Commercial/Healthcare Exchange PA Criteria

Effective: December 2009

Prior Authorization: Stelara

Products Affected: Stelara (ustekinumab) subcutaneous solution and intravenous infusion

Medication Description: Ustekinumab is an interleukin (IL)-12 and IL-23 antagonist, a mechanism of action that differs from the tumor necrosis factor (TNF) blockers often used for similar inflammatory disease conditions.

Covered Uses:

1. Treatment of pediatric patients 6 years of age and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
2. Treatment of pediatric patients 6 years of age and older with active psoriatic arthritis.
3. Adult patients with moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy
4. Adult patients with active psoriatic arthritis, alone or in combination with methotrexate
5. Adult patients with moderately to severely active Crohn's disease
6. Adult patients with moderately to severely active ulcerative colitis

Exclusion Criteria: Concurrent use with a biologic DMARD.

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed

Age Restrictions:

1. Plaque psoriasis: 6 years of age and older
2. Psoriatic arthritis: 6 years of age and older
3. Crohn's disease/Psoriatic arthritis/Ulcerative Colitis: 18 years of age and older.

Prescriber Restrictions:

1. Crohn’s Disease or Ulcerative Colitis: Must be prescribed by, or in consultation with, a gastroenterologist.
2. Plaque Psoriasis, Active Psoriatic Arthritis, Pediatric Psoriatic arthritis: Must be prescribed by, or in consultation with, a dermatologist or rheumatologist.

Coverage Duration:

Initial: 3 months

Continuation: 3 years

Other Criteria:

Dosing Limitations:

Subcutaneous Adult Dosage Regimen (Psoriasis, Psoriatic Arthritis)

1. ***For patients weighing 100 kg or less, the recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks.***

2. ***For patients weighing more than 100 kg, the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.***

Subcutaneous Pediatric Dosage Regimen (Psoriatic Arthritis)

1. ***Pediatric patients ≥ 6 years of age weighing < 60 kg: 0.75 mg/kg SC at Week 0, Week 4, and then Q12W thereafter.***
2. ***Pediatric patients ≥ 6 years of age weighing 60 kg to 100 kg: 45 mg SC at Week 0, Week 4, and then Q12W thereafter.***
3. ***Pediatric patients ≥ 6 years of age weighing > 100 kg with co-existent moderate to severe plaque psoriasis: 90 mg SC at Week 0, Week 4, and then Q12W thereafter.***

Subcutaneous Adolescent Dosage Regimen (Psoriasis)
Administer Stelara subcutaneously at Weeks 0 and 4, then every 12 weeks thereafter.

Body Weight of Patient at the Time of Dosing	Recommended Dose
less than 60 kg	0.75 mg/kg
60 kg to 100 kg	45 mg
more than 100 kg	90 mg

****Note: Clinical criteria incorporated into the Stelara 90 mg quantity limit edit, approve additional quantity (to allow for 90 mg every 8 weeks) if the patient has a diagnosis of Crohn's Disease or Ulcerative Colitis.***

Initiation

Plaque Psoriasis
*Note: Stelara is a preferred product for the diagnosis of Plaque Psoriasis and does not require the use of Humira first

A. Patient has minimum body surface area involvement with plaque psoriasis of ≥ 10%; **AND**
B. Patient has a documented failure of, or intolerance to, or contraindication to at least one traditional systemic agent (e.g., MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant. *Women of childbearing age may be given special consideration for approval without systemic therapy when topical and phototherapy options have been tried and failed.*

Psoriatic Arthritis/Pediatric Psoriatic arthritis
*Note: Stelara is a preferred product for the diagnosis of Psoriatic Arthritis and does not require the use of Humira first

A. Patient has documented failure, intolerance, or contraindication to an adequate trial of NSAID/COX-2 or steroid therapy; **AND**
B. Patient has documented failure, intolerance, or contraindication to an adequate trial (at least 3 months) of ONE DMARD (e.g., methotrexate [oral or injectable], leflunomide, and sulfasalazine).

Crohn's Disease
*Note: Stelara is a preferred product for the diagnosis of Crohn's Disease and does not require the use of Humira first

A. Stelara is being prescribed by a gastroenterologist; **AND**
B. Patient has a diagnosis of moderately to severely active Crohn's disease; **AND**
C. Patient has had a previous trial with, contraindication to, or intolerance to at least **ONE** form of conventional therapy including: aminosalicylates (e.g. mesalamine and sulfasalazine), immunomodulators (i.e. azathioprine) or corticosteroids.

Ulcerative Colitis

A. Patient has a diagnosis of moderately to severely active ulcerative colitis; **AND**
B. Patient has had an inadequate response to other immunosuppressants, such as corticosteroids, azathioprine, and 6-mercaptopurine**.**

Continuation

A. Patient meets all initial authorization criteria; **AND**
B. Patient achieves or maintains a positive clinical response after at least 4 months of therapy with Stelara as evidenced by low disease activity or improvement in signs and symptoms of the condition.

*ConnectiCare does not consider alcohol use to be a clinical reason to use Stelara over methotrexate.

*ConnectiCare does not consider needle-phobia to be a clinical reason to use Stelara over self-injectable medications or oral medications.

References:

1. STELARA(R) subcutaneous injection, intravenous injection, ustekinumab subcutaneous injection, intravenous injection. Janssen Biotech, Inc (per manufacturer), Horsham, PA, 2017.
2. Product Information: STELARA(R) subcutaneous, intravenous injection, ustekinumab subcutaneous, intravenous injection. Janssen Biotech Inc (per FDA), Horsham, PA, 2022.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	12/2009
2	Update	Updated template to match EH; Removed Dosing and Administration (matched PI) CCI P&T Review History:12/09, 9/10, 12/11, 10/12, 10/13, 10/14, 11/15, 11/16, 11/17, 11/18; CCI Revision Record:11/12, 7/13, 10/13, 12/13, 10/14, 2/16, 11/16, 5/17, 11/17, 1/18,	All	7/26/2019

3	Update	Shortened Medication Description; Added new indication to match FDA Label	Medication Description Covered Uses Age Restrictions Prescriber Restrictions	11/20/2019
4	Update	Added Criteria for UC, required step through Humira	Other Criteria	12/27/2019
5	Update	Added Dosing Limitations according to FDA label	Other Criteria	6/2/2020
6	Update	Updated Age Restrictions from 12 years of age to 6 years of age and older for Pediatric Psoriasis	Covered Uses Age restrictions	8/4/2020
7	Update	Stelara is a preferred product for the treatment of Psoriasis, Psoriatic Arthritis, Crohn's Disease and Ulcerative Colitis; removed Humira as a preferred product for Ulcerative Colitis Removed Patient has chronic (greater than or equal to 1 year) plaque psoriasis;	Other Criteria	1/1/2021
8	Update	Added: Treatment of pediatric patients 6 years of age and older with active psoriatic arthritis. Age added: Psoriatic arthritis: 6 years of age and older Added Pediatric Psoriatic arthritis for prescriber restrictions <u>Subcutaneous Pediatric Dosage Regimen</u> (Psoriatic Arthritis) – added appropriate regimens Psoriatic Arthritis – added pediatric psoriatic arthritis and added OR CONTRAINDICATION into criteria verbiage	Covered uses Age Restrictions Prescriber Restrictions Dosing Limitations Criteria Initiation	10/20/2022