206-988-2000
206-988-2001
prnotification@kp.org

Kaiser Foundation Health Plan of Washington
Kaiser Foundation Health Plan of Washington Options, Inc.
Provider Communications, RCR-A3W-04
PO Box 34262, Seattle WA 98124-1262

May 21, 2025

ADDITION OF QUANTITY LIMITS FOR USTEKINUMAB BIOSIMILARS

Dear Provider,

Effective September 1, 2025, the criteria for ustekinumab biosimilars in Table 1 will be updated. These products are on the **non-Medicare** list of office-administered drugs requiring prior authorization. **This letter is a notification of the upcoming changes in coverage for these medications under the medical benefit.**

Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington, Options, Inc. (Kaiser Permanente) require 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.

Table 1. List of Ustekinumab Biosimilars that have Prior Authorization

BRAND NAME	GENERIC NAME	HCPCS
Yesintek	Ustekinumab-kfce	J3490, J3590
Otulfi	Ustekinumab-aauz	Q9999
Selarsdi	Ustekinumab-aekn	Q9998
Wezlana	Ustekinumab-auub	Q5137, Q5138
Imuldosa	Ustekinumab-srlf	J3490, J3590
Steqeyma	Ustekinumab-stba	J3490, J3590
Pyzchiva	Ustekinumab-ttwe	Q9996, Q9997

Prior Authorization Criteria for Intravenous Ustekinumab Biosimilars (changes are in bold):

DRUG NAME	COVERAGE CRITERIA

ustekinumab-kfce (Yesintek)
ustekinumab-aauz (Otulfi)
ustekinumab-aekn (Selarsdi)
ustekinumab-auub (Wezlana)
ustekinumab-srlf (Imuldosa)
ustekinumab-stba (Steqeyma)
	• Adult patients with moderately to severely active Crohn's disease with:
	  ○ Contraindication, or intolerance, to at least two TNF-inhibitors (e.g., adalimumab [Amjevita]), infliximab [Inflectra]) OR
	  ○ Inadequate response or loss of response to at least one TNF-inhibitor
	  ○ 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., adalimumab [Amjevita]), infliximab [Inflectra]). It is recommended that the TNF-inhibitor is used in

DRUG NAME	COVERAGE CRITERIA
ustekinumab-ttwe (Pyzchiva)	combination with azathioprine, 6-mercaptopurine, or methotrexate. Not covered for use in combination with disease-modifying or other biologic therapies, including (but not limited to): • infliximab, adalimumab, etanercept, vedolizumab, rituximab, abatacept, certolizumab, tocilizumab, golimumab, canakinumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast **Quantity Limit:** • **Crohn's disease and ulcerative colitis: Max dose 520 mg.**

Prior Authorization Criteria for Subcutaneous Ustekinumab Biosimilars (changes are in bold):

DRUG NAME	COVERAGE CRITERIA
ustekinumab-aauz (Otulfi) ustekinumab-aekn (Selarsdi) ustekinumab-auub (Wezlana) ustekinumab-srlf (Imuldosa) ustekinumab-stba (Steqeyma) ustekinumab-ttwe (Pyzchiva)	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer OR • Subcutaneous vial for pediatric patients less than 60 kg AND • Must meet clinical criteria (refer to pharmacy benefit) Not covered for use in combination with disease-modifying or other biologic therapies, including (but not limited to): ○ infliximab, adalimumab, etanercept, vedolizumab, rituximab, abatacept, certolizumab, tocilizumab, golimumab, canakinumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast Applicable codes: *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* K50 - K50.919, L40.0, L40.1, L40.4, L40.8, L40.9, L40.50 - L40.59, K51 - K51.919 • infliximab, adalimumab, etanercept, vedolizumab, rituximab, abatacept, certolizumab, tocilizumab, golimumab, canakinumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast **Quantity limit:** • **Psoriasis: 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.** • **Psoriatic arthritis: 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**

DRUG NAME	COVERAGE CRITERIA

	• **Crohn's disease and ulcerative colitis: For maintenance, subcutaneous 90 mg dose every 8 weeks after the initial intravenous dose.**
	  ○ **If patient has inadequate response or flare after 16 weeks of initiation of therapy, may request authorization for 90 mg every 4 weeks**
	  ○ **Initial approval of every 4-week dosing for one year.**
	  ○ **Reauthorization would require reassessment for reduction in signs and symptoms of disease.**

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/clinical-review/officeinject.

To request prior authorization review, please use the Referral Request online form (login required) located on the Kaiser Permanente provider website. 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,

Ravi Ubriani, MD, Chair
Pharmacy & Therapeutics Committee