# Clinical Policy: Guselkumab (Tremfya)

Reference Number: CP.PHAR.364
Effective Date: 08.29.17
Last Review Date: 11.24
Line of Business: Medicaid

Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

Guselkumab (Tremfya®) is an interleukin-23 (IL-23) blocker.

## FDA Approved Indication(s)

Tremfya is indicated for the treatment of:

- Adult patients with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy
- Adult patients with active psoriatic arthritis (PsA)
- Adult patients with moderately to severely active ulcerative colitis (UC)

## Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Tremfya is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Plaque Psoriasis** (must meet all)**:**

1. Diagnosis of moderate-to-severe PsO as evidenced by involvement of one of the following (a or b):
   a. ≥ 3% of total body surface area;
   b. Hands, feet, scalp, face, or genital area;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a, b, or c):
   a. Failure of a ≥ 3 consecutive month trial of methotrexate (MTX) at up to maximally indicated doses;
   b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
   c. Member has intolerance or contraindication to MTX, cyclosporine, and acitretin, and failure of phototherapy, unless contraindicated or clinically significant adverse effects are experienced;
5. Member meets ONE of the following, unless contraindicated or clinically significant adverse effects are experienced (a or b, *see Appendix D*):

a. Failure of a ≥ 3 consecutive month trial of one* adalimumab product (e.g., *Hadlima™, Simlandi®, Yusimry™, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*);
b. History of failure of two TNF blockers;

**Prior authorization may be required for adalimumab products*

6. Failure of a ≥ 3 consecutive month trial of Taltz®*, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for Taltz*
7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
8. Dose does not exceed 100 mg at weeks 0 and 4, followed by maintenance dose of 100 mg every 8 weeks.

**Approval duration: 6 months**

**B. Psoriatic Arthritis** (must meet all)**:**

1. Diagnosis of PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Failure of ALL* of the following*, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b c, and d, *see Appendix D*):
   a. One adalimumab product (e.g., *Hadlima, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless the member has had a history of failure of two TNF blockers;
   b. Otezla®;
   c. Taltz;
   d. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz®/Xeljanz XR®, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

   **Prior authorization may be required for adalimumab products, Otezla, Taltz, and Xeljanz/Xeljanz XR*
5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
6. Dose does not exceed 100 mg at weeks 0 and 4, followed by maintenance dose of 100 mg every 8 weeks.

**Approval duration: 6 months**

**C. Ulcerative Colitis** (must meet all)**:**

1. Diagnosis of UC;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 18 years;
4. Documentation of a Mayo Score ≥ 6 (*see Appendix E*);
5. Failure of an 8-week trial of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced;

6. Member meets both* of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a and b, *see Appendix D*):
   a. Failure of one adalimumab product (e.g., *Hadlima, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless the member has had history of failure of two TNF blockers;
   b. If member has had a history of failure of two TNF blockers, then failure of Zeposia®;

   **Prior authorization may be required for adalimumab products and Zeposia*
7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
8. Dose does not exceed both of the following (a and b):
   a. Induction (IV): 200 mg at weeks 0, 4, and 8;
   b. Maintenance (SC) (i or ii):
      i. 100 mg at week 16 and every 8 weeks thereafter;
      ii. 200 mg at week 12 and every 4 weeks thereafter.

**Approval duration: 6 months**

**D. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

## II. Continued Therapy

**A. All Indications in Section I** (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy;
3. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);

4. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. For PsO, PsA: 100 mg every 8 weeks;
   b. For UC: 200 mg every 4 weeks.

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 for Medicaid or evidence of coverage documents;

**B.** Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia®, Enbrel®, Humira® and its biosimilars, Remicade® and its biosimilars (Avsola™, Inflectra™, Renflexis™, Zymfentra®), Simponi®], interleukin agents [e.g., Actemra® (IL-6RA), Arcalyst® (IL-1 blocker), Bimzelx® (IL-17A and F antagonist), Cosentyx® (IL-17A inhibitor), Ilaris® (IL-1 blocker), Ilumya™ (IL-23 inhibitor), Kevzara® (IL-6RA), Kineret® (IL-1RA), Omvoh™ (IL-23 antagonist), Siliq™ (IL-17RA), Skyrizi™ (IL-23 inhibitor), Stelara® (IL-12/23 inhibitor), Taltz® (IL-17A inhibitor), Tofidence™ (IL-6), Tremfya® (IL-23 inhibitor), Wezlana™ (IL-12/23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo™, Olumiant™, Rinvoq™, Xeljanz®/Xeljanz® XR,], anti-CD20 monoclonal antibodies [Rituxan® and its biosimilars (Riabni™, Ruxience™, Truxima®), Rituxan Hycela®], selective co-stimulation modulators [Orencia®], integrin receptor antagonists [Entyvio®], tyrosine kinase 2 inhibitors [Sotyktu™], and sphingosine 1-phosphate receptor modulator [Velsipity™] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration
IL-23: interleukin-23
JAKi: Janus kinase inhibitors
MTX: methotrexate

PsA: psoriatic arthritis
PsO: plaque psoriasis
UC: ulcerative colitis

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| acitretin (Soriatane®) | **PsO**<br>25 or 50 mg PO daily | 50 mg/day |
| corticosteroids | **UC**<br>Prednisone 40 mg – 60 mg PO QD, then taper dose by 5 to 10 mg/week<br><br>Budesonide (Uceris®) 9 mg PO QAM for up to 8 weeks | Various |
| cyclosporine (Sandimmune®, Neoral®) | **PsO**<br>2.5 – 4 mg/kg/day PO divided BID | 4 mg/kg/day |
| methotrexate (Trexall®, Otrexup™, Rasuvo®, RediTrex®, Rheumatrex®, Jylamvo®) | **PsO**<br>10 to 25 mg/week IM, SC or PO or 2.5 mg PO Q12 hr for 3 doses/week | 30 mg/week |
| Hadlima (adalimumab-bwwd), Simlandi (adalimumab-ryvk), Yusimry (adalimumab-aqvh), adalimumab-aaty (Yuflyma®), adalimumab-adaz (Hyrimoz®), adalimumab-fkjp (Hulio®), adalimumab-adbm (Cyltezo®) | **PsA**<br>40 mg SC every other week<br><br>**PsO**<br>Initial dose:<br>80 mg SC<br><br>Maintenance dose:<br>40 mg SC every other week starting one week after initial dose<br><br>**UC**<br>Initial dose: 160 mg SC on Day 1, then 80 mg SC on Day 15<br><br>Maintenance dose: 40 mg SC every other week starting on Day 29 | 40 mg every other week |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| Otezla® (apremilast) | **PsA**<br>Initial dose:<br>Day 1: 10 mg PO QAM<br>Day 2: 10 mg PO QAM and 10 mg PO QPM<br>Day 3: 10 mg PO QAM and 20 mg PO QPM<br>Day 4: 20 mg PO QAM and 20 mg PO QPM<br>Day 5: 20 mg PO QAM and 30 mg PO QPM<br><br>Maintenance dose:<br>Day 6 and thereafter: 30 mg PO BID | 60 mg/day |
| Taltz® (ixekizumab) | **PsO**<br>Initial dose:<br>160 mg (two 80 mg injections) SC at week 0, then 80 mg SC at weeks 2, 4, 6, 8, 10, and 12<br>Maintenance dose:<br>80 mg SC every 4 weeks<br><br>**PsA**<br>Initial dose: 160 mg (two 80 mg injections) SC at week 0<br>Maintenance dose:<br>80 mg SC every 4 weeks | 80 mg every 4 weeks |
| Xeljanz® (tofacitinib) | **PsA**<br>5 mg PO BID | 10 mg/day |
| Xeljanz XR® (tofacitinib extended-release) | **PsA**<br>11 mg PO QD | 11 mg/day |
| Zeposia (ozanimod) | **UC**<br>Days 1-4: 0.23 mg PO QD<br>Days 5-7: 0.46 mg PO QD<br>Day 8 and thereafter: 0.92 mg PO QD | **UC**<br>0.92 mg/day |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*
None reported

*Appendix D: General Information*
- Definition of failure of MTX or DMARDs
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week.

However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.

- TNF blockers:
  - Etanercept (Enbrel®), adalimumab (Humira®) and its biosimilars, infliximab (Remicade®) and its biosimilars (Avsola™, Renflexis™, Inflectra®), certolizumab pegol (Cimzia®), and golimumab (Simponi®, Simponi Aria®).

*Appendix E: Mayo Score*

- Mayo Score: evaluates ulcerative colitis stage, based on four parameters: stool frequency, rectal bleeding, endoscopic evaluation, and Physician's global assessment. Each parameter of the score ranges from zero (normal or inactive disease) to 3 (severe activity) with an overall score of 12.

| Score | Decoding |
|---|---|
| 0 – 2 | Remission |
| 3 – 5 | Mild activity |
| 6 – 10 | Moderate activity |
| >10 | Severe activity |

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| PsA, PsO | Initial dose:<br>100 mg SC at weeks 0 and 4<br><br>Maintenance dose:<br>100 mg SC every 8 weeks | 100 mg/8 weeks |
| UC | Induction:<br>200 mg IV at weeks 0, 4, and 8<br><br>Maintenance:<br>100 mg SC at week 16, and every 8 weeks thereafter, or<br>200 mg SC at week 12, and every 4 weeks thereafter | 200 mg/4 weeks |

## VI. Product Availability

- Subcutaenous injection
  - Single-dose prefilled syringe: 100 mg/mL, 200 mg/2 mL
  - Single-dose One Press patient-controlled injector: 100 mg/mL
  - Single-dose prefilled pen (Tremfya Pen): 200 mg/2 mL
- Intravenous infusion
  - Single-dose vial: 200 mg/20 mL

## VII. References

1. Tremfya Prescribing Information. Horsham, PA: Janssen Biotech, Inc.; September 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761061s021lbl.pdf. Accessed September 19, 2024.

2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80:1029-72. doi:10.1016/j.aad.201811.057.
3. Gossec L, Baraliakos X, Kerschbaumer A, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. Ann Rheum Dis. 2020;79:700–712. doi:10.1136/annrheumdis-2020-217159.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. American College of Rheumatology. 2019; 71(1):5-32. doi: 10.1002/art.40726.
5. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology 2020;158:1450–1461. https://doi.org/10.1053/j.gastro.2020.01.006.
6. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology 2020;158:1450–1461. https://doi.org/10.1053/j.gastro.2020.01.006.

**Coding Implications**
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|---|---|
| J1628 | Injection, guselkumab, 1 mg |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 2Q 2020 annual review: no significant changes; references reviewed and updated. | 02.28.20 | 05.20 |
| RT2: Criteria added for new FDA indication: PsA; references reviewed and updated. | 08.25.20 | 11.20 |
| 2Q 2021 annual review: added additional criteria related to diagnosis of moderate-to-severe PsO per 2019 AAD/NPF guidelines specifying at least 3% BSA involvement or involvement of areas that severely impact daily function; added combination of bDMARDs under Section III; references reviewed and updated. | 02.23.21 | 05.21 |
| Per SDC and prior clinical guidance, for PsA removed Simponi as a redirect option and modified to require a trial of all; for Xeljanz redirection requirements added bypass for members with cardiovascular risk and qualified redirection to apply only for member that has not responded or is intolerant to one or more TNF blockers. | 08.25.21 | 11.21 |
| 2Q 2022 annual review: for PsO, allowed phototherapy as alternative to systemic conventional DMARD if contraindicated or clinically significant adverse effects are experienced; reiterated requirement | 02.21.22 | 05.22 |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| against combination use with a bDMARD or JAKi from Section III to Sections I and II; references reviewed and updated. | | |
| Template changes applied to other diagnoses/indications and continued therapy section, | 09.22.22 | |
| 2Q 2023 annual review: for PsA, added TNFi criteria to allow bypass if member has had history of failure of two TNF blockers; updated dosing in Appendix B to reflect dosing for redirected indications; references reviewed and updated. | 02.10.23 | 05.23 |
| Per July SDC: for PsA, removed criteria requiring use of Enbrel; for PsO and PsA, added criteria requiring use of one adalimumab product and stating Yusimry, Hadlima, unbranded adalimumab-fkjp, and unbranded adalimumab-adaz as preferred; updated Appendix B with relevant therapeutic alternatives. | 07.25.23 | |
| Per December SDC, added adalimumab-adbm to listed examples of preferred adalimumab products. | 12.06.23 | 02.24 |
| 2Q 2024 annual review: added Bimzelx, Zymfentra, Omvoh, Wezlana, Sotyktu, Tofidence, and Velsipity to section III.B; references reviewed and updated. | 01.25.24 | 05.24 |
| Per June SDC, added Simlandi to listed examples of preferred adalimumab products.<br>Per SDC, added unbranded adalimumab-aaty to listed examples of preferred adalimumab products. | 07.23.24 | 08.24 |
| RT4: added criteria for newly approved indication for UC; added appendix E with Mayo Score supplemental information; added new subcutaneous formulations [single-dose prefilled syringe 200 mg/2 mL; single-dose prefilled pen (Tremfya Pen) 200 mg/2 mL] and intravenous formulation [single-dose vial 200 mg/20 mL]. | 09.19.24 | 11.24 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering

benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.