with moderate to severe psoriasis with randomized withdrawal and retreatment: results from the phase III, double-blind, placebo- and active comparator-controlled VOYAGE 2 trial. *J Am Acad Dermatol*. 2017;76(3):418-431.
7. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. *Am J Gastroenterol*. 2025 Jun 3;120(6):1187-1224.
8. Scott FI, Ananthakrishnan AN, Click B, et al. AGA Living Clinical Practice Guideline on the Pharmacologic Management of Moderate-to-Severe Crohn's Disease. *Gastroenterology*. 2025;169(7):1397-1448.
9. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Care Res*. 2019;71(1):5-32.

10. Singh S, Loftus EV, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. *Gastroenterology*. 2024;167(7):1307-1343.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q1 annually.

July 2026: Criteria change: For PS, PsA, CD, and UC: Added allowance for patients currently established on a biologic or systemic immunomodulator agent that is FDA approved for treatment of the requested indication for those who have had positive clinical benefit from use of the biologic or systemic immunomodulator agent. For PS: Adjusted phototherapy conventional agent option to include both PUVA and UVB as examples. For PsA and PS: Added additional examples defining long-term damage interfering with function associated with severe psoriatic arthritis. For CD: Removed required trial and failure of conventional therapy; Replaced allowance for severely active disease with required demonstration of moderately to severely active disease by documented presence of symptoms of active disease plus evidence of active inflammation OR significant extent of disease or upper GI involvement on radiographic or endoscopic assessment OR corticosteroid-dependence or refractory to oral corticosteroids; Changes made to align with updated clinical guidelines. For UC: Removed required trial and failure of conventional therapy; Replaced allowance for severely active disease with required demonstration of moderately to severely active disease by documented presence of symptoms of active disease plus evidence of active inflammation or high-risk disease (with associated confirmatory criteria) OR corticosteroid-dependence or refractory to oral corticosteroids; Changes made to align with updated clinical guidelines. Other minor formatting changes made throughout policy for clarity with no change to intent. **Policy notification given 5/1/2026 for effective date 7/1/2026**.
October 2025: Criteria change: Expanded PS and PsA indication to patients 6 years of age and older who weigh at least 40 kg per FDA label update. Updated dosing table for UC indication to include IV OR SC for induction dosing and updated maximum units per FDA label update. Updated Site of Care medical necessity criteria to add additional bypass for patients with a history of severe adverse events or conditions that cause an increased risk for severe adverse event to align with the Place of Service for Medical Infusions policy for clarity of intent.
August 2025: Criteria change: For CD: Updated policy to allow bypassing conventional agents for severely active Crohn's disease.
April 2025: Criteria change: Added newly approved indication for adults with moderately to severely active Crohn's disease with corresponding criteria and dosing table updates. Updated maximum units according to indication.
September 2024: Criteria change: Added newly approved indication for adults with moderately to severely active ulcerative colitis with corresponding criteria and dosing table updates. Updated maximum units according to indication.
September 2023: Criteria change: For psoriatic arthritis: Removed hydroxychloroquine from list of conventional agents. Separated out intolerance/hypersensitivity criteria from FDA labeled contraindication criteria for clarity.
October 2021: Criteria change: Added Site of Care medical necessity criteria. **Policy notification given 8/2/2021 for effective date 10/1/2021**.

August 2021: Criteria change: Removed criteria points regarding medication history indicating use of another biologic immunomodulator agent FDA labeled for the treatment of the same condition. **Policy notification given 6/1/2021 for effective date 8/1/2021**.
June 2021: Criteria change: Medical record documentation required for all indications.
April 2021: Criteria change: PS: Addition of criteria for history of use of another biologic immunomodulator agent (or Otezla) for the same indication; BSA requirement changed to 10%, added option for concomitant severe PsA; added requirement that patient has no FDA labeled contraindications, and for TB testing; added maximum units; medical policy formatting change. **Policy notification given 2/26/2021 for effective date 4/28/2021**.
*Further historical criteria changes and updates available upon request from Medical Policy and/or Corporate Pharmacy.