HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

ETANERCEPT (ENBREL)

Generic	Brand	HICL	GCN	Exception/Other
ETANERCEPT	ENBREL	18830		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a patient with a diagnosis of moderate to severe rheumatoid arthritis (RA) and does the request meet **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Prescribed by (or in consultation with) a rheumatologist
   - Trial with **ONE** of the following:
     - o At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
     - o Biologic agent approved for RA (e.g., Enbrel, Humira, Xeljanz)

   If yes, continue to #6.
   If no, continue to #2.

2. Is the request for a patient with a diagnosis of psoriatic arthritis (PsA) and does the request meet **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Prescribed by (or in consultation with) a rheumatologist or dermatologist
   - Trial with **ONE** of the following:
     - o At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, or sulfasalazine
     - o Biologic agent approved for PsA (e.g., Enbrel, Humira, Xeljanz)

   If yes, continue to #6.
   If no, continue to #3.

3. Is the request for a patient with a diagnosis of ankylosing spondylitis (AS) and does the request meet **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Prescribed by (or in consultation with) a rheumatologist
   - Trial with **ONE** of the following:
     - o Prescription-strength NSAID (non-steroidal anti-inflammatory drug) such as: celecoxib, diclofenac, ibuprofen, naproxen, or meloxicam
     - o Biologic agent approved for AS (e.g., Enbrel, Humira)

   If yes, continue to #6.
   If no, continue to #4.

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ETANERCEPT (ENBREL)

INITIAL CRITERIA (CONTINUED)

4. Is the request for a patient with a diagnosis of juvenile idiopathic arthritis (JIA) and does the request meet **ALL** of the following criteria?
   - Patient is 2 years of age or older
   - Prescribed by (or in consultation with) a rheumatologist
   - Trial with **ONE** of the following:
     - o At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
     - o Biologic agent approved for JIA (e.g., Enbrel, Humira)

   If yes, continue to #6.
   If no, continue to #5.

5. Is the request for a patient with a diagnosis of moderate to severe plaque psoriasis (PsO) and does the request meet **ALL** of the following criteria?
   - Patient is 4 years of age or older
   - Prescribed by (or in consultation with) a dermatologist
   - Trial with **ONE** of the following:
     - o At least one course of systemic therapy for psoriasis such as: acitretin, cyclosporine, methotrexate, or oral methoxsalen plus UVA light (PUVA)
     - o Biologic agent approved for PsO (e.g., Enbrel, Humira, Stelara)

   If yes, continue to #6.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT (if diagnosis is not met): Per your health plan's Adalimumab (Humira) guideline, this medication is only covered for one of the following conditions: Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Plaque Psoriasis, and Juvenile Idiopathic Arthritis. Your provider did not indicate that you are being treated for any of these conditions and therefore your request was not approved.

   DENIAL TEXT (RA): Per your health plan's Etanercept (Enbrel) guideline, this medication is only covered for moderate to severe Rheumatoid Arthritis (RA) when you meet all of the following conditions:
   - Patient is 18 years of age or older
   - Prescribed by (or in consultation with) a rheumatologist
   - Trial with one of the following:
     - o At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
     - o Biologic agent approved for RA (e.g., Enbrel, Humira, Xeljanz), which also require prior authorization

   Your provider did not indicate **[specific criteria not met],** and therefore your request was not approved.
   (Initial denial text continued on next page)

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ETANERCEPT (ENBREL)

INITIAL CRITERIA (CONTINUED)

DENIAL TEXT (PsA): Per your health plan's Etanercept (Enbrel) guideline, this medication is only covered for Psoriatic Arthritis (PsA) when you meet all of the following conditions:

- Patient is 18 years of age or older
- Prescribed by (or in consultation with) a rheumatologist or dermatologist
- Trial with one of the following:
  - At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, or sulfasalazine
  - Biologic agent approved for PsA (e.g., Enbrel, Humira, Xeljanz), which also require prior authorization

Your provider did not indicate **[specific criteria not met]**, and therefore your request was not approved.

DENIAL TEXT (AS): Per your health plan's Etanercept (Enbrel) guideline, this medication is only covered for Ankylosing Spondylitis (AS) when you meet all of the following conditions:

- Patient is 18 years of age or older
- Prescribed by (or in consultation with) a rheumatologist
- Trial with one of the following:
  - Prescription-strength NSAID (non-steroidal anti-inflammatory drug) such as: celecoxib, diclofenac, ibuprofen, naproxen, or meloxicam
  - Biologic agent approved for AS (e.g., Enbrel, Humira), which also require prior authorization

Your provider did not indicate **[specific criteria not met]**, and therefore your request was not approved.

DENIAL TEXT (JIA): Per your health plan's Etanercept (Enbrel) guideline, this medication is only covered for Juvenile Idiopathic Arthritis (JIA) when you meet all of the following conditions:

- Patient is 2 years of age or older
- Prescribed by (or in consultation with) a rheumatologist
- Trial with one of the following:
  - At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
  - Biologic agent approved for JIA (e.g., Enbrel, Humira), which also require prior authorization

Your provider did not indicate **[specific criteria not met]**, and therefore your request was not approved.

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ETANERCEPT (ENBREL)

INITIAL CRITERIA (CONTINUED)

DENIAL TEXT (PsO): Per your health plan's Etanercept (Enbrel) guideline, this medication is only covered for moderate to severe plaque psoriasis (PsO) when you meet all of the following conditions:

- Patient is 4 years of age or older
- Prescribed by (or in consultation with) a dermatologist
- Trial with one of the following:
  - At least one course of systemic therapy for psoriasis such as: acitretin, cyclosporine, methotrexate, or oral methoxsalen plus UVA light (PUVA)
  - Biologic agent approved for PsO (e.g., Enbrel, Humira, Stelara), which also require prior authorization

Your provider did not indicate **[specific criteria not met]**, and therefore your request was not approved.

6. **Approve for 12 months by HICL up to 13 fills.** (Enbrel 50mg is hard-coded with a quantity of four syringes per 28 days. Enbrel 25mg is hard-coded with a quantity of eight syringes per 28 days.) Please use status code #056 and the approval text provided.
   APPROVAL TEXT (RA/PsA/AS/JIA): Your request for Enbrel **[___mg]** has been approved for a 12-month period for a quantity of ____ syringes per 28 days.

   If the request is for plaque psoriasis and for a new start, please enter an override for eight syringes per 28 days for the first 3 months. (**NOTE:** Please enter 'F' in the restriction field with a Max Quantity)
   - **First PA:** Approve eight syringes per 28 days for the first 3 months; fill count = 3.
   - **Second PA:** Approve for 9 months; fill count = 10. (NOTE: Please enter a start date 12 week after the start date of the first approval)

   APPROVAL TEXT (PsO): Your request for Enbrel **[___mg]** has been approved for a 12-month period for a quantity up to ____ syringes per 28 days for the first 3 months, and then ____ syringes per 28 days for the remaining 9 months.

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ETANERCEPT (ENBREL)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the request meet **ALL** of the following criteria?
   - Prescribed for one of the following diagnoses: rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, or plaque psoriasis
   - Prescribed by (or in consultation with) a dermatologist or rheumatologist
   - Documentation that the patient experienced improvement while on therapy

   If yes, **approve for 12 months by HICL up to 13 fills.** (Enbrel 50mg is hard-coded with a quantity of four syringes per 28 days. Enbrel 25mg is hard-coded with a quantity of eight syringes per 28 days.) Please use status code #056 and the approval text provided.
   APPROVAL TEXT: Your request for Enbrel **[___mg]** has been approved for a 12-month period for a quantity of ___syringes per 28 days.

   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Etanercept (Enbrel) guideline, authorization for renewal requires that you meet **ALL** of the following conditions:
   - Prescribed for one of the following diagnoses: rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, or plaque psoriasis
   - Prescribed by (or in consultation with) a dermatologist or rheumatologist
   - Documentation that the patient experienced improvement while on therapy

   Your provider did not indicate **[specific criteria not met],** and therefore your request was not approved.

RATIONALE
Ensure that appropriate diagnostic, utilization, and safety criteria are utilized for the management of requests for etanercept.

FDA APPROVED INDICATION
Rheumatoid arthritis, psoriatic arthritis, chronic moderate to severe plaque psoriasis, ankylosing spondylitis and juvenile idiopathic arthritis.

REFERENCES

- Immunex Corporation. Enbrel product information. Thousand Oaks, CA. November 2017.
- Braun J, Davis J et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with Ankylosing Spondylitis. Ann Rheum Dis. 2006; 65(3):316-20.
- Micromedex® Healthcare Series [database online]. Greenwood Village, Colo: Thomson Healthcare. Available at: https://www.thomsonhc.com/hcs/librarian.
- Smith CH, Anstey AV, et al. British association of dermatologists' guidelines for use of biological interventions in psoriasis 2005. Br J Dermatol 2005; 153:486-497.

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