AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Stelara and Biosimilars	Page:	1 of 13
Effective Date:	3/9/2026	Last Review Date:	1/2026

Applies to:	☐Illinois	☐Florida	☒Florida Kids
	☐New Jersey	☒Maryland	☐Michigan
	☒Pennsylvania Kids	☐Virginia	☒Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Stelara under the patient's prescription drug benefit.

Description:

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.

Applicable Drug List:

Preferred:
Imuldosa (ustekinumab-srlf)
Steqeyma (ustekinumab-stba)
Yesintek (ustekinumab-kfce)

Non-preferred:
Stelara (ustekinumab)
Otulfi (ustekinumab-aauz)
Pyzchiva (ustekinumab-ttwe)
Selarsdi (ustekinumab-aekn)
Starjemza (ustekinumab-hmny)
Wezlana (ustekinumab-auub)
ustekinumab (unbranded Stelara)
ustekinumab-aauz (unbranded Otulfi)
ustekinumab-aekn (unbranded Selarsdi)

ustekinumab-auub (unbranded Wezlana)
ustekinumab-srlf (unbranded Imuldosa)
ustekinumab-stba (unbranded Steqeyma)
ustekinumab-ttwe (unbranded Pyzchiva)

Policy/Guideline:

Documentation for all indications:
The patient is unable to take Imuldosa (ustekinumab-srlf), Steqeyma (ustekinumab-stba) and Yesintek (ustekinumab-kfce), where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

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 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 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

Approval Duration and Quantity Restrictions:

Approval:

Initial Approval:

- 6 months for Immune checkpoint inhibitor-related toxicity
- 12 months for all other indications

Renewal Approval:

- 6 months for Immune checkpoint inhibitor-related toxicity
- 12 months for all other indications

Quantity Level Limit:

- Stelara (ustekinumab) 130 mg/26 mL single-dose vial
  - 4 vials (1 dose)
  - Exception limit: N/A
- Stelara (ustekinumab) subcutaneous injection 45 mg/0.5 mL single-dose vial/prefilled syringe
  - 1 vial/syringe per 84 days
  - Exception limit: 2 vials/syringes per 28 days
- Stelara (ustekinumab) subcutaneous injection 90 mg/mL prefilled syringe
  - 1 syringe per 56 days
  - Exception limit: 2 syringes per 28 days
- ustekinumab 130 mg/26 mL single-dose vial
  - 4 vials (1 dose)

  - Exception limit: N/A
- ustekinumab subcutaneous injection 45 mg/0.5 mL single-dose vial/prefilled syringe
  - 1 vial/syringe per 84 days
  - Exception limit: 2 vials/syringes per 28 days
- ustekinumab subcutaneous injection 90 mg/mL prefilled syringe
  - 1 syringe per 56 days
  - Exception limit: 2 syringes per 28 days
- Imuldosa (ustekinumab-srlf) 130 mg/26 mL single-dose vial
  - 4 vials (1 dose)
  - Exception limit: N/A
- Imuldosa (ustekinumab-srlf) subcutaneous injection 45 mg/0.5 mL prefilled syringe
  - 1 syringe per 84 days
  - Exception limit: 2 syringes per 28 days
- Imuldosa (ustekinumab-srlf) subcutaneous injection 90 mg/mL prefilled syringe
  - 1 syringe per 56 days
  - Exception limit: 2 syringes per 28 days
- ustekinumab-srlf 130 mg/26 mL single-dose vial
  - 4 vials (1 dose)
  - Exception limit: N/A
- ustekinumab-srlf subcutaneous injection 45 mg/0.5 mL prefilled syringe
  - 1 syringe per 84 days
  - Exception limit:2 syringes per 28 days
- ustekinumab-srlf subcutaneous injection 90 mg/mL prefilled syringe
  - 1 syringe per 56 days
  - Exception limit:2 syringes per 28 days
- Otulfi (ustekinumab-aauz) 130 mg/26 mL single-dose vial
  - 4 vials (1 dose)
  - Exception limit: N/A
- Otulfi (ustekinumab-aauz) subcutaneous injection 45 mg/0.5 mL vial/prefilled syringe
  - 1 vial/syringe per 84 days
  - Exception limit: 2 vials/syringes per 28 days
- Otulfi (ustekinumab-aauz) subcutaneous injection 90 mg/mL prefilled syringe
  - 1 syringe per 56 days
  - Exception limit: 2 syringes per 28 days
- ustekinumab-aauz 130 mg/26 mL single-dose vial

  - 4 vials (1 dose)
  - Exception limit: N/A
- ustekinumab-aauz subcutaneous injection 45 mg/0.5 mL vial/prefilled syringe
  - 1 vial/syringe per 84 days
  - Exception limit: 2 syringes per 28 days
- ustekinumab-aauz subcutaneous injection 90 mg/mL prefilled syringe
  - 1 syringe per 56 days
  - Exception limit: 2 syringes per 28 days
- Pyzchiva (ustekinumab-ttwe) 130 mg/26 mL single-dose vial
  - 4 vials (1 dose)
  - Exception limit: N/A
- Pyzchiva (ustekinumab-ttwe) subcutaneous injection 45 mg/0.5 mL single-dose vial/prefilled syringe/autoinjector
  - 1 vial/syringe/autoinjector per 84 days
  - Exception limit: 2 vials/syringes/autoinjectors per 28 Days
- Pyzchiva (ustekinumab-ttwe) subcutaneous injection 90 mg/mL prefilled syringe/autoinjector
  - 1 syringe/autoinjector per 56 days
  - Exception limit: 2 syringes/autoinjectors per 28 days
- ustekinumab-ttwe 130 mg/26 mL single-dose vial
  - 4 vials (1 dose)
  - Exception limit: N/A
- ustekinumab-ttwe subcutaneous injection 45 mg/0.5 mL single-dose prefilled syringe
  - 1 syringe per 84 days
  - Exception limit: 2 syringes per 28 Days
- ustekinumab-ttwe subcutaneous injection 90 mg/mL prefilled syringe
  - 1 syringe per 56 days
  - Exception limit: 2 syringes per 28 days
- Selarsdi (ustekinumab-aekn) 130 mg/26 mL single-dose vial
  - 4 vials (1 dose)
  - Exception limit: N/A
- Selarsdi (ustekinumab-aekn) subcutaneous injection 45 mg/0.5 mL vial/prefilled syringe
  - 1 vial/syringe per 84 days
  - Exception limit: 2 vials/syringes per 28 days
- Selarsdi (ustekinumab-aekn) subcutaneous injection 90 mg/mL prefilled syringe

  - 1 syringe per 56 days
  - Exception limit: 2 syringes per 28 days
- ustekinumab-aekn 130 mg/26 mL single-dose vial
  - 4 vials (1 dose)
  - Exception limit: N/A
- ustekinumab-aekn subcutaneous injection 45 mg/0.5 mL vial/prefilled syringe
  - 1 vial/syringe per 84 days
  - Exception limit: 2 vials/syringes per 28 days
- ustekinumab-aekn subcutaneous injection 90 mg/mL prefilled syringe
  - 1 syringe per 56 days
  - Exception limit: 2 syringes per 28 days
- Starjemza (ustekinumab-hmny) 130 mg/26 mL single-dose vial:
  - 4 vials (1 dose)
  - Exception limit: N/A
- Starjemza (ustekinumab-hmny) subcutaneous injection 45 mg/0.5 mL single-dose vial/prefilled syringe:
  - 1 vial/syringe per 84 days
  - Exception limit: 2 vials/syringes per 28 days
- Starjemza (ustekinumab-hmny) subcutaneous injection 90 mg/mL prefilled syringe:
  - 1 syringe per 56 days
  - Exception limit: 2 syringes per 28 days
- Steqeyma (ustekinumab-stba) 130 mg/26 mL single-dose vial
  - 4 vials (1 dose)
  - Exception limit: N/A
- Steqeyma (ustekinumab-stba) subcutaneous injection 45 mg/0.5 mL single-dose vial/prefilled syringe
  - 1 vial/syringe per 84 days
  - Exception limit: 2 vials/syringes per 28 days
- Steqeyma (ustekinumab-stba) subcutaneous injection 90 mg/mL prefilled syringe
  - 1 syringe per 56 days
  - Exception limit: 2 syringes per 28 days
- ustekinumab-stba 130 mg/26 mL single-dose vial
  - 4 vials (1 dose)
  - Exception limit: N/A

- ustekinumab-stba subcutaneous injection 45 mg/0.5 mL single-dose vial/prefilled syringe
  - 1 vial/syringe per 84 days
  - Exception limit: 2 vials/syringes per 28 days
- ustekinumab-stba subcutaneous injection 90 mg/mL prefilled syringe
  - 1 syringe per 56 days
  - Exception limit: 2 syringes per 28 days
- Wezlana (ustekinumab-auub) 130 mg/26 mL single-dose vial
  - 4 vials (1 dose)
  - Exception limit: N/A
- Wezlana (ustekinumab-auub) subcutaneous injection 45 mg/0.5 mL single-dose vial/prefilled syringe/ConfiPen autoinjector
  - 1 vial/syringe/autoinjector per 84 days
  - Exception limit: 2 vials/syringes/autoinjectors per 28 days
- Wezlana (ustekinumab-auub) subcutaneous injection 90 mg/mL prefilled syringe/ConfiPen autoinjector
  - 1 syringe/autoinjector per 56 days
  - Exception limit: 2 syringes/autoinjectors per 28 days
- ustekinumab-auub 130 mg/26 mL single-dose vial
  - 4 vials (1 dose)
  - Exception limit: N/A
- ustekinumab-auub subcutaneous injection 45 mg/0.5 mL single-dose vial/prefilled syringe/autoinjector
  - 1 vial/syringe/autoinjector per 84 days
  - Exception limit: 2 vials/syringes/ autoinjectors per 28 days
- ustekinumab-auub subcutaneous injection 90 mg/mL prefilled syringe/autoinjector
  - 1 syringe/autoinjector per 56 days
  - Exception limit: 2 syringes/autoinjectors per 28 days
- Yesintek (ustekinumab-kfce) 130 mg/26 mL single-dose vial
  - 4 vials (1 dose)
  - Exceptionl imit: N/A
- Yesintek (ustekinumab-kfce) subcutaneous injection 45 mg/0.5 mL single-dose vial/prefilled syringe
  - 1 vial/syringe per 84 days
  - Exception limit: 2 vials/syringes per 28 days

- Yesintek (ustekinumab-kfce) subcutaneous injection 90 mg/mL prefilled syringe
  - 1 syringe per 56 days
  - Exception limit: 2 syringes per 28 days

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