USTEKINUMAB Biosimilars, injection for IV use

Does NOT include subcutaneous formulations

PA Criteria	Criteria Details
Description	Ustekinumab is a human interleukin-12 and -23 antagonist. Brand Name: **Stelara®** Biosimilars: • **Imuldosa** (ustekinumab-srlf) • **Otulfi** (ustekinumab-aauz) • **Pyzchiva** (ustekinumab-ttwe) • **Selarsdi** (ustekinumab-aekn) • **Starjemza** (ustekinumab-hmny) • **Steqeyma** (ustekinumab-stba) • **Wezlana** (ustekinumab-auub) • **Yesintek** (ustekinumab-kfce)
Covered Uses (FDA approved indication)	Ustekinumab is indicated for the treatment of: • **Adult** patients with: » moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy » active psoriatic arthritis (PsA) » moderately to severely active Crohn's disease » moderately to severely active ulcerative colitis • **Pediatric** patients 6 years of age and older with: » moderate to severe plaque psoriasis (PsO), who are candidates for phototherapy or systemic therapy » active psoriatic arthritis (PsA)
Dosing and Administration	Adult Patients with Plaque Psoriasis Subcutaneous Recommended Dosage: **Weight Range (kilograms)** / **Dosage** less than or equal to 100 kg: 45 mg administered subcutaneously initially and 4 weeks later, followed by 45 mg administered subcutaneously every 12 weeks greater than 100 kg: 90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered subcutaneously every 12 weeks **Pediatric Patients 6 Years of Age and Older with Plaque Psoriasis Subcutaneous Recommended Dosage:** Weight-based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter. **Weight Range (kilograms)** / **Dosage** less than 60 kg: 0.75 mg/kg 60 kg to 100 kg: 45 mg greater than 100 kg: 90 mg **Psoriatic Arthritis Adult Subcutaneous Recommended Dosage:** • The recommended dosage is 45 mg administered subcutaneously initially and 4 weeks later, followed by 45 mg administered subcutaneously every 12 weeks.

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- For patients with co-existent moderate-to-severe plaque psoriasis weighing greater than 100 kg, the recommended dosage is 90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered subcutaneously every 12 weeks.

Psoriatic Arthritis Pediatric 6 years of Age and Older Subcutaneous Recommended Dosage:
Weight-based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter.

Weight Range (kilograms)	Dosage
less than 60 kg	0.75 mg/kg
60 kg or more	45 mg
greater than 100 kg with co-existent moderate-to-severe plaque psoriasis	90 mg

IV Dosing

Crohn's Disease and Ulcerative Colitis Initial Adult Intravenous Recommended Dose:
A single intravenous infusion using weight-based dosing:

Weight Range (kilograms)	Recommended Dose
up to 55 kg	260 mg (2 vials)
greater than 55 kg to 85 kg	390 mg (3 vials)
greater than 85 kg	520 mg (4 vials)

Crohn's Disease and Ulcerative Colitis Maintenance Adult Subcutaneous Recommended Dosage:
A subcutaneous 90 mg dose 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.

Billing and Coding Information

	10-digit NDC	11-digit NDC
Imuldosa (ustekinumab-srlf) IV	69448-019-26	69448-0019-26
Otulfi (ustekinumab-aauz) IV	65219-828-05	65219-0828-05
Pyzchiva (ustekinumab-ttwe) IV	61314-654-94	61314-0654-94
Selarsdi (ustekinumab-aekn) IV	51759-708-13	51759-0708-13
Starjemza (ustekinumab-hmny) IV	0143-9171-01	00143-9171-01
Steqeyma (ustekinumab-stba) IV	72606-0029-1	72606-0029-01
Wezlana (ustekinumab-auub) IV	84612-066-01	84612-0066-01
Yesintek (ustekinumab-kfce) IV	83257-026-11	83257-0026-11

	HCPCS Code	Description
Imuldosa (ustekinumab-srlf)	Q5098	Injection, ustekinumab-srlf, biosimilar, 1 mg
Otulfi (ustekinumab-aauz)	Q9999	Injection, ustekinumab-aauz, biosimilar, 1 mg
Pyzchiva (ustekinumab-ttwe)	Q9997	Injection, ustekinumab-ttwe, biosimilar, 1 mg
Selarsdi (ustekinumab-aekn)	Q9998	Injection, ustekinumab-aekn, biosimilar, 1 mg
Starjemza (ustekinumab-hmny)	C9399 J3590	Unclassified drugs or biologicals Unclassified biologicals
Steqeyma (ustekinumab-stba)	Q5099	Injection, ustekinumab-stba, biosimilar, 1 mg
Wezlana (ustekinumab-auub)	Q5138	Injection, ustekinumab-auub, biosimilar, 1 mg
Yesintek (ustekinumab-kfce)	Q5100	Injection, ustekinumab-kfce, biosimilar, 1 mg

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	CPT Procedural Codes / **Description** 96365 — IV infusion for therapy, prophylaxis, or diagnosis; initial, up to 1 hour 96413 — Chemotherapy administration, IV infusion technique; up to 1 hour, single or initial substance/drug
Product Availability	Single-dose vial: 130 mg/26 mL injection for IV use
Contraindications	Clinically significant hypersensitivity to ustekinumab or to any of the excipients in STELARA® or its biosimilars.
Recommended Medical Monitoring	Ustekinumab has been associated with: • Serious infections • Theoretical Risk for Particular Infections (mycobacteria, salmonella and BCG) • Tuberculosis • Malignancies • Serious Hypersensitivity Reactions • Posterior Reversible Encephalopathy Syndrome (PRES) • Infection Risk with live vaccines • Noninfectious Pneumonia
Approval Criteria	a. Physician administered; in-office or HOPD i. Cannot be self-administered b. Crohn's Disease **(must meet all)**: i. Diagnosis of CD ii. Prescribed by or in consultation with a gastroenterologist iii. Patient age ≥ 18 years iv. Member meets **one** of the following: 1. Failure of a ≥ three consecutive month trial of at least ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine [6-MP], MTX) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated – **OR** – 2. Medical justification supports inability to use immunomodulators v. Failure of a ≥ three consecutive month trial of Humira®, unless contraindicated or clinically significant adverse effects are experienced. vi. Dose does not exceed: 1. **Initial dose (IV):** a. Weight ≤ 55 kg: 260 mg once b. Weight > 55 kg to 85 kg: 390 mg once c. Weight > 85 kg: 520 mg once 2. Subsequent maintenance doses will be self-administered subcutaneous injections; do NOT fall under Medicare Part B benefit

	c. Ulcerative Colitis **(must meet all)**: i. Diagnosis of UC ii. Prescribed by or in consultation with a gastroenterologist iii. Patient age ≥ 18 years iv. Documentation of a Mayo Score ≥ 6 v. Failure of an eight-week trial of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced vi. Failure of a ≥ three consecutive month trial of Humira or Simponi®, unless clinically significant adverse effects are experienced or both are contraindicated vii. Dose does not exceed: 1. **Initial dose (IV):** a. Weight ≤ 55 kg: 260 mg once b. Weight > 55 kg to 85 kg: 390 mg once c. Weight > 85 kg: 520 mg once 2. Subsequent maintenance doses will be self-administered subcutaneous injections; do NOT fall under Medicare Part B benefit
Age Restriction	Age ≥ 18 years
Coverage Duration	**Initial/Reauthorization:** Single dose for IV (subsequent doses self-administered as subQ injection) Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
Other Criteria (LCD, NCD, etc.)	None.
Misc Info, Appendix Etc.	None.

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	1/26/26	1/26/26	Tamara Chinarian, PharmD, Clinical Pharmacist	N/A
Approved	N/A	2/12/26	Pharmacy & Therapeutics (P&T) Committee	2/12/26