Ustekinumab Biosimilars IV Products: Imuldosa (Ustekinumab-srlf) Otulfi (Ustekinumab-aauz), Pyzchiva (Ustekinumab-ttwe), Selarsdi (Ustekinumab-aekn), Starjemza (Ustekinumab-hmny) Steqeyma (Ustekinumab-stba), Wezlana (Ustekinumab-auub), Yesintek (Ustekinumab-kfce)

(Intravenous)

Effective Date: 01/01/2020
Review Date: 11/20/2019, 12/20/2019, 1/22/20, 10/14/2021, 01/27/2022, 1/26/2023, 8/10/23, 12/07/2023, 01/04/2024, 02/14/2024, 01/22/2025, 04/30/2025, 06/25/2025, 02/17/2026, 08/17/2026

Scope: Medicaid, Commercial, Medicare

I. Length of Authorization

Crohn's Disease and Ulcerative Colitis:
Coverage will be provided once (one time dose) for 2 months

** For members that meet criteria, ustekinumab 90 mg (subcutaneous dose) will be approved for every 8 weeks thereafter for 4 months with one of the preferred formulary ustekinumab biosimilar products: Otulfi (Ustekinumab-aauz), Selarsdi (Ustekinumab-aekn), Steqeyma (Ustekinumab-stba), or Yesintek (Ustekinumab-kfce) for Medicaid and Commercial ONLY**

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

Subcutaneous
• Ustekinumab 45 mg vial/prefilled syringe:
  ○ Loading: 1 syringe at weeks 0 & 4
  ○ Maintenance: 1 syringe every 12 weeks
• Ustekinumab 90 mg prefilled syringe:
  ○ Loading: 1 syringe at weeks 0 & 4
  ○ Maintenance: 1 syringe every 8 weeks

Intravenous • Ustekinumab 130 mg (5 mg/mL) single-dose vial: 4 vials

B. Max Units (per dose and over time) [HCPCS Unit]:

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Indication	Max Units
Plaque Psoriasis & Psoriatic Arthritis with co-existent moderate-severe Plaque Psoriasis	Subcutaneous Loading *: • 90 billable units at weeks 0 & 4; maintenance dosing 12 weeks later Subcutaneous Maintenance: • 90 billable units every 12 weeks
Psoriatic Arthritis	Subcutaneous Loading *: • 45 billable units at weeks 0 & 4; maintenance dosing 12 weeks later Subcutaneous Maintenance: • 45 billable units every 12 weeks
Crohn's Disease & Ulcerative Colitis	Intravenous Induction *: • 520 billable units Subcutaneous Maintenance: • 90 billable units 8 weeks after induction & every 8 weeks thereafter

III. Summary of Evidence

Ustekinumab is a human interleukin-12 and -23 antagonist 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), alone or in combination with methotrexate, moderately to severely active Crohn's disease (CD) who have failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker or failed or were intolerant to treatment with one or more TNF blockers. The clinical studies evaluating ustekinumab assessed its safety and efficacy in treating psoriasis, psoriatic arthritis, and Crohn's disease. In psoriasis, two large multicenter, randomized, double-blind, placebo-controlled studies (Ps STUDY 1 and Ps STUDY 2) enrolled 1,996 adults with plaque psoriasis. The primary endpoints were the proportion of subjects achieving at least a 75% reduction in the Psoriasis Area and Severity Index (PASI 75) score at Week 12 and treatment success as assessed by the Physician's Global Assessment (PGA). Both studies showed significant improvements in PASI 75 and PGA scores in the ustekinumab treatment groups compared to placebo. Subjects who achieved a PASI 75 response by Week 28 and continued on ustekinumab maintained their response through Week 52, with 89% of subjects staying PASI 75 responders.

In psoriatic arthritis (PsA), the safety and efficacy of ustekinumab were assessed in two randomized, double-blind, placebo-controlled studies (PsA STUDY 1 and PsA STUDY 2) involving 927 adults with active PsA.. The primary endpoint was the percentage of patients achieving an ACR 20 response at Week 24. Both studies showed that ustekinumab significantly outperformed placebo in achieving ACR 20, ACR 50, and PASI 75 responses, indicating improvements in both arthritis and skin symptoms.

In psoriasis, two large multicenter, randomized, double-blind, placebo-controlled studies (Ps STUDY 1 and Ps STUDY 2) enrolled 1,996 adults with plaque psoriasis. The primary endpoints were the proportion of subjects achieving at least a 75% reduction in the Psoriasis Area and Severity Index (PASI 75) score at Week 12 and treatment success as assessed by the Physician's Global Assessment (PGA). Both studies showed significant improvements in PASI 75 and PGA

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scores in the ustekinumab treatment groups compared to placebo. Subjects who achieved a PASI 75 response by Week 28 and continued on ustekinumab maintained their response through Week 52, with 89% of subjects staying PASI 75 responders.

In Crohn's disease, ustekinumab was evaluated in three randomized, double-blind, placebo-controlled clinical studies (CD-1, CD-2, and CD-3). Studies CD-1 and CD-2 were induction trials involving 1,409 patients with moderately to severely active Crohn's disease, who were randomized to receive either ustekinumab or placebo. At Week 6, ustekinumab showed a significantly higher proportion of patients achieving clinical response, defined as a reduction in the Crohn's Disease Activity Index (CDAI) score by 100 points, and clinical remission, defined as a CDAI score of less than 150, compared to placebo. After 44 weeks, 47% of patients on ustekinumab were in clinical remission and corticosteroid-free, compared to 30% in the placebo group. Common adverse events include vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, and fatigue.

IV. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND
- Member is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; AND
- Member has been evaluated and screened for the presence of latent (tuberculosis) TB infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; AND
- Member does not have an active infection, including clinically important localized infections; AND
- Member will not receive live vaccines during therapy; AND
- Ustekinumab will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., adalimumab (e.g., Hadlima), Enbrel (etanercept), Remicade (infliximab), Simponi (golimumab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), Tremfya (guselkumab), Icotyde (icotrokinra), Ilumya (tildrakizumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), Omvoh (mirikizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Velsipity (etrasimod), etc.); AND
- If the request is for Stelara IV or non-preferred ustekinumab biosimilars (e.g.,, Imuldosa, Wezlana, Pyzchiva, Starjemza), the member has had an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab [i.e., Otulfi (Ustekinumab-aauz), Selarsdi (Ustekinumab-aekn), Steqeyma (Ustekinumab-stba), or Yesintek (Ustekinumab-kfce)] at maximum tolerated doses

Crohn's Disease † [1,10-12,14,18,24]

- Member must be 2 years of age or older; AND

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- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
- Member has documented moderate to severe active disease; AND
- If 6 years of age or older, member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of infliximab IV OR adalimumab at maximum tolerated doses.

Ulcerative Colitis † [1,13,19-23,29]

- Member must be 18 years of age or older; AND
- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
- Member has documented moderate to severe active UC; AND
- Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of infliximab IV OR adalimumab at maximum tolerated doses.

† FDA Approved Indication(s); **‡** Compendia recommended indication(s); **Φ** Orphan Drug

V. Dosage/Administration

Indication	Dose
Crohn's Disease & Ulcerative Colitis	Intravenous Induction Dose (one-time only)*: • ≤ 55 kg: 260 mg • > 55 kg to 85 kg: 390 mg • > 85 kg: 520 mg Subcutaneous Maintenance Dose: • 90 mg given 8 weeks after the initial IV dose, then every 8 weeks thereafter
*One loading dose per lifetime	

VI. Billing Code/Availability Information

HCPCS Code:

- J3357 – Ustekinumab, for subcutaneous injection, 1 mg; 1 billable unit = 1 mg
- J3358 – Ustekinumab, for intravenous injection, 1 mg; 1 billable unit = 1 mg
- Q9996 – Ustekinumab-ttwe (pyzchiva), subcutaneous, biosimilar, 1mg; 1 billable unit = 1 mg
- Q9997 – Ustekinumab-ttwe (pyzchiva), intravenous, biosimilar, 1 mg; 1 billable unit = 1 mg
- Q9998 – Ustekinumab-aekn (selarsdi SC, IV), biosimilar, 1 mg; 1 billable unit = 1 mg
- Q9999 – Ustekinumab-aauz (Otulfi SC, IV), biosimilar, 1mg; 1 billable unit = 1 mg
- J3590 – Ustekinumab-kfce (Yesintek SC, IV) or Ustekinumab-stba (Steqeyma SC, IV) or Ustekinumab-hmny (Starjemza SC,IV)
- Q5137 – Ustekinumab-auub (Wezlana SC); 1 mg; 1 billable unit = 1 mg
- Q5138 – Ustekinumab-auub (Wezlana IV); 1 mg; 1 billable unit = 1 mg

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- Q5098 – Ustekinumab-srlf (Imuldosa SC, IV); 1 mg; 1 billable unit = 1 mg
- Q5164 – Ustekinumab-mny (starjemza), biosimilar, 1 mg; 1 billable unit = 1 mg

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Appendix 1 – Covered Diagnosis Codes

Subcutaneous (J3357)

ICD-10	ICD-10 Description
K50.00	Crohn's disease of small intestine without complications

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ICD-10	ICD-10 Description
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complications
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess

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ICD-10	ICD-10 Description
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.019	Ulcerative (chronic) pancolitis with unspecified complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.219	Ulcerative (chronic) proctitis with unspecified complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.519	Left sided colitis with unspecified complications
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with intestinal obstruction
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.818	Other ulcerative colitis with other complication
K51.819	Other ulcerative colitis with unspecified complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding

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ICD-10	ICD-10 Description
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
K51.919	Ulcerative colitis, unspecified with unspecified complications
K52.1	Toxic gastroenteritis and colitis
L40.0	Psoriasis vulgaris
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.59	Other psoriatic arthropathy
R19.7	Diarrhea, unspecified

Intravenous (J3358)

ICD-10	ICD-10 Description
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications

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ICD-10	ICD-10 Description
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complications
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.019	Ulcerative (chronic) pancolitis with unspecified complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.219	Ulcerative (chronic) proctitis with unspecified complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess

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ICD-10	ICD-10 Description
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.519	Left sided colitis with unspecified complications
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with intestinal obstruction
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.818	Other ulcerative colitis with other complication
K51.819	Other ulcerative colitis with unspecified complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
K51.919	Ulcerative colitis, unspecified with unspecified complications
K52.1	Toxic gastroenteritis and colitis
R19.7	Diarrhea, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

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Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale:

Ustekinumab was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Ustekinumab according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

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