STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IXEKIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IXEKIZUMAB	TALTZ	43193		GPI-10 (9025055400)	

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, genital area, or face

   If yes, **approve for a total of 6 months by HICL or GPI-10 as follows:**
   - **For patients who are 6 years to 17 years of age, enter TWO approvals:**
     - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 2mL per 28 days.**
     - **SECOND APPROVAL: Approve for 5 months with a quantity limit of 1mL per 28 days (Start date is 3 WEEKS AFTER the START date of the first approval).**
   - **For patients who are 18 years of age or older, enter THREE approvals:**
     - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 3mL per 28 days.**
     - **SECOND APPROVAL: Approve for 2 months with a quantity limit of 2mL per 28 days (Start date is 3 WEEKS AFTER the START date of the first approval).**
     - **THIRD APPROVAL: Approve for 3 months with a quantity limit of 1mL per 28 days (Start date is 1 WEEK BEFORE the END date of the second approval).**

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

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

3. 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 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.

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

   If yes, **approve for a total of 6 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 3mL per 28 days.**
   - **SECOND APPROVAL: Approve for 2 months with a quantity limit of 2mL per 28 days (Start date is 3 WEEKS AFTER the START date of the first approval).**
   - **THIRD APPROVAL: Approve for 3 months with a quantity limit of 1mL per 28 days (Start date is 1 WEEK BEFORE the END date of the second approval).**

   If no, **approve for a total of 6 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 2mL per 28 days.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of 1mL per 28 days (Start date is 3 WEEKS AFTER the START date of the first approval).**

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of ankylosing spondylitis (AS) 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 rheumatologist
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, **approve for a total of 6 months by entering TWO approvals by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 2mL per 28 days.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of 1mL per 28 days (Start date is 3 WEEKS AFTER the START date of the first approval).**

   If no, continue to #6.

6. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) 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 rheumatologist
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

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

7. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic (e.g., Cosentyx [secukinumab], Cimzia [certolizumab]) and is switching to the requested drug
   - The patient has C-reactive protein (CRP) levels above the upper limit of normal
   - The patient has sacroiliitis on magnetic resonance imaging (MRI)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of 1mL per 28 days.**
   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: *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 **IXEKIZUMAB (Taltz)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)

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 (a type of skin doctor)
   3. You had a trial of or 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

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You had a trial of or contraindication (harmful for) to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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INITIAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You had a trial of or contraindication (harmful for) to an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

E. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You had a trial of or contraindication (harmful for) to an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
   4. You meet ONE of the following:
      a. You were previously stable on another biologic (such as Cosentyx [secukinumab], Cimzia [certolizumab]) and are switching to the requested drug
      b. You have C-reactive protein (CRP; a measure of how much inflammation you have) levels above the upper limit of normal
      c. You have sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)

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 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 or GPI-10 with a quantity limit of 1mL per 28 days.**
   If no, continue to #2.

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IXEKIZUMAB

RENEWAL CRITERIA (CONTINUED)

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 or GPI-10 with a quantity limit of 1mL per 28 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of 1mL per 28 days.**
   If no, do not approve.
   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 **IXEKIZUMAB (Taltz)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
      1. You achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50% or more
   C. **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
   D. **If you have ankylosing spondylitis OR non-radiographic axial spondyloarthritis, renewal also requires:**
      1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy

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IXEKIZUMAB

RENEWAL CRITERIA (CONTINUED)

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 Taltz.

REFERENCES

- Taltz [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; September 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A　　Created: 04/16
Commercial Effective: 07/01/23　　Client Approval: 05/23　　P&T Approval: 04/23

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