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 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 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
   - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Cosentyx, Enbrel, Humira, Otezla, Stelara, Tremfya, Skyrizi [**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 or GPI-10 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.

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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 had a previous trial of or contraindication to at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Cosentyx, Enbrel, Humira, Stelara, Xeljanz IR/XR, Otezla [**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 or GPI-10 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, continue to #3.

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

3. 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 given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to an NSAID
   - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Enbrel, Humira, Cosentyx [**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 or GPI-10 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 ankylosing spondylitis requires that 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 no, do not approve.
   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: dry, itchy skin patches with scales)
      2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
      3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

B. **If you have moderate to severe 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 dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions 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. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Otezla, Stelara, Tremfya, Skyrizi

C. **If you have psoriatic arthritis (PsA), 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 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
   4. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Xeljanz/XR, Otezla, Stelara

D. **If you have ankylosing spondylitis (AS), 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 muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Cosentyx

NOTE: 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.

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.

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IXEKIZUMAB

GUIDELINES FOR USE (CONTINUED)

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 (#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 or GPI-10 with a quantity limit of 1mL (#1 80mg/mL syringe/autoinjector) per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) **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 (#1 80mg/mL syringe/autoinjector) 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: dry, itchy skin patches with scales)
      2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
      3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   B. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
      1. You achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

   (Renewal denial text continued on next page)

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IXEKIZUMAB

RENEWAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis (PsA), 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 (AS), 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) score while on therapy

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]. Eli Lilly and Company: Indianapolis, IN: August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 04/16
Client Approval: 02/20
P&T Approval: 01/20