RX.PA.053.CCH STELARA (USTEKINUMAB)

The purpose of this policy is to define the prior authorization process for Stelara® (ustekinumab) for intravenous administration or subcutaneous administration by a healthcare provider through medical buy and bill. Requests for self-administered subcutaneous utilization should be directed to the pharmacy benefit manager (PBM) for review.

Stelara® (ustekinumab) is indicated for the treatment of:

- Patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- Adult patients (18 years or older) with:
    - Active psoriatic arthritis, alone or in combination with methotrexate
    - Moderately to severely active Crohn's disease
    - Moderately to severely active ulcerative colitis

DEFINITIONS

Enthesitis – inflammation of sites where tendons or ligaments insert into the bone. It is also called enthesopathy, or any pathologic condition involving the enthuses. The enthuses are any point of attachment of skeletal muscles to the bone, where recurring stress or inflammatory autoimmune disease can cause inflammation or occasionally fibrosis and calcification.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Stelara® (ustekinumab), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed under the respective diagnosis:

For all diagnoses:

- Must have a negative tuberculosis skin test [such as Tuberculin PPD (purified protein derivative) test] or Interferon-Gamma Release Assay (IGRA) whole-blood test [such as QuantiFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.TB test (T-Spot)]
- Must not be used in combination with a biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD (such as Xeljanz (tofacitinib), Olumiant (baracitinib), or Otezla (apremilast))
- Must have no evidence of infection
- Must have first Stelara dose administered in a physician office by a healthcare professional
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling.

1. Plaque psoriasis:

- Must be prescribed by or in consultation with a dermatologist
- Must be age 6 or older
- Must have a diagnosis of moderate-to-severe plaque psoriasis
- Must have a minimum body surface area involvement of >5% (members with plaque psoriasis of palms, soles, head and neck, or genitalia are not required to have a minimum body surface area involvement)
- Must have an adequate trial of topical treatments, phototherapy, or photochemotherapy with an inadequate response, or significant side effects/toxicity, or have a contraindication to these therapies
- Must have an adequate trial (of at least 3 months) of a conventional systemic therapy (e.g., methotrexate, cyclosporine, or acitretin) with an inadequate response, or significant side effects/toxicity, or have a contraindication to these therapies (see Appendix 1)
- Must have an adequate trial (of at least 3 months) and failure of at least 2 preferred biologic DMARDs (such as TNF-alpha inhibitors) with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies.
    - Preferred alternatives covered through the pharmacy benefit may be found via https://countycare.com/formulary-tool/

2. Psoriatic arthritis:

- Must be prescribed by or in consultation with a rheumatologist or dermatologist
- Must be age 18 years or older
- Must have a diagnosis of active psoriatic arthritis

- Must meet ONE of the following:
  - *For predominantly axial disease or enthesitis:* Must have an adequate trial (of at least 4 weeks each) with TWO NSAIDs at anti-inflammatory doses with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy
  - *For all other types of psoriatic arthritis:* Must have an adequate trial of at least 3 months increased to a therapeutically effective dose on methotrexate or other conventional disease modifying anti-rheumatic drug (DMARD), such as sulfasalazine or leflunomide with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies (See Appendix 1)
- Must have an adequate trial (of at least 3 months) and failure of at least 2 preferred biologic or targeted synthetic DMARDs (such as TNF-alpha inhibitors or JAK inhibitors) with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies
  - Preferred alternatives covered through the pharmacy benefit may be found via https://countycare.com/formulary-tool/

3. Crohn's Disease

- Must be prescribed by or in consultation with a gastroenterologist
- Must be age 18 years or older
- Must have a diagnosis of moderately to severely active Crohn's disease
- Must have an adequate trial on a therapeutically effective dose of conventional therapy including corticosteroids OR immunosuppressants (e.g., azathioprine, 6-mercaptopurine) (See Appendix 2) with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
- Must have an adequate trial (of at least 3 months) and failure of at least 2 preferred tumor necrosis factor (TNF)-alpha inhibitors with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies
  - Preferred self-injectable alternatives covered through the pharmacy benefit may be found via https://countycare.com/formulary-tool/

4. Ulcerative Colitis

- Must be prescribed by or in consultation with a gastroenterologist
- Must be age 18 years or older
- Must have a diagnosis of moderately to severely active Ulcerative Colitis
- Must have an adequate trial of conventional therapy including corticosteroids, 5-ASA agents (e.g., sulfasalazine, mesalamine), OR immunosuppressants (e.g., azathioprine, 6-mercaptopurine) (see Appendix 3) with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies

- Must have an adequate trial (of at least 3 months) and failure of at least 2 preferred tumor necrosis factor (TNF)-alpha inhibitors with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies
    - Preferred self-injectable alternatives covered through the pharmacy benefit may be found via https://countycare.com/formulary-tool/

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation of the following:

- Member must be prescribed a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- Member must have achieved or maintained positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition
- Must not be used in combination with a biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD (such as Xeljanz (tofacitinib), Olumiant (baracitinib), or Otezla (apremilast))

Limitations:

Length of Authorization (if above criteria met)	

Initial Authorization	• Up to 1 year
	• Plaque psoriasis: Stelara is covered according to the following weight-based doses:
	  ○ A quantity of 2 vials/syringes is covered for the first month of treatment
	  ○ Patients weighing ≤ 100kg (220 lbs): 45mg vials/syringe
	  ○ Patients weighing > 100kg (220 lbs): 90mg syringe
	• Psoriatic arthritis:
	  ○ A quantity of two 45mg vials/syringes is covered for the first month of treatment
	• Crohn's Disease and Ulcerative Colitis: an initial starting dose for IV administration lasting 8 weeks is approved as follows:

	○ Patients weighing ≤ 55kg (121 lbs): 260mg (2 vials of 130mg) ○ Patients weighing > 55kg (121 lbs) and ≤ 85kg (187 lbs): 390 mg (3 vials of 130mg) ○ Patients weighing > 85 kg (187 lbs): 520mg (4 vials of 130mg) ○ Maintenance dose of one 90mg syringe every 8 weeks is approved
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

APPENDIX 1

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin
• Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease • Breastfeeding • Drug interaction • Cannot be used due to risk of treatment-related toxicity (e.g., true allergy, severe side effects that cannot be resolved with dosage or administration modification) • Pregnancy or currently planning pregnancy • Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, renal impairment)

APPENDIX 2

Examples of Conventional Therapy Options for CD
Mild to moderate disease – induction of remission: Oral budesonide Alternatives: metronidazole, ciprofloxacin, rifaximin Mild to moderate disease – maintenance of remission: Azathioprine, mercaptopurine Alternatives: oral budesonide, methotrexate intramuscularly (IM) or subcutaneously (SC), sulfasalazine Moderate to severe disease – induction of remission: Prednisone, methylprednisolone intravenously (IV) Alternatives: methotrexate IM or SC

Moderate to severe disease – maintenance of remission:
Azathioprine, mercaptopurine
Alternative: methotrexate IM or SC

Perianal and fistulizing disease – induction of remission
No trial is needed

Perianal and fistulizing disease – maintenance of remission
No trial is needed

APPENDIX 3

Examples of Conventional Therapy Options for UC
Mild to moderate disease – induction of remission: Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa), balsalazide, olsalazine Rectal mesalamine (e.g., Canasa, Rowasa) Rectal hydrocortisone (e.g., Colocort, Cortifoam) Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine Mild to moderate disease – maintenance of remission: Oral mesalamine, balsalazide, olsalazine, rectal mesalamine Alternatives: azathioprine, mercaptopurine, sulfasalazine Severe disease – induction of remission: Prednisone, hydrocortisone IV, methylprednisolone IV Alternatives: cyclosporine IV, tacrolimus, sulfasalazine Severe disease – maintenance of remission: Azathioprine, mercaptopurine Alternative: sulfasalazine Pouchitis Metronidazole, ciprofloxacin Alternative: rectal mesalamine

HCPCS Code

HCPCS code	Brand	Description
J3357	STELARA	INJECTION USTEKINUMAB, 1 MG
J3358	STELARA IV	USTEKINUMAB FOR IV INJECTION, 1 MG

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RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Initial review	3/22