STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

USTEKINUMAB

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

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) **OR** moderate to severe plaque psoriasis (PsO) with co-existent psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or given in consultation with a dermatologist
   - The patient has psoriatic lesions involving greater than or equal to 10% body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
   - The patient had a previous trial of or contraindication to at least **ONE** or more forms of conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   - Documentation of the patient's current weight

   If yes, **approve for a total of 6 months by GPID or GPI-14 as follows:**
   Patients weighing 100kg (220 lbs) or less:
   Enter both of the following approvals:
   - **Loading dose: Approve for 1 month with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 28 days for 1 fill.**
   - **Maintenance dose: Approve for 5 months with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 84 days for 2 fills with a start date after the end date of the previous fill.**

   Patients weighing over 100kg (220 lbs):
   Enter both of the following approvals:
   - **Loading dose: Approve for 1 month with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 28 days for 1 fill.**
   - **Maintenance dose: Approve for 5 months with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 84 days for 2 fills with a start date after the end date of the previous fill.**

   APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis **OR** moderate to severe PsO with co-existent psoriatic arthritis requires that 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 **AND** documentation of the patient's current weight.

   If no, continue to #2.

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INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
   - The patient had a previous trial of or contraindication to at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for a total of 6 months by GPID or GPI-14 as follows:**
   - **Loading dose: Approve for 1 month with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 28 days for 1 fill.**
   - **Maintenance dose: Approve for 5 months with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 84 days for 2 fills with a start date after the end date of the previous fill.**

   APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   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 given in consultation with a gastroenterologist
   - The patient had a previous trial of or contraindication to at least **ONE** conventional agent, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   - Documentation of the patient's current weight

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

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INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe active Ulcerative Colitis (UC) **AND** meet the following criterion?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a gastroenterologist
   - The patient had a previous trial of or contraindication to at least **ONE** conventional agent, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   - Documentation of the patient's current weight

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

5. Does the patient have non-self-administered (NSA) drug benefit coverage?

   If yes, continue to #6.
   If no, **approve maintenance dose for 6 months by GPID or GPI-14 with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days for 3 fills.**
   APPROVAL TEXT: Stelara subcutaneous has been approved for 6 months for maintenance treatment. Stelara intravenous loading dose is excluded from your pharmacy benefit coverage.

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INITIAL CRITERIA (CONTINUED)

6. Has the patient **already received** the intravenous loading dose of Stelara for the treatment of CD or UC?

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days for 3 fills.**

   If no, **enter two approvals for a total of 6 months by GPID or GPI-14 as follows:**
   First approval - Please enter one of the following loading doses based on the patient's weight (NOTE: Do not enter a loading dose if the member does not have coverage for non-self-administered drug benefit. Please deny for benefit exclusion.):
   Patients weighing 55kg (121 lbs.) or less:
   - **Loading dose: Approve for 2 months by GPID or GPI-14 with a quantity limit of 52mL (two 130mg/26mL vials) per 56 days for 1 fill.**

   Patients weighing over 55kg up to 85kg (122 lbs. up to 187 lbs.):
   - **Loading dose: Approve for 2 months by GPID or GPI-14 with a quantity limit of 78mL (three 130mg/26mL vials) per 56 days for 1 fill.**

   Patients weighing over 85kg (187 lbs.):
   - **Loading dose: Approve for 2 months by GPID or GPI-14 with a quantity limit of 104mL (four 130mg/26mL vials) per 56 days for 1 fill.**

   Second approval:
   - **Maintenance dose: Approve for 4 months by GPID or GPI-14 with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days for 2 fills with a start date after the end date of the previous fill.**

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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 rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Psoriatic arthritis (PsA: joint pain and swelling without red scaly skin patches)
   2. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   3. Moderate to severe Crohn's Disease (CD: type of inflammatory disease that affects lining of digestive tract)
   4. Moderate to severe active Ulcerative Colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe plaque psoriasis (PsO) OR moderate to severe plaque psoriasis (PsO) with co-existent psoriatic arthritis (PsA), approval also requires:**
   1. You are 6 years of age or older
   2. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) or psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried at least ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   5. Your current weight has been documented

C. **If you have psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) OR dermatologist (skin doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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INITIAL CRITERIA (CONTINUED)

D. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. Your current weight has been documented

E. **If you have moderate to severe active Ulcerative Colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. Your current weight has been documented

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) without co-existent plaque psoriasis (PsO) and experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 84 days.**
   If no, continue to #2.

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **OR** moderate to severe plaque psoriasis (PsO) with co-existent psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - 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
   - Documentation of the patient's current weight

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   Patients weighing 100kg (220 lbs.) or less:
   - **Approve for 12 months with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 84 days.**

   Patients weighing over 100kg (220 lbs.):
   - **Approve for 12 months with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 84 days.**

   If no, continue to #3.

3. 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 (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days.**

   If no, continue to #4.

4. 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 (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) 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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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: joint pain and swelling without red scaly skin patches)
   2. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   3. Moderate to severe Crohn's Disease (CD: type of inflammatory disease that affects lining of digestive tract)
   4. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract
B. **If you have psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO), 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 (PsO) OR moderate to severe plaque psoriasis with co-existent psoriatic arthritis (PsA), 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
   2. Your current weight has been documented

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 2020.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 09/07/20
Created: 10/09
Client Approval: 08/20
P&T Approval: 10/20