

Prior Authorization DRUG Guidelines

TREMFYA (guselkumab)

Effective Date: 10/24/2017

Date Developed: 10/24/2017 by Catherine R. Sanders, MD and ESI P&T

Date Approved by P&T Committee: 10/24/17, 1/23/18, 1/22/19

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Tremfya is a fully human immunoglobulin (Ig)G monoclonal antibody that binds to interleukin (IL)-23, a pro-inflammatory cytokine. It binds to the p19 subunit of IL-23 and inhibits the intracellular and downstream signaling of IL-23 which is required for the terminal differentiation and survival of T helper (Th)17 cells. Tremfya inhibits the release of proinflammatory cytokines and chemokines.

Pre-Authorization Criteria:

Moderate to Severe Plaque Psoriasis in patients who are candidates for systemic therapy or phototherapy: Approve for 3 months if the patient meets ALL of the following criteria (I, ii, and ii):

- i) The patient is ≥ 18 years of age; AND
- ii) The patient meets ONE of the following conditions (a or b);
 - a) The patient has tried at least one traditional systemic agent for psoriasis (e.g. methotrexate, cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant.
NOTE: An exception to the requirement above can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic (e.g. Enbrel, Cosentyx, Humira, Remicade, Inflectra, Siliq, Stelara or Taltz. These patients are not required to “step back” and try a traditional systemic agent; OR
 - b) The patient has a contraindication to methotrexate, as determined by the prescribing physician; AND
 - c) Tremfya is prescribed by or in consultation with a dermatologist.

Tremfya is not to be approved for the following: concurrent use with other biologics or with targeted synthetic disease-modifying antirheumatic drugs (DMARDs). Note: this does not exclude the use of methotrexate in combination with Tremfya.

Dosing: 100 mg subcutaneously at Weeks 0 and 4 and then once every 8 weeks thereafter.

Dosing Forms:

Prefilled syringe, subcutaneous: Tremfya 100 mg/mL

Revision History:

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