SmartHealth

Ascension

Etanercept

(Enbrel®) J1438

Covered with prior authorization

Etanercept (Enbrel®) may be authorized when the following criteria are met:

- Diagnosis of rheumatoid arthritis (RA); **AND**
- Individual is 18 years of age or older with moderate to severe RA; **AND**
    - Individual has had an inadequate response to methotrexate titrated to maximally tolerated dose; **OR**
    - If methotrexate is not tolerated or contraindicated, the individual has had an inadequate response to, is intolerant of, or has a contraindication to other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **AND**
- Dose is 50 mg once weekly with or without methotrexate (MTX).

OR

- Diagnosis of polyarticular juvenile idiopathic arthritis (PJIA); **AND**
- Individual is 2 years of age or older with moderate to severe PJIA; **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic disease modifying anti-rheumatic agents (DMARDs) (such as methotrexate)]; **AND**
- Dose is 0.8 mg/kg weekly, with a maximum of 50 mg per week.

OR

- Diagnosis of psoriatic arthritis (PsA); **AND**
- Individual is 18 years of age or older with moderate to severe PsA; **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, or leflunomide)]; **AND**
- Dose is 50 mg once weekly with or without methotrexate (MTX).

OR

- Diagnosis of ankylosing spondylitis (AS); **AND**
- Individual is 18 years of age or older with moderate to severe AS; **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as NSAIDs or nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as sulfasalazine)]; **AND**
- Dose is 50 mg once weekly.

OR

- Diagnosis of chronic moderate to severe (that is, extensive or disabling) plaque psoriasis (Ps) (Psoriasis vulgaris); **AND**
- Individual is 4 years of age or older; **AND**

Developed by: Medical Specialty Prior Authorization Team, April 2022
Approved by: Ambulatory Care Expert Review Panel, April 2022; Therapeutic Affinity Group, May 2022

    - Plaque Ps (psoriasis vulgaris) involves greater than three percent (3%) body surface area (BSA); **OR**
    - Plaque Ps (psoriasis vulgaris) involves less than or equal to three percent (3%) (BSA) involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia); **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate); **AND**
- Dose is age-appropriate:
    - Adult: 50 mg twice weekly for 3 months, followed by 50 mg once weekly
    - Pediatric: 0.8 mg/kg weekly, with a maximum of 50 mg per week.

AND

- Prescriber specialty is in Rheumatology or Dermatology

Exclusion criteria:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
- In combination with other TNF antagonists, apremilast, JAK inhibitors, ozanimod, or other biologic drugs (such as abatacept, anakinra, IL-17 inhibitors, IL-23 inhibitors, rituximab, tocilizumab, ustekinumab, or vedolizumab), or cyclophosphamides.
- Tuberculosis, other active serious infections, or a history of recurrent infections.
- If initiating therapy, the individual has not had a tuberculin skin test (TST), or a Centers for Disease Control (CDC-) and Prevention-recommended equivalent, to evaluate for latent tuberculosis(unless switching therapy from another targeted immune modulator and no new risk factors).
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

Initial authorization for approved indications is up to 12 months.

Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease. Clinical documentation provided must be from within the most recent 12 months.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Enbrel is a tumor necrosis factor (TNF) blocker indicated for the treatment of:

- Rheumatoid Arthritis (RA)
- Psoriatic Arthritis (PsA)

- Polyarticular Juvenile Idiopathic Arthritis (JIA) in individuals aged 2 years or older
- Ankylosing Spondylitis (AS)
- Plaque Psoriasis (PsO) in individuals 4 years or older

References:

Enbrel® (etanercept) label. (2020, August). Accessdata.fda.gov. Retrieved April 22, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/103795s5582lbl.pdf

Fraenkel, L., Bathon, J. M., England, B. R., & et al. (2021, June 8). 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research*, *73*(7), 924 - 939. Wiley Online Library. 10.1002/acr.24596

Criteria History/ Revision Information:

Date	Summary of Changes
April 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
May 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.