PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	**Enbrel (etanercept)**

a) Adult: 50 mg subcutaneously once weekly
b) Pediatric: weight < 63 kg: 0.8 mg/kg once weekly; weight 63 kg or more: 50 mg once weekly

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease (ie. decreased joint swelling and pain, improved skin appearance, improved quality of life, etc).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Rheumatoid Arthritis

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of moderately to severely active RA; AND
4. Member must have a trial and failure of, or intolerance to methotrexate for at least 3 months; *Note*: If methotrexate is contraindicated, one of the following conventional DMARDs must be trialed instead: leflunomide, sulfasalazine, or hydroxychloroquine; AND
5. Member has had a negative tuberculosis test within the past 12 months.
6. **Dosage allowed/Quantity limit:** 50 mg once weekly. (4 syringes/autoinjectors per 28 days).

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes demonstrate improvement of RA signs and symptoms (e.g. fewer number of painful and swollen joints, achievement of remission, slowed progression of joint damage, etc).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Enbrel (etanercept) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/08/2017	New policy for Enbrel created. Policies SRx-0042 and SRx-00423 achieved. For diagnosis of PsO: immunosuppressive drug criterion was separated from score requirement was added; age was adjusted for pediatric indication. For RA: non-biologic DMARDS were listed. List of diagnoses considered not medically necessary was added.
02/26/2019	Pediatric dosing added to PsO indication. Clarifications entered for AS and PsA on NSAIDs trial length. References added. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. Symptoms of back pain for AS extended till before age of 50. Other drugs options allowed for PsA if there is an - SI score improvement incorporated into general chart noted documentation requirements.
11/22/2020	Replaced list of excluded diagnoses with the generic statement. Updated references. For all diagnoses: Removed repeat TB in reauth for all diagnoses.

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20. Smolen JS, Landewé RBM, Bijlsma JWJ, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*. 2020;79(6):685-699.
21. Zhao S, et al. Etanercept for the treatment of rheumatoid arthritis. *Immunotherapy*. 2018 Feb 27;10(6).
22. Lau AN, et al. Effectiveness Of Etanercept In Elderly Patients With Rheumatoid Arthritis: A Single Center Retrospective Study. *American College of Rheumatology*. Meeting Abstract Number: 1476
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