

## ustekinumab subcutaneous injection (STELARA)

### Diagnoses Considered for Coverage:

- Plaque Psoriasis (PsO)
- Psoriatic Arthritis (PsA)
- Crohn's disease (CD)
- Ulcerative colitis (UC)

### Coverage Criteria:

#### For Plaque Psoriasis:

##### INITIAL AUTHORIZATION

- Patient is at least 6 years old, **and**
- Prescribed or recommended by a Rheumatologist or Dermatologist, **and**
- Inadequate response, intolerable side effect, or contraindication to one of the following: methotrexate, cyclosporine (Neoral), acitretin (Soriatane), **or** PUVA/UVB, **and**
- Not being used in combination with another targeted biologic, **and**
- Dose does not exceed one of the following:
  - *For  $\leq 100$  kg (220 lbs.)* - 45 mg given subcutaneously week #0, week #4, then every 12 weeks, **or**
  - *For  $> 100$  kg (220 lbs.)* - 90 mg given subcutaneously week #0, week #4, then every 12 weeks.

**Coverage Duration:** 24 weeks

##### REAUTHORIZATION

- Patient has shown improvement in the baseline PASI (or BSA if provided on initial request) score after the end of the initial 24 week course, **and**
- Not being used in combination with another targeted biologic, **and**
- Dose does not exceed one of the following:
  - *For  $\leq 100$  kg (220 lbs.)* - 45 mg given subcutaneously every 12 weeks, **or**
  - *For  $> 100$  kg (220 lbs.)* - 90 mg given subcutaneously every 12 weeks.

**Coverage Duration:** one year

#### For Psoriatic Arthritis:

- Prescribed or recommended by a rheumatologist, **and**
- Inadequate response or intolerable side effect with methotrexate, leflunomide, or sulfasalazine, **and**
- Not being used in combination with other targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors, JAK inhibitors), **and**

- Dose does not exceed one of the following:
  - For  $\leq 100$  kg (220 lbs) - 45 mg given subcutaneously on week #0 and week #4, followed by a maintenance dose of 45 mg given subcutaneously every 12 weeks, **or**
  - For  $> 100$  kg (220 lbs) - 90 mg given subcutaneously on week #0 and week #4, followed by a maintenance dose of 90 mg given subcutaneously every 12 weeks.

**Coverage Duration:** one year

**For Crohn's disease:**

**INITIAL AUTHORIZATION**

- Patient is at least 18 years old, **and**
- Patient has already received Stelara intravenous induction dosing and request is for maintenance therapy, **and**
- Dose does not exceed 90 mg subcutaneous given 8 weeks after the Stelara intravenous induction dose, then every 8 weeks thereafter.

**Coverage Duration:** one year

**REAUTHORIZATION**

- Patient has shown improvement in Crohn's disease, **and**
- Dose does not exceed 90 mg subcutaneous given every 8 weeks.

**Coverage Duration:** one year

**For ulcerative colitis:**

- Patient is at least 18 years old, **and**
- Being used for SQ maintenance therapy following IV induction dosing, **and**
- Not being used in combination with other targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors, JAK inhibitors), **and**
- Dose does not exceed 90 mg subcutaneous given 8 weeks after the intravenous induction dose, then every 8 weeks thereafter.

**Coverage Duration:** one year

**Coverage Duration:** see criteria above

Effective Date: 09/27/2023