CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Tremfya (guselkumab)
BENEFIT TYPE	Pharmacy or Medical
STATUS	Prior Authorization Required

Tremfya (guselkumab) is an anti-psoriatic agent, interleukin-23 inhibitor, and monoclonal antibody initially approved by the FDA in 2017. It is currently FDA approved for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy and active psoriatic arthritis in adults. Plaque psoriasis is a skin disease that causes dry, raised, red patches covered with silvery scales on the skin, whereas psoriatic arthritis affects points where tendons and ligaments attach to bones- causing painful, sausage-like swelling of the fingers and toes.

Tremfya (guselkumab) will be considered for coverage when the following criteria are met:

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. **Dosage allowed/Quantity limit:** 100 mg administered by subcutaneous injection at Week 0, Week 4 and every 8 weeks thereafter. Tremfya has a quantity limit of 1 syringe every 8 weeks after loading doses.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. 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 all the above requirements are met, 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. **Dosage allowed/Quantity limit:** 100 mg administered by subcutaneous injection at Week 0, Week 4 and every 8 weeks thereafter. Tremfya has a quantity limit of 1 syringe every 8 weeks after loading doses.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided that show improvement of signs and symptoms of disease (ie. decreased joint swelling and pain, improved skin appearance, improved quality of life, etc).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Tremfya (guselkumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

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 reauthorization.
02/22/2022	Transferred policy to new format; Removed initial criteria from reauthorization; Updated wording for biologic DMARDs; Clarified reauth criteria
03/17/2022	Removed preferred biologic trials.
05/15/2024	Added medical benefit option.

References:

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Effective date: 10/01/2024
Revised date: 05/15/2024