

**Generic:** guselkumab (FDA approved 07/13/2017)

**Company:** Janssen Biotech

**Agent for:** Plaque psoriasis

**Indications:** Treatment for moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy

**Mechanism of Action:** Tremfya is a human monoclonal antibody that selectively blocks IL-23, which plays an active role in plaque psoriasis. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses. Tremfya inhibits the release of proinflammatory cytokines and chemokines.

**COMPARABLE DRUG:** Biologics (Humira, Enbrel, Remicade, Stelara, Cosentyx, Taltz, Siliq), systemic treatments (methotrexate, Otezla).

#### COST PER MONTH (WAC)

TREMFYA 100 MG= \$5,245.50

ENBREL 50 MG= \$4812.17

HUMIRA 40 MG = \$4,811.33

STELARA 45MG = \$3,444.49

STELARA 90MG = \$6883.69

OTEZLA 30MG = \$2,958.00

COSENTYX 150MG = \$4,793.35

TALTZ 80 MG= \$5,173.87

SILIQ 210 MG = \$3,791.38

#### ADVANTAGES:

- First and only biologic approved that selectively blocks IL-23.
- Demonstrated superior results in skin clearance compared to Humira in analyses at weeks 16, 24 and 48.
- Intended for use under physician supervision and guidance, but patients may self-inject after physician approval and training.

#### DISADVANTAGES:

- Patients need to be evaluated for TB prior to treatment. Tremfya should not be administered to patients with an active TB infection.
- All age appropriate vaccines should be completed before starting treatment on

Tremfya. Use of live vaccines should be avoided in patients on treatment.

- Before injection, Tremfya needs to be removed from refrigerator and allowed to reach room temperature (30 minutes) without removal of needle cap.

**MOST IMPORTANT RISKS/ADVERSE EVENTS:** May increase risk of infections. Treatment should not be initiated in patients with a clinically important active infection until it is treated.

**MOST COMMON ADVERSE EVENTS:** Most common adverse reactions include upper respiratory infections, headache, injection site reactions, arthralgia, diarrhea, gastroenteritis, tinea infections, and herpes simple infections.

**USUAL DOSAGE:** Two starter doses of 100 mg are administered by subcutaneous injections at weeks 0 and 4. Afterwards, Tremfya is administered as 100 mg subcutaneous injections once every eight weeks. Should not be injected into areas where skin is tender, bruised, red, thick, scaly, or affected by psoriasis.

**PRODUCT:** 100 mg guselkumab / 1 mL in a single dose prefilled glass syringe with a half inch needle with guard. Clear and colorless to light yellow solution that may contain small translucent particles. Does not contain preservatives. Should be stored in a refrigerator at 2°C to 8°C (36°F to 46°F) in original carton away from light. Do not freeze or shake. Any unused portions should be thrown away.

**COMMENTS:** Plaque psoriasis is the most common type of psoriasis. It is thought to be an inherited disease that is triggered by environmental factors. It is characterized by itchy plaques of elevated, scaling, inflamed skin usually found on the scalp, elbows and knees. There is no cure for psoriasis yet, but there are treatments to reduce the symptoms. Common treatments aim to remove plaques and scales and to slow down the growth of cells. During clinical trials, subjects reported seeing greater improvements in symptoms after 16 weeks compared to those on placebo. Tremfya differs from other treatments for plaque psoriasis by blocking IL-23 rather than IL-17.