

Clinical Policy: Guselkumab (Tremfya)

Reference Number: IL.ERX.SPA.217

Effective Date: 06.01.21

Last Review Date: 05.21

Line of Business: Illinois 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)

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 ≥ 18 years;
4. Failure of at least TWO of the following, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Enbrel®, Humira®, Cimzia®;
**Prior authorization may be required for Enbrel, Humira, and Cimzia*
5. Member meets one of the following (a or b):
 - 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 at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
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

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 at least TWO of the following, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Cimzia, Xeljanz[®]/Xeljanz[®] XR;
**Prior authorization may be required for Enbrel, Humira, Cimzia, and Xeljanz/Xeljanz XR*
5. 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. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. 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. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 or evidence of coverage documents;
- B.** Combination use of biological disease-modifying antirheumatic drugs (bDMARDs), including any tumor necrosis factor (TNF) antagonists [Cimzia[®], Enbrel[®], Simponi[®], Avsola[™], Inflectra[™], Remicade[®], Renflexis[™]], interleukin agents [Arcalyst[®] (IL-1 blocker), Ilaris[®] (IL-1 blocker), Kineret[®] (IL-1RA), Actemra[®] (IL-6RA), Kevzara[®] (IL-6RA), Stelara[®] (IL-12/23 inhibitor), Cosentyx[®] (IL-17A inhibitor), Taltz[®] (IL-17A inhibitor), Siliq[™] (IL-17RA), Ilumya[™] (IL-23 inhibitor), Skyrizi[™] (IL-23 inhibitor), Tremfya[®] (IL-23 inhibitor)], janus kinase inhibitors (JAKi) [Xeljanz[®]/Xeljanz[®] XR, Rinvoq[™]], anti-CD20 monoclonal antibodies [Rituxan[®], Riabni[™], Ruxience[™], Truxima[®], and Rituxan Hycela[®]], selective co-stimulation modulators [Orencia[®]], or integrin receptor antagonists [Entyvio[®]] 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
cyclosporine (Sandimmune [®] , Neoral [®])	PsO 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
methotrexate (Rheumatrex®)	PsO 10 – 25 mg/week PO or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
Enbrel® (etanercept)	PsA 25 mg SC twice weekly or 50 mg SC once weekly PsO <i>Adults:</i> <u>Initial dose:</u> 50 mg SC twice weekly for 3 months <u>Maintenance dose:</u> 50 mg SC once weekly <i>Pediatrics:</i> Weight < 63 kg: 0.8 mg/kg SC once weekly Weight ≥ 63 kg: 50 mg SC once weekly	50 mg/week
Humira® (adalimumab)	PsA 40 mg SC every other week PsO <u>Initial dose:</u> 80 mg SC <u>Maintenance dose:</u> 40 mg SC every other week starting one week after initial dose	40 mg every other week
Cimzia® (certolizumab)	PsA <u>Initial dose:</u> 400 mg SC at 0, 2, and 4 weeks <u>Maintenance dose:</u> 200 mg SC every other week (or 400 mg SC every 4 weeks) PsO 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 may be considered.	400 mg every 4 weeks
Xeljanz® (tofacitinib immediate-release)	PsA 5 mg PO BID	10 mg/day
Xeljanz XR® (tofacitinib extended-release)	PsA 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.

V. Dosage and Administration

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

VI. Product Availability

Single-dose prefilled syringe: 100 mg/mL

VII. References

1. Tremfya Prescribing Information. Horsham, PA: Janssen Biotech, Inc.; July 2020. Available at: <https://www.tremfyahcp.com/>. Accessed January 6, 2021.
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;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;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.
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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;80:1029-72. doi:10.1016/j.aad.201811.057.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.22.21	05.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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