GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meets all of the following criteria?
   - therapy initiated by or in consultation with a rheumatologist or dermatologist
   - previous trial with at least one of the following DMARDs (disease-modifying antirheumatic drug) agents such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - 18 years of age or older
   - previous trial with the preferred formulary TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

If yes, approve for 4 months as follows:
   - Approve for 1 month of 1mL (two 45mg/0.5mL prefilled syringes) per 28 days.
   - Approve for 3 months of 0.5mL (one 45mg/0.5mL prefilled syringe) per 84 days with a start date after the end date of the previous fill (total initial approval of 1.5mL per 4 months).

APPROVAL TEXT: Renewal of USTEKINUMAB 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 #2.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meets all of the following criteria?
   - therapy initiated by or in consultation with a dermatologist
   - plaque psoriasis involve at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, or genital area
   - previous trial with at least one or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   - 18 years of age or older
   - documentation of patient's current weight
   - previous trial with the preferred formulary TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

If yes, **approve as follows**:

**Patients weighing 100kg (220 lbs) or less:**
- Approve for 1 month for 1mL (two 45mg/0.5mL prefilled syringes) per 28 days.
- Approve for 3 months for 0.5mL (one 45mg/0.5mL prefilled syringe) per 84 days with a start date after the end date of the previous fill (total initial approval of 1.5mL per 4 months).

**Patients weighing over 100kg (220 lbs):**
- Approve for a total initial of 4 months by HICL as follows:
  - Approve for 1 month for 2mL (two 90mg/mL prefilled syringes) per 28 days.
  - Approve for 3 months of 1mL (one 90mg/mL prefilled syringe) per 84 days with a start date after the end date of the previous fill (total initial approval of 3mL per 4 months).

**APPROVAL TEXT:** Renewal of **USTEKINUMAB** requires documentation that the patient has achieved clear or minimal disease (Physician's Global Assessment equal to zero or one) or documentation of the percentage of decrease in PASI (Psoriasis Area and Severity Index) and documentation of the patient's current weight. 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)

INITIAL DENIAL TEXT: Our guideline for USTEKINUMAB requires a diagnosis of psoriatic arthritis or moderate to severe plaque psoriasis. Additional guideline requirements apply.

For patients with psoriatic arthritis requires all of the following:
- therapy initiated by or in consultation with a rheumatologist or dermatologist
- previous trial with at least one of the following DMARDs (disease-modifying antirheumatic drug) agents such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- 18 years of age or older
- previous trial with the preferred formulary TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

For patients with moderate to severe plaque psoriasis requires all of the following:
- therapy initiated by or in consultation with a dermatologist
- plaque psoriasis involve at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, or genital area
- previous trial with at least one or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- 18 years of age or older
- documentation of patient's current weight
- previous trial with the preferred formulary TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

RENEWAL CRITERIA

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) and the following criteria?
   - documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy

   If yes, approve for 12 months by HICL for 0.5ml (one 45mg/0.5mL prefilled syringe) 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) and meets all of the following criteria?
   • documentation 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
   • documentation of patient’s current weight

   If yes, approve for 12 months as follows:
   **Patients weighing 100kg (220 lbs) or less:**
   • Approve for 12 months by HICL for up to 0.5mL (one 45mg/0.5mL prefilled syringe) per 84 days.
   **Patients weighing over 100kg (220 lbs):**
   • Approve for 12 months by HICL for up to 1mL (one 90mg/mL prefilled syringe) per 84 days.

   If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

RENEWAL DENIAL TEXT: Our guideline for USTEKINUMAB renewal requires a diagnosis of psoriatic arthritis or moderate to severe plaque psoriasis. Additional guideline requirements apply.

Renewal for the diagnosis of psoriatic arthritis requires:
   • documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy

Renewal for the diagnosis of moderate to severe plaque psoriasis requires all of the following:
   • documentation that the patient has achieved clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more
   • documentation of patient's current weight

RATIONALE
Ensure that appropriate diagnostic, utilization, and safety criteria are utilized for the management of ustekinumab.

The Psoriasis Area Severity Index (PASI) is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 to 72.

The Physician’s Global Assessment (PGA) is used to determine the subject’s psoriasis lesions overall at a given time point. Overall lesions are graded for induration, erythema, and scaling based on a scale from 0 to 5, with higher scores indicating greater severity.

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USTEKINUMAB

RATIONALE (CONTINUED)
Total PGA Scores
0 = Cleared
1 = Minimal
2 = Mild
3 = Moderate
4 = Marked
5 = Severe

FDA APPROVED INDICATIONS
Stelara is a human interleukin-12 and -23 antagonist indicated for the treatment of adult patients (18 years or older) with:
- moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy
- active psoriatic arthritis (PsA), alone or in combination with methotrexate

DOSAGE
Psoriasis
- For patients weighing <100 kg (220 lbs), the recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks.
- For patients weighing >100 kg (220 lbs), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.

Psoriatic Arthritis
- The recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks.
- For patients with co-existent moderate-to-severe plaque psoriasis weighing >100 kg (220 lbs), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.

REFERENCES

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Created: 10/09  
Effective: 01/01/16  
Client Approval: 11/15