

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Guselkumab Subcutaneous 100 mg (Tremfya Subcutaneous 100 mg)

Notes:

- Quantity Limits: Yes
- ^ Adequate trial is defined as the following:
 - Phototherapy – 8 weeks
 - Systemic non-biologics for psoriasis – 6 weeks
 - Methotrexate for psoriatic arthritis – 3 months
 - Biologics – 12 weeks
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Initiation (new start) criteria: Formulary **guselkumab subcutaneous 100 mg (Tremfya Subcutaneous 100 mg)** will be covered on the prescription drug benefit for when the following criteria are met:

1. Prescriber is a dermatologist and patient has a diagnosis of psoriasis
 - Patient has failed an adequate trial^ of phototherapy (unless documented by prescriber phototherapy not appropriate)
 - Patient has failed an adequate trial^, or patient has an allergy or intolerance* to, at least 1 of the following (or contraindication to all):
 - Methotrexate
 - Acitretin
 - Cyclosporine
 - Patient has failed an adequate trial^, or has an allergy, intolerance*, or contraindication to an ustekinumab product (criteria based)
 - Patient has failed an adequate trial^, or has an allergy, intolerance*, or contraindication to secukinumab (criteria based)
2. Prescriber is a dermatologist or a rheumatologist and patient has a diagnosis of psoriatic arthritis
 - Patient has failed an adequate trial^, has an intolerance* to, or has a contraindication to methotrexate (methotrexate not required if patient has dactylitis (inflammation of finger or toe) and/or enthesitis [inflammation of the entheses])
 - Patient has failed an adequate trial^, has an intolerance*, or has a contraindication to at least 1 of the following:
 - Infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
 - Adalimumab product (criteria based)

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All plans offered and underwritten by
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- Patient has failed an adequate trial[^], or has an allergy, intolerance*, or contraindication to an ustekinumab product (criteria based)
 - Patient has failed an adequate trial[^], or has an allergy, intolerance*, or contraindication to secukinumab (criteria based)
3. Prescriber is a gastroenterologist and patient has a diagnosis of moderate to severe ulcerative colitis
- Patient has failed an adequate trial[^], has an intolerance*, or has a contraindication to the following:
 - Infliximab product
 - Ustekinumab product (criteria based)
 - Patient has received, or is scheduled to receive, 3 loading doses of guselkumab IV

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Formulary **guselkumab (Tremfya)** will be covered on the prescription drug benefit for when the following criteria are met:

1. Prescriber is a dermatologist and patient has a diagnosis of psoriasis
- Patient has failed treatment with, has an allergy or intolerance* to an ustekinumab product (criteria based) OR an adalimumab product (criteria based) (or contraindication to both)
 - Patient has failed treatment with, or has an allergy, intolerance*, or contraindication to secukinumab (criteria based)
2. Prescriber is a dermatologist or a rheumatologist and patient has a diagnosis of psoriatic arthritis
- Patient has failed treatment with, or has an allergy, intolerance*, or contraindication to at least 1 of the following:
 - Infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
 - Adalimumab product (criteria based)
 - Patient has failed treatment with, or has an allergy, intolerance*, or contraindication to an ustekinumab product (criteria based)

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- Patient has failed treatment with, or has an allergy, intolerance*, or contraindication to secukinumab (criteria based)
3. Prescriber is a gastroenterologist and patient has a diagnosis of moderate to severe ulcerative colitis
 - Patient is currently stable on guselkumab