# 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-aekn

## 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)
Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

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**

The 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 adult members for treatment of moderately to severely active Crohn's disease.

**Ulcerative Colitis (UC)**

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

**Immune Checkpoint Inhibitor-Related Toxicity**

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

**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.

**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 |
|---|---|---|
| Stelara (Ustekinumab)<br>Wezlana (Ustekinumab-auub) | Crohn's Disease | Route of Administration: Intravenous<br>≥18 Years<br><56kg<br>260mg once<br><br>56 -<86kg<br>390mg once<br><br>≥86kg<br>520mg once |
| Stelara (Ustekinumab)<br>Wezlana (Ustekinumab-auub) | Crohn's Disease | Route of Administration: Subcutaneous<br>≥18 Years<br>90mg every 4 weeks |
| Stelara (Ustekinumab)<br>Wezlana (Ustekinumab-auub) | Immune Checkpoint Inhibitor-Related Toxicity | Route of Administration: Intravenous<br><56kg<br>260mg once |

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|---|---|---|
| | | 56 -<86kg<br>390mg once<br><br>≥86kg<br>520mg once |
| Stelara (Ustekinumab)<br>Wezlana (Ustekinumab-auub) | Immune Checkpoint Inhibitor-Related Toxicity | Route of Administration: Subcutaneous<br>90mg every 8 weeks |
| Stelara (Ustekinumab)<br>Wezlana (Ustekinumab-auub) | Plaque Psoriasis | Route of Administration: Subcutaneous<br>≥18 Year(s)<br><101kg<br>Initial: 45mg on weeks 0 and 4<br>Maintenance: 45mg every 12 weeks<br><br>≥ 6 to <18 Year(s)<br>< 60kg<br>Initial: 0.75mg/kg on weeks 0 and 4<br>Maintenance: 0.75mg/kg every 12 weeks<br><br>60 - < 101kg<br>Initial: 45mg on weeks 0 and 4<br>Maintenance: 45mg every 12 weeks<br><br>≥6 Year(s)<br>≥101kg<br>Initial: 90mg on weeks 0 and 4<br>Maintenance: 90mg every 12 weeks |
| Stelara (Ustekinumab)<br>Wezlana (Ustekinumab-auub) | Psoriatic Arthritis | Route of Administration: Subcutaneous<br>≥18 Year(s)<br>Initial: 45mg on weeks 0 and 4<br>Maintenance: 45mg every 12 weeks<br><br>≥6 to <18 Year(s)<br><60kg<br>Initial: 0.75mg/kg on weeks 0 and 4<br>Maintenance: 0.75mg/kg every 12 weeks<br><br>≥60kg<br>Initial: 45mg on weeks 0 and 4<br>Maintenance: 45mg every 12 weeks<br><br>≥6 Year(s)<br>≥101kg |

| | | |
|---|---|---|
| | | Initial: 90mg on weeks 0 and 4<br>Maintenance: 90mg every 12 weeks |
| Stelara (Ustekinumab)<br>Wezlana (Ustekinumab-auub) | Ulcerative Colitis | Route of Administration: Intravenous<br>≥18 Year(s)<br><56kg<br>260mg once<br><br>56- < 86kg<br>390mg once<br><br>≥ 86kg<br>520mg once |
| Stelara (Ustekinumab)<br>Wezlana (Ustekinumab-auub) | Ulcerative Colitis | Route of Administration: Subcutaneous<br>≥18 Years<br>90mg every 4 weeks |

## 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).

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**EFFECTIVE DATE** 5/31/2025

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