Clinical Policy: Adalimumab (Humira)
Reference Number: ERX.SPA.166
Effective Date: 10.01.16
Last Review Date: 05.18

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Adalimumab (Humira®) is a tumor necrosis factor (TNF) blocker.

FDA Approved Indication(s)
Humira is indicated for the treatment of:

- Rheumatoid arthritis (RA): 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 RA
- Juvenile idiopathic arthritis (JIA): Reducing signs and symptoms of moderately to severely active polyarticular JIA (PJIA) in patients 2 years of age and older.
- Psoriatic arthritis (PsA): Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA.
- Ankylosing spondylitis (AS): Reducing signs and symptoms in adult patients with active AS.
- Adult Crohn’s disease (CD): Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active CD who have had an inadequate response to conventional therapy. Reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.
- Pediatric CD: Reducing signs and symptoms and inducing and maintaining clinical remission in patients 6 years of age and older with moderately to severely active CD who have had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine (6-MP), or methotrexate (MTX).
- Ulcerative colitis (UC): 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). The effectiveness of Humira has not been established in patients who have lost response to or were intolerant to TNF blockers.
- Plaque psoriasis (PsO): 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.
- Hidradenitis suppurativa (HS): The treatment of moderate to severe hidradenitis suppurativa.
- Uveitis (UV): The treatment of non-infectious intermediate, posterior and panuveitis in adult patients.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Humira is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Rheumatoid Arthritis (must meet all):
      1. Diagnosis of RA;
      2. Prescribed by or in consultation with a rheumatologist;
      3. Age ≥ 18 years;
      4. Member meets one of the following (a or b):
         a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
         b. If intolerance or contraindication to MTX (see Appendix C), failure of a ≥ 3 consecutive month trial of at least ONE conventional disease-modifying antirheumatic drug (DMARD)
(e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;

5. Does not exceed 40 mg every other week.

Approval duration: 6 months

B. Polyarticular Juvenile Idiopathic Arthritis (must meet all):
   1. Diagnosis of PJIA;
   2. Prescribed by or in consultation with a rheumatologist;
   3. Age ≥ 2 years;
   4. Member meets one of the following (a or b):
      a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
      b. If intolerance or contraindication to MTX (see Appendix C), failure of a ≥ 3 consecutive month trial of sulfasalazine or leflunomide at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;

5. Dose does not exceed one of the following (a, b, or c):
   a. Weight 10 kg (22 lbs) to <15 kg (33 lbs): 10 mg every other week;
   b. Weight 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg every other week;
   c. Weight ≥ 30 kg (66 lbs): 40 mg every other week.

Approval duration: 6 months

C. Psoriatic Arthritis (must meet all):
   1. Diagnosis of PsA;
   2. Prescribed by or in consultation with a dermatologist or rheumatologist;
   3. Age ≥ 18 years;
   4. Member meets one of the following (a or b):
      a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
      b. If intolerance or contraindication to MTX (see Appendix C), failure of a ≥ 3 consecutive month trial of cyclosporine, sulfasalazine, or leflunomide at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;

5. Dose does not exceed 40 mg every other week.

Approval duration: 6 months

D. Ankylosing Spondylitis (must meet all):
   1. Diagnosis of AS;
   2. Prescribed by or in consultation with a rheumatologist;
   3. Age ≥ 18 years;
   4. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;

5. Dose does not exceed 40 mg every other week.

Approval duration: 6 months

E. Crohn’s Disease (must meet all):
   1. Diagnosis of CD;
   2. Prescribed by or in consultation with a gastrointestinal (GI) specialist;
   3. Age ≥ 6 years;
   4. Failure of a ≥ 3 consecutive month trial of at least ONE immunomodulator (e.g., azathioprine, 6-MP, MTX) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;

5. Dose does not exceed one of the following (a or b):
   a. Adults: 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every other week starting Day 29;
   b. Pediatrics (i or ii):
i. Weight 17 kg (37 lbs) to < 40 kg (88 lbs.): 80 mg on Day 1 and 40 mg on Day 15, followed by maintenance dose of 20 mg every other week starting Day 29;
ii. Weight ≥ 40 kg (88 lbs): 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every other week starting Day 29.

Approval duration: 6 months

F. Ulcerative Colitis (must meet all):
   1. Diagnosis of UC;
   2. Prescribed by or in consultation with a GI specialist;
   3. Age ≥ 18 years;
   4. Failure of a ≥ 3 consecutive month trial of azathioprine, 6-MP, or an aminosalicylate (e.g., sulfasalazine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   5. Dose does not exceed 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every other week starting Day 29.

Approval duration: 6 months

G. Plaque Psoriasis (must meet all):
   1. Diagnosis of PsO;
   2. Prescribed by or in consultation with a dermatologist or rheumatologist;
   3. Age ≥ 18 years;
   4. Member meets one of the following (a or b):
      a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
      b. If intolerance or contraindication to MTX (see Appendix C), failure of a ≥ 3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   5. Dose does not exceed 80 mg initial dose, followed by maintenance dose of 40 mg every other week starting one week after initial dose.

Approval duration: 6 months

H. Hidradenitis Suppurativa (must meet all):
   1. Diagnosis of HS;
   2. Prescribed by a dermatologist, rheumatologist, or GI specialist;
   3. Age ≥ 18 years;
   4. Documentation of Hurley stage II or stage III (see Appendix C);
   5. Failure of a ≥ 3 consecutive month trial of systemic antibiotic therapy (e.g., clindamycin, minocycline, doxycycline, rifampin) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   6. Dose does not exceed 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every week starting Day 29.

Approval duration: 6 months

I. Uveitis (must meet all):
   1. Diagnosis of non-infectious intermediate, posterior, or panuveitis;
   2. Prescribed by or in consultation with an ophthalmologist or rheumatologist;
   3. Age ≥ 18 years;
   4. Failure of a ≥ 2 week trial of a systemic corticosteroid (e.g., prednisone) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   5. Failure of a trial of a non-biologic immunosuppressive therapy (e.g., azathioprine, methotrexate, mycophenolate mofetil, cyclosporine, tacrolimus, cyclophosphamide, chlorambucil) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   6. Dose does not exceed 80 mg initial dose, followed by maintenance dose of 40 mg every other week starting one week after initial dose.
Approval duration: 6 months

J. Other diagnoses/indications
   1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy
   A. All Indications in Section I (must meet all):
      1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
      2. Member is responding positively to therapy;
      3. If request is for a dose increase, new dose does not exceed one of the following (a, b, or c):
         a. RA (i or ii):
            i. 40 mg every other week;
            ii. 40 mg every week, if documentation supports inadequate response to a ≥ 3 month trial of 40 mg every other week or member is not a candidate for concurrent methotrexate and Humira due to contraindications or intolerance;
         b. PJIA, PsA, AS, CD, UC, PsO, UV: 40 mg every other week;
         c. HS: 40 mg every week.
   Approval duration: 12 months

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
         Approval duration: Duration of request or 6 months (whichever is less); or
      2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:
   A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information
   Appendix A: Abbreviation/Acronym Key
   6-MP: 6-mercaptopurine
   AS: ankylosing spondylitis
   CD: Crohn’s disease
   DMARD: disease-modifying antirheumatic drug
   FDA: Food and Drug Administration
   Gi: gastrointestinal
   HS: hidradenitis suppurative
   MTX: methotrexate

   Appendix B: Therapeutic Alternatives
   This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>acitretin (Soriatane®)</td>
<td>PsO 25 or 50 mg PO QD</td>
<td>50 mg/day</td>
</tr>
<tr>
<td>azathioprine (Azasan®, Imuran®)</td>
<td>RA 1 mg/kg/day PO QD or divided BID</td>
<td>2.5 mg/kg/day</td>
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<tr>
<td>Drug Name</td>
<td>Dosing Regimen</td>
<td>Dose Limit/ Maximum Dose</td>
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<tr>
<td>CD*, UC*, UV*</td>
<td>Chlorambucil (Leukeran®)</td>
<td>UV* 0.2 mg/kg PO QD, then taper to 0.1 mg/kg PO QD or less 0.2 mg/kg/day</td>
</tr>
<tr>
<td>clindamycin (Cleocin®) + rifampin (Rifadin®)</td>
<td>HS* Clindamycin 300 mg PO BID and rifampin 300 mg PO BID</td>
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</tr>
<tr>
<td>corticosteroids</td>
<td>CD* Prednisone 40 mg PO QD for 2 weeks or IV 50 – 100 mg Q6H for 1 week Budesonide (Entocort EC®) 6 – 9 mg PO QD UV* Prednisone 5 – 60 mg/day PO in 1 – 4 divided doses</td>
<td></td>
</tr>
<tr>
<td>Cuprimine® (d-penicillamine)</td>
<td>RA* Initial dose: 125 or 250 mg PO QD Maintenance dose: 500 – 750 mg/day PO QD</td>
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<tr>
<td>cyclophosphamide (Cytoxan®)</td>
<td>UV* 1 – 2 mg/kg/day PO</td>
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<tr>
<td>cyclosporine (Sandimmune®, Neoral®)</td>
<td>PsO 2.5 mg/kg/day PO divided BID PsA* 2.5 – 3 mg/kg/day PO QD RA 2.5 – 4 mg/kg/day PO divided BID UV* 2.5 – 5 mg/kg/day PO in divided doses</td>
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</tr>
<tr>
<td>doxycycline (Acticlate®)</td>
<td>HS* 50 – 100 mg PO BID</td>
<td></td>
</tr>
<tr>
<td>hydroxychloroquine (Plaquenil®)</td>
<td>RA* Initial dose: 400 – 600 mg/day PO QD Maintenance dose: 200 – 400 mg/day PO QD</td>
<td></td>
</tr>
<tr>
<td>leflunomide (Arava®)</td>
<td>PJIA* Weight &lt; 20 kg: 10 mg every other day PO Weight 20 - 40 kg: 10 mg/day PO Weight &gt; 40 kg: 20 mg/day PO PsA* 100 mg/day PO loading dose for 3 days followed by 20 mg/day PO QD</td>
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</tbody>
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**Adalimumab**

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**Ensemble**

**Pharmacy Solutions**

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<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-mercaptopurine</td>
<td>CD*, UC* 50 mg PO QD or 1 – 2 mg/kg/day PO</td>
<td>2 mg/kg/day</td>
</tr>
<tr>
<td>methotrexate (Rheumatrex®)</td>
<td>CD*, UC* 15 – 25 mg/week IM or SC</td>
<td>30 mg/week</td>
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<td></td>
<td>PsO 10 – 25 mg/week PO or 2.5 mg PO Q12 hr for 3 doses/week</td>
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<tr>
<td></td>
<td>PJIA* 10 – 20 mg/m²/week PO, SC, or IM</td>
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<tr>
<td></td>
<td>PsA* 7.5 – 15 mg/week PO</td>
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</tr>
<tr>
<td></td>
<td>RA 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week</td>
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<tr>
<td></td>
<td>UV* 7.5 – 20 mg/week PO</td>
<td></td>
</tr>
<tr>
<td>minocycline</td>
<td>HS 50 – 100 mg PO BID</td>
<td>200 mg/day</td>
</tr>
<tr>
<td>methotrexate (Rheumatrex®)</td>
<td>UV* 500 – 1,000 mg PO BID</td>
<td>3 g/day</td>
</tr>
<tr>
<td>NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)</td>
<td>AS* Varies</td>
<td>Varies</td>
</tr>
<tr>
<td>Pentasa® (mesalamine)</td>
<td>CD, UC 1,000 mg PO QID</td>
<td>4 g/day</td>
</tr>
<tr>
<td>Ridaura® (auranofin)</td>
<td>RA 6 mg PO QD or 3 mg PO BID</td>
<td>9 mg/day (3 mg TID)</td>
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<tr>
<td>sulfasalazine (Azulfidine®)</td>
<td>PJIA* 30-50 mg/kg/day PO divided BID</td>
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<tr>
<td></td>
<td>PsA* 2 g/day PO QD</td>
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<tr>
<td></td>
<td>RA 2 g/day PO in divided doses</td>
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<tr>
<td></td>
<td>UC Initial dose: 3 – 4 g/day PO in divided doses (not to exceed Q8 hrs)</td>
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<td></td>
<td>Maintenance dose: 2 g PO daily</td>
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<tr>
<td>Drug Name</td>
<td>Dosing Regimen</td>
<td>Dose Limit/Maximum Dose</td>
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<tr>
<td>tacrolimus (Prograf®)</td>
<td>CD 0.27 mg/kg/day PO in divided doses or 0.15 – 0.29 mg/kg/day PO</td>
<td>N/A</td>
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<tr>
<td></td>
<td>UV 0.1-0.15 mg/kg/day PO</td>
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</tbody>
</table>

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

*Off-label

Appendix C: General Information

- Definition of failure of MTX or DMARDs:
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.

- Examples of positive response to therapy may include, but are not limited to:
  - Reduction in joint pain/swelling/tenderness
  - Improvement in ESR/CRP levels
  - Improvements in activities of daily living

- Hidradenitis suppurativa:
  - HS is sometimes referred to as: "acne inversa, acne conglobata, apocrine acne, apocrinitis, Fox-den disease, hidradenitis axillaris, HS, pyoderma sinifica fistulans, Velpeau’s disease, and Verneuil’s disease."
  - In HS, Hurley stages are used to determine severity of disease. Hurley stage II indicates moderate disease, and is characterized by recurrent abscesses, with sinus tracts and scarring, presenting as single or multiple widely separated lesions. Hurley stage III indicates severe disease, and is characterized by diffuse or near-diffuse involvement presenting as multiple interconnected tracts and abscesses across an entire area.

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>RA</td>
<td>40 mg SC every other week</td>
<td>40 mg/week</td>
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<tr>
<td></td>
<td>Some patients with RA not receiving concomitant methotrexate may benefit from increasing the frequency to 40 mg every week</td>
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<tr>
<td>PJIA</td>
<td>Weight 10 kg (22 lbs) to &lt;15 kg (33 lbs): 10 mg SC every other week  Weight 15 kg (33 lbs) to &lt; 30 kg (66 lbs): 20 mg SC every other week  Weight ≥ 30 kg (66 lbs): 40 mg SC every other week</td>
<td>40 mg every other week</td>
</tr>
<tr>
<td>PsA</td>
<td>40 mg SC every other week</td>
<td>40 mg every other week</td>
</tr>
<tr>
<td>AS</td>
<td>40 mg SC every other week</td>
<td>40 mg every other week</td>
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</tbody>
</table>
| CD         | Initial dose:  
  Adults: 160 mg SC on Day 1, then 80 mg SC on Day 15  
  Pediatrics:  
  Weight 17 kg (37 lbs) to < 40 kg (88 lbs): 80 mg SC on Day 1, then 40 mg SC on Day 15  
  Weight ≥ 40 kg (88 lbs): 160 mg SC on Day 1, then 80 mg SC on Day 15 | 40 mg every other week |
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<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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<tr>
<td></td>
<td>Maintenance dose:</td>
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<td></td>
<td>Adults: 40 mg SC every other week starting on Day 29</td>
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<td></td>
<td>Pediatrics:</td>
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<td></td>
<td>Weight 17 kg (37 lbs) to &lt; 40 kg (88 lbs): 20 mg SC every other week starting on Day 29</td>
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<tr>
<td></td>
<td>Weight ≥ 40 kg (88 lbs): 40 mg SC every other week starting on Day 29</td>
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<tr>
<td>UC</td>
<td>Initial dose:</td>
<td>40 mg every other week</td>
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<td></td>
<td>160 mg SC on Day 1, then 80 mg SC on Day 15</td>
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<td></td>
<td>Maintenance dose:</td>
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<td></td>
<td>40 mg SC every other week starting on Day 29</td>
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<tr>
<td>PsO</td>
<td>Initial dose:</td>
<td>40 mg every other week</td>
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<td></td>
<td>80 mg SC</td>
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<td>UV</td>
<td>Maintenance dose:</td>
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<tr>
<td></td>
<td>40 mg SC every other week starting one week after initial dose</td>
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<tr>
<td>HS</td>
<td>Initial dose:</td>
<td>40 mg/week</td>
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<td></td>
<td>160 mg SC on Day 1, then 80 mg SC on Day 15</td>
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<td></td>
<td>Maintenance dose:</td>
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<td></td>
<td>40 mg SC once weekly starting on Day 29</td>
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</tbody>
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### VI. Product Availability
- Single-use prefilled pen: 80 mg/0.8 mL, 40 mg/0.8 mL, 40 mg/0.4 mL
- Single-use prefilled syringe: 80 mg/0.8 mL, 40 mg/0.8 mL, 40 mg/0.4 mL, 20 mg/0.2 mL, 10 mg/0.2 mL, 10 mg/0.1 mL
- Single-use vial for institutional use only: 40 mg/0.8 mL

### VII. References

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy split from USS.SPMN.24 Irritable Bowel Disease (IBD) Treatments, USS.SPMN.41 Psoriasis Treatments, and USS.SPMN.44 Rheumatoid Arthritis and Ankylosing Spondylitis Treatments. Converted to new template. Added new indications: hidradenitis suppurativa and uveitis. Removed all safety criteria. Adding dosing criteria per PI. Modified approval duration to 6 months for initial and 12 months for re-auth with the exception of UC which is 2 months (time to clinical remission per PI) and 12 months. Uveitis: per the 2014 Levy-Clarke et al expert panel recommendations, Humira may be used as a steroid sparing strategy or earlier in the course of disease depending on underlying cause, presentation, and patient characteristics; therefore, criteria provides information about other therapies but does not require that they be tried first. List of other therapies informed by UptoDate. HS: added staging criteria informed by PI clinical trials, European guidelines, and UpToDate. AS: removed question related to axial vs peripheral disease; removed requirement for trial of methotrexate or sulfasalazine. pJIA: removed question related to number of affected joints as development of arthritis in &gt; 4 joints is required for the diagnosis; modified criteria to require trial of methotrexate, unless contraindicated; added sulfasalazine as an alternative to methotrexate if methotrexate is contraindicated. RA: added age requirement per PI; modified criteria to require trial of methotrexate, unless contraindicated; added sulfasalazine as an alternative to methotrexate if methotrexate is contraindicated. PsO: removed duration of trial for topical and phototherapy. UC: removed questions about steroid-refractory disease and rapidly progressive disease-related symptoms while on conventional oral therapy. Updated references. For all trial/failure requirements, indicated that member can also meet criteria if intolerant (as opposed to just contraindicated) to therapy in question. Modified the following initial criteria sets: RA and pJIA: indicated that disease must be moderately to severely active. PsA: modified trial/failure requirement- instead of requiring 2 or more nonbiologic DMARDs (such as cyclosporine, sulfasalazine, azathioprine, hydroxychloroquine), criteria now requires MTX. If MTX is contraindicated, then</td>
<td>08.16</td>
<td>09.16</td>
</tr>
<tr>
<td></td>
<td>11.16</td>
<td>12.16</td>
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### Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>Cyclosporine, sulfasalazine, leflunomide, cyclosporine, or azathioprine may be trialed. CD: removed option for trial/failure of corticosteroid. UC: indicated that disease must be moderately to severely active; removed option for trial/failure of corticosteroid. PsO: indicated that disease must be chronic; removed option for trial/failure of Otezla per PDL.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4Q17 Annual Review</td>
<td>10.02.17</td>
<td>11.17</td>
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<tr>
<td>Converted to new template.</td>
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<td>For all indications: Diagnostic criteria modified to require verifiable information; Specified trial of conventional and biologic DMARDs for 3 months or greater; AS: added specialist requirement CD: simplified diagnostic criteria from requirement of poor prognostic factors to appropriate diagnosis only from specialist, CD, UC: removed “active” verbiage; PsA, pJIA, PsO: listed alternatives for those not a candidate for MTX PsO: removed requirement of topical tx since systemic tx is already required; Uveitis: allowed prescribed by or in consultation with a rheumatologist; RA: added requirement of inadequate response to 40 mg EOW before approval of every week; removed requirement for submission of diagnostic lab since a specialist is required to prescribe or be consulted HS: added gen info on Hurley stages added age requirement ≥ 18 years for all dx except pJIA and CD per PI Removed UpToDate references</td>
<td>02.27.18</td>
<td>05.18</td>
</tr>
<tr>
<td>2Q 2018 annual review: removed disease qualifiers (i.e., moderate-to-severe); modified trial and failure for RA to at least one conventional DMARD; modified gastroenterologist specialty requirement to gastrointestinal specialist for CD/UC; added age-specific max dosing requirement for CD; added aminosalicylate as an option for trial and failure for UC; generalized trial of failure of systemic antibiotics for HS modified trial and failure for UV to require both systemic corticosteroid and immunosuppressive therapy; references reviewed and updated.</td>
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### Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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