AETNA BETTER HEALTH®
Coverage Policy/Guideline

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| Name: | Stelara | Page: | 1 of 9 |
| Effective Date: | 11/15/2023 | Last Review Date: | 10/20023 |

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| 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:

A. FDA-Approved Indications
   1. Moderate to severe plaque psoriasis (PsO) in patients 6 years or older who are candidates for phototherapy or systemic therapy
   2. Active psoriatic arthritis (PsA) in patients 6 years or older
   3. Moderately to severely active Crohn's disease (CD) in adults
   4. Moderately to severely active ulcerative colitis (UC) in adults

B. Compendial Uses
   Immune checkpoint inhibitor-related toxicity

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

## Applicable Drug List:

Stelara

## Policy/Guideline:

**Documentation for all indications:**
The patient is unable to take THREE preferred products, 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:**

A. **Plaque psoriasis**
   1. Initial requests:
      i. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected.
      ii. 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.
   2. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

B. **Psoriatic arthritis**
   1. 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.
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. **Crohn's disease**
   Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

D. **Ulcerative colitis**
   Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

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

**Prescriber Specialty:**
The medication must be prescribed by or in consultation with one of the following**:**

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

**Criteria for Initial Approval:**

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

   2. Authorization of 12 months may be granted for treatment of moderate to severe plaque psoriasis in members 6 years of age or older when any of the following criteria is met:
      i. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.

ii. At least 10% of the body surface area (BSA) is affected
iii. At least 3% of body surface area (BSA) is affected and the member meets any of the following criteria:
   a. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
   b. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).

**B. Psoriatic arthritis (PsA)**

1. 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.

2. 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:
   i. Member has mild to moderate disease and meets one of the following criteria:
      a. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
      b. Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix), or another conventional synthetic drug (e.g., sulfasalazine).
      c. Member has enthesitis or predominantly axial disease.
   ii. Member has severe disease.

**C. Crohn's disease (CD)**

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

**D. Ulcerative colitis (UC)**

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

**E. 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:**

**A. Plaque psoriasis (PsO)**

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 moderate to severe plaque psoriasis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met:

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

**B. 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 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:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement

**C. Crohn's Disease (CD)**

1. 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 or fistulizing Crohn's disease and who achieve or maintain remission.

2. 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 or fistulizing 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:
   i. Abdominal pain or tenderness
   ii. Diarrhea

iii. Body weight
iv. Abdominal mass
v. Hematocrit
vi. Endoscopic appearance of the mucosa
vii. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

**D. Ulcerative colitis**

1. 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.

2. 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:
   i. Stool frequency
   ii. Rectal bleeding
   iii. Urgency of defecation
   iv. C-reactive protein (CRP)
   v. Fecal calprotectin (FC)
   vi. Endoscopic appearance of the mucosa
   vii. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

**E. Immune checkpoint inhibitor-related toxicity**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

**Other Criteria:**

For all indications: Member has had a documented negative TB test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 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. 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.

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug.

Stelara for intravenous administration will only be authorized to use for the treatment of Crohn's disease, ulcerative colitis, and immune checkpoint inhibitor-related toxicity.

**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**
1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
2. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. 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 130 mg/26 mL single-dose vial:

- Standard Limit: 4 vials (1 dose)

Stelara subcutaneous injection 45 mg/0.5 mL single-dose vial/prefilled syringe:

- Standard Limit: 1 vial/syringe per 84 days
- Exception Limit: 2 vials/syringes per 28 days*

Stelara (ustekinumab) subcutaneous injection 90 mg/mL prefilled syringe:

- Standard Limit: 1 syringe per 56 days
- Exception Limit: 2 syringes per 28 days*

**FDA-Recommended Dosing:**

**CD, UC intravenous induction**

- ≤ 55 kg: 260 mg (2 vials)
- > 55 kg to 85 kg: 390 mg (3 vials)
- > 85 kg: 520 mg (4 vials)

**PsO, adult**

- ≤ 100 kg: 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks
- > 100 kg: 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks

**PsO, pediatric (6-17 years old):** Weight based dosing at the initial dose, 4 weeks later, and then every 12 weeks thereafter

- < 60 kg: 0.75 mg/kg
- 60 kg to 100 kg: 45 mg
- > 100 kg: 90 mg

**PsA, adult**

- 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks
- > 100 kg with co-existent PsO: 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks

**PsA, pediatric (6-17 years old):** Weight based dosing at the initial dose, 4 weeks later, and then every 12 weeks thereafter

- < 60 kg: 0.75 mg/kg
- 60 kg or more: 45 mg
- > 100 kg with co-existent PsO: 90 mg

**CD, UC maintenance dose**

- 90 mg 8 weeks after the initial intravenous dose, then every 8 weeks thereafter

*Coverage up to the exception limits may be provided with prior authorization

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