

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Apremilast 75 mg extended release (Otezla XR 75 mg)

Notes:

- Quantity Limits: Yes
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- ^ Adequate trial is defined as the following:
 - Phototherapy – 8 weeks
 - Methotrexate for psoriatic arthritis – 3 months
 - Topical steroids and colchicine for Behçet's disease – 3 months
 - Psoriasis systemic medications – 6 weeks

Initiation (new start) criteria: Non-formulary **apremilast 75 mg extended release (Otezla XR 75 mg)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

1. Prescriber is a dermatologist and patient has a diagnosis of psoriasis
 - Patient is 6 years of age or older
 - Patient weighs 50 kg or more
 - Patient has failed an adequate trial^ of phototherapy (unless documented by prescriber phototherapy not appropriate)
 - Patient has tried and failed an adequate trial^ of, or patient has an allergy or intolerance* to at least 1 of the following systemic medications (or contraindication to all):
 - Methotrexate
 - Cyclosporine
 - Acitretin
 - Patient does not currently have an active prescription for a biologic DMARD or a Janus kinase inhibitor (oral or topical)
 - Patient has had a previous trial of apremilast immediate release (20 mg twice daily or 30 mg twice daily) with documented concerns about adherence to twice daily dosing
 - Patient is currently NOT taking any other medications dosed more than one time a day

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2. Prescriber is a dermatologist or rheumatologist and patient has a diagnosis of psoriatic arthritis
 - Patient is 6 years of age or older
 - Patient weighs 50 kg or more
 - 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 entheses])
 - Patient does not currently have an active prescription for a biologic DMARD or a Janus kinase inhibitor (oral or topical)
 - Patient has had a previous trial of apremilast immediate release (20 mg twice daily or 30 mg twice daily) with documented concerns about adherence to twice daily dosing
 - Patient is currently NOT taking any other medications dosed more than one time a day
3. Prescriber is a rheumatologist and patient has a diagnosis of oral ulcers associated with Behçet's disease
 - Patient is 18 years of age or older
 - Patient weighs 50 kg or more
 - Patient has failed an adequate trial[^], has an intolerance^{*} to, or has a contraindication to the following:
 - Topical steroids
 - Colchicine
 - Patient has had a previous trial of apremilast immediate release (20 mg twice daily or 30 mg twice daily) with documented concerns about adherence to twice daily dosing
 - Patient is currently NOT taking any other medications dosed more than one time a day

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Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **apremilast 75 mg extended release (Otezla XR 75 mg)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

1. Prescriber is a dermatologist and patient has a diagnosis of psoriasis
 - Patient is 6 years of age or older
 - Patient weighs 50 kg or more
 - Patient does not currently have an active prescription for a biologic DMARD or a Janus kinase inhibitor (oral or topical)
 - Patient has had a previous trial of apremilast immediate release (20 mg twice daily or 30 mg twice daily) with documented concerns about adherence to twice daily dosing
 - Patient is currently NOT taking any other medications dosed more than one time a day
2. Prescriber is a dermatologist or rheumatologist and patient has a diagnosis of psoriatic arthritis
 - Patient is 6 years of age or older
 - Patient weighs 50 kg or more
 - Patient does not currently have an active prescription for a biologic DMARD or a Janus kinase inhibitor (oral or topical)
 - Patient has had a previous trial of apremilast immediate release (20 mg twice daily or 30 mg twice daily) with documented concerns about adherence to twice daily dosing
 - Patient is currently NOT taking any other medications dosed more than one time a day
3. Prescriber is a rheumatologist and patient has a diagnosis of oral ulcers associated with Behçet's disease
 - Patient is 18 years of age or older
 - Patient weighs 50 kg or more
 - Patient has had a previous trial of apremilast immediate release (20 mg twice daily or 30 mg twice daily) with documented concerns about adherence to twice daily dosing
 - Patient is currently NOT taking any other medications dosed more than one time a day

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Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication: Non-formulary **apremilast 75 mg extended release (Otezla XR 75 mg)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

1. Prescriber is a dermatologist and patient has a diagnosis of psoriasis
 - Patient has responded to apremilast as determined by prescriber
 - Patient does not currently have an active prescription for a biologic DMARD or a Janus kinase inhibitor (oral or topical)
 - Patient has had a previous trial of apremilast immediate release (20 mg twice daily or 30 mg twice daily) with documented concerns about adherence to twice daily dosing
 - Patient is currently NOT taking any other medications dosed more than one time a day
2. Prescriber is a dermatologist or rheumatologist and patient has a diagnosis of psoriatic arthritis
 - Patient has responded to apremilast as determined by prescriber
 - Patient does not currently have an active prescription for a biologic DMARD or a Janus kinase inhibitor (oral or topical)
 - Patient has had a previous trial of apremilast immediate release (20 mg twice daily or 30 mg twice daily) with documented concerns about adherence to twice daily dosing
 - Patient is currently NOT taking any other medications dosed more than one time a day
3. Prescriber is a rheumatologist and patient has a diagnosis of oral ulcers associated with Behçet's disease
 - Patient has responded to apremilast as determined by prescriber
 - Patient has had a previous trial of apremilast immediate release (20 mg twice daily or 30 mg twice daily) with documented concerns about adherence to twice daily dosing
 - Patient is currently NOT taking any other medications dosed more than one time a day