

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Ustekinumab Subcutaneous Injection (Stelara Syringe)

Notes:

- Quantity Limits: Yes
- ^ Adequate trial is defined as the following:
 - Phototherapy – 8 weeks
 - Systemic non-biologics for psoriasis – 6 weeks
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- **Methotrexate not required if patient has dactylitis [inflammation of finger or toe] and/or enthesitis [inflammation of the entheses]
- ***Trial of a second TNF-inhibitor is NOT required if the patient experienced primary or secondary treatment failure with the first TNF-inhibitor despite a therapeutic drug level

Initiation (new start) criteria: Formulary **ustekinumab subcutaneous (Stelara subcutaneous syringe)** will be covered on the prescription drug benefit 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 tried and failed/intolerant to or has a contraindication to the following:
 - Secukinumab (criteria based)
2. Prescriber is a dermatologist or rheumatologist and patient has a diagnosis of psoriatic arthritis
 - Patient has tried and failed/intolerant to or has contraindication to methotrexate**
 - Patient has tried and failed/intolerant to or has a contraindication to the following:
 - Secukinumab (criteria based)
 - Guselkumab (criteria based)
 - Risankizumab-rzaa (criteria based)
 - At least one of the following:

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- Infliximab product
 - Adalimumab product (criteria based)
 - Etanercept (criteria based)
3. Prescriber is a gastroenterologist and patient has a diagnosis of Crohn's disease
- Patient has failed an adequate trial of, or patient has an allergy or intolerance* to the following:
 - At least 2 tumor necrosis factor (TNF)-inhibitors***
 - Infliximab product
 - Adalimumab product (criteria based)
 - Certolizumab (criteria based)
 - Patient has received, or is scheduled to receive, one dose of ustekinumab IV
4. Prescriber is a gastroenterologist and patient has a diagnosis of ulcerative colitis
- Patient has tried and failed/intolerant to the following:
 - Infliximab product
 - Tofacitinib (criteria based)
 - Patient has received, or is scheduled to receive, one dose of ustekinumab IV

Criteria for *new members* entering Kaiser Permanente already taking the medication who have not been reviewed previously:

1. Prescriber is a dermatologist and patient has a diagnosis of psoriasis
- If dose is 45 mg subcutaneously every 12 weeks:
 - Patient currently stable on ustekinumab
 - If dose is > 45 mg subcutaneously every 12 weeks:
 - Patient has tried and failed/intolerant to or has a contraindication to secukinumab (criteria based)
2. Prescriber is a dermatologist or rheumatologist and patient has a diagnosis of psoriatic arthritis
- If dose is 45 mg subcutaneously every 12 weeks:
 - Patient has tried and failed/intolerant to or has contraindication to methotrexate**
 - Patient has tried and failed/intolerant to or has a contraindication to secukinumab (criteria based)

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- If dose is > 45 mg subcutaneously every 12 weeks:
 - Patient has tried and failed/intolerant to or has contraindication to methotrexate**
 - Patient has tried and failed/intolerant to or has a contraindication to the following:
 - Secukinumab (criteria based)
 - Guselkumab (criteria based)
 - Risankizumab-rzaa (criteria based)
 - At least one of the following:
 - Infliximab product
 - Adalimumab product (criteria based)
 - Etanercept (criteria based)
- 3. Prescriber is a gastroenterologist and patient has a diagnosis of Crohn's disease
 - Patient currently stable on ustekinumab
- 4. Prescriber is a gastroenterologist and patient has a diagnosis of ulcerative colitis
 - Patient currently stable on ustekinumab

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