Government Health Plan (GHP) of Puerto Rico

Authorization Criteria – Tumor Necrosis Factor Alpha (TNFα) Adalimumab (Humira®)
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. Juvenile Rheumatoid Arthritis
3. Psoriatic Arthritis
4. Ankylosing Spondylitis
5. Plaque Psoriasis
6. Hydradenitis Suppurative – not covered
7. Uveitis
8. Adult Chron's Disease
9. Pediatric Chron's Disease
10. Ulcerative Colitis

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, M05.0, 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**
Adalimumab	SC	40 mg	Every other week
			Some patients NOT using MTX could benefit from an increase in dose frequency - 40 mg once a week

b. Juvenile Rheumatoid Arthritis

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: M08.0, M08.2, M08.3, M08.40 and M08.9).*
3. Patient is ≥ 2 years of age
4. 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.
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**
Adalimumab	SC	20 mg	Body weight > 15 kg - <30 kg – every other week
		40 mg	Body weight > 30 kg - every 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.

Doses to be approved for Ankylosing Spondylitis			
Agent	**Route**	**Dose**	**Frequency**
Adalimumab	SC	40 mg	Every other week

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. 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

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

F. Uveitis:

1. Prescriber restriction**:** Ophthalmologist.

2. Physician must document the diagnosis on the prescription:

Uveitis non-infectious intermediate posterior and panuveitis in adult patients (ICD10-CM: H20.0, H30.9).

3. Physician documents that:

The patient has failed corticosteroid therapy, or that its use is contraindicated, or certifies that adalimumab should be the first line of treatment because of a high risk of visual loss.

G. Adult and Pediatric Chron's Disease:

1. Prescribers restriction: Gastroenterologists or Pediatric Gastroenterologist (Applies to 1st prescription and every 12 months).

2. Physician must document the diagnosis on the prescription:

a. *Adult Crohn's Disease (CD):* Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. Reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab. (ICD-10-CM K50.00 o ICD-10-CM K50.10 o ICD-10-CM K50.90).

b. *Pediatric Crohn's Disease*: Reducing signs and symptoms and inducing and maintaining clinical remission in patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate. (ICD-10-CM K50.00 o ICD-10-CM K50.10 o ICD-10-CM K50.90).

3. Patient is ≥ 6 years of age

4. Induction Treatment: Physician must certify one of the following:

a. Patient has been treated with all of the following drugs and there is evidence of intolerance or failure to therapy:

i. Corticosteroids (e.g. Budesonide, Hydrocortisone) and,

ii. 6-mercaptopurine (6-MP, Purinethol) and/or azathioprine (Imuran) and/or Methotrexate (MTX) and,

iii. TNF-a Antagonist: Infliximab (Applies only to adult patients).

b. Patient has been diagnosed with Crohn's disease in severe stage or presents one or more of the following:

i. Intestinal obstruction
ii. Severe malnutrition
iii. Abscess formation
iv. Perianal fistulas

5. Maintenance Treatment for patients using corticosteroids or TNF-α antagonist
   a. Physician certifies that patient has achieved remission, and
   b. Physician documents previous use of corticosteroids.

I. Ulcerative Colitis

1. Prescribers restriction: Gastroenterologist (Applies to 1st prescription and every 12 months).

2. Physician must document diagnosis on the prescription:

a. Inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine (6-MP). The effectiveness of HUMIRA has not been established in patients who have lost response to or were intolerant to TNF blockers. (ICD-10-CM K51.90, K51.911, K51.912, K51.913, K51.914, K51.918, K51.919)

3. Physician documents that patient has been treated with of the following drugs and there is evidence of intolerance or failure to therapy:

a. 5-aminosalicylic acid on formulary (5-ASA: Mesalamine, Olsalazine, Sulfasalazine) and

b. Corticosteroids (e.g. Budesonide, Hydrocortisone).

Section III. References

1. Enbrel [package insert]. Thousand Oaks, CA: Amgen, Revised November 2013
2. Humira [package insert]. North Chicago, IL: AbbVie Inc. Revised June 2016.
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- α 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:	**December 01, 2016**
Revised:	**January 26, 2017 RA**
Revised:	**February 23, 2017 (Ps, PsA)**
Revised:	**March 30, 2017 (AE, UC, CD)**

GPI	GPI NAME
6627001500F420	Adalimumab Inj Kit 40 MG/0.8ML (50 MG/ML)
6627001500F805	Adalimumab Prefilled Syringe Kit 10 MG/0.2ML
6627001500F810	Adalimumab Inj Kit 20 MG/0.4ML
6627001500F820	Adalimumab Inj Kit 40 MG/0.8ML (50 MG/ML)