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 given in consultation with a rheumatologist
   - The patient had a previous 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.**

   APPROVAL TEXT: Renewal for moderate to severe rheumatoid 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 #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 given in consultation with a rheumatologist
   - The patient had a previous 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.**

   APPROVAL TEXT: Renewal for moderate to severe polyarticular juvenile idiopathic 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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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 given in consultation with a rheumatologist or dermatologist
   - The patient had a previous 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.**

   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 #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 given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to an NSAID (e.g., naproxen, ibuprofen, diclofenac)

   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.**

   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) while on therapy.

   If no, continue to #5.

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - 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 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

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Is the patient 18 years of age or older?

   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.**

   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 while on therapy.

   If no, continue to #7.

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

7. Is the patient aged 4 to 17 years old?

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.**

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 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 **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: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   4. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   5. Moderate to severe plaque psoriasis (PsO: dry, scaly, itchy skin patches)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

E. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the 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)

F. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 4 years of age or older
   2. Therapy 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 (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried 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

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: inflammation and stiffness in joints)
      2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
      3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
      4. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
      5. Moderate to severe plaque psoriasis (PsO: dry, scaly, itchy skin patches)
   B. **If you have moderate to severe rheumatoid arthritis (RA), 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 (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 moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), 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 (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) while on therapy.

F. **If you have moderate to severe plaque psoriasis (PsO), 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: 09/07/20

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P&T Approval: 01/20