

PHARMACY POLICY STATEMENT Kentucky 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 and Siliq QUANTITY LIMIT— see Dosage allowed below
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. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member has PsO for 6 months or longer; AND
5. Member has PsO involves 10% or more of the member's body surface area; AND
6. Member's Psoriasis Area and Severity Index (PASI) score is greater than or equal to 12; AND
7. Member has tried and failed to respond to treatment with at least **one** of the following:
 - a) At least 30 days of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
 - b) At least 30 days of phototherapy (i.e., UVB light therapy, Excimer laser treatments) (tanning beds emit mostly UVA light and therefore would not meet this criteria).
 - c) At least a 30-day trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene); AND
8. Member has tried and failed to respond to treatment with traditional first-line oral/systemic therapies (i.e., cyclosporine, methotrexate, acitretin) for at least 30 days; AND
9. Member has tried and failed treatment with at least **two** of the following: Cimzia, Cosentyx, Enbrel, Otezla and Siliq. Treatment failure requires at least for 30 days of therapy with each drug.
10. **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. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND

3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease (e.g., documented member’s PASI score improvement, etc.).

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 following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Active infections
- Ankylosing spondylitis
- Asthma
- Cellulitis
- Crohn’s Disease
- Dissecting scalp cellulitis
- For use in combination with other TNF-inhibitors (i.e., Humira, Kineret, Enbrel, Remicade)
- Giant-cell arteritis
- Infectious uveitis
- Juvenile idiopathic arthritis
- Lupus perino
- Osteoarthritis
- Psoriatic Arthritis
- Recurrent pregnancy loss
- Relapsing polychondritis
- Rheumatoid arthritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis (other than ankylosing spondylitis)
- Takayasu’s arteritis
- Ulcerative Colitis
- Vogt-Koyanagi

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.

References:

1. Tremfya [package insert]. East Hanover, NJ:Novartis Pharmaceuticals Corporation; 2015. Accessed on May 1, 2017.



2. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. *Journal of the American Academy of Dermatology*, Volume 65, Issue 1, 137 – 174.
3. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. *Arch Dermatol*. 2012 Jan;148(1):95-102.

Effective date: 04/01/2019

Revised date: 02/26/2019