Government Health Plan (GHP) of Puerto Rico

Authorization Criteria – Tumor Necrosis Factor Alpha (TNFα) - Etanercept (Enbrel®)

Managed by MCO

Section I. Prior Authorization Criteria

A. Physician must submit evidence of a NEGATIVE intradermal tuberculin (PPD) test result, or Negative results of a chest X-ray, or a certification of negative tuberculosis risk.
B. Patient must meet all criteria / requisites according to diagnosis (see *Section II for Specific criteria per diagnosis*)

1. Rheumatoid Arthritis
2. Polyarticular Juvenile Rheumatoid Arthritis (PJIA)
3. Psoriatic Arthritis
4. Ankylosing Spondylitis
5. Plaque Psoriasis

C. Assess clinical response after the first three months of treatment.

D. Treatment should be discontinued if failure to therapy or toxicity is documented.

E. Follow Package insert instructions for dose administration.

Sección II. Specific Criteria per Diagnosis

A. Rheumatoid Arthritis

1. Prescriber restriction: Rheumatologist (Applies to 1st prescription and every 12 months).
2. Physician must document the diagnosis on the prescription: *Rheumatoid Arthritis (ICD-10: M06.9, M05.00, M05.30 o M05.60).*
3. Physician certifies that patient was treated with one or more disease modifying anti-rheumatic drugs (see Table I) and failed therapy after three months of treatment or presented toxicity.

Doses to be approved for Rheumatoid Arthritis			
Agent	**Route**	**Dose**	**Frequency**
Etanercept	SC	25mg	Two times a week
	SC	50mg	Once a week

B. Polyarticular Juvenile Rheumatoid Arthritis (PJIA)

1. Prescriber restriction: Rheumatologists, Pediatric Rheumatologist (Applies to 1st prescription and every 12 months).
2. Physician must document the diagnosis on the prescription: *Juvenile Rheumatoid Arthritis (ICD-10: M08.00, M08.2, M08.3 o M08.4, M08.9)*
3. Physician certifies that patient was treated with one or more disease modifying anti-rheumatic drugs (see Table I) and failed therapy after three months of treatment or presented toxicity.

4. Patient is ≥ 2 years of age.

5. Patients with *Systemic Juvenile Idiopathic Arthritis and various degrees of synovitis:* physician certifies that patient was treated with anakinra and failed therapy after one month of treatment, or presented toxicity.

Doses to be approved for Juvenile Rheumatoid Arthritis			
Agent	**Route**	**Dose**	**Frequency**
Etanercept	SC	0.8mg/kg	Weekly (max 50 mg per week)

C. Psoriatic Arthritis

1. Prescriber restriction: Rheumatologist, Dermatologist (applies to 1st prescription and every 12 months).
2. Physician must document the diagnosis on the prescription: *Psoriatic Arthritis (ICD-10: L40.54 o L40.59)*
3. Physician certifies that patient was treated with one or more disease modifying anti-rheumatic drugs (see Table I) and failed therapy after six months of treatment or presented toxicity.

D. Ankylosing Spondylitis

1. Prescriber restriction: Rheumatologist (Applies to 1st prescription and every 12 months).
2. Physician must document the diagnosis on the prescription: *Ankylosing Spondylitis (ICD-10: M45.9)*
3. Patient must meet the following criteria according to the type of ankylosing spondylitis presented:

Symptomatic Axial disease	1. Physician documents that patient failed treatment with at least two NSAIDs for at least three months, except if NSAIDs are contraindicated or if patient has presented toxicity or intolerance.
Symptomatic Enthesitis	1. Physician documents that patient failed treatment with at least two NSAIDs for at least three months, except if NSAIDs are

	contraindicated or if patient has presented toxicity or intolerance, and 2. Physician certifies that patient failed treatment with at least two intra-articular steroid injections, except if these are contraindicated or patient presents intolerance.
Symptomatic Periferal Arthritis	1. Physician documents that patient failed treatment with at least two NSAIDs for at least three months, except if NSAIDs are contraindicated or if patient has presented toxicity or intolerance, and 2. Physician certifies that patient failed treatment with at least two intra-articular steroid injections, except if these are contraindicated or patient presents intolerance, and 3. Physician certifies that patient presented intolerance to treatment with sulfasalazine for at least four months, or that its use is contraindicated.

E. Plaque Psoriasis

1. Prescriber restriction: Dermatologist (applies to 1st prescription and every 12 months).
2. Physician must document the diagnosis on the prescription: *Plaque Psoriasis (ICD-10: L40.8).*
3. Patient is 4 years or older.
4. Physician documents that:
   a. Patient has failed treatment with one or more topical agents used for the management of plaque psoriasis, and
   b. Patient has failed treatment with one of the following systemic agents: methotrexate, cyclosporine, acitretin, oral corticosteroids (or use is contraindicated), and
   c. Patient has failed phototherapy, or use is contraindicated, or patient does not have access to phototherapy.

Table I. *Agents classified as disease-modifying anti-rheumatic drugs (DMARDs)*
Hydroxychloroquine
Leflunomide
Methotrexate (MTX)
Minocycline
Sulfasalazine

Section III. References

1. Enbrel [package insert]. Thousand Oaks, CA: Amgen, Revised November 2016.

2. Humira [package insert]. North Chicago, IL: AbbVie Inc. Revised May 2014
3. Cimzia [package insert]. Smyrna, GA: UCB, Inc. revised October 2013
4. Singh J, Furst D, Bharat A, et.al. 2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research*. 2012;64(5):625-639.
5. Ringold S, Weiss P, et.al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis. *Arthritis Care & Rheumatism.* 2013;65(10): 2499-2512.
6. Gottlieb A, Korman N, et.al. Guidelines of care for the management of psoriasis and psoriatic arthritis. J *Am Acad of Dermatol* 2088;58:851-64.
7. Braun J, Pham T, Sieper J, Davis J, van der Linden S, Dougados M, van der Heijde D International ASAS Consensus Statement for the Use of Anti-Tumour Necrosis Factor Agents in Patients with Ankylosing Spondylitis Ann Rheum Dis 2003 ; 62 : 817-824.
8. Callen JP, Krueger GG, Lebwohl M, McBurneyy EI, Mease P, Menter A, Paller AS, Pariser DM, Weinblatt M, Zimmermaan G AAD Consensus Statement on Psoriasis Therapies J Am Acad Dermatol 2003; 49(5): 897-899.
9. Remicade [package insert]. Horsham, PA: Janssen Biotech, Inc. Revised November 2013

Section IV. Review Log

Approved:	**September 8, 2006**
Revised:	**December 1st, 2009**
Revised:	**March 29, 2012**
Revised:	**March 27, 2014** (criteria for use of TNF-a in Crohn's disease were removed from this protocol, and stated in a separate protocol for gastroenterological conditions.
Revised:	**September 25, 2014**
Revised:	**December 11, 2014**
Revised:	**September 24, 2015 (Plaque Psoriasis)**
Revised:	**Janaury 26, 2017 (RA - PJIA)**
Revised:	**February 23, 2017 (Ps, PsA)**
Revised:	**March 30, 2017 (AS)**

GPI	GPI NAME
66290030002120	Etanercept For Subcutaneous Inj 25 MG
6629003000D530	Etanercept Subcutaneous Solution Auto-injector 50 MG/ML
6629003000E525	Etanercept Subcutaneous Soln Prefilled Syringe 25 MG/0.5ML
6629003000E530	Etanercept Subcutaneous Soln Prefilled Syringe 50 MG/ML