Commercial 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:

Plaque Psoriasis – Initial: 3 months, Continuation: 1 year
Psoriatic Arthritis – Initial: 6 months, Continuation: 1 year

Other Criteria:

Initiation

Plaque Psoriasis

Initial Therapy: Approve if the patient meets the following criteria

A. Patient has tried at least ONE traditional systemic agent for psoriasis for at least 3 months unless intolerant; **OR**
   Note: Examples include methotrexate, cyclosporine, acitretin, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested medication. Women of childbearing age may be given special consideration for approval without systemic therapy when topical and phototherapy options have been tried and failed. A biosimilar of the requested biologic does not count. A patient who has already tried a biologic for psoriasis is not required to "step back" and try a traditional systemic agent for psoriasis.
B. Patient has a contraindication to methotrexate, as determined by the prescriber; **AND**
C. Prescribed by, or in consultation with a dermatologist

Psoriatic Arthritis

Initial Therapy: Approve if the patient meets the following criteria

A. Patient has clinically diagnosed psoriatic arthritis **AND**
B. Prescribed by or in consultation with a rheumatologist or dermatologist

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.

References:

1. Tremfya® subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech/Johnson & Johnson July 2020.

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
5	Update	Removed Dosage Limitations Duration update: Psoriatic Arthritis – Initial: 6 months, Continuation: 1 year. Plaque Psoriasis – Initial: 3 months, Continuation: 1 year Removed current criteria for PsA/Plaque Psoriasis and replaced with Select criteria for implementation to label use Removal of *ConnectiCare does not consider alcohol use to be a clinical reason to use Tremfya over methotrexate.	Coverage Duration Other Criteria	12/19/2023