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 member 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 member 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 member has fistulizing disease

- Hidradenitis suppurativa (moderate to severe disease)
  - Prescribed by a dermatologist AND
  - The member is at least 18 years of age AND
Hurley Stage II or Hurley Stage III disease has been documented with at least 3 abscesses or inflammatory nodules **AND**

- Member has had an inadequate response to at least a 3-month trial of systemic antibiotics for treatment of the condition (unless antibiotic use is contraindicated)

- **Juvenile idiopathic arthritis:**
  - Prescribed by a rheumatologist **AND**
  - Member 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**
  - Member has had an inadequate response to PUVA or UVB therapy unless contraindicated **AND**
  - Member 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:
    - Member 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 member 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**
  - Member 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 member 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:
V. **Coverage Duration**

Coverage is provided as follows:
- For the treatment of hidradenitis suppurativa
  - Initial coverage is provided for 3 months and may be renewed
- For all other indications
  - Initial coverage is provided for 12 months and may be renewed.

VI. **Coverage Renewal Criteria**

Coverage can be renewed in 12-month intervals based upon the following criteria:
- For the treatment of hidradenitis suppurativa:
  - Coverage may be continued if there is a clear evidence of response to therapy defined as:
    - A reduction of 25% or more in the total abscess and inflammatory nodule count (compared to baseline) **AND**
    - No increase in abscesses and draining fistulas.
- For all other indications:
  - 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 – Starter Package for Crohn’s Disease, Ulcerative Colitis or Hidradenitis Suppurativa
- Humira Pen 40mg/0.8mL – Psoriasis/Uveitis Starter Package
- Prefilled Syringe Carton – 40mg/0.8mL, 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
<table>
<thead>
<tr>
<th>Date</th>
<th>Policy Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/15/12</td>
<td>clarified quantity limits and further clarified coverage requirements for Crohn’s Disease; included coverage for Ulcerative Colitis</td>
</tr>
<tr>
<td>12/15/13</td>
<td>no policy changes</td>
</tr>
<tr>
<td>3/15/14</td>
<td>no policy changes</td>
</tr>
<tr>
<td>1/1/15</td>
<td>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</td>
</tr>
<tr>
<td>7/1/15</td>
<td>formulary distinctions made, removal of need for Tb testing on members not at high risk</td>
</tr>
<tr>
<td>10/1/15</td>
<td>addition of coverage for hidradenitis suppurativa</td>
</tr>
<tr>
<td>3/15/16</td>
<td>no policy changes</td>
</tr>
<tr>
<td>8/31/16</td>
<td>addition of coverage for uveitis</td>
</tr>
<tr>
<td>1/1/17</td>
<td>no policy changes</td>
</tr>
<tr>
<td>1/1/18</td>
<td>updated available products</td>
</tr>
<tr>
<td>8/15/18</td>
<td>updated coverage criteria, coverage duration, and renewal criteria for the treatment of hidradenitis suppurativa</td>
</tr>
</tbody>
</table>

IX. References

1. Up-to-date Online, retrieved 12/17
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.

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 medication 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.