Generic Name: Adalimumab

Therapeutic Class or Brand Name: Humira®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 4/27/2021

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of one of the following conditions A through I AND must meet criteria listed under applicable diagnosis:

A. Active Ankylosing Spondylitis and criteria 1 and 2 are met:

1. Diagnosis must be established by a rheumatologist.
2. Minimum age requirement: 18 years old.

B. Moderately to Severely Active Rheumatoid Arthritis and criteria 1 through 3 are met:

1. History of treatment failure, intolerance, or contraindication to Methotrexate, or one other DMARD or second line drug (azathioprine, sulfasalazine, leflunomide, penicillamine, hydroxychloroquine, etc.).
2. Diagnosis must be established by a rheumatologist.
3. Minimum age requirement: 18 years old.

C. Moderately to Severely Active Polyarticular Juvenile Idiopathic Arthritis and criteria 1 through 3 are met:

1. History of treatment failure, intolerance, or contraindication to at least one DMARD (i.e., methotrexate, etc.).
2. Diagnosis must be established by a rheumatologist.
3. Minimum age requirement: 2 years old.

D. Active Psoriatic Arthritis (PsA) and criteria 1through 4 are met:

1. History of treatment failure, intolerance to, or contraindication to methotrexate or a second line DMARD.
2. Patient has severe PsA and severe psoriasis or has predominantly axial disease. See Table 1 under Appendix.
3. Diagnosis must be established by a rheumatologist or dermatologist.
4. Minimum age requirement: 18 years old.

E. Moderate to Severe Chronic Plaque Psoriasis and criteria 1 through 4 are met:

1. History of treatment failure, intolerance, or contraindication with phototherapy or photochemotherapy.
2. History of treatment failure, intolerance, or contraindication with at least one appropriate systemic agent (e.g., cyclosporine, methotrexate, acitretin, etc.).
3. Diagnosis must be established by a dermatologist or a rheumatologist.
4. Minimum age requirement: 18 years old.

F. Moderately to Severely active Crohn's Disease and criteria 1 through 3 are met:

1. Patient meets disease criteria a OR b below:
   a. Patient has documentation of at least one of the following:
      i. Deep ulceration
      ii. Extensive anatomical involvement
      iii. Fistulizing disease
      iv. Hospitalized previously due to Crohn's disease
      v. Penetrating and/or stricturing behavior
      vi. Prior surgical resection
   b. Treatment of acute exacerbation when at least one of criteria i. through iii. is met:
      i. Documented clinically significant treatment failure or contraindication with an appropriate course of corticosteroids (e.g., oral prednisone 40 to 60 mg daily, oral budesonide 9mg daily, or budesonide rectally with a course duration of at least 7 days).
      ii. Documentation patient is unable to taper an appropriate course of corticosteroids without disease worsening.
      iii. Documentation patient is stabilized for at least 8 weeks on conventional therapy (e.g., azathioprine, balsalazide, cyclosporin, mercaptopurine, mesalamine, and sulfasalazine) and is experiencing active disease flares.
2. Treatment must be prescribed by a gastroenterologist.
3. Minimum age requirement: 6 years old.

G. Moderately to Severely Active Ulcerative Colitis and criteria 1 through 3 are met:

1. Patient meets at least one of the treatment criteria a through c:
   a. Documented clinically significant treatment failure or contraindication with an appropriate course of corticosteroids (e.g., oral prednisone 40 – 60mg daily, oral budesonide 9mg daily, or budesonide rectally with a course duration of at least 7 days.
   b. Documentation the patient is unable to taper an appropriate course of corticosteroids without disease worsening.

c. Documentation patient is stabilized for at least 8 weeks on conventional therapy (e.g., azathioprine, balsalazide, cyclosporin, mercaptopurine, mesalamine, and sulfasalazine) and is experiencing active disease flares.

2. Treatment must be prescribed by a gastroenterologist.
3. Minimum age requirement: 5 years old.

H. Moderate to severe hidradenitis suppurativa and criteria 1 and 2 are met:

1. Treatment must be prescribed by a dermatologist.
2. Minimum age requirement: 12 years old.

I. Uveitis (non-infectious intermediate, posterior and panuveitis) and criteria 1 through 4 are met:

1. History of treatment failure, intolerance, or contraindication to corticosteroids (ophthalmic or systemic).
2. History of treatment failure, intolerance, or contraindication to at least one DMARD (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate, etc.).
3. Diagnosis must be established by an ophthalmologist.
4. Minimum age requirement: 2 years old.

II. Absence of active serious infection or sepsis.

III. Negative TB skin test within the previous 12 months or history of treatment for latent TB infection.

IV. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to preferred product(s).

EXCLUSION CRITERIA

- Coadministration of Humira® with another targeted immune modulator. Examples of targeted immune modulators include the following:
  - Actemra® (tocilizumab)
  - Cosentyx® (secukinumab)
  - Dupixent® (dupilumab)
  - Entyvio® (vedolizumab)
  - Ilaris® (canakinumab)
  - Ilumya™ (tildrakizumab-asmn)
  - Kevzara® (sarilumab)
  - Kineret® (anakinra)
  - Olumiant® (baricitinib)

- Orencia® (abatacept)
- Otezla® (apremilast)
- Riabni™ (rituximab-arrx)
- Rinvoq™ (upadacitinib)
- Rituxan® (rituximab)
- Ruxience® (rituximab-pvvr)
- Siliq™ (brodalumab)
- Stelara® (ustekinumab)
- Skyrizi® (risankizumab)
- Taltz® (Ixekizumab)
- TNF inhibitors [Avsola® (infliximab-axxq), Cimzia® (certolizumab pegol), Enbrel® (etanercept), Humira® (adalimumab), Inflectra® (infliximab-dyyb), Remicade® (infliximab), Renflexis® (infliximab-abda), Simponi®/Simponi® Aria® (golimumab)]
- Tremfya™ (guselkumab)
- Truxima® (rituximab-abbs)
- Tysabri® (natalizumab)
- Xeljanz®/XR (tofacitinib)

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Adult rheumatologic conditions (Ankylosing Spondylitis, Rheumatoid Arthritis, Psoriatic Arthritis):
  - Quantities of up to 2 of the 40mg pens or syringes every 28 days.

- Adult Plaque Psoriasis, Uveitis:
  - Quantities of up to 4 of the 40mg pens or syringes, or 1 x 80mg plus 2 x 40mg pens or syringes in the first 28 days, then in quantities of up to 2 of the 40mg pens or syringes every 28 days.
- Adult Inflammatory Bowel Disease (Crohn's Disease, Ulcerative Colitis):
  - Quantities of up to 6 of the 40mg or 3 of the 80mg pens or syringes in the first 28 days, then in quantities of up to 2 of the 40mg pens or syringes every 28 days.
- Hidradenitis suppurativa:

- Quantities of up to 6 of the 40mg or 3 of the 80mg pens or syringes in the first 28 days, then in quantities of up to 4 of the 40mg or 2 of the 80mg pens or syringes every 28 days.

- Polyarticular Juvenile Idiopathic Arthritis or Pediatric Uveitis
  - Quantities of up to 2 of the 10mg, 20mg or 40mg prefilled syringes every 28 days.
- Pediatric Crohn's Disease
  - 17kg to < 40kg: quantities of up to one (1) 80mg plus one (1) 40mg prefilled syringe for the first 28 days of therapy followed by 2 of the 20mg prefilled syringes every 28 days thereafter.
  - ≥ 40kg: quantities of up to three (3) 80mg for the first 28 days of therapy followed by two (2) 40mg prefilled syringes every 28 days thereafter.
- Pediatric Ulcerative colitis
  - 17kg to < 40kg: quantities of up to (4) 40mg pens or syringes OR (1) 80mg plus (2) 40 mg pens or syringes for the first 28 days of therapy followed by (4) 20 mg or (2) 40 mg pens or syringes every 28 days thereafter.
  - ≥ 40kg: quantities of up to (4) 80mg pens or syringes for the first 28 days of therapy followed by (4) 40mg or (2) 80mg every 28 days thereafter.

APPROVAL LENGTH

- **Authorization:** 4 months
- **Re-Authorization:** 1 year, with an updated letter of medical necessity or progress notes showing improvement or maintenance with medication.

APPENDIX

- Table 1 - Examples of severe psoriatic arthritis and severe psoriasis:

Severe Psoriatic Arthritis	Severe Psoriasis
• Erosive disease • Elevated markers of inflammation (ESR, CRP) attributable to PsA • Long-term damage that interferes with function (i.e., joint deformities) • Highly active disease that causes a major impairment in quality of life • Active PsA at many sites including dactylitis, enthesitis • Function-limiting PsA at a few sites • Rapidly progressive disease	• PASI of 12 or more • BSA of 5-10% or more • Significant involvement in specific areas • (e.g., face, hands or feet, nails, intertriginous areas, scalp) where the burden of the disease causes significant disability • Impairment of physical or mental functioning can warrant a designation of moderate-to-severe disease despite the lower amount of surface area of skin involved

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