Humira (adalimumab)

Line(s) of Business: HMO; PPO; QUEST Integration  
Effective Date: 10/01/2015

POLICY
A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
- Moderately to severely active rheumatoid arthritis (RA)
- Active polyarticular juvenile idiopathic arthritis (pJIA)
- Active psoriatic arthritis (PsA)
- Active ankylosing spondylitis (AS)
- Moderately to severely active Crohn’s disease (CD)
- Moderate to severely active ulcerative colitis (UC)
- Moderate to severe chronic plaque psoriasis (PsO)

Compendial Uses
- Axial spondyloarthritis
- Hidradenitis suppurativa

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
- Current and previous therapies documented in member’s chart or medical record
- Pretreatment tuberculosis (TB) screening with TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB) and TB treatment status (if applicable) documented in member’s chart or medical record
- For Crohn’s disease, documentation in member’s chart or medical record supporting the presence of fistulizing disease
- For rheumatoid arthritis, disease activity measure
  - Clinical Disease Activity Index (CDAI)
  - Disease Activity Score (DAS28-ESR or DAS28-CRP)
  - Patient Activity Scale (PAS) or Patient Activity Scale II (PAS-II)
  - Routine Assessment of Patient Index Data with 3 measures (RAPID-3)
  - Simplified Disease Activity Index (SDAI)
- For psoriasis, the following documentation is required:
  - Documentation supporting a history of plaque psoriasis for longer than six months
  - Percent of body surface area involvement
Results of treatment with methotrexate (MTX) such as ineffective treatment or intolerance, or documentation that MTX is contraindicated
• For continuation of therapy, documentation in member’s chart or medical record supporting a decrease in percent of body surface area involvement when compared to baseline must be submitted
• For psoriatic arthritis, the following documentation is required:
  o Documentation in member’s chart or medical record supporting the presence of active enthesitis/dactylitis, and/or predominant axial disease; or
  o Documentation in member’s chart or medical record supporting severely active disease
• For continuation of therapy, positive response to Humira therapy documented in member’s chart or medical record

C. EXCLUSIONS
• Untreated latent TB infection
  o Treatment must be initiated prior to starting Humira.
• Active tuberculosis infection
  o Treatment must be completed prior to starting Humira.

D. CRITERIA FOR APPROVAL
1. Moderately to severely active Crohn’s disease (CD)
   Authorization for 12 months may be granted for members who meet EITHER of the following criteria:
   i. Member has fistulizing disease
   ii. Member has at least one of the following:
     a. Inadequate response to conventional therapies for CD (e.g. mesalamine, sulfasalazine, ciprofloxacin, metronidazole, azathioprine, mercaptopurine, methotrexate, methylprednisolone, prednisone)
     b. Intolerance or contraindication to conventional therapy

Contraindications to conventional therapy – Examples
• History of intolerance or adverse event
• Alcoholic liver disease or other chronic liver disease
• Elevated liver transaminases
• Interstitial pneumonitis or clinically significant pulmonary fibrosis
• Renal impairment
• Pregnancy or planning pregnancy (female)
• Pregnancy or planning pregnancy (male)
• Breastfeeding
• Blood dyscrasias (eg, thrombocytopenia, leukopenia, significant anemia)
• Myelodysplasia
• Uncontrolled hypertension or diabetes
• Hypersensitivity
• Significant drug interaction
2. Moderately to severely active ulcerative colitis (UC)
Authorization for 12 months may be granted for members who meet EITHER of the following criteria:
   i. Member is dependent on corticosteroid therapy as described by:
      a. Member requires continuous corticosteroid therapy; or
      b. Corticosteroids cannot be successfully tapered without a return of UC symptoms
   ii. Member has at least one of the following:
      a. Inadequate response to conventional therapies for UC (e.g. mesalamine, sulfasalazine, azathioprine, mercaptopurine, methylprednisolone, prednisone, cyclosporine, tacrolimus)
      b. Intolerance or contraindication to conventional therapy

3. Moderately to severely active rheumatoid arthritis (RA)
Authorization of 24 months may be granted for members who meet ALL of the following criteria:
   i. Member has a definite diagnosis of RA as defined by the 2010 ACR/EULAR Classification Criteria for RA. (See G. APPENDIX.)
   ii. Member has moderately to severely active disease as evidenced by at least one of the following disease activity measures:
      a) CDAI > 10.0
      b) DAS28-ESR or DAS28-CRP ≥ 3.2
      c) PAS or PAS-II ≥ 3.71
      d) RAPID-3 > 2.0
      e) SDAI > 11.0
   iii. Member has at least one of the following:
      a) Inadequate response to at least a 3-month trial of MTX despite adequate dosing (i.e., titrated to 25-30 mg/week)
      b) Intolerance or contraindication to MTX
Contraindications to MTX – Examples:
   • History of intolerance or adverse event
   • Alcoholic liver disease or other chronic liver disease
   • Elevated liver transaminases
   • Interstitial pneumonitis or clinically significant pulmonary fibrosis
   • Renal impairment
   • Pregnancy or planning pregnancy (male or female)
   • Breastfeeding
   • Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
   • Myelodysplasia
   • Hypersensitivity
   • Significant drug interaction
      c) Inadequate response to at least a 3-month trial of a prior biologic DMARD or a targeted synthetic DMARD (e.g., Xeljanz)
      d) Intolerance to a prior biologic or targeted synthetic DMARD
      e) Severely active RA that warrants a biologic DMARD as first-line therapy
4. **Moderate to severe chronic plaque psoriasis**

Authorization of 6 months may be granted for members who meet ALL of the following criteria:

i. Treatment with Humira was recommended by a dermatologist

ii. Member has been diagnosed with moderate to severe chronic plaque psoriasis defined as the following

   a) At least 10% of body surface area (BSA) is affected, or crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected, and

   b) History of psoriasis 6 months or longer

iii. Plaque psoriasis is characterized by well-defined patches of red and raised skin

iv. Member has tried MTX for at least 3 months at a therapeutic dose and found it to be ineffective, or the member exhibited intolerance or allergy, or the use of MTX is contraindicated.

   a) Ineffective treatment is defined as symptoms and/or signs that are not resolved after completion of treatment at the recommended therapeutic dose and duration. If there is no recommended treatment time, the member must have had a meaningful trial.

   b) Intolerance is defined as having a recognized and reproducible or repeated adverse reaction that is clearly associated with taking the medication.

   c) Allergy is defined as a state of hypersensitivity produced by exposure to a particular antigen resulting in harmful immunologic reactions on subsequent exposures. The most common symptoms are skin rash or anaphylaxis.

v. Continuation of therapy is covered when initial therapy has been approved and there is a decrease in percent of body surface area involvement when compared to baseline.

5. **Active psoriatic arthritis (PsA)**

Authorization of 24 months may be granted for members who meet ANY of the following criteria:

i. Member has experienced an inadequate response to at least a 3-month trial of MTX, sulfasalazine, or leflunomide.

ii. Member has intolerance or contraindication to MTX, sulfasalazine, or leflunomide.

   **Contraindications to MTX, sulfasalazine, or leflunomide – Examples:**
   - History of intolerance or adverse event
   - Alcoholic liver disease or other chronic liver disease
   - Elevated liver transaminases
   - Interstitial pneumonitis or clinically significant pulmonary fibrosis
   - Renal impairment
   - Pregnancy or planning pregnancy
   - Breastfeeding
   - Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
   - Myelodysplasia
   - Hypersensitivity
   - Significant drug interaction
   - Intestinal obstruction
   - Urinary obstruction
   - Porphyria
iii. Member has experienced an inadequate response to at least a 3-month trial of a prior biologic DMARD.

iv. Member has experienced intolerance to a prior biologic DMARD.

v. Member’s condition is severely active as evidenced by ANY of the following:
   a) Multiple swollen joints
   b) Structural damage in the presence of inflammation
   c) Clinically relevant extra-articular manifestations

Extra-articular manifestations of psoriatic arthritis – Examples:
   • Cutaneous involvement:
     o Psoriasis
     o Erythema nodosum
     o Keratoderma blenorrhagicum
     o Circinate balanitis
     o Pyoderma gangrenosum
   • Bowel involvement
     o Crohn’s disease (CD)
     o Ulcerative colitis (UC)
     o a specific colitis (in presence of inflammatory bowel disease (IBD) that cannot be classified as CD or UC)
     o Severe and persistent diarrhea
   • Ocular involvement
     o Uveitis
     o Conjunctivitis
   • Cardiovascular involvement
     o Aortic insufficiency
     o Conduction disturbances (e.g., atrioventricular blocks, bundle branch blocks, and intraventricular blocks)
     o Thrombosis
     o Phlebitis
   • Urogenital involvement
     o Urethritis
     o Prostatitis
     o Balanitis
     o Vaginitis
     o Cervicitis amyloidosis (AA type)
     o IgA nephropathy
   • Pulmonary involvement: Apical pulmonary fibrosis

vi. Member has active enthesitis and/or dactylitis (i.e., sausage digit).

vii. Member has predominant axial disease (i.e., extensive spinal involvement).

6. Active ankylosing spondylitis (AS) and axial spondyloarthritis

Authorization of 24 months may be granted for members who meet both of the following criteria:

i. Member has experienced an inadequate response to at least 2 non-steroidal anti-inflammatory drugs (NSAIDs) over a 4-week period in total at maximum recommended or tolerated anti-inflammatory dose, OR has intolerance and/or contraindication to 2 or more NSAIDS
ii. Member has at least one of the following:
   a) Predominant axial disease (i.e., extensive spinal involvement)
   b) Inadequate response to a synthetic DMARD (e.g., sulfasalazine)
   c) Intolerance or contraindication to a synthetic DMARD
   d) Inadequate response to at least a 3-month trial of a prior biologic DMARD
   e) Intolerance to a prior biologic DMARD

7. Active polyarticular juvenile idiopathic arthritis
   Authorization of 24 months may be granted for members who meet ANY of the following criteria:
   i. Member has experienced an inadequate response to at least a 3-month trial of MTX
   ii. Member has intolerance or contraindication to MTX
   iii. Member has experienced an inadequate response to at least a 3-month trial of a prior biologic DMARD
   iv. Member has experienced intolerance to a prior biologic DMARD

8. Hidradenitis suppurativa
   Authorization of 24 months may be granted for members who meet the following criteria:
   i. Condition is severe and refractory to standard first-line treatment

E. CONTINUATION OF THERAPY
For indications other than Crohn’s disease, ulcerative colitis, and chronic plaque psoriasis, authorization of 24 months may be granted for all members (including new members) who meet ALL initial authorization criteria and achieve or maintain positive clinical response with Humira as evidenced by low disease activity (e.g., CDAI ≤ 10.0, DAS28 < 3.2, PAS or PAS ≤ 3.70, RAPID-3 ≤ 2.0 or SDAI ≤ 11.0 for RA) or improvement in signs and symptoms of the condition.

For Crohn’s disease and ulcerative colitis, authorization of 12 months may be granted for all members (including new members) who meet ALL initial authorization criteria and achieve or maintain positive clinical response with Humira as evidenced by low disease activity or improvement in signs and symptoms.

To receive authorization for an additional 6 months of therapy for chronic plaque psoriasis, documentation supporting a decrease in percent of body surface area involvement when compared to baseline must be submitted. Thereafter, authorization of 12 months may be granted.

F. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.
## G. APPENDIX

The 2010 ACR-EULAR Classification Criteria for RA is a score-based algorithm. A score of at least 6 out of 10 is necessary for classification of a patient as having definite RA.

### Classification Criteria for RA (score-based algorithm: add score of categories A-D)

<table>
<thead>
<tr>
<th>Category</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Joint Involvement</td>
<td></td>
</tr>
<tr>
<td>1 large joint*</td>
<td>0</td>
</tr>
<tr>
<td>2-10 large joints</td>
<td>1</td>
</tr>
<tr>
<td>1-3 small joints (with or without involvement of large joints)**</td>
<td>2</td>
</tr>
<tr>
<td>4-10 small joints (with or without involvement of large joints)</td>
<td>3</td>
</tr>
<tr>
<td>&gt;10 joints (at least one small joint)#</td>
<td>5</td>
</tr>
<tr>
<td>B. Serology (at least 1 test result is needed for classification)†</td>
<td></td>
</tr>
<tr>
<td>Negative RF and negative ACPA</td>
<td>0</td>
</tr>
<tr>
<td>Low-positive RF or low-positive ACPA</td>
<td>2</td>
</tr>
<tr>
<td>High-positive RF or high-positive ACPA</td>
<td>3</td>
</tr>
<tr>
<td>C. Acute-phase reactants (at least 1 test result is needed for classification)‡</td>
<td></td>
</tr>
<tr>
<td>Normal CRP and normal ESR</td>
<td>0</td>
</tr>
<tr>
<td>Abnormal CRP or abnormal ESR</td>
<td>1</td>
</tr>
<tr>
<td>D. Duration of symptoms§</td>
<td></td>
</tr>
<tr>
<td>&lt;6 weeks</td>
<td>0</td>
</tr>
<tr>
<td>≥6 weeks</td>
<td>1</td>
</tr>
</tbody>
</table>

* “Large joints” refers to shoulders, elbows, hips, knees, and ankles.

** “Small joints” refers to the metacarpophalangeal joints, proximal interphalangeal joints, second through fifth metatarsophalangeal joints, thumb interphalangeal joints, and wrists.

# In this category, at least 1 of the involved joints must be a small joint; the other joints can include any combination of large and additional small joints, as well as other joints not specifically listed elsewhere (e.g., temporomandibular, acromioclavicular, sternoclavicular, etc.).

† Negative refers to IU values that are less than or equal to the upper limit of normal (ULN) for the laboratory and assay; low-positive refers to IU values that are higher than the ULN but ≤3 times the ULN for the laboratory and assay; high-positive refers to IU values that are >3 times the ULN for the laboratory and assay. Where rheumatoid factor (RF) information is only available as positive or negative, a positive result should be scored as low-positive for RF; ACPA = anti-citrullinated protein antibody.

‡ Normal/abnormal is determined by local laboratory standards. CRP = C-reactive protein; ESR = erythrocyte sedimentation rate.

§ Duration of symptoms refers to patient self-report of the duration of signs or symptoms of synovitis (e.g., pain, swelling, tenderness) of joints that are clinically involved at the time of assessment, regardless of treatment status.
I. IMPORTANT REMINDER

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

J. REFERENCES


