Clinical Policy: Clinical Policy: Ustekinumab (Stelara), Ustekinumab-aauz, Ustekinumab-srlf (Imuldosa), (Otulfi), Ustekinumab-ttwe (Pyzchiva), Ustekinumab-aekn (Selarsdi), Ustekinumab-stba (Steqeyma), Ustekinumab-auub (Wezlana), Ustekinumab-kfce (Yesintek)

Reference Number: PA.CHIP.PHAR.264
Effective Date: 01/2026
Last Review Date: 10/2025

Description

Ustekinumab (Stelara®), ustekinumab-srlf (Imuldosa™), ustekinumab-aauz (Otulfi®), ustekinumab-ttwe (Pyzchiva®), ustekinumab-aekn (Selarsdi™), ustekinumab-stba (Steqeyma®), ustekinumab-auub (Wezlana™), and ustekinumab-kfce (Yesintek™) are human interleukin-12 (IL-12) and -23 (IL-23) antagonists.

FDA Approved Indication(s)

Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Wezlana, and Yesintek are indicated for the treatment of:

- Patients 6 years and older with moderate-to-severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- Patients 6 years and older with active psoriatic arthritis (PsA)
- Adult patients with moderately to severely active Crohn's disease (CD)
- Adult patients with moderately to severely active ulcerative colitis (UC)

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that the member has met all approval criteria.

It is the policy of PA Health & Wellness® that Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, ustekinumab, ustekinumab-aekn, ustekinumab-ttwe, Wezlana, and Yesintek are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Crohn's Disease (must meet all)**:**

1. Diagnosis of CD;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Failure of a ≥ 3 consecutive month trial of at least ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine [6-MP], MTX) at up to maximally indicated doses, unless clinicallysignificant adverse effects are experienced or all are contraindicated;
   b. Medical justification supports inability to use immunomodulators (*see Appendix E*);
5. For requests other than the following preferred biosimilars, member must use all of the following preferred biosimilars, unless clinically significant adverse effects are experienced or all are contraindicated: Otulfi, Pyzchiva (branded), Steqeyma, Yesintek;
   **Prior authorization may be required for ustekinumab products*
6. Member does not have combination use with biological disease-modifying antirheumatic

drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
7. Dose does not exceed both of the following (a and b):
   a. Initial dose (IV):
      i. Weight ≤ 55 kg: 260 mg once;
      ii. Weight > 55 kg to 85 kg: 390 mg once;
      iii. Weight > 85 kg: 520 mg once;
   b. Maintenance dose (SC): 90 mg 8 weeks after the initial IV dose, followed by maintenance dose of 90 mg every 8 weeks.

Approval duration: 6 months

A. Plaque Psoriasis (must meet all)**:**
1. Diagnosis of moderate-to-severe PsO as evidenced by involvement of one of the following (a or b):
   a. ≥ 3% of total body surface area;
   b. Hands, feet, scalp, face, or genital area;
2. Request is for SC formulation;
3. Prescribed by or in consultation with a dermatologist or rheumatologist;
4. Age ≥ 6 years;
5. Member meets one of the following (a, b, or c):
   a. Failure of a ≥ 3 consecutive month trial of methotrexate (MTX) at up to maximally indicated doses;
   b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
   c. Member has intolerance or contraindication to MTX, cyclosporine, and acitretin, and failure of phototherapy, unless contraindicated or clinically significant adverse effects are experienced;
6. For requests other than the following preferred biosimilars, member must use all of the following preferred biosimilars, unless clinically significant adverse effects are experienced or all are contraindicated: Otulfi, Pyzchiva (branded), Steqeyma, Yesintek;
   **Prior authorization may be required for ustekinumab products*
7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
8. Dose does not exceed one of the following (*see Appendix G for dose rounding guidelines*) (a or b):
   a. Adult: weight-based dosing initially and 4 weeks later, followed by maintenance dose every 12 weeks (i or ii);
      i. Weight ≤ 100 kg: 45 mg per dose;
      ii. Weight > 100 kg: 90 mg per dose;
   b. Pediatric: weight-based dosing initially and 4 weeks later, followed by maintenance dose every 12 weeks (i, ii, or iii);
      i. Stelara, Otulfi, Pyzchiva, Wezlana, and Yesintek only: Weight < 60 kg: 0.75 mg/kg per dose;
      ii. Weight 60 kg to 100 kg: 45 mg per dose;
      iii. Weight > 100 kg: 90 mg per dose.

Approval duration: 6 months

B. Psoriatic Arthritis (must meet all)**:**
1. Diagnosis of PsA;
2. Request is for SC formulation;
3. Prescribed by or in consultation with a dermatologist or rheumatologist;
4. Age ≥ 6 years;
5. For requests other than the following preferred biosimilars, member must use all of the following preferred biosimilars, unless clinically significant adverse effects are experienced or all are contraindicated: Otulfi, Pyzchiva (branded), Steqeyma, Yesintek;
   **Prior authorization may be required for ustekinumab products*
6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
7. Dose does not exceed one of the following (a or b):
   a. Adult: weight-based dosing initially and 4 weeks later, followed by maintenance dose every 12 weeks (i or ii):
      i. 45 mg per dose;
      ii. Co-existent PsO and weight > 100 kg: 90 mg per dose;
   b. Pediatric: weight-based dosing initially and 4 weeks later, followed by maintenance dose every 12 weeks (i, ii, or iii):
      i. Stelara, Otulfi, Pyzchiva, Wezlana, and Yesintek only: Weight < 60 kg: 0.75 mg/kg per dose;
      ii. Weight ≥ 60 kg: 45 mg per dose;
      iii. Co-existent PsO and weight > 100 kg: 90 mg per dose.

Approval duration: 6 months

C. Ulcerative Colitis (must meet all)**:**
1. Diagnosis of UC;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 18 years;
4. Documentation of a Mayo Score ≥ 6 or modified Mayo Score ≥ 5 (*see Appendix F*);
5. Failure of an 8-week trial of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced;
6. For requests other than the following preferred biosimilars, member must use all of the following preferred biosimilars, unless clinically significant adverse effects are experienced or all are contraindicated: Otulfi, Pyzchiva (branded), Steqeyma, Yesintek;
   **Prior authorization may be required for ustekinumab products*
7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
8. Dose does not exceed both of the following (a and b):
   a. Initial dose (IV):
      i. Weight ≤ 55 kg: 260 mg once;
      ii. Weight > 55 kg to 85 kg: 390 mg once;
      iii. Weight > 85 kg: 520 mg once;
   b. Maintenance dose (SC): 90 mg 8 weeks after the initial IV dose, followed by

maintenance dose of 90 mg every 8 weeks.

Approval duration: 6 months

D. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Fidelis benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. Request is for SC formulation;
4. For requests other than the following preferred biosimilars, member must use all of the following preferred biosimilars, unless clinically significant adverse effects are experienced or all are contraindicated: Otulfi, Pyzchiva (branded), Steqeyma, Yesintek;
   **Prior authorization may be required for ustekinumab products*
5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
6. If request is for a dose increase, new dose does not exceed one of the following (a, b, or c):
   a. PsO alone (*see Appendix G for dose rounding guidelines*) (i or ii):
      i. Adults (a or b):
         a) Weight ≤ 100 kg: 45 mg every 12 weeks;
         b) Weight > 100 kg: 90 mg every 12 weeks;
      ii. Pediatrics (a, b, or c):
         a) Stelara, Otulfi, Pyzchiva, Wezlana, and Yesintek only: Weight < 60 kg: 0.75 mg/kg every 12 weeks;
         b) Weight 60 kg to 100 kg: 45 mg every 12 weeks;
         c) Weight > 100 kg: 90 mg every 12 weeks;
   b. PsA (i or ii):
      i. Adults (a or b):
         a) 45 mg every 12 weeks;
         b) Co-existent PsO and weight > 100 kg: 90 mg every 12 weeks;

ii. Pediatrics (a, b, or c):
   a) Stelara, Otulfi, Pyzchiva, Wezlana, and Yesintek only: Weight < 60 kg: 0.75 mg/kg every 12 weeks;
   b) Weight ≥ 60 kg: 45 mg every 12 weeks;
   c) Co-existent PsO and weight > 100 kg: 90 mg every 12 weeks;

c. CD, UC: 90 mg every 8 weeks.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents;

B. Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia®, Enbrel®, Humira® and its biosimilars, Remicade® and its biosimilars, Simponi®], interleukin agents [e.g., Actemra® (IL-6RA) and its biosimilars, Arcalyst® (IL-1 blocker), Bimzelx® (IL-17A and F antagonist), Cosentyx® (IL-17A inhibitor), Ilaris® (IL-1 blocker), Ilumya™ (IL-23 inhibitor), Kevzara® (IL-6RA), Kineret® (IL-1RA), Omvoh™ (IL-23 antagonist), Siliq™ (IL-17RA), Skyrizi™ (IL-23 inhibitor), Spevigo® (IL-36 antagonist), Stelara® (IL-12/23 inhibitor) and its biosimilars, Taltz® (IL-17A inhibitor), Tremfya® (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo™, Olumiant™, Rinvoq™, Xeljanz®/Xeljanz® XR,], anti-CD20 monoclonal antibodies [Rituxan® and its biosimilars], selective co-stimulation modulators [Orencia®], integrin receptor antagonists [Entyvio®], tyrosine kinase 2 inhibitors [Sotyktu™], and sphingosine 1-phosphate receptor modulator [Velsipity™] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

6-MP: 6-mercaptopurine
CD: Crohn's disease
FDA: Food and Drug Administration
GI: gastrointestinal
IL-12: interleukin-12
IL-23: interleukin-23
JAKi: Janus kinase inhibitors
MTX: methotrexate
PsO: plaque psoriasis
PsA: psoriatic arthritis
TNF: tumor necrosis factor
UC: ulcerative colitis

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
acitretin (Soriatane®)	**PsO** 25 or 50 mg PO daily	50 mg/day
azathioprine (Azasan®, Imuran)	**CD** 1.5 – 2.5 mg/kg/day PO	2.5 mg/kg/day
corticosteroids	**CD*** prednisone 40 mg – 60 mg PO QD for 1 to 2 weeks, then taper daily dose by 5 mg weekly until 20 mg PO QD, and then continue with 2.5 – 5 mg decrements weekly or IV 50 – 100 mg Q6H for 1 week budesonide (Entocort EC®) 6 – 9 mg PO QD **UC** *Adult:*	Various

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Prednisone 40 mg – 60 mg PO QD, then taper dose by 5 to 10 mg/week Budesonide (Uceris®) 9 mg PO QAM for up to 8 weeks	
cyclosporine (Sandimmune®, Neoral®)	**PsO** 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
6-mercaptopurine (Purixan®)	**CD** 50 mg PO QD or 1 – 2 mg/kg/day PO	2 mg/kg/day
methotrexate (Trexall®, Otrexup™, Rasuvo®, RediTrex®, Rheumatrex®, Jylamvo®)	**CD*** 15 – 25 mg/week IM or SC **PsO** 10 to 25 mg/week IM, SC or PO or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
Pentasa® (mesalamine)	**CD** 1,000 mg PO QID	4 g/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): clinically significant hypersensitivity to ustekinumab products or any of the excipients
- Boxed warning(s): none reported

Appendix D: General Information

- Definition of failure of MTX or DMARDs
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Examples of positive response to therapy may include, but are not limited to:
  - Reduction in joint pain/swelling/tenderness
  - Improvement in erythrocyte sedimentation rate/C-reactive protein (ESR/CRP) levels
  - Improvements in activities of daily living

Appendix E: Immunomodulator Medical Justification

- The following may be considered for medical justification supporting inability to use an immunomodulator for Crohn's disease:
  - Inability to induce short-term symptomatic remission with a 3-month trial of systemic glucocorticoids
  - High-risk factors for intestinal complications may include:
    - Initial extensive ileal, ileocolonic, or proximal GI involvement
    - Initial extensive perianal/severe rectal disease
    - Fistulizing disease (e.g., perianal, enterocutaneous, and rectovaginal fistulas)
    - Deep ulcerations
    - Penetrating, stricturing or stenosis disease and/or phenotype
    - Intestinal obstruction or abscess
  - High risk factors for postoperative recurrence may include:
    - Less than 10 years duration between time of diagnosis and surgery
    - Disease location in the ileum and colon
    - Perianal fistula
    - Prior history of surgical resection
    - Use of corticosteroids prior to surgery

Appendix F: Mayo Score or Modified Mayo Score

- Mayo Score: evaluates ulcerative colitis stage, based on four parameters: stool frequency, rectal bleeding, endoscopic evaluation and Physician's global assessment. Each parameter of the score ranges from zero (normal or inactive disease) to 3 (severe activity) with an overall score of 12.

Score	Decoding
0 – 2	Remission
3 – 5	Mild activity
6 – 10	Moderate activity
>10	Severe activity

- Modified Mayo Score: developed from the full Mayo score and evaluates ulcerative colitis stage, based on three parameters: stool frequency, rectal bleeding, and endoscopic evaluation. The modified Mayo Score gives a maximum overall score of 9. The FDA currently accepts the modified Mayo Score for the assessment of disease activity in pivotal UC clinical trials.

Appendix G: Dose Rounding Guidelines for PsO

Weight-based Dose Range	Quantity Recommendation
Subcutaneous, Syringe	
≤ 46.99 mg	1 syringe of 45 mg/0.5 mL
47 to 94.49 mg	1 syringe of 90 mg/1 mL
94.5 to 141.49 mg	1 syringe of 45 mg/0.5 mL and 1 syringe of 90 mg/1 mL
Subcutaneous, Vial	
≤ 46.99 mg	1 vial of 45 mg/0.5 mL
47 to 94.49 mg	2 vials of 45 mg/0.5 mL

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Ustekinumab (Stelara), ustekinumab-srlf (Imuldosa), ustekinumab-aauz (Otulfi), ustekinumab-ttwe (Pyzchiva), ustekinumab-aekn (Selarsdi), ustekinumab-stba (Steqeyma), ustekinumab-auub (Wezlana), ustekinumab-kfce (Yesintek) **Also see Appendix G: Dose Rounding Guidelines for Weight-Based Doses*	CD, UC	Weight based dosing IV at initial dose: Weight ≤ 55 kg: 260 mg Weight > 55 kg to 85 kg: 390 mg Weight > 85 kg: 520 mg Maintenance dose: 90 mg SC every 8 weeks	90 mg every 8 weeks
	PsO	Weight based dosing SC at weeks 0 and 4, followed by maintenance dose every 12 weeks *Adult:* Weight ≤ 100 kg: 45 mg Weight > 100 kg: 90 mg *Pediatrics (age 6 years to 17 years):* **Stelara, Otulfi, Pyzchiva, Wezlana, Yesintek:** Weight < 60 kg: 0.75 mg/kg **Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Wezlana, Yesintek:** Weight 60 to 100 kg: 45 mg Weight > 100 kg: 90 mg	90 mg every 12 weeks
	PsA	Weight based dosing SC at weeks 0 and 4, followed by maintenance dose every 12 weeks *Adult:* 45 mg SC at weeks 0 and 4, followed by 45 mg every 12 weeks *Pediatrics (age 6 years to 17 years):* Weight based dosing SC at weeks 0 and 4, then every 12 weeks thereafter **Stelara, Otulfi, Pyzchiva, Wezlana, Yesintek:** Weight < 60 kg: 0.75 mg/kg **Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Wezlana, Yesintek:** Weight ≥ 60 kg: 45 mg	45 mg every 12 weeks

Drug Name	Indication	Dosing Regimen	Maximum Dose
	PsA with co-existent PsO	Weight > 100 kg: 90 mg SC at weeks 0 and 4, followed by 90 mg every 12 weeks	90 mg every 12 weeks

VI. Product Availability

Drug Name	Availability
Ustekinumab (Stelara)	• Single-dose prefilled syringe for SC injection: 45 mg/0.5 mL, 90 mg/mL • Single-dose vial for SC injection: 45 mg/0.5 mL • Single-dose vial for IV infusion: 130 mg/26 mL
Ustekinumab-aauz (Otulfi)	• Single-dose prefilled syringe for SC injection: 45 mg/0.5 mL, 90 mg/mL • Single-dose vial for SC injection: 45 mg/0.5 mL • Single-dose vial for IV infusion: 130 mg/26 mL
Ustekinumab-aekn (Selarsdi)	• Single-dose prefilled syringe for SC injection: 45 mg/0.5 mL, 90 mg/mL • Single-dose vial for IV infusion: 130 mg/26 mL
Ustekinumab-auub (Wezlana)	• Single-dose prefilled syringe for SC injection: 45 mg/0.5 mL, 90 mg/mL • Single-dose vial for SC injection: 45 mg/0.5 mL • Single-dose prefilled autoinjector (ConfiPen) for SC injection: 45 mg/0.5 mL, 90 mg/mL • Single-dose vial for IV infusion: 130 mg/26 mL
Ustekinumab-kfce (Yesintek)	• Single-dose prefilled syringe for SC: 45 mg/0.5 mL, 90 mg/mL • Single-dose vial for SC: 45 mg/0.5 mL • Single-dose vial for IV: 130 mg/26 mL
Ustekinumab-srlf (Imuldosa)	• Single-dose prefilled syringe for SC injection: 45 mg/0.5 mL, 90 mg/mL • Single-dose vial for IV infusion: 130 mg/26 mL
Ustekinumab-stba (Steqeyma)	• Single-dose prefilled syringe for SC injection: 45 mg/0.5 mL, 90 mg/mL • Single-dose vial for IV infusion: 130 mg/26 mL
Ustekinumab-ttwe (Pyzchiva)	• Single-dose prefilled syringe for SC injection: 45 mg/0.5 mL, 90 mg/mL • Single-dose vial for SC injection: 45 mg/0.5 mL • Single-dose vial for IV infusion: 130 mg/26 mL

VII. References

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Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to- date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
C9399, J3590	Unclassified drugs or biologicals
J3357	Ustekinumab, for subcutaneous injection,1 mg
J3358	Ustekinumab, for intravenous injection, 1 mg
Q5137	Injection, ustekinumab-auub (wezlana), biosimilar, subcutaneous, 1 mg
Q5138	Injection, ustekinumab-auub (wezlana), biosimilar, intravenous, 1 mg
Q9996	Injection, ustekinumab-ttwe (pyzchiva), subcutaneous, 1 mg
Q9997	Injection, ustekinumab-ttwe (pyzchiva), intravenous, 1 mg
Q9998	Injection, ustekinumab-aekn (selarsdi), 1 mg
Q9999	Injection, ustekinumab-aauz (otulfi), biosimilar, 1 mg

Reviews, Revisions, and Approvals	Date
Policy created	10/2025