

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Tremfya (guselkumab)
BILLING CODE	For medical - C9029 (1 unit = 1 mg) For Rx- must use valid NDC code for self-administered product
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Enbrel and Humira 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 (PP)

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), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member has PP for 6 months or longer; AND
5. Member has PP 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 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) (tanning beds emit mostly UVA light and therefore would not meet this criteria).
 - c) At least a 4 week trial with topical antipsoriatic agents (i.e. anthralin, calcipotriene, coal tar, corticosteroids, tazarotene); AND
8. Member has tried and failed to respond to treatment of an immunosuppressant (i.e. cyclosporine, methotrexate, acetretin) for at least a 12 week trial; AND
9. Member has tried and failed treatment with **both** Enbrel and Humira.
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 6 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; AND

4. Documented member's PASI score improvement.

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. Kineret, Enbrel, Remicade)
- Giant-cell arteritis
- Guttate psoriasis
- 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
- Vogt-Koyanagi

DATE	ACTION/DESCRIPTION
10/19/2017	New policy for Tremfya created.

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: 03/01/2018
 Revised date: 10/19/2017