

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Enbrel (etanercept)

CG-DRUG-65

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year unless otherwise specified*

Medications	Quantity Limit
Enbrel (etanercept) 25 mg/mL vial*	8 vials
Enbrel (etanercept) 25 mg/0.5 mL (0.51 mL) prefilled syringe*	8 syringes
Enbrel (etanercept) 50 mg/mL (0.98 mL) prefilled syringe*, SureClick® autoinjector*	4 syringes/autoinjectors
Enbrel (etanercept) 50 mg/mL Mini prefilled cartridge with AutoTouch*	4 cartridges

*Initiation of therapy for adult Plaque Psoriasis (Ps): May approve up to 2 (two) additional 25 mg vials (25 mg/mL) or syringes [(25 mg/0.5 mL (0.51 mL)] OR 1 (one) additional 50 mg syringe [50 mg/mL (0.98 mL)], pen (50 mg/0.5 mL), autoinjector [50 mg/mL (0.98 mL)], or cartridge (50 mg/mL) per week in the first 3 months (84 days) of treatment.

APPROVAL CRITERIA

- I. **Individual has been on Enbrel (etanercept) in the past 180 days (medications samples/ coupons/ discount cards are excluded from consideration as a trial); OR**
- II. Diagnosis of Rheumatoid Arthritis
 - A. Individual is 18 years of age or older; **AND**
 - B. Individual has a diagnosis of moderately to severely active rheumatoid arthritis; **AND**
 - C. Agent is used for any of the following reasons:
 1. To reduce signs for symptoms; **OR**
 2. To induce or maintain clinical response; **OR**
 3. To inhibit the progression of structural damage; **OR**
 4. To improve physical function; **AND**
 - D. Individual has failed to respond to, is intolerant of, or has a medical contraindication to one or more non biologic disease modifying anti-rheumatic agents (DMARDs);

OR

- III. Diagnosis of Active Ankylosing Spondylitis

PAGE 1 of 4 09/21/2018

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CRX-ALL-0276-18

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- A. Individual is 18 years of age or older; **AND**
- B. Individual has diagnosis of active Ankylosing Spondylitis; **AND**
- C. Agent is used to reduce signs or symptoms of the disease; **AND**
- D. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as NSAIDs or non biologic DMARDs);

OR

IV. Diagnosis of Juvenile Idiopathic Arthritis

- A. Individual is 2 years of age or older; **AND**
- B. Individuals with a diagnosis of moderate to severely active juvenile idiopathic arthritis; **AND**
- C. Agent is used for **any** of the following reasons:
 - 1. To reduce signs or symptoms; **OR**
 - 2. To induce or maintain clinical response; **AND**
- D. Individual has failed to respond to, is intolerant of, or has a medical contraindication to one or more non biologic disease modifying anti-rheumatic agents (DMARDs);

OR

V. Diagnosis of Psoriatic Arthritis Individual is 18 years of age or older; **AND**

- A. Individual has active psoriatic arthritis; **AND**
- B. Agent is used for **any** of the following reasons:
 - 1. To reduce signs or symptoms; **OR**
 - 2. To induce or maintain clinical response; **OR**
 - 3. To inhibit the progression of structural damage; **OR**
 - 4. To improve physical function; **AND**
- C. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy. (such as non biologic DMARDs);

OR

VI. Diagnosis of Plaque Psoriasis

- A. Individual is 4 years of age or older; **AND**
- B. Individual has a diagnosis of chronic moderate to severe plaque psoriasis (that is, extensive or disabling) with EITHER of the following:
 - 1. Plaque psoriasis involving greater than 5% of body surface area; **OR**
 - 2. Plaque psoriasis involving less than or equal to 5% of body surface area involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia); **AND**
- C. Agent is used for **any** of the following reasons:
 - 1. To reduce signs or symptoms; **OR**
 - 2. To induce or maintain clinical response; **AND**

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D. Individual has failed to respond to, is intolerant of, or has a medical contraindication to the use of phototherapy or other systemic therapies (such as methotrexate, acitretin, or cyclosporine).

Enbrel (etanercept) may **not** be approved for an individual with any of the following:

- I. In combination with other TNF antagonists; **OR**
- II. In combination with tofacitinib citrate; **OR**
- III. In combination with the following non-TNF immunomodulatory drugs: abatacept, anakinra, cyclophosphamides, or vedolizumab; **OR**
- IV. Tuberculosis, invasive fungal infection, other active serious infections, or a history of recurrent infections; **OR**
- V. Individual has not had a tuberculin skin test, or a CDC-recommended equivalent, to evaluate for latent tuberculosis; **OR**
- VI. If the above approval criteria are not met and for all other indications, including but not limited to treatment of asthma, disc-herniation-induced radiculopathy or sciatica, graft-versus-host disease, inclusion-body myositis, inflammatory bowel disease, hidradenitis suppurativa, sarcoidosis, septic shock, Sjogren’s syndrome, and Wegener’s granulomatosis.

Note: Enbrel (etanercept) has a black box warning related to the increased risk of developing serious infections that could result in hospitalization or death. Individuals should be closely monitored for the development of infection during and after treatment with discontinuation of therapy if the individual develops a serious infection or sepsis. Reported infections include: Tuberculosis, invasive fungal infections (including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis), and infections (bacterial, viral, or other) due to opportunistic pathogens (including Legionella and Listeria). The risks and benefits of treatment with Enbrel should be considered prior to initiating in individuals with chronic or recurrent infection. Enbrel is not indicated for the use in pediatric individuals due to reports of lymphoma and other malignancies developing in children and adolescents treated with tumor necrosis factor (TNF) blockers.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

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