

Kaiser Foundation Health Plan of Washington
 Kaiser Foundation Health Plan of Washington Options, Inc.
 CONTRACT MANAGER NAME
 Provider Communications, RCB-C2W-02
 PO Box 34262, Seattle WA 98124-1262

SEPTEMBER 30, 2021

USTEKINUMAB (STELARA) UPDATES TO COVERAGE UNDER THE MEDICAL BENEFIT

Dear Provider,

Effective December 1, 2021, ustekinumab (Stelara) subcutaneous vial and syringes will **NOT** be covered under the medical benefit. **This letter is a notification of the upcoming change in coverage for this medication under the medical benefit.** Pharmacy benefit coverage remains available for members who meet prior authorization criteria but Stelara will no longer be covered under the medical benefit for self-administration formulations:

- Stelara 45 mg single dose vial, 0.5 mL (NDC 57894-0060-02)
- Stelara 45 mg syringe, 0.5 mL (NDC 57894-0060-03)
- Stelara 90 mg syringe, 1 mL (NDC 57894-0061-03)

This change does **NOT affect the infusion formulation** (NDC 57894-0054-27) or anyone who meets exception criteria outlined in the table below.

Specialty medications under the pharmacy benefit, such as Stelara, are restricted to Kaiser Permanente Washington Specialty Pharmacy for non-Medicare members. Send prescriptions via fax to 1-800-340-4230 or call at 1-800-483-3945.

Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington, Options, Inc. (Kaiser Permanente) requires prior authorization for a select group of injectable drugs that may be administered under the medical benefit in a physician’s office or by home infusion. These reviews are intended to ensure consistent benefit adjudication as well as appropriate utilization in accordance with the Kaiser Permanente Pharmacy & Therapeutics Committee’s evidence-based criteria for coverage.

Prior Authorization Criteria for Ustekinumab (Stelara) [changes are in bold]:

DRUG NAME	COVERAGE CRITERIA
USTEKINUMAB	<p>Subcutaneous vial and syringe not covered under the medical benefit. May be covered under the pharmacy benefit.</p> <ul style="list-style-type: none"> • Exception criteria may be considered for the following patient populations: <ul style="list-style-type: none"> ○ Subcutaneous vial for pediatric patients < 60 kg. ○ Subcutaneous syringes for patients with impaired manual dexterity, impaired vision, or who are unable to use prefilled syringes safely AND ○ Patient meets clinical criteria below <p>Covered for:</p> <ul style="list-style-type: none"> • Adult patients with moderate to severe plaque psoriasis who have not had an adequate response to topical psoriasis treatments, secukinumab,

DRUG NAME	COVERAGE CRITERIA
	<p>one preferred IL-23 inhibitor (guselkumab, risankizumab), and at least two of the following:</p> <ul style="list-style-type: none"> ○ 12-week trial of phototherapy ○ Acitretin ○ Apremilast ○ Induction trial of cyclosporine ○ Methotrexate <ul style="list-style-type: none"> ● Pediatric/adolescent patients 12-17 years old with moderate to severe plaque psoriasis who have contraindication or inadequate response to the following: <ul style="list-style-type: none"> ○ topical psoriasis treatment and ○ methotrexate or a 12-week trial of phototherapy and ○ etanercept ● Adult patients with psoriatic arthritis who have failure, intolerance or contraindication to methotrexate, secukinumab, and one other preferred biologic (e.g., guselkumab, etanercept, adalimumab, infliximab-dyyb). ● Adult patients with moderately to severely active Crohn’s disease with: <ul style="list-style-type: none"> ○ Contraindication, or intolerance, to at least two TNF-inhibitors (e.g., infliximab-dyyb, adalimumab), OR Inadequate response with or loss of response to at least one TNF-inhibitor, AND contraindication, intolerance or loss of response to vedolizumab. ○ It is recommended that TNF-inhibitors are used in combination with azathioprine, 6-mercaptopurine, or methotrexate. ● Adult patients with moderately to severely active ulcerative colitis who have contraindication, intolerance, or loss of response to at least one TNF-inhibitor (e.g., infliximab-dyyb, adalimumab) and vedolizumab. It is recommended that the TNF-inhibitor is used in combination with azathioprine, 6-mercaptopurine, or methotrexate. <p>Quantity limit:</p> <ul style="list-style-type: none"> ● <u>Plaque psoriasis</u>: Patients ≤ 100 kg: starting dose 45 mg, max dose 45 mg. Administration at 0, 4 weeks, then every 12 weeks. Patients > 100 kg: starting dose 45 mg, max dose 90 mg. Administration at 0, 4 weeks, then every 12 weeks. ● <u>Psoriatic arthritis</u>: 45mg at week 0, followed by 45 mg 4 weeks later and every 12 weeks thereafter. Increase to 90 mg if patient is more than 100 kg ● <u>Crohn’s disease and ulcerative colitis</u>: For induction, max dose 520 mg one time. For maintenance, subcutaneous 90 mg dose every 8 weeks after the initial intravenous dose.

Additional Information

A complete list of office-administered injectable drugs requiring prior authorization can be found on the Kaiser Permanente provider website at <https://wa-provider.kaiserpermanente.org/provider-manual> under the “Authorization & Clinical Review” section. Using the website search feature, search for the term “Non-Medicare Injectable Drugs Requiring Prior Authorization”.

To request prior authorization review, please use the Referral Request online form located on the Kaiser Permanente provider website listed above. You can also fax your request to the Review Services department toll-free at 1-888-282-2685.

Thank you for the care you provide to our members, your patients. If you have any questions about this process, please call Review Services at 1-800-289-1363, Monday through Friday from 8 a.m. to 5 p.m.

Sincerely,

A handwritten signature in black ink that reads "Peter Barkett MD". The signature is written in a cursive style with a large initial "P" and a long horizontal stroke at the end.

Peter Barkett, MD, Chair
Pharmacy & Therapeutics Committee