BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 07/09/14
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

STELARA® (ustekinumab)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Stelara is a human IgG1K monoclonal antibody that binds with high affinity and specificity to the p40 protein subunit used by both the interleukin (IL)-12 and IL-23 cytokines. IL-12 and IL-23 are naturally occurring cytokines that are involved in inflammatory and immune responses, such as natural killer cell activation and CD4+ T-cell differentiation and activation.

Definitions:

Adult: Age 18 years and older

Preferred Tumor Necrosis Factor (TNF) Medications:
- Enbrel®
- Humira®
- Remicade®

STELARA (ustekinumab) (cont.)

Definitions: (cont.)

Significant Adverse Drug Event:
A significant adverse drug event is when an individual's outcome is death, life-threatening, hospitalization (initial or prolonged), disability resulting in a significant, persistent, or permanent change, impairment, damage or disruption in the individuals' body function/structure, physical activities or quality of life, or requires intervention to prevent permanent impairment or damage.

Criteria:

See Resources section for FDA-approved dosage.

- FDA-approved dosage of Stelara is considered ***medically necessary*** for adults with moderately to severely active plaque psoriasis who are candidates for phototherapy or systemic therapy with documentation of **ALL** of the following:

  1. Failed response to the preferred TNF medications Enbrel **AND** Humira **AND** Remicade (unless otherwise contraindicated) with documentation of **ANY** of the following: [1]

     - Individual's condition has not improved or has worsened
     - Individual experienced a significant adverse drug event to the preferred TNF medications
     - Individual is intolerant to the preferred TNF medications
     - Individual is non-adherent to the preferred TNF medications

  2. Failed response to **ONE** of the following conventional treatments (unless otherwise contraindicated):

     - Systemic therapy (Cyclosporin **or** Methotrexate **or** Retinoids)
     - PUVA therapy
     - Phototherapy

  3. No evidence of active serious infections including clinically important localized infections or sepsis when initiating or continuing therapy
  4. Evidence of testing for latent tuberculosis before Stelara use and during therapy and any treatment for latent infection has been initiated prior to Stelara therapy
  5. Stelara is not being used concurrently with live vaccines, immunosuppressive agents or phototherapy
  6. Dosage is not greater than the FDA approved dosing for the labeled indication (refer to dosing table)

STELARA (ustekinumab) (cont.)

Criteria: (cont.)

- FDA-approved dosage of Stelara is considered ***medically necessary*** for adults with active psoriatic arthritis, alone or in combination with methotrexate, with documentation of **ALL** of the following:

  1. Failed response to the preferred TNF medications Enbrel **AND** Humira **AND** Remicade (unless otherwise contraindicated) with documentation of **ANY** of the following: [1]

     - Individual's condition has not improved or has worsened
     - Individual experienced a significant adverse drug event to the preferred TNF medications
     - Individual is intolerant to the preferred TNF medications
     - Individual is non-adherent to the preferred TNF medications

  2. No evidence of active serious infections, including clinically important localized infections or sepsis, when initiating or continuing therapy
  3. Evidence of testing for latent tuberculosis before Stelara use and during therapy and any treatment for latent infection has been initiated prior to Stelara therapy
  4. Stelara is not being used concurrently with live vaccines, immunosuppressive agents or phototherapy
  5. Dosage is not greater than the FDA-approved dosing for the labeled indication (refer to dosing table)

- Stelara for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

[1] Not applicable for current members on Stelara prior to 07/09/14 or new members who are actively being treated with Stelara prior to their effective date with BCBSAZ. (Excludes any changes in route of administration, such as changing intravenous delivery to subcutaneous delivery.)

STELARA (ustekinumab) (cont.)

Resources:

Stelara Package Insert:

- FDA-approved indication and dosage:

Indication	Recommended Dose
Adult moderate to severe plaque psoriasis	Stelara is administered by subcutaneous injection. For patients weighing ≤ 100kg (220 lbs.), the recommended dose is 45mg initially and 4 weeks later, followed by 45 mg every 12 weeks. For patients weighing > 100kg (220 lbs.), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.
Adult active psoriatic arthritis	Stelara is administered by subcutaneous injection. The recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks. For patients with co-existent moderate-to-severe plaque psoriasis weighing >100 kg (220 lbs.), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.