BlueCross BlueShield of Tennessee

Policy

Medical Policy Manual **Approved Rev: Do Not Implement until 6/30/26**

Ustekinumab Products: Ustekinumab (Stelara®); Ustekinumab-auub (Wezlana™); Ustekinumab-srlf (Imuldosa™); Ustekinumab-aauz (Otulfi™); Ustenkinumab-ttwe (Pyzchiva™), Ustekinumab-aekn (Selarsdi™); Ustenkinumab-stba (Steqeyma™); Ustenkinumba-kfce (Yesintek™); ustekinumab; ustekinumab-aauz, ustekinumab-stba, ustekinumab-aekn ; ustekinumab-auub; ustenkinumab-ttwe, Ustekinumab-hmny (Starjemza)

Some agents on this policy may require step therapy *See* "Step Therapy Requirements for Provider Administered Specialty Medications" Document at:
https://www.bcbst.com/docs/providers/Comm_BC_PAD_Step_Therapy_Guide.pdf

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- Moderate to severe plaque psoriasis (PsO) in patients 6 years and older who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis (PsA) in patients 6 years and older
- Moderately to severely active Crohn's disease (CD) in adults
- Moderately to severely active ulcerative colitis (UC) in adults

Compendial Uses

Immune checkpoint inhibitor-related toxicity

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

Plaque psoriasis (PsO)
Initial requests
- Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).

- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests
Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

Psoriatic arthritis (PsA)
Initial requests
Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests
Chart notes or medical record documentation supporting positive clinical response.

Crohn's disease (CD) and ulcerative colitis (UC)
Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Immune checkpoint inhibitor-related toxicity
Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following**:**

- Plaque psoriasis: dermatologist
- Psoriatic arthritis: rheumatologist or dermatologist
- Crohn's disease and ulcerative colitis: gastroenterologist
- Immune checkpoint inhibitor-related toxicity: gastroenterologist, hematologist or oncologist

COVERAGE CRITERIA

Plaque psoriasis (PsO)

Authorization of 12 months may be granted for members 6 years of age and older who have previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for treatment of moderate to severe plaque psoriasis.

Authorization of 12 months may be granted for members 6 years of age and older for treatment of moderate to severe plaque psoriasis when any of the following criteria is met:

- Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- At least 10% of body surface area (BSA) is affected.
- At least 3% of body surface area (BSA) is affected and the member meets either of the following criteria:
  - Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
  - Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).

Psoriatic arthritis (PsA)

Authorization of 12 months may be granted for members 6 years of age or older who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.

Authorization of 12 months may be granted for members 6 years of age or older for treatment of active psoriatic arthritis when either of the following criteria is met:

- Member has mild to moderate disease and meets one of the following criteria:
  - Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
  - Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix), or another conventional synthetic drug (e.g., sulfasalazine).
  - Member has enthesitis
- Member has severe disease.

Crohn's disease (CD)

Authorization of 12 months may be granted for treatment of moderately to severely active Crohn's disease.

Ulcerative colitis (UC)

Authorization of 12 months may be granted for treatment of moderately to severely active ulcerative colitis.

Immune checkpoint inhibitor-related toxicity

Authorization of 6 months may be granted for treatment of immune checkpoint inhibitor-related diarrhea or colitis when the member has experienced an inadequate response, intolerance, or has a contraindication to infliximab or vedolizumab.

CONTINUATION OF THERAPY

Plaque psoriasis (PsO)

Authorization of 12 months may be granted for all members 6 years of age and older (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when either of the following is met:

- Reduction in body surface area (BSA) affected from baseline
- Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

Psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members 6 years of age or older (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of swollen joints
- Number of tender joints
- Dactylitis

- Enthesitis
- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

Crohn's Disease (CD)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain remission.

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Abdominal pain or tenderness
- Diarrhea
- Body weight
- Abdominal mass
- Hematocrit
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
- Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

Ulcerative colitis

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Stool frequency
- Rectal bleeding
- Urgency of defecation
- C-reactive protein (CRP)
- Fecal calprotectin (FC)
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
- Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

Immune checkpoint inhibitor-related toxicity

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

OTHER

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

APPENDIX

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Imuldosa IV (Ustekinumab-srlf)	Crohn's Disease	Route of Administration: Intravenous ≥18 year(s) <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Imuldosa IV (Ustekinumab-srlf)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration: Intravenous <56kg 260mg once 56 - <86kg 390mg once

		≥86kg 520mg once
Imuldosa IV (Ustekinumab-srlf)	Ulcerative Colitis	Route of Administration: Intravenous ≥18 year(s) <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Imuldosa SC (Ustekinumab-srlf)	Crohn's Disease	Route of Administration: Subcutaneous ≥18 year(s) 90mg every 8 weeks; 90mg every 4 weeks for incomplete response
Imuldosa SC (Ustekinumab-srlf)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration: Subcutaneous 90mg every 8 weeks
Imuldosa SC (Ustekinumab-srlf)	Plaque Psoriasis	Route of Administration: Subcutaneous ≥18 year(s) <101kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks 60 - <101kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 year(s) ≥101kg Initial: 90mg on weeks 0 and 4 Maintenance: 90mg every 12 weeks
Imuldosa SC (Ustekinumab-srlf)	Psoriatic Arthritis	Route of Administration: Subcutaneous ≥18 year(s) Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 to <18 year(s) ≥60kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks
Imuldosa SC (Ustekinumab-srlf)	Psoriatic Arthritis with Co-existent Plaque Psoriasis	Route of Administration: Subcutaneous ≥6 year(s) ≥101kg Initial: 90mg on weeks 0 and 4 Maintenance: 90mg every 12 weeks
Imuldosa SC (Ustekinumab-srlf)	Ulcerative Colitis	Route of Administration: Subcutaneous ≥18 year(s)

		90mg every 8 weeks; 90mg every 4 weeks for incomplete response
Otulfi IV (Ustekinumab-aauz)	Crohn's Disease	Route of Administration: Intravenous ≥18 year(s) <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Otulfi IV (Ustekinumab-aauz)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration :Intravenous <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Otulfi IV (Ustekinumab-aauz)	Ulcerative Colitis	Route of Administration: Intravenous ≥18 year(s) <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Otulfi SC (Ustekinumab-aauz)	Crohn's Disease	Route of Administration: Subcutaneous ≥18 year(s) 90mg every 8 weeks; 90mg every 4 weeks for incomplete response
Otulfi SC (Ustekinumab-aauz)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration: Subcutaneous 90mg every 8 weeks
Otulfi SC (Ustekinumab-aauz)	Plaque Psoriasis	Route of Administration: Subcutaneous ≥18 year(s) <101kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks 60 - <101kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 year(s)

		≥101kg Initial: 90mg on weeks 0 and 4 Maintenance: 90mg every 12 weeks
Otulfi SC (Ustekinumab-aauz)	Psoriatic Arthritis	Route of Administration: Subcutaneous ≥18 year(s) Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 to <18 year(s) ≥60kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks
Otulfi SC (Ustekinumab-aauz)	Psoriatic Arthritis with Co-existent Plaque Psoriasis	Route of Administration: Subcutaneous ≥6 year(s) ≥101kg Initial: 90mg on weeks 0 and 4 Maintenance: 90mg every 12 weeks
Otulfi SC (Ustekinumab-aauz)	Ulcerative Colitis	Route of Administration: Subcutaneous ≥18 year(s) 90mg every 8 weeks; 90mg every 4 weeks for incomplete response
Pyzchiva IV (Ustekinumab-ttwe)	Crohn's Disease	Route of Administration: Intravenous ≥18 year(s) <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Pyzchiva IV (Ustekinumab-ttwe)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration: Intravenous <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Pyzchiva IV (Ustekinumab-ttwe)	Ulcerative Colitis	Route of Administration: Intravenous ≥18 year(s) <56kg 260mg once 56 - <86kg 390mg once

		≥86kg 520mg once
Pyzchiva SC (Ustekinumab-ttwe)	Crohn's Disease	Route of Administration: Subcutaneous ≥18 year(s) 90mg every 8 weeks; 90mg every 4 weeks for incomplete response
Pyzchiva SC (Ustekinumab-ttwe)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration: Subcutaneous 90mg every 8 weeks
Pyzchiva SC (Ustekinumab-ttwe)	Plaque Psoriasis	Route of Administration: Subcutaneous ≥18 year(s) <101kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 to <18 year(s) <60kg Initial: 0.75mg/kg on weeks 0 and 4 Maintenance: 0.75mg/kg every 12 weeks 60 - <101kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 year(s) ≥101kg Initial: 90mg on weeks 0 and 4 Maintenance: 90mg every 12 weeks
Pyzchiva SC (Ustekinumab-ttwe)	Psoriatic Arthritis	Route of Administration: Subcutaneous ≥18 year(s) Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 to <18 year(s) <60kg Initial: 0.75mg/kg on weeks 0 and 4 Maintenance: 0.75mg/kg every 12 weeks ≥60kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks
Pyzchiva SC (Ustekinumab-ttwe)	Psoriatic Arthritis with Co-existent Plaque Psoriasis	Route of Administration: Subcutaneous ≥6 year(s) ≥101kg Initial: 90mg on weeks 0 and 4 Maintenance: 90mg every 12 weeks
Pyzchiva SC (Ustekinumab-ttwe)	Ulcerative Colitis	Route of Administration: Subcutaneous ≥18 year(s) 90mg every 8 weeks;

		90mg every 4 weeks for incomplete response
Selarsdi IV (Ustekinumab-aekn)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration: Intravenous <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Selarsdi IV (Ustekinumab-aekn)	Crohn's Disease	Route of Administration: Intravenous ≥18 year(s) <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Selarsdi IV (Ustekinumab-aekn)	Ulcerative Colitis	Route of Administration: Intravenous ≥18 year(s) <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Selarsdi SC (Ustekinumab-aekn)	Crohn's Disease	Route of Administration: Subcutaneous ≥18 year(s) 90mg every 8 weeks; 90mg every 4 weeks for incomplete response
Selarsdi SC (Ustekinumab-aekn)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration: Subcutaneous 90mg every 8 weeks
Selarsdi SC (Ustekinumab-aekn)	Plaque Psoriasis	Route of Administration: Subcutaneous ≥18 year(s) <101kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 to <18 year(s) <60kg Initial: 0.75mg/kg on weeks 0 and 4 Maintenance: 0.75mg/kg every 12 weeks 60 - <101kg

		Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 year(s) ≥101kg Initial: 90mg on weeks 0 and 4 Maintenance: 90mg every 12 weeks
Selarsdi SC (Ustekinumab-aekn)	Psoriatic Arthritis	Route of Administration: Subcutaneous ≥18 year(s) Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 to <18 year(s) <60kg Initial: 0.75mg/kg on weeks 0 and 4 Maintenance: 0.75mg/kg every 12 weeks ≥60kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks
Selarsdi SC (Ustekinumab-aekn)	Psoriatic Arthritis with Co-existent Plaque Psoriasis	Route of Administration: Subcutaneous ≥6 year(s) ≥101kg Initial: 90mg on weeks 0 and 4 Maintenance: 90mg every 12 weeks
Selarsdi SC (Ustekinumab-aekn)	Ulcerative Colitis	Route of Administration: Subcutaneous ≥18 year(s) 90mg every 8 weeks; 90mg every 4 weeks for incomplete response
Starjemza (Ustekinumab-hmny)	Crohn's Disease	Route of Administration: Intravenous ≥18 year(s) <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Starjemza (Ustekinumab-hmny)	Crohn's Disease	Route of Administration: Subcutaneous ≥18 year(s) 90mg every 8 weeks; 90mg every 4 weeks for incomplete response
Starjemza (Ustekinumab-hmny)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration: Intravenous <56kg 260mg once 56 - <86kg

		390mg once ≥86kg 520mg once
Starjemza (Ustekinumab-hmny)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration: Subcutaneous 90mg every 8 weeks
Starjemza (Ustekinumab-hmny)	Plaque Psoriasis	Route of Administration: Subcutaneous ≥18 year(s) <101kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 to <18 year(s) <60kg Initial: 0.75mg/kg on weeks 0 and 4 Maintenance: 0.75mg/kg every 12 weeks 60 - <101kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 year(s) ≥101kg Initial: 90mg on weeks 0 and 4 Maintenance: 90mg every 12 weeks
Starjemza (Ustekinumab-hmny)	Psoriatic Arthritis	Route of Administration: Subcutaneous ≥18 year(s) Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 to <18 year(s) <60kg Initial: 0.75mg/kg on weeks 0 and 4 Maintenance: 0.75mg/kg every 12 weeks ≥60kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks
Starjemza(Ustekinumab-hmny)	Psoriatic Arthritis with Co-existent Plaque Psoriasis	Route of Administration: Subcutaneous ≥6 year(s) ≥101kg Initial: 90mg on weeks 0 and 4 Maintenance: 90mg every 12 weeks
Starjemza (Ustekinumab-hmny)	Ulcerative Colitis	Route of Administration: Intravenous ≥18 year(s) <56kg 260mg once 56 - <86kg 390mg once

		≥86kg 520mg once
Starjemza (Ustekinumab-hmny)	Ulcerative Colitis	Route of Administration: Subcutaneous ≥18 year(s) 90mg every 8 weeks; 90mg every 4 weeks for incomplete response
Stelara (Ustekinumab)	Crohn's Disease	Route of Administration: Intravenous ≥18 year(s) <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Stelara (Ustekinumab)	Crohn's Disease	Route of Administration: Subcutaneous ≥18 year(s) 90mg every 8 weeks; 90mg every 4 weeks for incomplete response
Stelara (Ustekinumab)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration: Intravenous <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Stelara (Ustekinumab)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration: Subcutaneous 90mg every 8 weeks
Stelara (Ustekinumab)	Plaque Psoriasis	Route of Administration: Subcutaneous ≥18 year(s) <101kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 to <18 year(s) <60kg Initial: 0.75mg/kg on weeks 0 and 4 Maintenance: 0.75mg/kg every 12 weeks 60 - <101kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 year(s) ≥101kg

		Initial: 90mg on weeks 0 and 4 Maintenance: 90mg every 12 weeks
Stelara (Ustekinumab)	Psoriatic Arthritis	Route of Administration: Subcutaneous ≥18 year(s) Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 to <18 year(s) <60kg Initial: 0.75mg/kg on weeks 0 and 4 Maintenance: 0.75mg/kg every 12 weeks ≥60kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks
Stelara (Ustekinumab)	Psoriatic Arthritis with Co-existent Plaque Psoriasis	Route of Administration: Subcutaneous ≥6 year(s) ≥101kg Initial: 90mg on weeks 0 and 4 Maintenance: 90mg every 12 weeks
Stelara (Ustekinumab)	Ulcerative Colitis	Route of Administration: Intravenous ≥18 year(s) <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Stelara (Ustekinumab)	Ulcerative Colitis	Route of Administration: Subcutaneous ≥18 year(s) 90mg every 8 weeks; 90mg every 4 weeks for incomplete response
Steqeyma IV (Ustekinumab-stba)	Crohn's Disease	Route of Administration: Intravenous ≥18 year(s) <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Steqeyma IV (Ustekinumab-stba)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration: Intravenous <56kg 260mg once 56 - <86kg

		390mg once ≥86kg 520mg once
Steqeyma IV (Ustekinumab-stba)	Ulcerative Colitis	Route of Administration: Intravenous ≥18 year(s) <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Steqeyma SC (Ustekinumab-stba)	Crohn's Disease	Route of Administration: Subcutaneous ≥18 year(s) 90mg every 8 weeks; 90mg every 4 weeks for incomplete response
Steqeyma SC (Ustekinumab-stba)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration: Subcutaneous 90mg every 8 weeks
Steqeyma SC (Ustekinumab-stba)	Plaque Psoriasis	Route of Administration: Subcutaneous ≥18 year(s) <101kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks 60 - <101kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 year(s) ≥101kg Initial: 90mg on weeks 0 and 4 Maintenance: 90mg every 12 weeks
Steqeyma SC (Ustekinumab-stba)	Psoriatic Arthritis	Route of Administration: Subcutaneous ≥18 year(s) Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 to <18 year(s) ≥60kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks
Steqeyma SC (Ustekinumab-stba)	Psoriatic Arthritis with Co-existent Plaque Psoriasis	Route of Administration: Subcutaneous ≥6 year(s) ≥101kg Initial: 90mg on weeks 0 and 4 Maintenance: 90mg every 12 weeks

Steqeyma SC (Ustekinumab-stba)	Ulcerative Colitis	Route of Administration: Subcutaneous ≥18 year(s) 90mg every 8 weeks; 90mg every 4 weeks for incomplete response
Wezlana IV (Ustekinumab-auub)	Crohn's Disease	Route of Administration: Intravenous ≥18 year(s) <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Wezlana IV (Ustekinumab-auub)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration: Intravenous <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Wezlana IV (Ustekinumab-auub)	Ulcerative Colitis	Route of Administration: Intravenous ≥18 year(s) <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Wezlana SC (Ustekinumab-auub)	Crohn's Disease	Route of Administration: Subcutaneous ≥18 year(s) 90mg every 8 weeks; 90mg every 4 weeks for incomplete response
Wezlana SC (Ustekinumab-auub)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration: Subcutaneous 90mg every 8 weeks
Wezlana SC (Ustekinumab-auub)	Plaque Psoriasis	Route of Administration: Subcutaneous ≥18 year(s) <101kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 to <18 year(s) <60kg Initial: 0.75mg/kg on weeks 0 and 4

		Maintenance: 0.75mg/kg every 12 weeks 60 - <101kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 year(s) ≥101kg Initial: 90mg on weeks 0 and 4 Maintenance: 90mg every 12 weeks
Wezlana SC(Ustekinumab-auub)	Psoriatic Arthritis	Route of Administration: Subcutaneous ≥18 year(s) Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 to <18 year(s) <60kg Initial: 0.75mg/kg on weeks 0 and 4 Maintenance: 0.75mg/kg every 12 weeks ≥60kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks
Wezlana SC (Ustekinumab-auub)	Psoriatic Arthritis with Co-existent Plaque Psoriasis	Route of Administration: Subcutaneous ≥6 year(s) ≥101kg Initial: 90mg on weeks 0 and 4 Maintenance: 90mg every 12 weeks
Wezlana SC (Ustekinumab-auub)	Ulcerative Colitis	Route of Administration: Subcutaneous ≥18 year(s) 90mg every 8 weeks; 90mg every 4 weeks for incomplete response
Yesintek IV (Ustekinumab-kfce)	Crohn's Disease	Route of Administration: Intravenous ≥18 year(s) <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Yesintek IV (Ustekinumab-kfce)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration: Intravenous <56kg 260mg once 56 - <86kg 390mg once

		≥86kg 520mg once
Yesintek IV (Ustekinumab-kfce)	Ulcerative Colitis	Route of Administration: Intravenous ≥18 year(s) <56kg 260mg once 56 - <86kg 390mg once ≥86kg 520mg once
Yesintek SC (Ustekinumab-kfce)	Crohn's Disease	Route of Administration: Subcutaneous ≥18 year(s) 90mg every 8 weeks; 90mg every 4 weeks for incomplete response
Yesintek SC (Ustekinumab-kfce)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration: Subcutaneous 90mg every 8 weeks
Yesintek SC (Ustekinumab-kfce)	Plaque Psoriasis	Route of Administration: Subcutaneous ≥18 year(s) <101kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 to <18 year(s) <60kg Initial: 0.75mg/kg on weeks 0 and 4 Maintenance: 0.75mg/kg every 12 weeks 60 - <101kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 year(s) ≥101kg Initial: 90mg on weeks 0 and 4 Maintenance: 90mg every 12 weeks
Yesintek SC (Ustekinumab-kfce)	Psoriatic Arthritis	Route of Administration: Subcutaneous ≥18 year(s) Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks ≥6 to <18 year(s) <60kg Initial: 0.75mg/kg on weeks 0 and 4 Maintenance: 0.75mg/kg every 12 weeks ≥60kg Initial: 45mg on weeks 0 and 4 Maintenance: 45mg every 12 weeks

Yesintek SC (Ustekinumab-kfce)	Psoriatic Arthritis with Co-existent Plaque Psoriasis	Route of Administration: Subcutaneous ≥6 year(s) ≥101kg Initial: 90mg on weeks 0 and 4 Maintenance: 90mg every 12 weeks
Yesintek SC (Ustekinumab-kfce)	Ulcerative Colitis	Route of Administration: Subcutaneous ≥18 year(s) 90mg every 8 weeks; 90mg every 4 weeks for incomplete response

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; June 2025.
2. Imuldosa [package insert]. Raleigh, NC: Accord BioPharma Inc.; October 2024.
3. Otulfi [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; September 2024.
4. Pyzchiva [package insert]. Princeton, NJ: Sandoz Inc.; December 2024.
5. Selarsdi [package insert]. Leesburg, VA: Alvotech USA Inc.; October 2024.
6. Starjemza [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; May 2025.
7. Steqeyma [package insert]. Jersey City, NJ: Celltrion USA, Inc.; June 2025.
8. ustekinumab [package insert]. Horsham, PA: Janssen Biotech, Inc.; April 2025.
9. ustekinumab-aauz [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; April 2025
10. ustekinumab-aekn [package insert]. Leesburg, VA: Alvotech USA Inc.; October 2024.
11. ustekinumab-auub [package insert]. Thousand Oaks, CA: Amgen Inc.; September 2025.
12. ustekinumab-stba [package insert]. Jersey City, NJ: Celltrion USA, Inc.; April 2025
13. ustekinumab-ttwe [package insert]. Grand Cayman, Cayman Islands: Quallent Pharmaceuticals Health LLC; March 2025.
14. Wezlana [package insert]. Thousand Oaks, CA: Amgen Inc.; December 2024.
15. Yesintek [package insert]. Cambridge, MA: Biocon Biologics Inc.; November 2024.
16. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.

17. Gossec L, Baraliakos X, Kerschbaumer A, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. Ann Rheum Dis. 2020;79(6):700-712.
18. Gladman DD, Antoni C, Mease P, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. Ann Rheum Dis 2005;64(Suppl II):ii14–ii17.
19. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. Am J Gastroenterol. 2011;106(Suppl 1):S2-S25.
20. Lichtenstein GR, Loftus ~~Jr~~ EV, Afzali A, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2025;120:1225-1264.
21. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072.
22. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on January 21, 2025 from: https://www.cdc.gov/tb/testing/index/html.
23. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol.2025;120:1187-1224.
24. Singh S, Loftus EV Jr, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. Gastroenterology. 2024;167(7):1307-1343.
25. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32. doi:10.1002/art.40726.
26. Menter A, Cordero KM, Davis DM, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis in pediatric patients. J Am Acad Dermatol. 2020;82(1):161-201.
27. Menter A, Gelfand JM, Connor C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6): 1445-86.
28. Scott FI, Ananthakrishnan AN, Click B, et al. AGA Living Clinical Practice Guideline on the Pharmacologic Management of Moderate -to-Severe Crohn's Disease. Gastroenterology. 2025;169(7):1397-1448.
29. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 14, 2025.
30. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. Nat Rev Rheumatol. 2022;18(8):465-479.
31. NCCN Clinical Practice Guidelines in Oncology® (NCCN Guidelines®). Management of Immunotherapy-related Toxicities. Version 1.2025. Available at: www.nccn.org. Accessed January 21, 2025.

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