CORE, ADVANTAGE, AND PLUS DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

USTEKINUMAB (PART D)

Generic	Brand	HICL	GCN	Exception/Other
USTEKINUMAB	STELARA	36187		

PAYMENT DETERMINATION CRITERIA

NOTE: This section is for administrative purposes to determine Medicare Part B versus Medicare Part D funding for Stelara (ustekinumab) intravenous infusion route.

Requests for subcutaneous (SC/SQ) Stelara (ustekinumab) do not require Payment Determination.

1. Is the request for intravenous (IV) infusion of Stelara for the treatment of moderate to severe Crohn's disease (CD) or moderate to severe ulcerative colitis (UC)?

   If yes, continue to #2.
   If no, **approve for 12 months by HICL under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

2. Is this a pharmacy call?

   If yes, continue to #4.
   If no, continue to #3.

3. Is the requested medication going to be filled at a pharmacy?

   If yes, continue to #4.
   If no, **Refer to plan. (This should be processed under the member's medical benefit)**

4. Is the internal HQ code AHF01, AHF02, ASP02, BAY01, BHP03, CHG09, CLC01, CLH01, CPL01, EHC01, GLD01, HTH05, MCX01, MRI03, MVS01, MVS09, MVS10, MVS11, PRW01, RPS01, UHC01?

   If yes, continue to #7.
   If no, continue to #5.

5. Is the pharmacy dispensing the drug directly to the member or member's representative?

   If yes, continue to #7.
   If no, continue to #6.

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USTEKINUMAB (PART D)

PAYMENT DETERMINATION CRITERIA (CONTINUED)

6. Is the internal HQ code SUM03 or VHP01?

   If yes, **Refer to plan. (The health plan makes the final payment determination decision)**
   - **For CSR's: refer the caller to contact the plan, provide the plan's phone number, and advise that the plan will make the UNSAID BvD Prior Authorization Payment determination and Clinical determination for this particular product. (Do Not Enter any override).**
   - **For PAC's: Send an email to plan (reference UNSAID section of PACIP).**

   If no, **approve for 12 months by HICL under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

7. Is the intravenous infusion administered via an external infusion pump?

   If yes, continue to #8.
   If no, **approve for 12 months by HICL under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

8. Is the requested drug specifically covered under the applicable Medicare Part B coverage policies (National and/or Local Coverage Policies)?

   If yes, **approve Stelara 130mg/26mL (for the induction dose) for 12 months by GPID under Part B (Deny under Part D before approving under Part B. Populate the B vs. D field with a 'B' in the PA override field).**

   If no, **approve for 12 months by HICL under Part D (Populate the B vs. D field with a 'D' in the PA override field).**

Customer Service Representative review stops here.

Guideline interpretation beyond this point requires Clinical/Technician review.

USTEKINUMAB (PART D)

CLINICAL DETERMINATION CRITERIA

Do not review Part D guidelines with physicians; if the caller wishes to initiate an oral request, then a verbal MRF must be completed. Please check the applicable CS note for processing.

***********Pharmacist/PAC Alert************
(For Internal Use Only)

IMPORTANT FORMULARY NOTE:
The prior authorization guideline may not apply to all products. Please ensure requested drug is on the member's formulary. Refer to formulary print for specific details.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes**, approve for 6 months by GPID for all of the following strengths with no quantity limits:**
   - **Stelara 45mg/0.5mL vial**
   - **Stelara 45mg/0.5mL prefilled syringe**
   - **Stelara 90mg/mL prefilled syringe**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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USTEKINUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affect the hands, feet, genital area, or face
   - The patient had a trial of or contraindication to ONE conventional therapy such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

   If yes, **approve for 6 months by GPID for all of the following strengths with no quantity limits:**
   - **Stelara 45mg/0.5mL vial**
   - **Stelara 45mg/0.5mL prefilled syringe**
   - **Stelara 90mg/mL prefilled syringe**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional therapy such as corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, continue to #5.
   If no, continue to #4.

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USTEKINUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional therapy, such as a corticosteroid (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Is the prescriber requesting an intravenous infusion induction dose of **Stelara 130mg/26mL**?

   If yes, **enter two approvals for a total of 6 months as follows:**
   - **<u>INDUCTION DOSE:</u> Approve Stelara 130mg/26mL for 2 months by GPID under Part D with no quantity limit (Populate B vs. D field with a 'D' in the PA override field).**
   - **<u>MAINTENANCE DOSE:</u> Approve for 4 months by GPID under Part D for all of the following strengths with no quantity limits:**
     - **Stelara 45mg/0.5mL vial**
     - **Stelara 45mg/0.5mL prefilled syringe**
     - **Stelara 90mg/mL prefilled syringe**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, **approve for 6 months by GPID for all of the following strengths with no quantity limits:**
   - **Stelara 45mg/0.5mL vial**
   - **Stelara 45mg/0.5mL prefilled syringe**
   - **Stelara 90mg/mL prefilled syringe**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

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USTEKINUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **USTEKINUMAB (Stelara)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Psoriatic arthritis (PsA: a type of skin or joint condition)
   2. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have psoriatic arthritis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (skin doctor)
   3. You have tried ONE DMARD (disease-modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless you have a contraindication (harmful for)

C. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (skin doctor)
   3. You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have tried ONE standard treatment such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine, unless you have a contraindication (harmful for)

D. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You have tried ONE standard treatment such as a corticosteroid (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine, unless you have a contraindication (harmful for)

(Initial denial text continued on next page)

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USTEKINUMAB (PART D)

INITIAL CRITERIA (CONTINUED)

E. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You have tried ONE standard treatment such as a corticosteroid (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine, unless you have a contraindication (harmful for)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) or moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient continues to benefit from the medication

   If yes, **approve for 12 months by GPID for all of the following strengths with no quantity limits:**
   - **Stelara 45mg/0.5mL vial**
   - **Stelara 45mg/0.5mL prefilled syringe**
   - **Stelara 90mg/mL prefilled syringe**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, continue to #2.

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USTEKINUMAB (PART D)

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) or moderate to severe ulcerative colitis (UC)?

   If yes, **approve for 12 months by GPID for all of the following strengths with no quantity limits:**
   - **Stelara 45mg/0.5mL vial**
   - **Stelara 45mg/0.5mL prefilled syringe**
   - **Stelara 90mg/mL prefilled syringe**

   APPROVAL TEXT (IF APPLICABLE): The requested drug has a plan limit of [XX] per [XX] days.

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **USTEKINUMAB (Stelara)** requires the following rules be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Psoriatic arthritis (PsA: a type of skin or joint condition)
      2. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      3. Moderate to severe Crohn's disease (CD: a type of bowel disorders)
      5. Moderate to severe ulcerative colitis (UC: a type of digestive disorders)
   B. **If you have psoriatic arthritis or moderate to severe plaque psoriasis, renewal also requires:**
      1. You continue to benefit from the medication

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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USTEKINUMAB (PART D)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Stelara.

The requested drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Drugs filled by a pharmacy and shipped directly to the physician's office or clinic on behalf of a member may be covered under Part B. Drugs administered via an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare coverage policies (National and/or Local Coverage Policies). Drugs administered via an external pump that are not included under the applicable Medicare coverage policies are covered under Part D. A CMS website to assist with National and Local Coverage Determination for B versus D review is http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

REFERENCES

- Stelara [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; July 2022.

For Part D use only:

USTEKINUMAB (PART D)	
Covered uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE.
Age Restrictions	N/A
Prescriber Restrictions	INITIAL:PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: PSA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG). PSO: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A PUVA (PHOTOTHERAPY ULTRAVIOLET LIGHT A), UVB (ULTRAVIOLET LIGHT B), TOPICAL CORTICOSTEROIDS, CALCIPOTRIENE, ACITRETIN, METHOTREXATE, OR CYCLOSPORINE. CD, UC: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A CORTICOSTEROID (E.G., BUDESONIDE, METHYLPREDNISOLONE), AZATHIOPRINE, MERCAPTOPURINE, METHOTREXATE, OR MESALAMINE.

	RENEWAL: PSA, PSO: CONTINUES TO BENEFIT FROM THE MEDICATION.

For Part D use only:

USTEKINUMAB IV (PART D)	
Covered uses	ALL FDA APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	2 MONTHS
Other Criteria	CD, UC: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A CORTICOSTEROID (E.G., BUDESONIDE, METHYLPREDNISOLONE), AZATHIOPRINE, MERCAPTOPURINE, METHOTREXATE, OR MESALAMINE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.

Core	Advantage	Plus
Yes	Yes	Yes

Part D Effective: 01/01/23 Created: 10/09
Commercial Effective: N/A Client Approval: 10/22 P&T Approval: 10/22