Pharmacy Management Drug Policy

SUBJECT: Enbrel (etanercept) – for Ankylosing Spondylitis, Juvenile Idiopathic Arthritis, Plaque Psoriasis, Psoriatic Arthritis, and Rheumatoid Arthritis
POLICY NUMBER: PHARMACY-13
EFFECTIVE DATE: 05/2009
LAST REVIEW DATE: 03/06/2025

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☐ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☐ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☐ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Enbrel® (Etanercept) binds specifically to TNF and blocks its interaction with cell-surface tumor necrosis factor receptors (TNFRs). TNF is a naturally occurring cytokine that is involved in normal inflammatory and immune responses.

Enbrel® is indicated for:

- reducing the signs and symptoms in patients with active ankylosing spondylitis
- the treatment of adult & pediatric patients 4 years of age and older with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy
- reducing the signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older
- reducing the signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis.
- reducing the signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active RA

POLICY:

Based upon our assessment and review of the peer-reviewed literature Enbrel® has been medically proven to be effective and therefore, **medically necessary** for the treatment of the following diagnoses if specific criteria are met:

I. **Ankylosing Spondylitis**
1. Must be prescribed by or in consultation with a Rheumatologist **AND**
2. Must be at least 18 years old **AND**
3. Member must have a diagnosis of Ankylosing Spondylitis **AND**
4. Must have refractory disease defined by failure of or intolerance to at least **TWO** different NSAIDS at maximum strength for at least 1 month each
5. Approved dosing is 50mg/week

II. **Juvenile Idiopathic Arthritis**

1. Must be prescribed by or in consultation with a Rheumatologist **AND**
2. Member must be at least 2 years old **AND**
3. Member must have moderately to severely active polyarticular juvenile idiopathic arthritis **AND**
4. Member must have failed to respond to and/or is intolerant to approved disease- modifying antirheumatic drugs (DMARDs) agents, such as methotrexate, NSAIDs, analgesics or corticosteroids either alone or in combination
5. The recommended dose for pediatric patients ages 2 to 17 years with active polyarticular-course JIA is 0.8mg/kg per week up to a maximum of 50mg per week

III. **Plaque Psoriasis**

a. Enbrel is medically appropriate if **ALL** the following are met:
   1. Must be prescribed by or in consultation with a Dermatologist or Rheumatologist **AND**
   2. Member must be at least 4 years of age **AND**
   3. Member must have moderate to severe chronic plaque psoriasis that involves at least 10% of their body surface area (BSA). Consideration will be given to those who have less than 10% body surface area involvement but have severe disease of sensitive areas or areas causing significant disruption in normal activities (such as the hands, feet, face, genitalia) **AND**
   4. The patient must be a candidate for systemic therapy or phototherapy and meet for **ONE** of the following (**a or b**)
      a. The patient must have had a 3-month trial of systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) that resulted in an inadequate response (failure). A 3-month trial will not be required if the member experienced serious side effects during a trial of one of the aforementioned agents **OR**
      b. The patient must have had a 3-month trial of Ultraviolet B (UVB) Phototherapy or Psoralen Ultraviolet A (PUVA) Phototherapy that resulted in an inadequate response (failure)

b. Authorization period and dosing limitations:
   1. **Adult dosing** (age 18 and up):
      i. Coverage of Enbrel in psoriasis patients is limited to 50mg twice weekly for the first 3 months, and then maintenance therapy not exceeding doses of 50mg per week
         1. Quantity # 8 of 50mg/ 30 days for initial 3 months
         2. Quantity # 4 of 50mg/ 30 days or # 8 of 25mg/ 30 days for maintenance therapy
      ii. If adequate response is not achieved after 24 weeks, a constant dose of 50 mg twice weekly may be considered.
   2. **Pediatric Dosing** (age 4 – 17)
      i. Given as 0.8mg/kg weekly, up to a maximum of 50mg/week

IV. **Psoriatic Arthritis**

1. Must be prescribed by or in consultation with a Dermatologist or Rheumatologist **AND**
2. Must be at least 2 years of age **AND**
3. Must have a diagnosis of active Psoriatic Arthritis
4. Approved dosing
   a. Adult: 50 mg/week
   b. Pediatric
      i. 63 kg or more: 50 mg/week
      ii. Less than 63 kg: 0.8 mg/kg/week

V. **Rheumatoid Arthritis**
1. Must be prescribed by or in consultation with a Rheumatologist **AND**
2. Must be at least 18 years of age **AND**
3. Member must have a diagnosis of moderately to severely active rheumatoid arthritis **AND**
4. Must have failed to respond to and/or is intolerant to approved disease-modifying antirheumatic drug (DMARD) agents, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
5. Approved dosing is 50mg per week. Doses higher than 50mg per week are not recommended based on a study of Enbrel 50mg twice weekly in patients with rheumatoid arthritis suggesting a higher incidence of adverse events but similar ACR response rates

The following are **non-FDA approved indications** which **may be considered medically appropriate:**

VI. **Hidradenitis Suppurativa**
1. Must be prescribed by or in consultation with a Dermatologist **AND**
2. Must have a diagnosis of stage II or III severe refractory hidradenitis suppurativa with recurrent abscesses
3. Must have had a minimum of a three-month trial of systemic antibiotics (such as minocycline, doxycycline, clindamycin, rifampin) which failed to provide clinical improvement
4. Initial approval will be for 25mg twice a week for 3 months, Continuation of therapy will require documented improvement of disease.

VII. **Graft versus Host Disease:**
1. Member must have moderate (grade 2) to severe (grade 3 to 4) GVHD.
2. The member must have failed to respond to conventional immunosuppressive therapy, such as methotrexate, prednisone, tacrolimus and/or cyclosporine.
3. Initial approval will be for 25mg twice a week for 4 weeks, then weekly dosing thereafter for up to 3 months (12 weeks total dosing). Continuation of therapy will require documented improvement of disease.

POLICY GUIDELINES:

1. Unless otherwise stated above within the approval time period section, approval time periods will be for 1 year
   - Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline-supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
2. Utilization Management are contract dependent and coverage criteria may be dependent on the contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions.
3. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Non-Formulary Medication Exception Review Policy for all Lines of Business (Pharmacy-69).

4. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
   - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
   - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
   - The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
   - The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
   - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
   - The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
5. Etanercept is self-administered and therefore falls under the pharmacy benefit.
6. **Concurrent use of Inflammatory Agents**
   a. Enbrel as well as other immunomodulating therapies or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) (Stelara, Cimzia, Remicade, biosimilars, etc.) should not be administered in combination with another biologic or targeted synthetic DMARD used for an inflammatory condition. Combination therapy is generally not recommended due to the added risk of immunosuppression, potential for a higher rate of adverse effects, and lack of evidence for additive therapy. NOTE: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with biologics and targeted synthetic DMARDs.
   b. Requests for the concurrent use of inflammatory agents will be evaluated for safety and efficacy and are subject to off-label review.
   c. Otezla in combination with biologic DMARD therapy (such as adalimumab, Enbrel, Cosentyx, etc.) is not FDA approved or supported with a high level of clinically valid medical evidence for the treatment of plaque psoriasis or psoriatic arthritis. Therefore, these requests are considered combination therapy and are considered not medically necessary.
7. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
8. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.

UPDATES:

DATE	REVISION
03/06/2025	Revised
02/17/2025	Revised
8/15/2024	Reviewed / P&T Committee Approval
06/04/2024	Revised
12/06/2023	Revised
08/24/2023	P&T Committee Approval
03/15/2023	Revised
01/01/2023	Revised
9/22/2022	P&T Committee Approval
02/2022	Revision
9/2021	Reviewed / P&T Committee Approval
01/2021	Revision
09/16/2020	P&T Approval
08/2020	Revision
02/2020	Revision
12/2019	Review
09/19/2019	P&T Approval
12/2018	Review
12/2017	Revision
04/2017	Revision
11/2016	Revision
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12/2014	Revision
12/2013	Revision
10/2013	Revision
06/2013	Revision
02/2013	Revision
08/2011	Revision
07/2010	Revision
06/2009	Created

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