Clinical Pharmacy Program Guidelines for Humira

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td>Humira (adalimumab)</td>
</tr>
<tr>
<td>Markets in scope</td>
<td>Arizona, California, Florida-CHIP, Hawaii, Maryland, Nevada, New Jersey, New York, Ohio, Pennsylvania, Rhode Island</td>
</tr>
<tr>
<td>Issue Date</td>
<td>9/2009</td>
</tr>
<tr>
<td>Pharmacy and Therapeutics Approval Date</td>
<td>3/2019</td>
</tr>
<tr>
<td>Effective Date</td>
<td>5/2019</td>
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</tbody>
</table>

1. **Background:**

Humira (adalimumab) is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. It is indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 2 years of age and older. Humira is also indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. It is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis. Humira is indicated for 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 and reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab. Humira is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric 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. Humira is also indicated for 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). Humira is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. Humira is indicated for the treatment of moderate to severe hidradenitis suppurativa. Finally, Humira is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients.

2. **Coverage Criteria:**

A. **Rheumatoid Arthritis (RA)**

1. **Initial Authorization**
a. Diagnosis of moderately to severely active rheumatoid arthritis

-AND-

b. History of failure, contraindication, or intolerance to one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine]

-AND-

c. Patient is not receiving Humira in combination with any of the following:

   (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
   (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
   (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Humira therapy

-AND-

b. Patient is not receiving Humira in combination with any of the following:

   (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
   (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
   (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

Authorization will be issued for 12 months.

B. Polyarticular Juvenile Idiopathic Arthritis

1. Initial Authorization

a. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

-AND-
b. Patient is not receiving Humira in combination with any of the following:

   (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab),
       Cimzia (certolizumab), Simponi (golimumab)]
   (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
   (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

**Authorization will be issued for 12 months.**

2. **Reauthorization**

   a. Documentation of positive clinical response to Humira therapy

   -AND-

   b. Patient is not receiving Humira in combination with any of the following:

   (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab),
       Cimzia (certolizumab), Simponi (golimumab)]
   (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
   (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

**Authorization will be issued for 12 months.**

C. **Psoriatic Arthritis**

1. **Initial Authorization**

   a. Diagnosis of active psoriatic arthritis

   -AND-

   b. Patient is not receiving Humira in combination with any of the following:

   (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab),
       Cimzia (certolizumab), Simponi (golimumab)]
   (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
   (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

**Authorization will be issued for 12 months.**

2. **Reauthorization**

   a. Documentation of positive clinical response to Humira therapy
b. Patient is not receiving Humira in combination with any of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab),
Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

**Authorization will be issued for 12 months.**

D. **Plaque Psoriasis**

1. **Initial Authorization**

   a. Diagnosis of moderate to severe chronic plaque psoriasis

   -AND-

   b. Patient is not receiving Humira in combination with any of the following:

   (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab),
Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

**Authorization will be issued for 12 months.**

2. **Reauthorization**

   a. Documentation of positive clinical response to Humira therapy

   -AND-

   b. Patient is not receiving Humira in combination with any of the following:

   (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab),
Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

**Authorization will be issued for 12 months.**
E. Ankylosing Spondylitis

1. Initial Authorization
   a. Diagnosis of ankylosing spondylitis
      -AND-
   b. Patient is not receiving Humira in combination with any of the following:
      
      (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab),
          Cimzia (certolizumab), Simponi (golimumab)]
      (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
      (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

   Authorization will be issued for 12 months.

2. Reauthorization
   a. Documentation of positive clinical response to Humira therapy
      -AND-
   b. Patient is not receiving Humira in combination with any of the following:
      
      (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab),
          Cimzia (certolizumab), Simponi (golimumab)]
      (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
      (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

   Authorization will be issued for 12 months.

F. Crohn’s Disease

1. Initial Authorization
   a. Diagnosis of moderately to severely active Crohn’s disease
      -AND-
   b. One of the following:

      (1) Patient has had an inadequate response to conventional therapies for
          Crohn’s disease (examples include anti-inflammatory drugs, corticosteroids,
or oral immunosuppressive agents)

-OR-

(2) Patient has lost response or intolerant to Remicade (infliximab)

-AND-

c. Patient is not receiving Humira in combination with any of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Humira therapy

-AND-

b. Patient is not receiving Humira in combination with any of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

Authorization will be issued for 12 months.

G. Ulcerative Colitis

1. Initial Authorization

a. Diagnosis of moderately to severely active ulcerative colitis

-AND-

b. History of failure, contraindication, or intolerance to one of the following conventional therapies:
(1) Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
(2) 6-mercaptopurine (Purinethol)
(3) Azathioprine (Imuran)
(4) Methotrexate (Rheumatrex, Trexall)

-AND-

c. Patient is not receiving Humira in combination with any of the following:

   (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab),
       Cimzia (certolizumab), Simponi (golimumab)]
   (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
   (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

Authorization will be issued for 12 months.

2. Reauthorization

   a. Documentation of positive clinical response to Humira therapy

   -AND-

   b. Patient is not receiving Humira in combination with any of the following:

   (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab),
       Cimzia (certolizumab), Simponi (golimumab)]
   (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
   (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

Authorization will be issued for 12 months.

H. Hidradenitis Suppurativa

   1. Initial Authorization

   a. Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II
      or III)

   -AND-

   b. Patient is not receiving Humira in combination with any of the following:

   (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab),
       Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Humira therapy

-AND-

b. Patient is not receiving Humira in combination with any of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

Authorization will be issued for 12 months.

I. Uveitis (UV)

1. Initial Authorization

a. Diagnosis of non-infectious uveitis

-AND-

b. Uveitis is classified as one of the following:

(1) intermediate
(2) posterior
(3) panuveitis

-AND-

c. Patient is not receiving Humira in combination with any of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

Authorization will be issued for 12 months.
2. **Reauthorization**

   a. Documentation of positive clinical response to Humira therapy

   -AND-

   b. Patient is not receiving Humira in combination with **any** of the following:

   (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab),
       Cimzia (certolizumab), Simponi (golimumab)]
   (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
   (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

   **Authorization will be issued for 12 months.**

3. **References:**


<table>
<thead>
<tr>
<th>Program</th>
<th>Program type – Prior Authorization</th>
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</thead>
<tbody>
<tr>
<td>Date</td>
<td>Change</td>
</tr>
<tr>
<td>9/2009</td>
<td>Guidelines taken from previously approved AmeriChoice and Unison policies and updated based upon evidence in the literature.</td>
</tr>
<tr>
<td>12/2009</td>
<td>Guidelines revised to remove criteria for Ulcerative Colitis.</td>
</tr>
<tr>
<td>12/2010</td>
<td>Annual Review</td>
</tr>
<tr>
<td>12/2011</td>
<td>Annual Review</td>
</tr>
<tr>
<td></td>
<td>• Changed requirement of history of failure of 2 DMARDs to history of failure of 1 DMARD for rheumatoid arthritis and psoriatic arthritis</td>
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<td></td>
<td>• Created Humira once weekly dosing criteria for rheumatoid arthritis</td>
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<td></td>
<td>• Specified “moderate to severe” for the severity of disease required for polyarticular JIA</td>
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<td></td>
<td>• Changed prerequisite medication requirements for polyarticular JIA and psoriatic arthritis</td>
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<tr>
<td>Date</td>
<td>Changes</td>
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<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
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</table>
| 6/2012  | Specified severity of disease for plaque psoriasis  
|         | Changed prerequisite therapy to one phototherapy and one systemic therapy  
|         | Specified severity of disease for Crohn’s disease  
|         | Combined fistulizing and nonfistulizing Crohn’s disease to have the same prerequisite requirements.                                      |
|         | Cimzia added to policy for rheumatoid arthritis (III.A.) and Crohn’s disease (III.F.)                                                 |
| 9/2012  | Added option of additional alternative therapy failure of infliximab for initial therapy of Humira.  
|         | No change to Cimzia for Crohn’s disease.                                                                                           |
| 2/2015  | Converted existing multidrug policy to a Humira specific policy.  
|         | Updated criteria to align with current UHC clinical criteria template.  
|         | Removed age requirement for all indications.  
|         | Removed prescriber requirement for all reauthorization criteria sections.  
|         | Added “Janus kinase inhibitor” to all areas noting that the patient should not receive Cimzia in combination with other immunomodulator/biologic DMARDs. |
| 12/2015 | Policy updated with the new FDA-approved indication for hidradenitis suppurativa  
|         | Prescriber requirement was modified to read, “Prescribed by or in consultation with a(n)….” for all indications  
|         | Removed endnotes related to age restrictions since criteria no longer have age restrictions.                                      |
| 3/2016  | Updated Juvenile Idiopathic Arthritis (JIA) initial therapy to include leflunomide as a part of the DMARD requirement  
|         | Updated the list of conventional therapies required in the Crohn’s disease (CD) criteria to remove aminosalicylates  
|         | Updated the list of conventional therapies required for ulcerative colitis (UC) criteria to add aminosalicylates  
|         | Removed all “notes to prescriber”  
<p>|         | Annual Review- Updated policy template                                                                                             |</p>
<table>
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<tr>
<th>Date</th>
<th>Changes</th>
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<tr>
<td>10/2016</td>
<td>Added not to use in combination with Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] to all sections Added prescriber requirement for Hidradenitis Suppurativa Added criteria for Uveitis</td>
</tr>
<tr>
<td>3/2017</td>
<td>Updated ulcerative colitis initial authorization duration to 12 months to match initial authorization durations for other indications. Updated policy template.</td>
</tr>
<tr>
<td>4/2017</td>
<td>Added hydroxychloroquine to example list of non-biologic DMARDs</td>
</tr>
<tr>
<td>8/2018</td>
<td>Minor updates to the background and formatting. Updated references.</td>
</tr>
<tr>
<td>3/2019</td>
<td>Removed prescriber check. Revised UC reauthorization criteria to align with language in other programs. Removed prerequisite medications from JIA and AS sections. Updated references.</td>
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