Mountain-Pacific Quality Health

Montana Healthcare Programs
Physicians Administered Drug Coverage Interim Criteria

STELARA® (ustekinumab)

I. Medication Description

Stelara® is an interleukin-12 and interleukin-23 antagonist indicated for:

- Moderate to severe plaque psoriasis in adults and children 6 years of age and older who are candidates for systemic therapy or phototherapy
- Active psoriatic arthritis in adults and children 6 years of age and older
- Moderately to severely active ulcerative colitis in adults
- Moderately to severely active Crohn's disease in adults

II. Position Statement

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

III. Initial Coverage Criteria

Moderate to Severe Plaque Psoriasis:

Member must meet all the following criteria:

- Member must be 6 years of age or older.
- Member must have diagnosis of moderate to severe plaque psoriasis.
- Must be prescribed by or in consult with an appropriate specialist (dermatologist/rheumatologist).
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Must have a trial and inadequate response or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List.
- Prescriber attests to the following:
    - The member has been screened for tuberculosis (TB) prior to initiating treatment.
    - The provider will monitor for active infection, malignancies, Posterior Reversible Encephalopathy Syndrome (PRES) and noninfectious pneumonia.
- Provider attests member **will not** use Stelara® concomitantly with other biologics.

Active Psoriatic Arthritis:

Member must meet all the following criteria:

- Member must be 6 years of age or older.
- Member must have diagnosis of psoriatic arthritis.
- Must be prescribed by or in consult with an appropriate specialist (rheumatologist).
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Must have a trial and inadequate response or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List.
- Prescriber attests to the following:

    - The member has been screened for TB prior to initiating treatment.
    - The provider will monitor for active infection, malignancies, Posterior Reversible Encephalopathy Syndrome (PRES) and noninfectious pneumonia.
- Provider attests member **will not** use Stelara® concomitantly with other biologics.

Moderately to Severely Active Ulcerative Colitis

Member must meet all the following criteria:

- Member must be 18 years of age or older.
- Member must have diagnosis of moderately to severely active ulcerative colitis.
- Must be prescribed by or in consult with an appropriate specialist (gastroenterologist).
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Must have a trial and inadequate response or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List.
- Prescriber attests to the following:
    - The member has been screened for TB prior to initiating treatment.
    - The provider will monitor for active infection, malignancies, Posterior Reversible Encephalopathy Syndrome (PRES) and noninfectious pneumonia.
- Provider attests member **will not** use Stelara® concomitantly with other biologics.

Moderately to Severely Active Crohn's Disease

Member must meet all the following criteria:

- Member must be 18 years of age or older.
- Member must have diagnosis of moderately to severely active Crohn's disease.
- Must be prescribed by or in consult with an appropriate specialist (gastroenterologist).
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Must have a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List.
- Prescriber attests to the following:
    - The member has been screened for TB prior to initiating treatment.
    - The provider will monitor for active infection, malignancies, Posterior Reversible Encephalopathy Syndrome (PRES) and noninfectious pneumonia.
- Provider attests that member **will not** use Stelara® concomitantly with other biologics.

IV. Renewal Coverage Criteria

- Member has documentation of positive clinical response to therapy (reduction in the frequency and/or severity of symptoms and exacerbations).
- Annual specialist consult provided if prescriber not a specialist.
- Provider attests member **will not** use Stelara® concomitantly with other biologics.

V. Quantity Limitations

Moderate to Severe Plaque Psoriasis:

- In **adults with psoriasis** the subcutaneous dose is weight-based:
    - ≤ 100kg = 45mg initially and 4 weeks later, then every 12 weeks
    - > 100kg = 90mg initially and 4 weeks later, then every 12 weeks

- In **pediatric patients aged 6 to 17 with psoriasis** the subcutaneous dose is weight-based:
    - < 60kg = 0.75mg/kg at week 0 and 4, then every 12 weeks
    - 60 - 100kg = 45mg at week 0 and 4, then every 12 weeks
    - > 100kg = 90mg at week 0 and 4, then every 12 weeks

Active Psoriatic Arthritis:

- In **adults with psoriatic arthritis** the subcutaneous dose is weight-based:
  - ≤ 100kg = 45mg initially and 4 weeks later, followed by 45mg every 12 weeks
  - > 100kg = 90mg initially and 4 weeks later, followed by 90mg every 12 weeks

- In **pediatric patients aged 6 to 17 with psoriatic arthritis** the subcutaneous dose is weight-based:
  - < 60kg = 0.75mg/kg at week 0 and 4, then every 12 weeks
  - ≥ 60kg = 45mg at week 0 and 4, then every 12 weeks
  - > 100kg with co-existent moderate to severe plaque psoriasis = 90mg at week 0 and 4, then every 12 weeks

Moderately to Severely Active Ulcerative Colitis:

- IV infusion for initial dose for **ulcerative colitis**
  - Initial intravenous infusion of Stelara® is based on body weight at time of dosing
    - Up to 55kg = 260mg
    - > 55kg to 85kg = 390mg
    - > 85kg = 520mg
- Subcutaneous injection for maintenance in **ulcerative colitis**
  - 90mg dose 8 weeks after initial IV dose, then every 8 weeks thereafter

Moderately to Severely Active Crohn's Disease:

- IV infusion for initial dose for **Crohn's Disease**
  - Initial intravenous infusion of Stelara® is based on body weight at time of dosing
    - Up to 55kg = 260mg
    - > 55kg to 85kg = 390mg
    - > 85kg = 520mg
- Subcutaneous injection for maintenance in **Crohn's Disease**
  - 90mg dose 8 weeks after initial IV dose, then every 8 weeks thereafter

VI. Coverage Duration

Plaque Psoriasis

- Initial approval: 3 doses (weeks 0, 4 and 16). Update required prior to dose at 28 weeks.
- Renewal approval duration: 1 year

Psoriatic Arthritis

- Initial approval: 3 doses (weeks 0, 4, and 16). Update required prior to dose at 28 weeks.
- Renewal approval duration: 1 year

Ulcerative Colitis

- Initial approval: 2 doses (infusion week 0, injection week 8). Update required prior to injection at week 16.
- Renewal approval duration: 1 year

Crohn's Disease

- Initial approval: 2 doses (infusion week 0, injection week 8). Update required prior to injection at week 16.
- Renewal approval duration: 1 year