Commercial/Healthcare Exchange PA Criteria

Effective: November 2017

Prior Authorization: Tremfya

Products Affected: Tremfya (guselkumab) subcutaneous solution

Medication Description: Guselkumab is a human monoclonal IgG1 lambda antibody that inhibits inflammatory and immune responses by selectively binding and inhibiting the p19 subunit of interleukin 23. Guselkumab also inhibits the release of cytokines and chemokines which promote inflammation.

Covered Uses:

1. Treatment of moderate to severe plaque psoriasis
2. Treatment of adult patients with active psoriatic arthritis

Exclusion Criteria: Concurrent use with a biologic DMARD.

Required Medical Information:

1. Diagnosis
2. Previous medications tried and failed

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Tremfya is prescribed by, or in consultation with, a dermatologist or rheumatologist.

Coverage Duration:
Initial: 3 months
Continuation: 3 years

Other Criteria:

Dosing Limitations: Only allow additional quantity for loading dose purposes.
The recommended dose is 100 mg at Week 0, Week 4, and every 8 weeks thereafter.

Initiation

Plaque Psoriasis

A. Patient has chronic (greater than or equal to 1 year) plaque psoriasis; AND
B. Patient has minimum body surface area involvement with plaque psoriasis of ≥ 10%; AND
C. Patient has a documented failure of, or intolerance to, or contraindication to at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant. *Women of childbearing age may be given special consideration for approval without systemic therapy when topical and phototherapy options have been tried and failed.*

Psoriatic Arthritis

A. The patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy; **AND**
B. Patient has documented failure or intolerance to an adequate trial (at least 3 months) of ONE DMARD (e.g., methotrexate [oral or injectable], leflunomide, and sulfasalazine); AND

C. Patient has a documented failure of, or intolerance to, **TWO** of the following medications [documentation required]: Humira, Enbrel, Otezla, Stelara SC, Cosentyx, OR Xeljanz/Xeljanz XR.

Continuation

A. Patient meets all initial authorization criteria; **AND**
B. Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Tremfya as evidenced by low disease activity or improvement in signs and symptoms of the condition.

*ConnectiCare does not consider alcohol use to be a clinical reason to use Tremfya over methotrexate.

References:

1. TREMFYA(TM) subcutaneous injection, guselkumab subcutaneous injection. Janssen Biotech, Inc (per FDA), Horsham, PA, 2017.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	Policy Update	CCI to adopt EH Policy Template, Changed continuation duration from 1 to 3 years CCI Revision History: 1/18	All	6/28/2019
3	Update	Added Dosing Limitations according to FDA label	Other Criteria	5/4/2020
4	Update	Added criteria to require the use of TWO preferred products prior to Tremfya for PsA	Covered Uses Prescriber Restrictions Other Criteria	9/25/2020