STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

USTEKINUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
USTEKINUMAB	STELARA	36187		GPI-10 (9025058500) (5250407000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. 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 had a trial of or contraindication to ONE or more forms of conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic (e.g., Cimzia [certolizumab], Cosentyx [secukinumab]) and is switching to the requested drug
   - The patient has psoriasis covering 3% or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, face, or genital area

   If yes, **enter two approvals for a total of 6 months by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 1mL per 28 days for 1 fill.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of 1mL per 84 days for 2 fills (Start date is 3 weeks AFTER the start date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guidelines.

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

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INITIAL CRITERIA (CONTINUED)

4. Does the patient have coexistent moderate to severe plaque psoriasis (PsO)?

   If yes, **enter two approvals for a total of 6 months by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 1mL per 28 days for 1 fill.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of 1mL per 84 days for 2 fills (Start date is 3 weeks AFTER the start date of the first approval).**

   If no, **enter two approvals for a total of 6 months by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 0.5mL per 28 days for 1 fill.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of 0.5mL per 84 days for 2 fills (Start date is 3 weeks AFTER the start date of the first approval).**

5. 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 agent, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

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

6. Does the patient have a diagnosis of moderate to severe active 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 agent, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

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

   If yes, **enter two approvals for a total of 6 months by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 2 months by GPID or GPI-14 with a quantity limit of 104mL (130mg/26mL) per 56 days for 1 fill.**
   - **SECOND APPROVAL: Approve for 4 months by GPID or GPI-14 with a quantity limit of 1mL (45mg/0.5mL or 90mg/mL) per 56 days for 2 fills (Start date is 7 weeks AFTER the start date of the first approval).**

   If no, **approve for 6 months by GPID or GPI-14 with a quantity limit of 1mL per 56 days for 3 fills.**

   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 rules be met for approval:

   A. You have ONE of the following diagnoses:
      1. Psoriatic arthritis (PsA: a type of skin and 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 active ulcerative colitis (UC: a type of digestive disorder)

   B. **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 (type of skin doctor)
      3. You have tried or have a contraindication (harmful for) to ONE or more forms of standard therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine
      4. You meet ONE of the following:
         a. You were previously stable on another biologic (such as Cimzia [certolizumab], Cosentyx [secukinumab]) and are switching to the requested drug
         b. You have psoriasis covering 3% or more of body surface area (BSA)
         c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, or face

   (Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

C. **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 (type of immune system doctor) OR dermatologist (type of skin doctor)
   3. You have tried or have a contraindication (harmful for) to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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 or have a contraindication (harmful for) to ONE standard therapy, such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

E. **If you have moderate to severe active 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 or have a contraindication (harmful for) to ONE standard therapy, such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

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

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have coexistent moderate to severe plaque psoriasis (PsO)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 1mL per 84 days.**
   If no, **approve for 12 months by GPID or GPI-14 with a quantity limit of 0.5mL per 84 days.**

3. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 1mL per 84 days.**
   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 1mL per 56 days.**
   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 1mL per 56 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

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 and 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, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

C. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

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.

RATIONALE

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

REFERENCES

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

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 10/09
Client Approval: 05/23
P&T Approval: 04/23