

**Clinical Policy: Guselkumab (Tremfya)**

Reference Number: MDN.CP.PHAR.364

Effective Date: 04.01.22

Last Review Date: 12.19.23

Line of Business: Meridian IL Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**

Guselkumab (Tremfya<sup>®</sup>) 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)

**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<sup>®</sup> 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.  $\geq 3\%$  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  $\geq 18$  years;
4. Member meets one of the following (a, b, or c):
  - a. Failure of a  $\geq 3$  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  $\geq 3$  consecutive month trial of cyclosporine 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, and cyclosporine, , and failure of phototherapy, unless contraindicated or clinically significant adverse effects are experienced;

5. Failure of TWO of the following, each used for  $\geq 3$  consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Cimzia<sup>®</sup>, Cosentyx<sup>®</sup>, Enbrel<sup>®</sup>, Humira<sup>®</sup>, unless the member has had a history of failure of two TNF blockers;  
*\*Prior authorization may be required for Cimzia, Enbrel, and Humira*
6. 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*);
7. 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  $\geq 18$  years;
4. Failure of TWO of the following\*, each used for  $\geq 3$  consecutive months, unless the member has had a history of failure of two TNF blockers, clinically significant adverse effects are experienced, or all are contraindicated (a, b, c, and d):
  - a. Cimzia<sup>®</sup>;
  - b. Enbrel<sup>®</sup>;
  - c. Humira<sup>®</sup>;
  - d. Cosentyx<sup>®</sup>
5. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz<sup>®</sup>/Xeljanz XR<sup>®</sup>, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;  
*\*Prior authorization may be required for Cimzia, Enbrel, Humira, and Xeljanz/Xeljanz XR*
6. 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*);
7. 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. Other diagnoses/indications**

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):
  - c. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - d. 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 100 mg every 8 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):
  - e. 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
  - f. 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 of biological disease-modifying antirheumatic drugs (bDMARDs), including any tumor necrosis factor (TNF) antagonists [Cimzia<sup>®</sup>, Enbrel<sup>®</sup>, Humira and its biosimilars, Simponi<sup>®</sup>, Avsola<sup>™</sup>, Inflectra<sup>™</sup>, Remicade<sup>®</sup>, Renflexis<sup>™</sup>], interleukin agents [Arcalyst<sup>®</sup> (IL-1 blocker), Ilaris<sup>®</sup> (IL-1 blocker), Kineret<sup>®</sup> (IL-1RA), Actemra<sup>®</sup> (IL-6RA), Kevzara<sup>®</sup> (IL-6RA), Stelara<sup>®</sup> (IL-12/23 inhibitor), Cosentyx<sup>®</sup> (IL-17A inhibitor), Taltz<sup>®</sup> (IL-17A inhibitor), Siliq<sup>™</sup> (IL-17RA), Ilumya<sup>™</sup> (IL-23 inhibitor), Skyrizi<sup>™</sup> (IL-23 inhibitor), Tremfya<sup>®</sup> (IL-23 inhibitor)], janus kinase inhibitors (JAKi) [Xeljanz<sup>®</sup>/Xeljanz<sup>®</sup> XR, Rinvoq<sup>™</sup>], anti-CD20 monoclonal antibodies [Rituxan<sup>®</sup>, Riabni<sup>™</sup>, Ruxience<sup>™</sup>, Truxima<sup>®</sup>, and Rituxan Hycela<sup>®</sup>], selective co-stimulation modulators [Orencia<sup>®</sup>], or integrin receptor antagonists [Entyvio<sup>®</sup>] because of the possibility of increased immunosuppression, neutropenia and increased risk of infection.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

IL-23: interleukin-23

MTX: methotrexate

PsA: psoriatic arthritis

PsO: plaque psoriasis

*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 <sup>®</sup> )	<b>PsO</b> 25 or 50 mg PO daily	50 mg/day
cyclosporine (Sandimmune <sup>®</sup> , Neoral <sup>®</sup> )	<b>PsO</b> 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
methotrexate (Trexall <sup>®</sup> , Otrexup <sup>™</sup> , Rasuvo <sup>®</sup> , RediTrex <sup>®</sup> , Jylamvo <sup>®</sup> ) Rheumatrex <sup>®</sup> )	<b>PsO</b> 10 to 25 mg/week IM, SC or PO or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
	<b>PsO</b> <i>Adults:</i> Initial dose: 50 mg SC twice weekly for 3 months Maintenance dose:	

Enbrel® (etanercept)	<p>50 mg SC once weekly</p> <p><i>Pediatrics:</i> Weight &lt; 63 kg: 0.8 mg/kg SC once weekly Weight ≥ 63 kg: 50 mg SC once weekly</p> <p><b>PsA</b> 25 mg SC twice weekly or 50 mg SC once weekly</p>	50 mg/week
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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Otezla® (apremilast)	<p><b>PsA</b> Initial dose:</p> <p>Day 1: 10 mg PO QAM Day 2: 10 mg PO QAM and 10 mg PO QPM Day 3: 10 mg PO QAM and 20 mg PO QPM Day 4: 20 mg PO QAM and 20 mg PO QPM Day 5: 20 mg PO QAM and 30 mg PO QPM</p> <p>Maintenance dose: Day 6 and thereafter: 30 mg PO BID</p>	60 mg/day
Taltz® (ixekizumab)	<p><b>PsO</b> Initial dose: 160 mg (two 80 mg injections) SC at week 0, then 80 mg SC at weeks 2, 4, 6, 8, 10, and 12 Maintenance dose: 80 mg SC every 4 weeks</p> <p><b>PsA</b> Initial dose: 160 mg (two 80 mg injections) SC at week 0 Maintenance dose: 80 mg SC every 4 weeks</p>	80 mg every 4 weeks
Cimzia® (certolizumab)	<p><b>PsO</b> 400 mg SC every other week. For some patients (with body weight ≤ 90 kg), a dose of 400 mg SC at 0, 2 and 4 weeks, followed by 200 mg SC every other week starting on treatment week 6 may be considered.</p>	400 mg every other week
Xeljanz® (tofacitinib)	<p><b>PsA</b> 5 mg PO BID</p>	10 mg/day

Xeljanz XR <sup>®</sup> (tofacitinib extended-release)	<b>PsA</b> 11 mg PO QD	11 mg/day
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*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) 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.
  
- Psoriatic Arthritis: According to the 2018 American College of Rheumatology and National Psoriasis Foundation guidelines, TNF inhibitors or oral small molecules (e.g., methotrexate, sulfasalazine, cyclosporine, leflunomide, apremilast) are preferred over other biologics (e.g., interleukin-17 inhibitors or interleukin-12/23 inhibitors) for treatment-naïve disease. TNF inhibitors are also generally recommended over oral small molecules as first-line therapy unless disease is not severe, member prefers oral agents, or TNF inhibitor therapy is contraindicated.
  
- TNF blockers:
  - Etanercept (Enbrel<sup>®</sup>), adalimumab (Humira<sup>®</sup>), adalimumab-atto (Amjevita<sup>™</sup>), infliximab (Remicade<sup>®</sup>) and infliximab biosimilars (Avsola<sup>™</sup>, Renflexis<sup>™</sup>, Inflectra<sup>®</sup>), certolizumab pegol (Cimzia<sup>®</sup>), and golimumab (Simponi<sup>®</sup>, Simponi Aria

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
PsA, PsO	Initial dose:	100 mg every 8 weeks
	100 mg SC at weeks 0 and 4	
	Maintenance dose:	
	100 mg SC every 8 weeks	

**VI. Product Availability**

Single-dose prefilled syringe or One Press patient-controlled injector: 100 mg/mL

**VII. References**

1. Tremfya Prescribing Information. Horsham, PA: Janssen Biotech, Inc.; July 2020. Available at: <https://www.tremfyahcp.com/>. Accessed February 10, 2023.

2. Blauvelt A, PappKA, 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 Mar;76(3):405-417. Doi: 10.1016/j.jaad.2016.11.041. Epub 2017 Jan 2.
3. 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 Mar;76(3):418-431. Doi: 10.1016/j.jaad.2016.11.042. Epub 2017 Jan 2.
4. Nakamura M, Lee K, Jeon C, et al. Guselkumab for the Treatment of Psoriasis: A Review of Phase III Trials. *Dermatol Ther (Heidelb)*. 2017. Doi: 10.1007/s13555-017-0187-0.
5. 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*. 2017. Doi: 10.1111/bjd.15750.
6. Singh JA, Guyatt G, Ogdie A. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. *Arthritis and Rheumatology*. 2019; 71(1):5-32.
7. 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;80:102972. doi:10.1016/j.aad.201811.057.

**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
Policy created, adapted from CP.PHAR.364	04.01.22	04.22
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; template changes applied to other diagnoses/indications and continued therapy section; references reviewed and updated.	4.21.23	
4Q annual review: updated Plaque psoriasis and psoriatic arthritis sections; references reviewed.	12.19.23	



**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.

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**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.

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