HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

USTEKINUMAB (STELARA)

Generic	Brand	HICL	GCN	Exception/Other
USTEKINUMAB	STELARA		28158, 28159	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a patient with a diagnosis of moderate to severe plaque psoriasis (PsO) and does the request meet **ALL** of the following criteria?
   - Patient is 12 years of age or older
   - Prescribed by (or in consultation with) a dermatologist
   - Trial with **ONE** of the following:
     - o At least one course of systemic therapy for psoriasis such as: acitretin, cyclosporine, methotrexate, or oral methoxsalen plus UVA light (PUVA)
     - o Biologic agent approved for PsO (e.g., Stelara, Enbrel, Humira)

   If yes, continue to #4.
   If no, continue to #2.

2. Is the request for a patient with a diagnosis of psoriatic arthritis (PsA) and does the request meet **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Prescribed by (or in consultation with) a rheumatologist or dermatologist
   - Trial with **ONE** of the following:
     - o At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, or sulfasalazine
     - o Biologic agent approved for PsA (e.g., Stelara, Enbrel, Humira)

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

3. Is the request for a patient with a diagnosis of moderate to severe Crohn's disease (CD) and does the request meet **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Prescribed by (or in consultation with) a gastroenterologist
   - Trial with a biologic agent approved for CD (e.g., Stelara, Enbrel, Humira) **OR** a trial with at least **TWO** of the following conventional therapies:
     - o Corticosteroids (such as prednisone, prednisolone, methylprednisolone, budesonide)
     - o 5-Aminosalicylates (such as sulfasalazine, mesalamine, olsalazine, balsalazide)
     - o Immunosuppressants/Immunomodulators (such as 6-mercaptopurine, azathioprine, methotrexate)

   If yes, continue to #4.
   If no, do not approve. Please use status code #238 and the denial text provided.
   (Initial denial text continued on next page)

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USTEKINUMAB (STELARA)

INITIAL CRITERIA (CONTINUED)

DENIAL TEXT (if diagnosis is not met): Per your health plan's Ustekinumab (Stelara) guideline, this medication is only covered for one of the following conditions: Psoriatic Arthritis, Plaque Psoriasis, Crohn's Disease. Your provider did not indicate that you are being treated for one of these conditions and therefore your request was not approved.

DENIAL TEXT (PsO): Per your health plan's Ustekinumab (Stelara) guideline, this medication is only covered for moderate to severe Plaque Psoriasis (PsO) when you meet all of the following conditions:

- Patient is 12 years of age or older
- Prescribed by (or in consultation with) a dermatologist
- Trial with one of the following:
  - At least one course of systemic therapy for psoriasis such as: acitretin, cyclosporine, methotrexate, or oral methoxsalen plus UVA light (PUVA)
  - Biologic agent approved for PsO (e.g., Stelara, Enbrel, Humira), which also require prior authorization

Your provider did not indicate **[specific criteria not met]**, and therefore your request was not approved.

DENIAL TEXT (PsA): Per your health plan's Ustekinumab (Stelara) guideline, this medication is only covered for Psoriatic Arthritis (PsA) when you meet all of the following conditions:

- Patient is 18 years of age or older
- Prescribed by (or in consultation with) a rheumatologist or dermatologist
- Trial with one of the following:
  - At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, or sulfasalazine
  - Biologic agent approved for PsA (e.g., Stelara, Enbrel, Humira), which also require prior authorization

Your provider did not indicate that **[specific criteria not met]**, and therefore your request was not approved.

DENIAL TEXT (CD): Per your health plan's Ustekinumab (Stelara) guideline, this medication is only covered for moderate to severe Crohn's disease (CD) when you meet all of the following conditions:

- Patient is 18 years of age or older
- Prescribed by (or in consultation with) a gastroenterologist
- Trial with a biologic agent approved for CD (e.g., Stelara, Enbrel, Humira), which also require prior authorization, or with at least two of the following conventional therapies:
  - Corticosteroids (such as prednisone, prednisolone, methylprednisolone, budesonide)
  - 5-Aminosalicylates (such as sulfasalazine, mesalamine, olsalazine, balsalazide)
  - Immunosuppressants/Immunomodulators (such as 6-mercaptopurine, azathioprine, methotrexate)

Your provider did not indicate that **[specific criteria not met]**, and therefore your request was not approved.

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USTEKINUMAB (STELARA)

INITIAL CRITERIA (CONTINUED)

4. **Approve for 12 months by HICL up to 5 fills.**
   Please use status code #056 and the approval text provided. (Stelara is hard-coded with a quantity of one prefilled syringe/vial per 84 days; 0.5 ml per 45 mg vial or syringe and 1 ml per 90 mg syringe)

   If the request is for PsO or PsA and the member is new to therapy, please enter 2 PAs as follows:
   - **First PA: Approve one syringe per 28 days for the first two months; fill count of 2.**
   - **Second PA: Approve one syringe per 84 days for the remaining 10 months; fill count of 3. (NOTE:** Please enter a start date 10 weeks after the initial PA.)

   If the request is for CD, please enter an override for one syringe per 56 days for up to 7 fills. (PAC NOTE: Please enter 56 in the MIN_DS field)

   APPROVAL TEXT (PsO or PsA and new start): Your request for Stelara has been approved for a 12-month period for a quantity of one prefilled syringe per month for the first two months, and then one syringe per 12 weeks for the remaining 10 months.
   APPROVAL TEXT (PsO or PsA and maintenance dosing): Your request for Stelara has been approved for a 12-month period for up to one prefilled syringe per 12 weeks.
   APPROVAL TEXT (CD): Your request for Stelara has been approved for a 12-month period for up to one prefilled syringe per 8 weeks.

RENEWAL CRITERIA

1. Does the request meet **ALL** of the following criteria?
   - Prescribed for one of the following diagnoses: psoriatic arthritis, chronic plaque psoriasis, Crohn's disease
   - Prescribed by (or in consultation with) a dermatologist, rheumatologist, or gastroenterologist
   - Documentation that the patient experienced improvement while on therapy

   If yes, **approve for 12 months by HICL up to 5 fills.** Please use status code #056 and the approval text provided.
   If the request is for CD, please enter an override for one syringe per 56 days for up to 7 fills.
   APPROVAL TEXT (PsO or PsA): Your request for Stelara has been approved for a 12-month period for up to one prefilled syringe per 12 weeks.
   APPROVAL TEXT (CD): Your request for Stelara has been approved for a 12-month period for up to one prefilled syringe per 8 weeks.

   If no, do not approve. Please use status code #238 and the denial text provided.
   (Renewal denial text continued on next page)

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USTEKINUMAB (STELARA)

RENEWAL CRITERIA (CONTINUED)

DENIAL TEXT: Per your health plan's Ustekinumab (Stelara) guideline, authorization for renewal requires that you meet **ALL** of the following conditions:

- Prescribed for one of the following diagnoses: psoriatic arthritis, chronic plaque psoriasis, Crohn's disease
- Prescribed by (or in consultation with) a dermatologist, rheumatologist, or gastroenterologist
- Documentation that the patient experienced improvement while on therapy

Your provider did not indicate that **[specific criteria not met]**, and therefore your request was not approved.

RATIONALE

Ensure appropriate utilization criteria are met for the management of requests for ustekinumab for use as monotherapy or in combination with methotrexate or other non-biologic DMARD and promote use of preferred agents Humira and Enbrel.

FDA APPROVED INDICATIONS

Stelara is a human interleukin-12 and -23 antagonist indicated for the treatment of adult patients with:

- moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy (18 years or older)
- active psoriatic arthritis (PsA), alone or in combination with methotrexate (12 years or older)
- moderately to severely active Crohn's disease (18 years or older) who have:
  - failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed treatment with a tumor necrosis factor (TNF) blocker or
  - failed or were intolerant to treatment with one or more TNF blockers

DOSING

Psoriasis (adult)

- If ≤ 100 kg, 45 mg initially and 4 weeks later (day 29), and then 45 mg every 12 weeks
- If > 100kg, 90 mg initially and 4 weeks later (day 29), and then 90 mg every 12 weeks.

Psoriasis (adolescent)

- If < 60 kg, 0.75 mg/kg initially and 4 weeks later (day 29), and then 0.75 mg/kg every 12 weeks
- If 60 kg to 100 kg, 45 mg initially and 4 weeks later (day 29), and then 45 mg every 12 weeks
- If > 100kg, 90 mg initially and 4 weeks later (day 29), and then 90 mg every 12 weeks

Psoriatic Arthritis

- 45 mg initially and 4 weeks later (day 29), and then 45 mg every 12 weeks
- If co-existent plaque psoriasis and weight > 100 kg, 90 mg initially and 4 weeks later (day 29), and then 90 mg every 12 weeks

Crohn's Disease

- Eight weeks after an initial intravenous dose, 90 mg and every 8 weeks thereafter

REFERENCES

- Janssen Biotech, Inc. Stelara prescribing information. Horsham, PA. October 2017.
- Centocor Ortho Biotech. Stelara Dossier. Horsham, PA. September 2009.

Created: 09/14
Effective: 05/01/19 Client Approval: 05/09/19 P&T Approval: 09/17/18

Revised: 5/9/2019