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 18 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% of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, or face
   - The patient has had a previous trial of 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
   - The patient has had a previous trial of any TWO of the following formulary preferred immunomodulators: Cosentyx, Enbrel, Humira, Otezla, or Stelara (NOTE: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

   If yes, approve for a total of 6 months by entering THREE approvals by HICL as follows:
   - FIRST APPROVAL: approve for 4 weeks with a quantity limit of 3mL (#3 80mg/mL syringes or autoinjectors) per 28 days.
   - SECOND APPROVAL: approve for 8 weeks with a quantity limit of 2mL (#2 80mg/mL syringes or autoinjectors) per 28 days (Please enter a start date of 4 WEEKS AFTER the START date of the first approval).
   - THIRD APPROVAL: approve for 12 weeks with a quantity limit of 1mL (#1 80mg/mL syringe or autoinjector) per 28 days (Please enter a start date of 4 WEEKS AFTER the END date of the second approval).

   APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis 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.

   If no, continue to #2.

   CONTINUED ON NEXT PAGE
IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) 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 has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   • The patient has had a previous trial of any TWO of the following formulary preferred immunomodulators: Cosentyx, Enbrel, Humira, Otezla, or Stelara (NOTE: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, approve for a total of 6 months by entering TWO approvals by HICL as follows:
• FIRST APPROVAL: approve for 4 weeks with a quantity limit of 2mL (#2 80mg/mL syringes or autoinjectors) per 28 days.
• SECOND APPROVAL: approve for 20 weeks with a quantity limit of 1mL (#1 80mg/mL syringe or autoinjector) per 28 days (Please enter a start date of 4 WEEKS AFTER the START date of the first approval).

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, do not approve.

INITIAL DENIAL TEXT: The guideline named IXEKIZUMAB (Taltz) requires a diagnosis of moderate to severe plaque psoriasis (PsO) or psoriatic arthritis (PsA). In addition, the following criteria must be met:

For the diagnosis of moderate to severe plaque psoriasis (PsO), approval requires that:
• The patient is 18 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% of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, or face
• The patient has had a previous trial of 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
• The patient has had a previous trial of any TWO of the following formulary preferred immunomodulators: Cosentyx, Enbrel, Humira, Otezla, or Stelara

(Initial denial text continued on next page)
IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

For the diagnosis of psoriatic arthritis (PsA), approval requires that:

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient has had a previous trial of any TWO of the following formulary preferred immunomodulators: Cosentyx, Enbrel, Humira, Otezla, or Stelara

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

1. 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 HICL with a quantity limit of 1mL (#1 80mg/mL syringe/autoinjector) per 28 days.
   If no, continue to #2.

2. 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, approve for 12 months by HICL with a quantity limit of 1mL (#1 80mg/mL syringe/autoinjector) per 28 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: The guideline named IXEKIZUMAB (Taltz) requires a diagnosis of moderate to severe plaque psoriasis (PsO) or psoriatic arthritis (PsA) for renewal. In addition, the following criteria must be met:

For the diagnosis of moderate to severe plaque psoriasis (PsO), approval 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

For the diagnosis of psoriatic arthritis (PsA), approval requires that:
- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

RATIONALE
Ensure appropriate utilization of Taltz based on its FDA approved indications.

FDA APPROVED INDICATIONS
Taltz is a humanized interleukin-17A antagonist indicated for the treatment of adults with:
- Moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
- Psoriatic arthritis

DOSAGE AND ADMINISTRATION
Taltz is administered by subcutaneous injection.

Plaque Psoriasis (PsO): The recommended dose is 160 mg (two 80 mg injections) at Week 0, followed by 80 mg at Weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks.

Psoriatic arthritis (PsA): The recommended dose is 160 mg by subcutaneous injection (two 80 mg injections) at week 0, followed by 80 mg every 4 weeks.

For psoriatic arthritis patients with coexistent moderate-to-severe plaque psoriasis, use the dosing regimen for plaque psoriasis.

DOSAGE FORMS AND STRENGTHS
Prefilled autoinjector:
- 80 mg/mL single-dose prefilled autoinjector

Prefilled syringe:
- 80 mg/mL single-dose prefilled syringe

REFERENCES

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Effective: 06/01/19