Overview
Humira (adalimumab) is a tumor necrosis factor (TNF) blocker indicated for:
- Treatment of active ankylosing spondylitis
- Treatment of active psoriatic arthritis
- Treatment of moderate to severe plaque psoriasis (PsO)
- Treatment of moderately to severely active rheumatoid arthritis (RA)
- Treatment of moderately to severe polyarticular juvenile idiopathic arthritis (pJIA)
- Treatment of moderate to severe Crohn’s disease (CD)
- Treatment of moderate to severe hidradenitis suppurativa (HS)
- Treatment of moderate to severe ulcerative colitis (UC)
- Treatment of non-infectious uveitis

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with Humira, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR
Authorization may be granted if the member meets ALL following criteria and documentation has been submitted:

Moderate to Severe Rheumatoid Arthritis (RA) and Polyarticular Juvenile Idiopathic Arthritis (pJIA)
Prescriber provides documentation of ALL of the following:
- Appropriate diagnosis
• **ONE** of the following:
  a. Paid claims or physician documented inadequate response or adverse reaction to at least **ONE**
     traditional DMARD (See Appendix B) or contraindication to traditional DMARDs
  b. Paid claims or physician documented inadequate response or adverse reaction to **ONE**
     biologic DMARD that is FDA-approved for the requested indication

• Dosing is appropriate

**Psoriatic Arthritis (PsA)**
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Appropriate dosing

**Ankylosing spondylitis (AS)**
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Paid claims or physician documented inadequate response or adverse reaction to **TWO** NSAIDs or
   contraindication to **ALL** NSAIDs
3. Appropriate dosing (see appendix A)

NOTE: Requests for Humira® in non-radiographic axial spondylarthritis may be approved if all criteria
are met.

**Moderate to Severe Plaque Psoriasis**
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. **ONE** of the following:
   a. Paid claims or physician documented inadequate response or adverse reaction to **ONE**
      conventional therapy (see appendix B)
      i. topical agent
      ii. phototherapy
      iii. systemic agent
   b. Contraindication to **ALL** conventional therapies:
      i. topical agents
      ii. phototherapy
      iii. systemic agents
   c. Paid claims or physician documented inadequate response or adverse reaction to **ONE**
      biologic DMARD that is FDA-approved for plaque psoriasis
3. Appropriate dosing

**Moderate to Severe Crohn’s Disease (CD) and Moderate to Severe Ulcerative Colitis (UC)**
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Appropriate dosing

NOTE: Requests for Humira may be approved for fistulizing Crohn’s disease if all above criteria are met.

**Non-infectious Uveitis**
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. ONE of the following:
   a. Paid claims or physician documented inadequate response or adverse reaction to ONE topical or systemic glucocorticoid
   b. Contraindication to ALL topical and systemic glucocorticoids
3. ONE of the following:
   a. Paid claims or physician documented inadequate response or adverse reaction to ONE systemic immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate, cyclosporine, tacrolimus, cyclophosphamide)
   b. Contraindication to ALL systemic immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate, cyclosporine, tacrolimus, cyclophosphamide)
4. Appropriate dosing

Moderate to severe Hidradenitis Suppurativa (Hurley Stage II or Hurley Stage III disease)
Prescriber provides documentation of ALL the following:
1. Appropriate diagnosis*
2. Appropriate dosing

* For mild hidradenitis suppurativa (Hurley Stage I disease), requests for Humira® (adalimumab) may be approvable if there are paid claims (within the past 6 months) or prescriber provides inadequate response or adverse reaction to ONE oral antibiotic or contraindication to ALL oral antibiotics (e.g. rifampin, clindamycin, tetracycline, doxycycline, minocycline)

**Continuation of Therapy**
Reauthorization requires physician documentation of continuation of therapy, positive response to therapy, FDA approved indication and appropriate dosing.

**Limitations**
1. Initial approvals will be granted for:
   a. Plaque Psoriasis: 3 months.
   b. All other diagnosis: 6 months.
2. Reauthorizations will be granted for 12 months
3. The following quantity limits apply:

<table>
<thead>
<tr>
<th>Product</th>
<th>Quantity limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humira Inj 10mg/0.2mL</td>
<td>2 injections per 28 days</td>
</tr>
<tr>
<td>Humira Inj 10mg/0.1mL</td>
<td></td>
</tr>
<tr>
<td>Humira Inj 20mg/0.2mL</td>
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<tr>
<td>Humira Kit 20mg/0.4mL</td>
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<tr>
<td>Humira Pediatric Inj Crohn’s</td>
<td></td>
</tr>
<tr>
<td>Humira Pen Kit CD/UC/HS</td>
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<tr>
<td>Humira Pen Kit PS/UV</td>
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<tr>
<td>Humira Inj 40mg/0.8mL</td>
<td>3 injections per 28 days</td>
</tr>
<tr>
<td>Humira Inj 40mg/0.4mL</td>
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<tr>
<td>Humira Pen Inj 40mg/0.4mL</td>
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<tr>
<td>Humira Pen – Psoriasis Starter</td>
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</tr>
<tr>
<td>Humira Pediatric Crohn’s Disease</td>
<td>6 syringes per 28 days</td>
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</table>

**Appendices**

**Appendix A**
### Pediatric Dosing

<table>
<thead>
<tr>
<th>Pediatric Dosing</th>
<th>Humira® (adalimumab)</th>
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<tbody>
<tr>
<td><strong>Crohn’s disease (moderate-severe) (≥ 6 years old, weight 17 kg to &lt;40 kg):</strong></td>
<td>80 mg SQ at week 0 (may administer as 4 injections in 1 day or 2 injections daily for 2 consecutive days), 40 mg SQ week 2 (day 15), then 20 mg SQ every other week starting at week 4 (day 29).</td>
</tr>
<tr>
<td><strong>Crohn’s disease (moderate-severe) (≥ 6 years old, weight ≥ 40 kg):</strong></td>
<td>160 mg SQ at week 0 (may administer as 4 injections in 1 day or 2 injections daily for 2 consecutive days), 80 mg SQ week 2 (day 15), then 40 mg SQ every other week starting at week 4 (day 29).</td>
</tr>
<tr>
<td><strong>Juvenile Idiopathic Arthritis (≥ 2 years old):</strong></td>
<td></td>
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</tbody>
</table>
| Weight 10kg to < 15kg: | 10 mg SQ every other week  
| 15kg to < 30kg: | 20 mg SQ every other week  
| > 30kg: | 40mg every other week |

### Appendix B. Conventional Therapies for Plaque Psoriasis

#### Conventional Treatment Lines

<table>
<thead>
<tr>
<th>Conventional Treatment Lines</th>
<th>Agents Used</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Topical Agents</strong></td>
<td>emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors</td>
</tr>
<tr>
<td><strong>Systemic Agents</strong></td>
<td>Traditional DMARDs: methotrexate, apremilast, acitretin,</td>
</tr>
<tr>
<td><strong>Phototheraphy</strong></td>
<td>ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)</td>
</tr>
</tbody>
</table>

### Appendix C: Traditional DMARDs

<table>
<thead>
<tr>
<th>Traditional DMARDs*</th>
<th>Agents Used</th>
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</thead>
<tbody>
<tr>
<td>azathioprine</td>
<td>methotrexate*</td>
</tr>
<tr>
<td>cyclosporine</td>
<td>sulfasalazine*</td>
</tr>
<tr>
<td>hydroxychloroquine*</td>
<td>thalidomide</td>
</tr>
<tr>
<td>Leflunomide</td>
<td></td>
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</tbody>
</table>

If a member has a contraindication to ALL of the most commonly used traditional DMARDs* (methotrexate, sulfasalazine, and hydroxychloroquine), a trial with a traditional DMARD may be bypassed.

### Appendix D: Off-Label Indications

#### More frequent/Higher doses
Requests more frequent or higher doses of injectable biologics, may be approved if ALL of the following is provided:
1. Documentation of severe disease
2. Documented partial response to FDA-approved dosing of current biologic therapy
3. Documentation of specialist consult for the requested indication

### Pulmonary Sarcoidosis
Prescriber provides documentation of ALL of the following:
1. Member has an appropriate diagnosis of sarcoidosis with pulmonary involvement
2. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication to ALL of the following:
a. Systemic glucocorticoids
b. ONE traditional DMARD (methotrexate, azathioprine, leflunomide, or mycophenolate)

Takayasu Arteritis (TAK)
Prescriber provides documentation of ALL of the following:
1. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication to ALL of the following:
   a. Systemic glucocorticoids
   b. ONE traditional DMARD (methotrexate, azathioprine, leflunomide, or mycophenolate)

References
13. Page RL 2nd, O'Bryant CL, Cheng D, et al; American Heart Association Clinical Pharmacology and Heart Failure and Transplantation Committees of the Council on Clinical Cardiology; Council on Cardiovascular Surgery and Anesthesia; Council on Cardiovascular and Stroke Nursing; and Council...


**Review History**

03/21/2005 – Reviewed
05/15/2005 – Effective
02/27/2006 – Reviewed and revised
02/25/2008 – Reviewed and revised
02/23/2009 – Reviewed and revised
02/22/2010 – Reviewed and revised
02/28/2011 – Reviewed
02/27/2012 – Reviewed and revised
02/25/2013 – Reviewed and revised
02/24/2013 – Reviewed and revised
02/23/2015 – Reviewed and revised
02/2016 – Reviewed in P&T Meeting
02/2017 – Reviewed and revised (adopted SGM) in P&T Meeting
03/01/2018 – Reviewed and revised (adopted MH RS)
11/26/2018 – Reviewed and revised
10/21/2020 – Reviewed and Updated; separated out Comm/Exch vs. MassHealth; updated Overview; Matched MassHealth Preferred Unified Formulary for implementation 1/1/2021
11/17/2021 – Reviewed and Updated Nov P&T; matched with MH UPPL for implementation 1/1/2022; added appendix with traditional DMARDS and off label indications based on evidence. Effective 01/01/2022
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