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August 29, 2025

USTEKINUMAB (STELARA) AND INFLIXIMAB (REMICADE) UPDATED PRIOR AUTHORIZATION CRITERIA

Dear Provider,

Ustekinumab (Stelara) and Infliximab (Remicade) are on the **non-Medicare** list of office-administered drugs requiring prior authorization. **Effective December 1, 2025,** the prior authorization for Ustekinumab (Stelara) and Infliximab (Remicade) will be updated. **This letter is a notification of the change in prior authorization criteria required before administering these medications in a physician's office.**

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.

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

DRUG NAME	COVERAGE CRITERIA

USTEKINUMAB	Crohn's Disease
	• Age ≥ 18 years
	• Diagnosis of moderately to severely active Crohn's disease
	• Failed an adequate trial, or has an allergy, intolerance, or contraindication to the following:
	  ○ ≥ 2 TNF Inhibitors
	  ▪ (adalimumab [e.g., Amjevita], infliximab [e.g., Inflectra])
	  ▪ Note:
	  • Second TNF inhibitor not required if inadequate response or loss of response with previous TNF inhibitor
	  • It is recommended that TNF inhibitors be used in combination with azathioprine, 6-mercaptopurine, or methotrexate
	  ○ IL-12/23 Inhibitors (all the following):
	  ▪ ~~**Two Ustekinumab biosimilars**~~
	  ▪ **Ustekinumab-kfce (Yesintek)**
	  ▪ **Additional ustekinumab biosimilar (e.g., ustekinumab-aekn [Selarsdi])**
	• Quantity Limit: Max dose 520 mg
	• Not covered for use in combination with disease-modifying or other biologic therapies
	
	Ulcerative Colitis
	• Age ≥ 18 years
	• Diagnosis of moderately to severely active ulcerative colitis
	• Failed an adequate trial, or has an allergy, intolerance, or contraindication to the following:
	  ○ ≥ 1 TNF Inhibitor

DRUG NAME	COVERAGE CRITERIA
	▪ (adalimumab [e.g., Amjevita], infliximab [e.g., Inflectra]) ▪ Note: It is recommended that TNF inhibitors be used in combination with azathioprine, 6-mercaptopurine, or methotrexate o IL-12/23 Inhibitors (all the following): ▪ ~~**Two Ustekinumab biosimilars**~~ ▪ **Ustekinumab-kfce (Yesintek)** ▪ **Second ustekinumab biosimilar (e.g., ustekinumab-aekn [Selarsdi])** • Quantity Limit: Max dose 520 mg • Not covered for use in combination with disease-modifying or other biologic therapies

Prior Authorization Criteria for Infliximab (Remicade) (changes are in bold):

DRUG NAME	COVERAGE CRITERIA
INFLIXIMAB	<u>Ankylosing Spondylitis</u> • **Age ≥ 18 years** • Diagnosis of active ankylosing spondylitis • Failed an adequate trial, or has an allergy, intolerance, or contraindication to the following: o TNF Inhibitors (all the following): ▪ infliximab-dyyb (Inflectra) ▪ **adalimumab (e.g., Amjevita)** o **IL-17 Inhibitor:** ▪ **secukinumab (Cosentyx)** • Quantity Limit: o Induction: Infusion at weeks 0, 2, and 6 (max dose 1000 mg) o Maintenance: Every 6 weeks (max frequency) • Not covered for use in combination with disease-modifying or other biologic therapies <u>Crohn's Disease</u> • **Age ≥ 6 years** • Diagnosis of moderately to severely active Crohn's disease • Failed an adequate trial, or has an allergy, intolerance, or contraindication to the following: o TNF Inhibitors: ▪ Biosimilar infliximab (e.g., Inflectra) • Quantity Limit: o Induction: Infusion at weeks 0, 2, and 6 (max dose 1000 mg) o Maintenance: Every 6 weeks (max frequency) • Not covered for use in combination with disease-modifying or other biologic therapies <u>Psoriasis</u> • **Age ≥ 18 years** • Diagnosis of moderate to severe psoriasis • Failed an adequate trial, or has an allergy, intolerance, or contraindication to the following: o TNF Inhibitors: ▪ infliximab-dyyb (Inflectra) o **IL-12/23 Inhibitor:** ▪ **ustekinumab (e.g., Yesintek)** • Quantity Limit: o Induction: Infusion at weeks 0, 2, and 6 (max dose 1000 mg) o Maintenance: Every 8 weeks (max frequency)

DRUG NAME	COVERAGE CRITERIA

	• Not covered for use in combination with disease-modifying or other biologic therapies
	
	<u>Psoriatic Arthritis</u>
	• **Age ≥ 18 years**
	• Diagnosis of psoriatic arthritis
	• Failed an adequate trial, or has an allergy, intolerance, or contraindication to the following:
	  ○ TNF Inhibitors:
	  ▪ infliximab-dyyb (Inflectra)
	  ○ **IL-12/23 Inhibitor:**
	  ▪ **ustekinumab (e.g., Yesintek)**
	  ▪ **Note: IL-12/23 inhibitor not required for patients with axial disease or severe (rapidly progressive, erosive) disease**
	• Quantity Limit:
	  ○ Induction: Infusion at weeks 0, 2, and 6 (max dose 1000 mg)
	  ○ Maintenance: Every 8 weeks (max frequency)
	• Not covered for use in combination with disease-modifying or other biologic therapies
	
	<u>Rheumatoid Arthritis</u>
	• **Age ≥ 18 years**
	• Diagnosis of rheumatoid arthritis
	• Failed an adequate trial, or has an allergy, intolerance, or contraindication to the following:
	  ○ TNF Inhibitors:
	  ▪ infliximab-dyyb (Inflectra)
	  ○ **IL-6 Inhibitor:**
	  ▪ **tocilizumab (e.g., Tyenne)**
	• Quantity Limit:
	  ○ Induction: Infusion at weeks 0, 2, and 6 (max dose 1000 mg)
	  ○ Maintenance: Every 4 weeks (max frequency)
	• Not covered for use in combination with disease-modifying or other biologic therapies
	
	<u>Sarcoidosis</u>
	• **Age ≥ 18 years**
	• Diagnosis of sarcoidosis
	• Failed an adequate trial, or has an allergy, intolerance, or contraindication to the following:
	  ○ TNF Inhibitors:
	  ▪ Biosimilar infliximab (e.g., Inflectra)
	• Quantity Limit:
	  ○ Induction: Infusion at weeks 0, 2, and 6 (max dose 1000 mg)
	  ○ Maintenance: Every 8 weeks (max frequency)
	• Not covered for use in combination with disease-modifying or other biologic therapies
	
	<u>Ulcerative Colitis</u>
	• **Age ≥ 6 years**
	• Diagnosis of moderately to severely active ulcerative colitis
	• Failed an adequate trial, or has an allergy, intolerance, or contraindication to the following:
	  ○ TNF Inhibitors:
	  ▪ Biosimilar infliximab (e.g., Inflectra)
	• Quantity Limit:

DRUG NAME	COVERAGE CRITERIA
	○ Induction: Infusion at weeks 0, 2, and 6 (max dose 1000 mg) ○ Maintenance: Every 6 weeks (max frequency) • Not covered for use in combination with disease-modifying or other biologic therapies

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 8:00 a.m. to 5:00 p.m.

Sincerely,

Ravi Ubriani, MD, Chair
Pharmacy & Therapeutics Committee