

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Ustekinumab Biosimilars (Subcutaneous)

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
 - Topical/oral antibiotics – 8 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 entheses)

Ustekinumab-kfce (Yesintek): Formulary preferred

Initiation (new start) criteria: Formulary **ustekinumab-kfce (Yesintek)** 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
2. Prescriber is a dermatologist or rheumatologist and patient has a diagnosis of psoriatic arthritis
 - Patient has failed an adequate trial^, has an intolerance*, or has a contraindication to methotrexate**
3. Prescriber is a gastroenterologist and patient has a diagnosis of Crohn's disease or ulcerative colitis
 - Patient has received, or is scheduled to receive, one dose of ustekinumab product IV

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4. Prescriber is a dermatologist and patient has a diagnosis of hidradenitis suppurativa
 - Patient has failed an adequate trial[^], or patient has an allergy or intolerance* to, the following (or contraindication to all):
 - Topical clindamycin 1%
 - Oral antibiotic

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Formulary **ustekinumab-kfce (Yesintek)** 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 or hidradenitis suppurativa
 - Patient currently stable on ustekinumab-kfce
2. Prescriber is a dermatologist or rheumatologist and patient has a diagnosis of psoriatic arthritis
 - Patient currently stable on ustekinumab-kfce
3. Prescriber is a gastroenterologist and patient has a diagnosis of Crohn's disease or ulcerative colitis
 - Patient currently stable on ustekinumab-kfce

Ustekinumab-aauz, ustekinumab-auub, ustekinumab-stba ustekinumab-ttwe, ustekinumab-aekn: Non-formulary non-preferred

Initiation (new start) criteria: Non-formulary **ustekinumab-aauz, ustekinumab-auub, ustekinumab-stba ustekinumab-ttwe, or ustekinumab-aekn** 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):

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- Methotrexate
 - Acitretin
 - Cyclosporine
 - Patient has a documented allergic reaction to ustekinumab-kfce (does not include injection site reaction) **OR** patient has failed an adequate trial[^] of ustekinumab-kfce
2. Prescriber is a dermatologist or rheumatologist and patient has a diagnosis of psoriatic arthritis
 - Patient has failed an adequate trial[^], has an intolerance*, or has a contraindication to methotrexate**
 - Patient has a documented allergic reaction to ustekinumab-kfce (does not include injection site reaction) **OR** patient has failed an adequate trial[^] of ustekinumab-kfce
 3. Prescriber is a gastroenterologist and patient has a diagnosis of Crohn's disease or ulcerative colitis
 - Patient has a documented allergic reaction to ustekinumab-kfce (does not include injection site reaction) **OR** patient has failed an adequate trial[^] of ustekinumab-kfce

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **ustekinumab-aauz, ustekinumab-auub, ustekinumab-stba, ustekinumab-ttwe, or ustekinumab-aekn** 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 currently stable on ustekinumab biosimilar
 - Patient has a documented allergic reaction to ustekinumab-kfce (does not include injection site reaction) **OR** patient has failed an adequate trial[^] of ustekinumab-kfce
2. Prescriber is a dermatologist or rheumatologist and patient has a diagnosis of psoriatic arthritis
 - Patient currently stable on ustekinumab biosimilar

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- Patient has a documented allergic reaction to ustekinumab-kfce (does not include injection site reaction) **OR** patient has failed an adequate trial^ of ustekinumab-kfce
3. Prescriber is a gastroenterologist and patient has a diagnosis of Crohn's disease or ulcerative colitis
- Patient currently stable on ustekinumab biosimilar
 - Patient has a documented allergic reaction to ustekinumab-kfce (does not include injection site reaction) **OR** patient has failed an adequate trial^ of ustekinumab-kfce

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