# Clinical Policy: : Guselkumab (Tremfya)

Reference Number: PA.CHIP.PHAR.364
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## 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)
- Adult patients with moderately to severely active Crohn's disease (CD)

## Policy/Criteria

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

It is the policy of PA Health & Wellness® 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 one ustekinumab product (e.g. *Otulfi®,*

*Pyzchiva® (branded), Steqeyma®, Yesintek™ are preferred*), unless clinically significant adverse effects are experienced or all are contraindicated;
**Prior authorization may be required for ustekinumab products*

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. One ustekinumab product (e.g. *Otulfi®, Pyzchiva® (branded), Steqeyma®, Yesintek™ are preferred*);
   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, ustekinumab products, 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 or modified Mayo Score ≥ 5 (*see Appendix E*);
5. Failure of an 8-week trial of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced;
6. Failure of one of the following, used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a or b):
   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. One ustekinumab product (e.g. *Otulfi®, Pyzchiva® (branded), Steqeyma®, Yesintek™ are preferred*);

**Prior authorization may be required for adalimumab products and ustekinumab products*

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):
   - 100 mg at week 16 and every 8 weeks thereafter;
   - 200 mg at week 12 and every 4 weeks thereafter.

   **Approval duration: 6 months**

**D. Crohn's Disease** (must meet all)**:**

1. Diagnosis of CD;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Failure of a ≥ 3 consecutive month trial of at least ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine [6-MP], MTX) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
   b. Medical justification supports inability to use immunomodulators (*see Appendix F*);
5. Member meets of one* of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a or 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*), used for ≥ 3 consecutive months;
   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 one ustekinumab product (e.g. *Otulfi®, Pyzchiva® (branded), Steqeyma®, Yesintek™ are preferred*), unless clinically significant adverse effects are experienced or all are contraindicated;
      **Prior authorization may be required for ustekinumab products*
7. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK 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 (i or ii):
   - 200 mg (IV) at weeks 0, 4, and 8;
   - 400 mg (SC) at weeks 0, 4, and 8;

   b. Maintenance (SC) (i or ii):
   - 100 mg at week 16 and every 8 weeks thereafter;
   - 200 mg at week 12 and every 4 weeks thereafter.

   **Approval duration: 6 months**

**E. 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 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 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 Fidelis 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 CD, 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 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 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, Simponi®], interleukin agents [e.g., Actemra® (IL-6RA) and its biosimilars, 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), Spevigo® (IL-36 antagonist), Stelara® (IL-12/23 inhibitor) and its biosimilars, Taltz® (IL-17A inhibitor), Tremfya® (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo™, Olumiant™, Rinvoq™, Xeljanz®/Xeljanz® XR,], anti-CD20 monoclonal antibodies [Rituxan® and its biosimilars], 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*

CD: Crohn's disease
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 |
| azathioprine (Azasan®, Imuran®) | **CD***<br>1.5 – 2.5 mg/kg/day PO | 2.5 mg/kg/day |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| 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 |
| 6-mercaptopurine (Purixan®) | **CD***<br>50 mg PO QD or 0.75 – 1.5 mg/kg/day | 1.5 mg/kg/day |
| methotrexate (Trexall®, Otrexup™, Rasuvo®, RediTrex®, Rheumatrex®, Jylamvo®) | **CD***<br>15 – 25 mg/week IM or SC<br><br>**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®) | **CD, 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<br><br>**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 | 40 mg every other week |
| 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: | 60 mg/day |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| | Day 6 and thereafter: 30 mg PO BID | |
| Otulfi® (ustekinumab-aauz), Pyzchiva® (ustekinumab-ttwe), Steqeyma® (ustekinumab-stba), Yesintek™ (ustekinumab-kfce) | **CD, UC**<br>Weight based dosing IV at initial dose:<br>Weight ≤ 55 kg: 260 mg<br>Weight > 55 kg to 85 kg: 390 mg<br>Weight > 85 kg: 520 mg<br><br>Maintenance dose:<br>90 mg SC every 8 weeks<br><br>**PsO**<br>Weight based dosing SC at weeks 0 and 4, followed by maintenance dose every 12 weeks<br><br>*Adult:*<br>Weight ≤ 100 kg: 45 mg<br>Weight > 100 kg: 90 mg<br><br>*Pediatrics (age 6 years to 17 years):*<br>**Otulfi, Pyzchiva, Yesintek:**<br>Weight < 60 kg: 0.75 mg/kg<br><br>**Otulfi, Pyzchiva, Steqeyma, Yesintek:**<br>Weight 60 to 100 kg: 45 mg<br>Weight > 100 kg: 90 mg<br><br>**PsA**<br>Weight based dosing SC at weeks 0 and 4, followed by maintenance dose every 12 weeks<br><br>*Adult:*<br>45 mg SC at weeks 0 and 4, followed by 45 mg every 12 weeks<br><br>*Pediatrics (age 6 years to 17 years):*<br>Weight based dosing SC at weeks 0 and 4, then every 12 weeks thereafter<br><br>**Otulfi, Pyzchiva, Yesintek:**<br>Weight < 60 kg: 0.75 mg/kg<br><br>**Otulfi, Pyzchiva, Steqeyma, Yesintek:**<br>Weight ≥ 60 kg: 45 mg | CD, UC:<br>90 mg every 8 weeks<br><br>PsO:<br>90 every 12 weeks<br><br>PsA:<br>45 mg every 12 weeks |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| 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 |

*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 or Modified 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 |

- Modified Mayo Score: developed from the full Mayo score and evaluates ulcerative colitis stage, based on three parameters: stool frequency, rectal bleeding, and endoscopic evaluation. The modified Mayo Score gives a maximum overall score of 9. The FDA currently accepts the modified Mayo Score for the assessment of disease activity in pivotal UC clinical trials.

*Appendix F: Immunomodulator Medical Justification*

- The following may be considered for medical justification supporting inability to use an immunomodulator for CD:
  - Inability to induce short-term symptomatic remission with a 3-month trial of systemic glucocorticoids
  - High-risk factors for intestinal complications may include:
    - Initial extensive ileal, ileocolonic, or proximal GI involvement
    - Initial extensive perianal/severe rectal disease
    - Fistulizing disease (e.g., perianal, enterocutaneous, and rectovaginal fistulas)
    - Deep ulcerations
    - Penetrating, stricturing or stenosis disease and/or phenotype
    - Intestinal obstruction or abscess
  - For TNF-inhibitors, high risk factors for postoperative recurrence may include:
    - Less than 10 years duration between time of diagnosis and surgery
    - Disease location in the ileum and colon
    - Perianal fistula
    - Prior history of surgical resection
    - Use of corticosteroids prior to surgery

**V. Dosage and Administration**

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| CD | Induction:<br>200 mg IV at weeks 0, 4, and 8, or<br>400 mg SC 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 |
| 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 | 200 mg/4 weeks |

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| | 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 | |

## VI. Product Availability

- Subcutaneous 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): 100 mg/mL, 200 mg/2 mL
- Intravenous infusion
  - Single-dose vial: 200 mg/20 mL

## VII. References

1. Tremfya Prescribing Information. Horsham, PA: Janssen Biotech, Inc.; March 2025. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761061s027lbl.pdf. Accessed March 27, 2025.
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9. Singh S, Loftus EV Jr, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. Gastroenterology. 2024 Dec;167(7):1307-1343. doi: 10.1053/j.gastro.2024.10.001. PMID: 39572132.

## 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 |
|---|---|
| Policy created | 10/2025 |