Ustekinumab:
Imuldosa®; Otulfi™; Pyzchiva®; Selarsdi™; Starjemza™; Stelara®; Steqeyma®; Ustekinumab§; Ustekinumab-aauz§; Ustekinumab-aekn§; Ustekinumab-stba§; Ustekinumab-ttwe§; Wezlana™; Yesintek™
(Intravenous/Subcutaneous)

Document Number: OHSU HEALTHSERVICES-0117

Last Review Date: 09/04/2025
Date of Origin: 02/15/2011
Dates Reviewed: 03/2011, 06/2011, 09/2011, 12/2011, 03/2012, 06/2012, 09/2012, 03/2013, 06/2013, 09/2013, 11/2013, 12/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 06/2015, 09/2015, 12/2015, 03/2016, 06/2016, 9/2016, 10/2016, 11/2016, 03/2017, 06/2017, 09/2017, 10/2017, 03/2018, 06/2018, 10/2018, 10/2019, 12/2019, 07/2020, 08/2020, 10/2021, 04/2022, 06/2022, 09/2022, 08/2023, 10/2023, 12/2023, 06/2024, 08/2024, 10/2024, 11/2024, 01/2025, 02/2025, 03/2025, 04/2025, 05/2025, 07/2025, 08/2025, 09/2025

I. Length of Authorization [1-9,44-52]

- Initial: Prior authorization validity will be provided initially for 6 months, unless otherwise specified.
  - Crohn's Disease and Ulcerative Colitis: Prior authorization validity will be provided initially for 8 weeks.
  - Immune Checkpoint Inhibitor-Related Toxicities: Prior authorization validity will be provided initially for a one-time intravenous induction dose plus up to 3 subcutaneous maintenance doses.
- Renewal: Prior authorization validity may be renewed annually thereafter, unless otherwise specified.
  - Dose escalation requests for Crohn's Disease and Ulcerative Colitis: Prior authorization validity will be provided for 3 months with continued renewal annually thereafter (*See Section V for continuation details).*
  - Immune Checkpoint Inhibitor-Related Toxicities: Prior authorization validity may not be renewed.

II. Dosing Limits

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

Indication	Max Units
Plaque Psoriasis & Psoriatic Arthritis with co-existent moderate-severe Plaque Psoriasis	Subcutaneous Loading: • 90 billable units (90 mg) at weeks 0 & 4; maintenance dosing 12 weeks later Subcutaneous Maintenance: • 90 billable units (90 mg) every 12 weeks
Psoriatic Arthritis	Subcutaneous Loading: • 45 billable units (45mg) at weeks 0 & 4; maintenance dosing 12 weeks later Subcutaneous Maintenance: • 45 billable units (45 mg) every 12 weeks
Crohn's Disease & Ulcerative Colitis	Intravenous Induction: • 520 billable units (520 mg) x 1 dose Subcutaneous Maintenance: • 90 billable units (90 mg) 8 weeks after induction & every 8 weeks thereafter
Immune Checkpoint Inhibitor-Related Toxicities	Intravenous Induction: • 520 billable units (520 mg) x 1 dose Subcutaneous Maintenance: • 90 billable units (90 mg) 8 weeks after induction & every 8 weeks thereafter x 3 doses

III. Initial Approval Criteria [1-9]

Self-administered injectable medications are not covered when supplied in a provider's office, clinic or facility.

Prior authorization validity is provided in the following conditions:

- Patient is at least 18 years of age (unless otherwise specified); **AND**
- Patient is up to date with all age-appropriate vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**

Universal Criteria

- **Selarsdi (ustekinumab-aekn), Yesintek (ustekinumab-kfce), and Steqeyma (ustekinumab-stba) are the preferred ustekinumab products.** If the request is for any other ustekinumab biosimilar, patient must try and have an inadequate response, contraindication, or intolerance to Selarsdi, Yesintek, AND Steqeyma. If the request is for Stelara, patient must try and have an inadequate response, contraindication, or intolerance to ALL ustekinumab biosimilar products; **AND**

- Patient 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**
- Patient does not have an active infection, including clinically important localized infections; **AND**

- Patient will not receive live vaccines during therapy; **AND**
- Patient is not on concurrent treatment with another biologic therapy or targeted synthetic therapy; **AND**

Plaque Psoriasis (PsO) † [1-9,38,53-57]

- Patient is at least 6 years of age; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented moderate to severe plaque psoriasis for at least 6 months with at least one of the following:
  - Involvement of at least 3% of body surface area (BSA); **OR**
  - Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**
  - Incapacitation or serious emotional consequences due to plaque location (e.g., hands, feet, head and neck, genitalia, etc.) or with intractable pruritis; **AND**
- Patient meets ALL of the following **¥**:
  - Patient did not respond adequately (or is not a candidate) to a 4-week minimum trial of topical agents (i.e., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, roflumilast, retinoic acid derivatives, and/or vitamin D analogues); **AND**
  - Patient did not respond adequately (or is not a candidate to a 3-month minimum trial of at least ONE non-biologic systemic agent (i.e., immunosuppressives, retinoic acid derivatives, and/or methotrexate); **AND**
  - Patient did not respond adequately (or is not a candidate*******) to a 3-month minimum trial of phototherapy (i.e., psoralens with UVA light [PUVA] or UVB with coal tar or dithranol)

¥ *Note: For patients already established on biologic therapy, targeted synthetic therapy, or those with > 10% BSA involvement, trial and failure of topical agents, non-biologic systemic agents, and phototherapy is not required.*

Adult Psoriatic Arthritis (PsA) † [1-9,17,58,68]

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented moderate to severe active disease; **AND**
  - For patients with predominantly axial disease OR enthesitis, a failure of at least a 4-week trial of ONE non-steroidal anti-inflammatory drug (NSAID), unless use is contraindicated; **OR**
  - For patients with peripheral arthritis OR dactylitis, a failure of at least a 3-month trial of ONE conventional synthetic disease-modifying anti-rheumatic drug (csDMARD) (e.g., methotrexate, azathioprine, sulfasalazine, leflunomide, hydroxychloroquine, etc.); **OR**
  - Patient is already established on biologic or targeted synthetic therapy for the treatment of PsA

Juvenile Psoriatic Arthritis (JPsA) † [1-9,59,60]

- Patient is at least 6 years of age; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented moderate to severe active polyarticular disease; **AND**
- May be used as a single agent or in combination with methotrexate; **AND**
    - Patient has had at least a 1-month trial and failure (unless contraindicated or intolerant) of previous therapy with either oral non-steroidal anti-inflammatory drugs (NSAIDs) OR conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) (e.g., methotrexate, leflunomide, sulfasalazine, etc.); **OR**
    - Patient is already established on biologic or targeted synthetic therapy for the treatment of JPsA

Crohn's Disease † [1-9,26,32,70,73]

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented moderate to severe active disease; **AND**
    - Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate); **OR**
    - Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of a TNF modifier (e.g., adalimumab, certolizumab, or infliximab); **OR**
    - Patient has evidence of high-risk disease for which corticosteroids or immunomodulators are inadequate and biologic therapy is necessary; **OR**
    - Patient is already established on biologic or targeted synthetic therapy for the treatment of CD

Ulcerative Colitis † [1-9,27,65,74]

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented moderate to severe active disease; **AND**
    - Documented failure or ineffective response to a minimum 3-month trial of conventional therapy [aminosalicylates, corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate, etc.] at maximum tolerated doses, unless there is a contraindication or intolerance to use; **OR**
    - Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of a TNF modifier such as adalimumab, golimumab, or infliximab; **OR**

- Patient is already established on a biologic or targeted synthetic therapy for the treatment of UC

Management of Immune Checkpoint Inhibitor-Related Toxicities ‡ [43,44]

- Patient has been receiving therapy with an immune checkpoint inhibitor; **AND**
  - Patient has diarrhea or colitis that is refractory to infliximab and/or vedolizumab; **AND**
    - Patient has mild (G1) diarrhea or colitis with persistent or progressive symptoms and is lactoferrin/calprotectin positive; **OR**
    - Patient has moderate (G2) to severe (G3-4) diarrhea or colitis

***Examples of contraindications to phototherapy (PUVA or UVB) include the following: [39,40,57]
– Xeroderma pigmentosum – Other rare photosensitive genodermatoses (e.g., trichothiodystrophy, Cockayne syndrome, Bloom syndrome, Rothmund-Thomson syndrome) *(UVB only)* – Genetic disorders associated with increased risk of skin cancer (e.g., Gorlin syndrome, oculocutaneous albinism) *(UVB only)* – Pregnancy or lactation *(PUVA only)* – Lupus Erythematosus – History of one of the following: photosensitivity diseases (e.g., chronic actinic dermatitis, solar urticaria), melanoma, non-melanoma skin cancer, extensive solar damage *(PUVA only),* or treatment with arsenic or ionizing radiation – Immunosuppression in an organ transplant patient *(UVB only)* – Photosensitizing medications *(PUVA only)* – Severe liver, renal, or cardiac disease *(PUVA only)* – Young age < 12 years old *(PUVA only)* – Anatomical location has been deemed ineligible for phototherapy (i.e., face, genital, scalp, or nail)
Note: *Patients who do not have access to phototherapy will be reviewed on a case-by-case basis*

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

IV. Renewal Criteria [1-9]

Prior authorization validity may be renewed based upon the following criteria:

- **Selarsdi (ustekinumab-aekn), Yesintek (ustekinumab-kfce), and Steqeyma (ustekinumab-stba) are the preferred ustekinumab products.** If the request is for any other ustekinumab biosimilar, patient must try and have an inadequate response, contraindication, or intolerance to Selarsdi, Yesintek, AND Steqeyma. If the request is for Stelara, patient must try and have an inadequate response, contraindication, or intolerance to ALL ustekinumab biosimilar products; **AND**

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Duration of authorization has not been exceeded (*refer to Section I*); **AND**

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious infections, malignancy, severe hypersensitivity reactions, posterior reversible encephalopathy syndrome (PRES) or reversible posterior leukoencephalopathy syndrome (RPLS), non-infectious pneumonia, etc.; **AND**

Plaque Psoriasis (PsO) [53,57,61,66,67]

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as redness, thickness, scaliness, and/or the amount of surface area involvement (a total BSA involvement ≤ 1%), and/or an improvement on a disease activity scoring tool [e.g., Psoriasis Area and Severity Index (PASI) score ≤ 3, physician's global assessment (PGA) score ≤ 1, etc.].

Adult Psoriatic Arthritis (PsA) [23,62,69]

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, improvement on imaging (X-ray, ultrasound, or MRI), and/or an improvement on a disease activity scoring tool.

Juvenile Psoriatic Arthritis (JPsA) [63,64,69]

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, improvement on imaging (X-ray, ultrasound, or MRI), and/or an improvement on a disease activity scoring tool [e.g. an improvement on a composite scoring index such as Juvenile Arthritis Disease Activity Score (JADAS) or the American College of Rheumatology (ACR) Pediatric (ACR-Pedi 30) of at least 30% improvement from baseline in three of six variables].

Crohn's Disease [42,71,72]

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight regain, hematocrit, presence of extra-intestinal complications, use of anti-diarrheal drugs, tapering or discontinuation of corticosteroid therapy, improvement in biomarker levels [i.e., fecal calprotectin or serum C-reactive protein (CRP)], and/or an improvement on a disease activity scoring tool (e.g., Harvey-Bradshaw Index score, etc.).

Ulcerative Colitis [27-31,75]

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, endoscopic activity, tapering or discontinuation of corticosteroid therapy, normalization of C-reactive protein (CRP) or fecal calprotectin (FC), and/or an improvement on a disease activity scoring tool.

V. Dosage/Administration [1-9,43-52]

Indication	Dose
Plaque Psoriasis	Adult Subcutaneous Loading Dose: • ≤100 kg: 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later • >100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later Adult Subcutaneous Maintenance Dose: • ≤100 kg: 45 mg every 12 weeks • >100 kg: 90 mg every 12 weeks
	Pediatric Subcutaneous Loading Dose: • <60 kg: 0.75 mg/kg at weeks 0 & 4, then begin maintenance dosing 12 weeks later *(**NOTE:** This dosing ONLY applies to Pyzchiva, Stelara/Ustekinumab, Wezlana, Selarsdi/Ustekinumab-aekn, Otulfi/Ustekinumab-aauz, Starjemza, Steqeyma, and Yesintek)* • 60 – 100 kg: 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later • >100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later Pediatric Subcutaneous Maintenance Dose: • <60 kg: 0.75 mg/kg every 12 weeks *(**NOTE:** This dosing ONLY applies to Pyzchiva, Stelara/Ustekinumab, Wezlana, Selarsdi/Ustekinumab-aekn, Otulfi/Ustekinumab-aauz, Starjemza, Steqeyma, and Yesintek)* • 60 – 100 kg: 45 mg every 12 weeks • >100 kg: 90 mg every 12 weeks
Psoriatic Arthritis	Adult Subcutaneous Loading Dose: • 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later • Co-existing moderate to severe plaque psoriasis AND weighing >100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later Adult Subcutaneous Maintenance Dose: • 45 mg every 12 weeks • Co-existing moderate to severe plaque psoriasis AND weighing >100 kg: 90 mg every 12 weeks
	Pediatric Subcutaneous Loading Dose: • <60 kg: 0.75 mg/kg at weeks 0 & 4, then begin maintenance dosing 12 weeks later *(**NOTE:** This dosing ONLY applies to Pyzchiva, Stelara/Ustekinumab, Wezlana, Selarsdi/Ustekinumab-aekn, Otulfi/Ustekinumab-aauz, Starjemza, Steqeyma, and Yesintek)* • ≥60 kg: 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later • Co-existing moderate to severe plaque psoriasis AND weighing >100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later Pediatric Subcutaneous Maintenance Dose: • <60 kg: 0.75 mg/kg every 12 weeks *(**NOTE:** This dosing ONLY applies to Pyzchiva, Stelara/Ustekinumab, Wezlana, Selarsdi/Ustekinumab-aekn, Otulfi/Ustekinumab-aauz, Starjemza, Steqeyma, and Yesintek)* • ≥60 kg: 45 mg every 12 weeks

Indication	Dose
	• Co-existing moderate to severe plaque psoriasis AND weighing >100 kg: 90 mg every 12 weeks
Crohn's Disease & Ulcerative Colitis/ Immune Checkpoint Inhibitor-Related Toxicities	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 (*Note Immune Checkpoint Inhibitor Related Toxicity: Administer a one-time IV induction dose plus up to 3 subcutaneous maintenance doses only)*

- Crohn's Disease & Ulcerative Colitis dose escalation[45-52] (up to the maximum dose and frequency specified below) may occur upon clinical review on a case-by-case basis provided that the patient has:
  - Shown an initial response to therapy; **AND**
  - Received the initial intravenous loading dose as specified above; **AND**
  - Received a minimum of one subcutaneous maintenance dose as specified above; **AND**
  - Responded to therapy (by treatment week 16*) with subsequent loss of response; **AND**
  - Dose escalation must not exceed the following limits:
    - 90 mg subcutaneously every 4 weeks (certain patients may benefit from a smaller reduction in interval if they become symptomatic 5, 6, or 7 weeks after the prior administration)
      - ➢ Coverage will be provided for 3 months with continued approval (as specified in Sections I & IV) contingent upon demonstration of clinical improvement and ustekinumab levels (if available)**
        - Patients who do not regain response at a 4-week interval should discontinue therapy
        - Patients who are responding to therapy may continue with their current dosing**

*Note:

- Request for dose escalation prior to week 16 will be evaluated considering the patient's clinical picture regarding severity of inflammation, factors which may result in subtherapeutic response to standard dosing (e.g., hypoalbuminemia, prior TNF-I failure), timing of response and breakthrough/loss of response, presence of perianal fistula; **AND**
- ustekinumab trough (if available)** is <4.5 micrograms/mL

**ustekinumab trough levels must be obtained (if this is a covered test under the benefit).

- Patients who are well-controlled with a trough >4.5 micrograms/mL may be candidates to increase the interval between administrations from 4 weeks to 6 weeks. Response should be assessed after 3 months at this every 6-week interval. Those patients demonstrating loss of response may decrease the interval back to 90 mg subcutaneously every 4 weeks.
- Patients whose trough is <4.5 micrograms/mL are candidates to decrease the interval between administrations from 8 weeks to as frequently as 4 weeks. Some patients may benefit from one additional IV loading dose in conjunction with this more frequent maintenance dosing interval.

VI. Billing Code/Availability Information

HCPCS Code(s):

- J3357 – Ustekinumab, for subcutaneous injection, 1 mg; 1 billable unit = 1 mg *(Stelara SQ Only; Includes unbranded biologic§)*
- J3358 – Ustekinumab, for intravenous injection, 1 mg; 1 billable unit = 1 mg *(Stelara IV Only; Includes unbranded biologic§)*
- J3590 – Unclassified biologics *(Imuldosa, Steqeyma/Ustekinumab-stba, Yesintek, and Starjemza ONLY) (Discontinue use on 07/01/2025 for Imuldosa, Steqeyma/Ustekinumab-stba, and Yesintek ONLY)*
- Q5137 – Injection, ustekinumab-auub (wezlana), biosimilar, subcutaneous, 1 mg; 1 billable unit = 1 mg
- Q5138 – Injection, ustekinumab-auub (wezlana), biosimilar, intravenous, 1 mg; 1 billable unit = 1 mg
- Q9996 – Injection, ustekinumab-ttwe (pyzchiva), subcutaneous, 1 mg; 1 billable unit = 1 mg *(Includes unbranded biologic§)*
- Q9997 – Injection, ustekinumab-ttwe (pyzchiva), intravenous, 1 mg; 1 billable unit = 1 mg *(Includes unbranded biologic§)*
- Q9998♦ – Injection, ustekinumab-aekn (selarsdi), biosimilar, 1 mg; 1 billable unit = 1 mg *(Includes unbranded biologic§)*
- Q9999♦ – Injection, ustekinumab-aauz (otulfi), biosimilar, 1mg; 1 billable unit = 1 mg *(Includes unbranded biologic§)*
- Q5098♦ – Injection, ustekinumab-srlf (imuldosa), biosimilar, 1 mg; 1 billable unit = 1 mg *(Effective 07/01/2025)*
- Q5100♦ – Injection, ustekinumab-kfce (yesintek), biosimilar, 1 mg; 1 billable unit = 1 mg *(Effective 07/01/2025)*
- Q5099♦ – Injection, ustekinumab-stba (steqeyma), biosimilar, 1 mg; 1 billable unit = 1 mg *(Includes unbranded biologic§) (Effective 07/01/2025)*

♦ ***Note****: CMS generally creates codes for products themselves, without specifying a route of administration in the code descriptor, as there might be multiple routes of administration for the same product. Drugs that fall under this category should be billed with either the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for subcutaneous injection of the drug.*

NDC(s):

- Subcutaneous
  - Stelara 45 mg/0.5 mL single-dose prefilled syringe: 57894-0060-xx
  - Stelara 90 mg/mL single-dose prefilled syringe: 57894-0061-xx
  - Stelara 45 mg/0.5 mL single-dose vial: 57894-0060-xx
  - Wezlana 45 mg/0.5 mL single-dose prefilled syringe: 84612-0076-xx and 84612-0876-xx

- Wezlana 90 mg/mL single-dose prefilled syringe: 84612-0089-xx and 84612-0889-xx
- Wezlana 45 mg/0.5 mL single-dose vial: 84612-0055-xx and 84612-0855-xx
- Yesintek 45 mg/0.5 mL single-dose prefilled syringe: 83257-0023-xx
- Yesintek 90 mg/mL single-dose prefilled syringe: 83257-0025-xx
- Yesintek 45 mg/0.5 mL single-dose vial: 83257-0024-xx
- Steqeyma 45 mg/0.5 mL single-dose prefilled syringe: 72606-0027-xx
- Steqeyma 90 mg/mL single-dose prefilled syringe: 72606-0028-xx
- Steqeyma 45 mg/0.5 mL single-dose vial: 72606-0060-xx
- Pyzchiva 45 mg/0.5 mL single-dose prefilled syringe: 61314-0651-xx
- Pyzchiva 90 mg/mL single-dose prefilled syringe: 61314-0652-xx
- Pyzchiva 45 mg/0.5 mL single-dose vial: 61314-0651-xx
- Otulfi 45 mg/0.5 mL single-dose prefilled syringe: 65219-0862-xx
- Otulfi 90 mg/mL single-dose prefilled syringe: 65219-0866-xx
- Otulfi 45 mg/0.5 mL single-dose vial: 65219-0864-xx
- Imuldosa 45 mg/0.5 mL single-dose prefilled syringe: 69448-0017-xx
- Imuldosa 90 mg/mL single-dose prefilled syringe: 69448-0018-xx
- Selarsdi 45 mg/0.5 mL single-dose prefilled syringe: 51759-0505-xx
- Selarsdi 90 mg/mL single-dose prefilled syringe: 51759-0607-xx
- Selarsdi 45 mg/0.5 mL single-dose vial: 51759-0505-xx
- Starjemza 45 mg/0.5 mL single-dose prefilled syringe: 00143-9168-xx
- Starjemza 90 mg/mL single-dose prefilled syringe: 00143-9170-xx
- Starjemza 45 mg/0.5 mL single-dose vial: 00143-9169-xx
- Ustekinumab 45 mg/0.5 mL single-dose prefilled syringe: 57894-0440-xx *(§Unbranded biologic of Stelara)*
- Ustekinumab 90 mg/mL single-dose prefilled syringe: 57894-0441-xx *(§Unbranded biologic of Stelara)*
- Ustekinumab 45 mg/0.5 mL single-dose vial: 57894-0440-xx *(§Unbranded biologic of Stelara)*
- Ustekinumab-aekn 45 mg/0.5 mL single-dose prefilled syringe: 51759-0709-xx (§*Unbranded biologic of Selarsdi*)
- Ustekinumab-aekn 90 mg/mL single-dose prefilled syringe: 51759-0710-xx (§*Unbranded biologic of Selarsdi*)
- Ustekinumab-aekn 45 mg/0.5 mL single-dose vial: 51759-0709-xx (§*Unbranded biologic of Selarsdi*)
- Ustekinumab-ttwe 45 mg/0.5 mL single-dose prefilled syringe: 82009-0160-xx (§*Unbranded biologic of Pyzchiva*)
- Ustekinumab-ttwe 90 mg/mL single-dose prefilled syringe: 82009-0162-xx (§*Unbranded biologic of Pyzchiva*)

  - Ustekinumab-aauz 45 mg/0.5 mL single-dose prefilled syringe: 65219-0862-xx (§*Unbranded biologic of Otulfi*)
  - Ustekinumab-aauz 90 mg/mL single-dose prefilled syringe: 65219-0866-xx (§*Unbranded biologic of Otulfi*)
  - Ustekinumab-aauz 45 mg/0.5 mL single-dose vial: 65219-0864-xx *(§Unbranded biologic of Otulfi)*
  - Ustekinumab-stba 45 mg/0.5 mL single-dose prefilled syringe: 72606-0055-xx (§*Unbranded biologic of Steqeyma*)
  - Ustekinumab-stba 90 mg/mL single-dose prefilled syringe: 72606-0056-xx (§*Unbranded biologic of Steqeyma*)
- Intravenous
  - Stelara 130 mg/26 mL (5 mg/mL) single-dose vial: 57894-0054-xx
  - Wezlana 130 mg/26 mL (5 mg/mL) single-dose vial: 84612-0066-xx
  - Yesintek 130 mg/26 mL (5 mg/mL) single-dose vial: 83257-0026-xx
  - Steqeyma 130 mg/26 mL (5 mg/mL) single dose vial: 72606-0029-xx
  - Pyzchiva 130 mg/26 mL (5 mg/mL) single-dose vial: 61314-0654-xx
  - Otulfi 130 mg/26 mL (5 mg/mL) single-dose vial: 65219-0868-xx
  - Imuldosa 130 mg/26 mL (5 mg/mL) single-dose vial: 69448-0019-xx
  - Selarsdi 130 mg/26 mL (5 mg/mL) single-dose vial: 51759-0708-xx
  - Starjemza 130 mg/26 mL (5 mg/mL) single-dose vial: 00143-9171-xx
  - Ustekinumab 130 mg/26 mL (5 mg/mL) single-dose vial: 57894-0444-xx *(§Unbranded biologic of Stelara)*
  - Ustekinumab-aekn 130 mg/26 mL (5 mg/mL) single-dose vial: 51759-0711-xx (§*Unbranded biologic of Selarsdi*)
  - Ustekinumab-ttwe 130 mg/26 mL (5 mg/mL) single-dose vial: 82009-0163-xx (§*Unbranded biologic of Pyzchiva*)
  - Ustekinumab-aauz 130 mg/26 mL (5 mg/mL) single-dose vial: 65219-0868-xx (§*Unbranded biologic of Otulfi*)
  - Ustekinumab-stba 130 mg/26 mL (5 mg/mL) single-dose vial: 72606-0057-xx (§*Unbranded biologic of Steqeyma*)

§*An unbranded biologic is the same as the brand biologic and uses the same cell-line as the brand-name reference biologic.*

VII. References

1. Stelara/Ustekinumab [package insert]. Horsham, PA; Janssen Biotech, Inc.; April 2025. Accessed April 2025.

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4. Pyzchiva/Ustekinumab-ttwe [package insert]. Yeonsu-gu, Incheon; Samsung Bioepis Co., Ltd.; March 2025. Accessed March 2025.
5. Otulfi/Ustekinumab-aauz [package insert]. Lake Zurich, IL; Fresenius Kabi USA, LLC; August 2025; Accessed August 2025.
6. Imuldosa [package insert]. Raleigh, NC; Accord BioPharma Inc; October 2024; Accessed February 2025.
7. Yesintek [package insert]. Cambridge, MA; Biocon Biologics Inc.; November 2024; Accessed February 2025.
8. Steqeyma/Ustekinumab-stba [package insert]. Yeonsu-gu, Incheon; Celltrion, Inc.; June 2025; Accessed July 2025.
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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

Subcutaneous

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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.59	Other psoriatic arthropathy
M08.80	Other juvenile arthritis, unspecified site
M08.811	Other juvenile arthritis, right shoulder
M08.812	Other juvenile arthritis, left shoulder
M08.819	Other juvenile arthritis, unspecified shoulder
M08.821	Other juvenile arthritis, right elbow
M08.822	Other juvenile arthritis, left elbow
M08.829	Other juvenile arthritis, unspecified elbow
M08.831	Other juvenile arthritis, right wrist
M08.832	Other juvenile arthritis, left wrist
M08.839	Other juvenile arthritis, unspecified wrist
M08.841	Other juvenile arthritis, right hand
M08.842	Other juvenile arthritis, left hand
M08.849	Other juvenile arthritis, unspecified hand
M08.851	Other juvenile arthritis, right hip
M08.852	Other juvenile arthritis, left hip
M08.859	Other juvenile arthritis, unspecified hip
M08.861	Other juvenile arthritis, right knee
M08.862	Other juvenile arthritis, left knee
M08.869	Other juvenile arthritis, unspecified knee
M08.871	Other juvenile arthritis, right ankle and foot
M08.872	Other juvenile arthritis, left ankle and foot
M08.879	Other juvenile arthritis, unspecified ankle and foot
M08.88	Other juvenile arthritis, other specified site
M08.89	Other juvenile arthritis, multiple sites
M08.9A	Juvenile arthritis, unspecified, other specified site
M08.911	Juvenile arthritis, unspecified, right shoulder
M08.912	Juvenile arthritis, unspecified, left shoulder
M08.919	Juvenile arthritis, unspecified, unspecified shoulder
M08.921	Juvenile arthritis, unspecified, right elbow
M08.922	Juvenile arthritis, unspecified, left elbow

ICD-10	ICD-10 Description
M08.929	Juvenile arthritis, unspecified, unspecified elbow
M08.931	Juvenile arthritis, unspecified, right wrist
M08.932	Juvenile arthritis, unspecified, left wrist
M08.939	Juvenile arthritis, unspecified, unspecified wrist
M08.941	Juvenile arthritis, unspecified, right hand
M08.942	Juvenile arthritis, unspecified, left hand
M08.949	Juvenile arthritis, unspecified, unspecified hand
M08.951	Juvenile arthritis, unspecified, right hip
M08.952	Juvenile arthritis, unspecified, left hip
M08.959	Juvenile arthritis, unspecified, unspecified hip
M08.961	Juvenile arthritis, unspecified, right knee
M08.962	Juvenile arthritis, unspecified, left knee
M08.969	Juvenile arthritis, unspecified, unspecified knee
M08.971	Juvenile arthritis, unspecified, right ankle and foot
M08.972	Juvenile arthritis, unspecified, left ankle and foot
M08.979	Juvenile arthritis, unspecified, unspecified ankle and foot
M08.98	Juvenile arthritis, unspecified, vertebrae
M08.99	Juvenile arthritis, unspecified, multiple sites
R19.7	Diarrhea, unspecified

Intravenous

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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage

Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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