ETANERCEPT

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<th>Brand</th>
<th>HICL</th>
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<td>ENBREL</td>
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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 meets all of the following criteria?
   - therapy initiated by or in consultation with a rheumatologist
   - previous trial to at least one of the following DMARD (disease-modifying antirheumatic drug) agent such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - 18 years of age or older
   - patient is not currently taking Kineret (anakinra) or Orencia (abatacept)

   If yes, approve initially for 3 months for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes/vials (1 kit) per 28 days.
   
   APPROVAL TEXT: Renewal 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 meets all of the following criteria?
   - therapy initiated by or in consultation with a rheumatologist
   - previous trial to at least one of the following DMARD (disease-modifying antirheumatic drug) agent such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - 2 years of age or older
   - patient is not currently taking Kineret (anakinra) or Orencia (abatacept)

   If yes, approve initially for 3 months for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes/vials (1 kit) per 28 days.
   
   APPROVAL TEXT: Renewal requires that the patient 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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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meets all of the following criteria?
   - therapy initiated by or in consultation with a rheumatologist or dermatologist
   - previous trial to at least one of the following DMARD (disease-modifying antirheumatic drug) agent such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - 18 years of age or older
   - patient is not currently taking Kineret (anakinra) or Orencia (abatacept)

   If yes, **approve initially for 4 months for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes/vials (1 kit) per 28 days.**

   **APPROVAL TEXT:** Renewal 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 meets all of the following criteria?
   - therapy initiated by or in consultation with a rheumatologist
   - 18 years of age or older
   - patient is not currently taking Kineret (anakinra) or Orencia (abatacept)

   If yes, **approve initially for 4 months for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes/vials (1 kit) per 28 days.**

   **APPROVAL TEXT:** Renewal requires that the patient has experienced an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI).
   If no, continue to #5.

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5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meets all of the following criteria?
   - therapy initiated by or in consultation with a dermatologist
   - plaque psoriasis involve at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, or genital area
   - 18 years of age or older
   - previous trial 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
   - patient is not currently taking Kineret (anakinra) or Orencia (abatacept)

   If yes, approve initially for 4 months for #16 of the 25mg syringes/vials (4 kits) per 28 days or #8 of the 50mg syringes/vials (2 kits) per 28 days.

   APPROVAL TEXT: Renewal for plaque psoriasis requires that the patient has achieved clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more. Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   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)

DENIAL TEXT: Our guideline for ETANERCEPT requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe polyarticular juvenile idiopathic arthritis, ankylosing spondylitis, or moderate to severe plaque psoriasis. Additional guideline requirements apply.

For patients with moderate to severe rheumatoid arthritis, approval requires all of the following:

- therapy be initiated by or in consultation with a rheumatologist
- a trial of at least one DMARD (disease-modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- 18 years of age or older
- patient is not currently taking Kineret (anakinra) or Orencia (abatacept)

For patients with moderate to severe polyarticular juvenile idiopathic arthritis, approval requires all of the following:

- therapy be initiated by or in consultation with a rheumatologist
- a trial of at least one DMARD (disease-modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- 2 years of age or older
- patient is not currently taking Kineret (anakinra) or Orencia (abatacept)

For patients with psoriatic arthritis, approval requires all of the following:

- therapy be initiated by or in consultation with a dermatologist or rheumatologist
- a trial of at least one DMARD (disease-modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- 18 years of age or older
- patient is not currently taking Kineret (anakinra) or Orencia (abatacept)

For patients with ankylosing spondylitis, approval requires all of the following:

- therapy initiated by or in consultation with a rheumatologist
- trial of Humira (adalimumab)
- 18 years of age or older
- patient is not currently taking Kineret (anakinra) or Orencia (abatacept)

For patients with moderate to severe plaque psoriasis, approval requires all of the following:

- therapy be initiated by or in consultation with a dermatologist
- psoriatic lesions covering greater than 10% of BSA (Body Surface Area) or lesions on the hands, feet, or genital area
- a trial to one or more forms of preferred therapies such as: such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- 18 years of age or older
- patient is not currently taking Kineret (anakinra) or Orencia (abatacept)

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RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meets the following criteria?
   • documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy

   If yes, **approve for 12 months for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes/vials (1 kit) per 28 days.**
   **APPROVAL TEXT:** Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meets the following criteria?
   • documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy

   If yes, **approve for 12 months for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes/vials (1 kit) per 28 days.**
   **APPROVAL TEXT:** Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, continue to #3.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meets the following criteria?
   • documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy

   If yes, **approve for 12 months for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes/vials (1 kit) per 28 days.**
   If no, continue to #4.

   CONTINUED ON NEXT PAGE
4. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meets the following criteria?
   - documentation 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)

   If yes, **approve for 12 months for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes/vials (1 kit) per 28 days.**

   **APPROVAL TEXT:** Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meets the following criteria?
   - documentation 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 yes, **approve for 12 months for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes/vials (1 kit) per 28 days.**

   **APPROVAL TEXT:** Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   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)

DENIAL TEXT: Our guideline for ETANERCEPT renewal requires a diagnosis of moderate to severe rheumatoid arthritis, moderate to severe juvenile polyarticular idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, or moderate to severe plaque psoriasis. Additional guideline requirements apply.

Renewal for the diagnosis of moderate to severe rheumatoid arthritis requires:
• documentation that the patient has experienced or maintained a 20% improvement in tender or swollen joint count while on therapy.

Renewal for the diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis requires:
• documentation that the patient has experienced or maintained a 20% improvement in tender or swollen joint count while on therapy.

Renewal for the diagnosis of psoriatic arthritis requires:
• documentation that the patient has experienced or maintained a 20% improvement in tender or swollen joint count while on therapy.

Renewal for the diagnosis of ankylosing spondylitis requires:
• documentation of at least a 50% improvement or increase of 2 units from baseline on the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index).

Renewal for the diagnosis of moderate to severe plaque psoriasis requires:
• documentation that the patient has achieved clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more.

RATIONALE
Ensure that appropriate diagnostic, utilization, and safety criteria are utilized for the management of requests for etanercept, renewal criteria based on clinical trials efficacy endpoints at week 12.

FDA APPROVED INDICATION
Enbrel is a tumor necrosis factor (TNF) blocker indicated for the treatment of:
• Rheumatoid Arthritis (RA)
• Polyarticular Juvenile Idiopathic Arthritis (JIA) in patients aged 2 years or older
• Psoriatic Arthritis (PsA)
• Ankylosing Spondylitis (AS)
• Plaque Psoriasis (PsO)
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DOISING
Enbrel is administered by subcutaneous injection.
- Adult RA and PsA: 50 mg once weekly with or without methotrexate (MTX)
- AS: 50 mg once weekly
- Adult PsO: 50 mg twice weekly for 3 months, followed by 50 mg once weekly
- PJIA: 0.8 mg/kg weekly, with a maximum of 50 mg per week

REFERENCES

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