

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Tremfya (guselkumab)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Cimzia, Cosentyx, Enbrel, Otezla, Xeljanz and Siliq QUANTITY LIMIT— 1 syringe every 8 weeks after loading doses
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Tremfya (guselkumab) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

PLAQUE PSORIASIS (PsO)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has clinical documentation of moderate to severe plaque psoriasis characterized by 3% or more of body surface area (BSA) or disease affecting sensitive areas (e.g., hands, feet, face, genitals, etc.); AND
4. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Member has tried and failed to respond to treatment with at least **one** of the following:
 - a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
 - b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments);
 - c) At least a 4 week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene, tacrolimus, pimecrolimus); AND
6. Member has tried and failed, or unable to tolerate a systemic non-biologic DMARD (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks; AND
7. Member has tried and failed treatment with at least **two** of the following: Cimzia, Cosentyx, Enbrel, Otezla and Siliq. Treatment failure requires at least 12 weeks of therapy with each drug.
8. **Dosage allowed:** 100 mg administered by subcutaneous injection at Week 0, Week 4 and every 8 weeks thereafter.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease (e.g., documented member's BSA improvement, etc.).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

PSORIATIC ARTHRITIS (PsA)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist or dermatologist; AND
3. Member has a documented diagnosis of active psoriatic arthritis (PsA); AND
4. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Member has met a 4-week trial of an NSAID taken at maximally tolerated doses AND a 3-month trial of a non-biologic DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless one of the following situations is met:
 - a) Non-biologic DMARD is not required for:
 - i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
 - b) NSAID and non-biologic DMARD are not required for:
 - i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life); AND
6. Member must have tried and failed treatment with at least **two** of the following: Enbrel, Cimzia, Cosentyx, Otezla, and Xeljanz (all require prior authorization). Treatment failure requires at least for 12 weeks of therapy with each drug.
7. **Dosage allowed:** 100 mg administered by subcutaneous injection at Week 0, Week 4 and every 8 weeks thereafter.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Tremfya (guselkumab) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
10/19/2017	New policy for Tremfya created.
02/26/2019	Humira was removed from criteria; Cimzia, Cosentyx, Otezla and Siliq added to trial agents list. Initial authorization length increased to 12 months. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. Reauthorization criteria on documented member's PASI score improvement incorporated into general chart noted documentation requirements.
09/23/2020	New indication Psoriatic Arthritis added. For PsO: Removed rheumatologist from prescriber. Removed PsO for 6 months or longer. Changed BSA to 3% or sensitive area involvement. Removed PASI score requirement. Removed repeated TB test for reauth.

References:

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3. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol*. 2020;82(6):1445-1486.
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7. ClinicalTrials.gov. A Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Participants With Active Psoriatic Arthritis Including Those Previously Treated With Biologic Anti-Tumor Necrosis Factor (TNF) Alpha Agent(s) (Discover-1). Identifier: NCT03162796. Available at: <https://clinicaltrials.gov/ct2/show/NCT03162796>.
8. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of Psoriatic Arthritis. *Arthritis Rheumatol*. 2019 Jan;71(1):5-32.
9. Gladman DD, Ritchlin C. Clinical manifestations and diagnosis of psoriatic arthritis. In: Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. Accessed September 23, 2020.
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Effective date: 04/01/2021

Revised date: 09/23/2020