I. Medication Description

Humira® binds specifically to tumor necrosis factor (TNF)–alpha and blocks its interaction with specific cell surface TNF receptors. TNF is a naturally occurring cytokine that is involved in healthy inflammatory and immune responses. Elevated levels of TNF are found in the synovial fluid of RA, including juvenile idiopathic arthritis, psoriatic arthritis, and ankylosing spondylitis patients, and they play an important role in the pathologic inflammation and joint destruction that are hallmarks of these diseases. Increased levels of TNF are also found in psoriasis plaques. In plaque psoriasis, treatment with adalimumab may reduce the epidermal thickness and infiltration of inflammatory cells.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Humira is provided for the following conditions when the listed criteria are met:

- Ankylosing spondylitis (active disease):
  - Prescribed by a rheumatologist AND
  - The patient has had inadequate results with at least two NSAIDs (unless NSAIDs are contraindicated)

- Crohn’s disease (moderate to severe):
  - Prescribed by a gastroenterologist AND
  - One of the following:
    - The patient has experienced treatment failure or intolerable side effects with an immune modulator such as azathioprine, 6MP, methotrexate (unless contraindicated) OR
    - The severity of the condition requires rapid improvement not attainable with immune modulators OR
    - The patient has fistulizing disease

- Hidradenitis suppurativa (moderate to severe disease)

- Juvenile idiopathic arthritis:
  - Prescribed by a rheumatologist AND
Patient has tried therapy with at least one non-biologic DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated)

- **Plaque psoriasis (moderate to severe disease):**
  - Prescribed by a rheumatologist or dermatologist **AND**
  - At least 10% of BSA affected or less than 10% BSA affected but with palmar, plantar, head/neck, or genitalia involvement **AND**
  - Patient has had an inadequate response to PUVA or UVB therapy unless contraindicated **AND**
  - Patient has had an inadequate response to non-biologic systemic therapy (i.e. methotrexate, cyclosporine, acitretin) unless contraindicated

- **Psoriatic arthritis (active disease):**
  - Prescribed by a rheumatologist or dermatologist **AND**
  - One of the following:
    - Patient has tried therapy with at least one non-biologic DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated) **OR**
    - If predominantly axial disease is documented, the patient has experienced treatment failure with at least two oral NSAIDs (unless NSAIDs are contraindicated)

- **Rheumatoid arthritis (moderate to severe disease):**
  - Prescribed by a rheumatologist **AND**
  - Patient has tried therapy with at least one non-biologic DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated)

- **Ulcerative colitis (moderate to severe disease):**
  - Prescribed by a gastroenterologist **AND**
  - One of the following:
    - The patient has experienced treatment failure or intolerable side effects with an immune modulator such as azathioprine, 6MP, methotrexate (unless contraindicated) **OR**
    - The severity of the condition requires rapid improvement not attainable with immune modulators

- **Uveitis:**
  - Prescribed by an ophthalmologist or rheumatologist **AND**
  - Prescribed for the treatment of non-infectious intermediate, posterior, or panuveitis

### IV. Quantity Limitations

- Quantity will be limited to 2 syringes (80mg) every month, with exceptions as outlined below:
  - **Rheumatoid Arthritis:** up to 160 mg every 28 days
  - **Crohn’s Disease/Ulcerative Colitis:** Initial 28 days: 240 mg
  - **Plaque Psoriasis:** Initial 28 days: 160 mg
  - **Hidradenitis suppurativa:** Initial 28 days: up to 240mg; maintenance every 28 days: 160mg
  - **Uveitis:** initial 28 days: 160mg
V. **Coverage Duration**

Initial coverage is provided for 12 months and may be renewed.

VI. **Coverage Renewal Criteria**

Coverage can be renewed based upon the following criteria:

- Clinical response or remission of disease is maintained with continued use **AND**
- Absence of unacceptable toxicity from the drug

VII. **Billing/Coding Information**

Supplied as:

- Humira Pen Carton – 40mg/0.8mL and 40mg/0.4mL
- Humira Pen 40mg/0.8mL and 40mg/0.4mL – Starter Package for Crohn’s Disease, Ulcerative Colitis or Hidradenitis Suppurativa
- Humira Pen 40mg/0.8mL and 40mg/0.4mL – Psoriasis/Uveitis Starter Package
- Prefilled Syringe Carton – 40mg/0.8mL, 40mg/0.4mL, 20mg/0.4mL, and 10mg/0.2mL
- Humira Prefilled Syringe 40mg/0.8mL – Pediatric Crohn’s Disease Starter Package (6 count and 3 count)

VIII. **Summary of Policy Changes**

- 4/1/11: Clarification of prior DMARD use requirements; Clarification of preferred agents: Humira and Enbrel; Clarification of first-line therapy requirements for Crohn’s Disease
- 1/1/12: no changes
- 12/15/12: clarified quantity limits and further clarified coverage requirements for Crohn’s Disease; included coverage for Ulcerative Colitis
- 12/15/13: no policy changes
- 3/15/14: no policy changes
- 1/1/15: clarified when topical therapy in psoriasis is first required; PsA guidelines updated to include recommendations for axial disease; requirements for one non-biologic DMARD in RA setting clarified
- 7/1/15: formulary distinctions made, removal of need for Tb testing on patients not at high risk
- 10/1/15: addition of coverage for hidradenitis suppurativa
- 3/15/16: no policy changes
- 8/31/16: addition of coverage for uveitis
- 1/1/17: no policy changes

IX. **References**

1. UpToDate Online, retrieved December 2010
3. Facts and Comparisons Online, retrieved December 2010

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary agent will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.