STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETANERCEPT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ETANERCEPT	ENBREL	18830		GPI-10 (6629003000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) 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 at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #2.

2. Does the patient have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #3.

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ETANERCEPT

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, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #4.

4. 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., naproxen, ibuprofen, meloxicam)

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 4 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 #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

6. 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 GPID or GPI-14 and enter two approvals as follows:**
   - **FIRST APPROVAL: approve for 3 months for the requested strength:**
     - **25mg syringes: #8mL per 28 days.**
     - **25mg vials: #16 vials OR #8mL per 28 days.**
     - **50mg syringes/cartridges: #8mL per 28 days.**
   - **SECOND APPROVAL: approve for the requested strength for the next 3 months:**
     - **25mg syringes: #4mL per 28 days.**
     - **25mg vials: #8 vials OR #4mL per 28 days.**
     - **50mg syringes/cartridges: #4mL per 28 days.**

   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 **ETANERCEPT (Enbrel)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
      4. Ankylosing spondylitis (AS: a type of joint condition)
      5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   B. **If you have moderate to severe rheumatoid 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)
      3. You had a trial of or contraindication (harmful for) to at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   (Initial denial text continued on next page)

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 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 ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **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

E. **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 naproxen, ibuprofen, meloxicam)

F. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 4 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 biologic (such as Cimzia [certolizumab], Cosentyx [secukinumab]) and are switching to the requested medication
      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

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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ETANERCEPT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **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 GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) **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 GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #3.

3. 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 GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #4.

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ETANERCEPT

RENEWAL CRITERIA (CONTINUED)

4. 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) while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #5.

5. 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 while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL 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 **ETANERCEPT (Enbrel)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
      4. Ankylosing spondylitis (AS: a type of joint condition)
      5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   B. **If you have moderate to severe rheumatoid 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.

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ETANERCEPT

RENEWAL CRITERIA (CONTINUED)

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 moderate to severe polyarticular juvenile idiopathic 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.

E. **If you have ankylosing spondylitis, 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) while on therapy.

F. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more 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 Enbrel.

REFERENCES

- Enbrel [Prescribing Information]. Thousand Oaks, CA: Immunex Corporation; March 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23

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