Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

STELARA® (ustekinumab) PA CRITERIA:

STELARA® (ustekinumab) is a human interleukin-12 and -23 antagonist indicated for the treatment of:

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

Prior authorization is required for STELARA® (ustekinumab). Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

Initial Authorization: 1 Year

1. The patient must meet the minimum age and weight requirements recommended by the package insert for the FDA approved indication; **AND**

2. The patient has a diagnosis of FDA approved indication; **AND**

3. The patient has a documented clinical justification from the prescriber on why all preferred biosimilars of ustekinumab must not be utilized; **AND**

4. Prescribed dose does not exceed the manufacturer's recommended dose based on the patient's age, weight and diagnosis.

Re-Authorization: 1 Year

1. The patient has a documented clinical justification from the prescriber on why the member could not be switched to any preferred biosimilars of ustekinumab. Note: A statement indicating that the patient is currently stabilized on brand STELARA® is not, on its own, considered an adequate clinical justification; **AND**

2. Patient continues to meet initial authorization criteria; **AND**

3. Prescribed dose does not exceed manufacturer's recommended dose based on the patient's age, weight, and diagnosis; **AND**

4. Documentation of positive clinical response to therapy.

STELARA® (ustekinumab) Dosing:

- Refer to manufacturer's prescribing information.

Formulation:

- STELARA® is available as 130mg/26mL single-dose vial for intravenous infusion, 45mg/0.5mL single-dose vial for subcutaneous injection, and 45mg/0.5mL or 90mg/1mL single-dose prefilled syringes for subcutaneous injection.