

# SPECIALTY GUIDELINE MANAGEMENT

## HUMIRA (adalimumab)

### POLICY

#### I. 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.

##### A. FDA-Approved Indications<sup>1</sup>

1. 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.
2. Reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older.
3. Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA.
4. Reducing signs and symptoms in adult patients with active AS.
5. 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. Reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.
6. 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 (6-MP), or methotrexate.
7. 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).
8. 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.
9. The treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older.
10. The treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older.

##### B. Compendial Uses

Axial spondyloarthritis<sup>2-4</sup>

Behcet's disease<sup>22,31</sup>

Pyoderma gangrenosum<sup>19-21,32</sup>

Oligoarticular juvenile idiopathic arthritis<sup>8</sup>

All other indications are considered experimental/investigational and not medically necessary.

#### II. DOCUMENTATION

<b>Reference number(s)</b>
2008-A

Submission of the following information is necessary to initiate the prior authorization review:

- A. Rheumatoid arthritis (RA)
  - 1. For initial requests:
    - i. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
    - ii. Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).
  - 2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.
- B. Articular juvenile idiopathic arthritis, ankylosing spondylitis (AS) and active axial spondyloarthritis:
  - 1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
  - 2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.
- C. Psoriatic arthritis (PsA): For continuation requests: Chart notes or medical record documentation supporting positive clinical response.
- D. Crohn's disease
  - 1. Initial requests
    - i. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
    - ii. Chart notes or medical record documentation supporting diagnosis of fistulizing Crohn's disease (if applicable)
  - 2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.
- E. Ulcerative colitis
  - 1. Initial requests
    - i. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
    - ii. Chart notes or medical record documentation of hospitalization due to acute, severe ulcerative colitis (if applicable)
  - 2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.
- F. Plaque psoriasis
  - 1. Initial requests:
    - i. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected.
    - ii. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
  - 2. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

- G. Hidradenitis suppurativa
  - 1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
  - 2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy.
- H. Non-infectious intermediate, posterior and panuveitis
  - 1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
  - 2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy.
- I. Behcet's disease (initial requests only): Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
- J. Pyoderma gangrenosum (initial requests only): Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy

### III. CRITERIA FOR INITIAL APPROVAL

- A. Moderately to severely active rheumatoid arthritis (RA)**<sup>1,5-7,35, 39, 40</sup>
  - 1. Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic DMARD (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis.
  - 2. Authorization of 12 months may be granted for treatment of moderately to severely active RA when all of the following criteria are met:
    - i. Member meets either of the following criteria:
      - a. Member has been tested for either of the following biomarkers and the test was positive:
        - 1. Rheumatoid Factor (RF)
        - 2. Anti-cyclic citrullinated peptide (anti-CCP)
      - b. Member has been tested for ALL of the following biomarkers:
        - 1. RF
        - 2. Anti-CCP
        - 3. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
    - ii. Member meets either of the following criteria:
      - a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
      - b. Member has an intolerance or contraindication to methotrexate (see Appendix A).
- B. Moderately to severely active articular juvenile idiopathic arthritis**<sup>1,8</sup>
  - 1. Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic DMARD indicated for moderately to severely active articular juvenile idiopathic arthritis.
  - 2. Authorization of 12 months may be granted for treatment of moderately to severely active articular juvenile idiopathic arthritis when any of the following criteria is met:

- i. The member has had an inadequate response to methotrexate or another non-biologic DMARD administered at an adequate dose and duration.
- ii. The member has risk factors (See Appendix E) and the member also meets one of the following:
  - a. High-risk joints are involved (e.g., cervical spine, wrist, or hip).
  - b. High disease activity.
  - c. Are judged to be at high risk for disabling joint disease.

**C. Active psoriatic arthritis (PsA)<sup>1,9-12,27</sup>**

Authorization of 12 months may be granted for treatment of active psoriatic arthritis (PsA).

**D. Active ankylosing spondylitis (AS) and active axial spondyloarthritis<sup>1,3,13,14</sup>**

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for treatment of active ankylosing spondylitis or active axial spondyloarthritis.
2. Authorization of 12 months may be granted for treatment of active ankylosing spondylitis and active axial spondyloarthritis when any of the following criteria is met:
  - i. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
  - ii. Member has an intolerance or contraindication to two or more NSAIDs.

**E. Moderately to severely active Crohn's disease (CD)<sup>1,15,16,18</sup>**

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for treatment of Crohn's disease.
2. Authorization of 12 months may be granted for treatment of moderately to severely active CD when the member has had an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix B).
3. Authorization of 12 months may be granted for treatment of fistulizing CD.

**F. Moderately to severely active ulcerative colitis (UC)<sup>1,15,28</sup>**

1. Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for treatment of moderately to severely active ulcerative colitis.
2. Authorization of 12 months may be granted for treatment of moderately to severely active UC when the member has had an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix C).
3. Authorization of 12 months may be granted for members who have ever been hospitalized for acute severe UC (e.g., continuous bleeding, severe toxic symptoms, including fever and anorexia).

**G. Moderate to severe plaque psoriasis (PsO)<sup>1,12,17, 23,29,30</sup>**

1. Authorization of 12 months may be granted for members who have previously received Otezla or a biologic indicated for the treatment of moderate to severe plaque psoriasis.
2. Authorization of 12 months may be granted for treatment of moderate to severe plaque psoriasis in members when any of the following criteria is met:
  - i. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
  - ii. At least 10% of the body surface area (BSA) is affected

- iii. At least 3% of body surface area (BSA) is affected and the member meets any of the following criteria:
  - a. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
  - b. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine and acitretin (see Appendix D).

**H. Moderate to severe hidradenitis suppurativa<sup>1</sup>**

- 1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for treatment of moderate to severe hidradenitis suppurativa.
- 2. Authorization of 12 months may be granted for treatment of moderate to severe hidradenitis suppurativa when either of the following is met:
  - i. Member has experienced an inadequate response to oral antibiotics for at least 90 days.
  - ii. Member has an intolerance or contraindication to oral antibiotics.

**I. Uveitis (non-infectious intermediate, posterior and panuveitis)<sup>1</sup>**

- 1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for non-infectious intermediate, posterior, and panuveitis.
- 2. Authorization of 12 months may be granted for treatment of non-infectious intermediate, posterior and panuveitis when either of the following is met:
  - i. Member has experienced an inadequate response with corticosteroids or immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate).
  - ii. Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate).

**J. Behcet's disease<sup>22,31</sup>**

- 1. Authorization of 12 months may be granted for members who have previously received Otezla or a biologic indicated for the treatment of Behcet's disease.
- 2. Authorization of 12 months may be granted for the treatment of Behcet's disease when the member has had an inadequate response to at least one nonbiologic medication for Behcet's disease (e.g., apremilast, colchicine, systemic glucocorticoids, azathioprine).

**K. Pyoderma gangrenosum<sup>19-21,32</sup>**

- 1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for treatment of pyoderma gangrenosum.
- 2. Authorization of 12 months may be granted for treatment of pyoderma gangrenosum when either of the following is met:
  - i. Member has experienced an inadequate response to corticosteroids or immunosuppressive therapy (e.g., cyclosporine or mycophenolate mofetil).
  - ii. Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil).

**IV. CONTINUATION OF THERAPY**

**A. Moderately to severely active rheumatoid arthritis (RA)<sup>1,5-7,35, 39, 40</sup>**

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain a

positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

**B. Moderately to severely active articular juvenile idiopathic arthritis<sup>1,8</sup>**

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active articular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement
3. Functional ability

**C. Active psoriatic arthritis (PsA)<sup>1,9-12,27</sup>**

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Skin and/or nail involvement

**D. Active ankylosing spondylitis (AS) and active axial spondyloarthritis<sup>1,3,13,14</sup>**

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active ankylosing spondylitis or active axial spondyloarthritis and who achieve or maintain positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Functional status
2. Total spinal pain
3. Inflammation (e.g. morning stiffness)

**E. Moderately to severely active Crohn's disease<sup>1,15,16,18</sup>**

1. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain remission.
2. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
  - i. Abdominal pain or tenderness
  - ii. Diarrhea
  - iii. Body weight
  - iv. Abdominal mass
  - v. Hematocrit
  - vi. Endoscopic appearance of the mucosa
  - vii. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

**F. Moderately to severely active ulcerative colitis<sup>1,15,28,36</sup>**



1. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.
2. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
  - i. Stool frequency
  - ii. Rectal bleeding
  - iii. Urgency of defecation
  - iv. C-reactive protein (CRP)
  - v. Fecal calprotectin (FC)
  - vi. Endoscopic appearance of the mucosa
  - vii. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

**G. Moderate to severe plaque psoriasis**<sup>1,12,17, 23,29,30</sup>

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met:

1. Reduction in body surface area (BSA) affected from baseline
2. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

**H. Moderate to severe hidradenitis suppurativa**<sup>1,37,38</sup>

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderate to severe hidradenitis suppurativa and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met:

1. Reduction in abscess and inflammatory nodule count from baseline
2. Reduced formation of new sinus tracts and scarring
3. Decrease in frequency of inflammatory lesions from baseline
4. Reduction in pain from baseline
5. Reduction in suppuration from baseline
6. Improvement in frequency of relapses from baseline
7. Improvement in quality of life from baseline
8. Improvement on a disease severity assessment tool from baseline

**I. Uveitis (non-infectious intermediate, posterior and panuveitis)**<sup>1, 33, 34</sup>

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for non-infectious intermediate, posterior, and panuveitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when the patient meets any of the following:

1. Reduced frequency of disease flares compared to baseline
2. Stability or improvement in anterior chamber (AC) cell grade compared to baseline
3. Stability or improvement in vitreous haze (VH) grade compared to baseline
4. Stability or improvement in visual acuity compared to baseline
5. Reduction in glucocorticoid requirements from baseline
6. No new active inflammatory chorioretinal and/or inflammatory retinal vascular lesions relative to baseline

#### **J. All other indications**

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for an indication outlined in Section III and who achieve or maintain a positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition.

#### **V. OTHER<sup>1,24</sup>**

For all indications: Member has had a documented negative TB test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)\* within 6 months of initiating therapy for persons who are naïve to biologic DMARDs or targeted synthetic DMARDs associated with an increased risk of TB, and repeated yearly for members with risk factors\*\* for TB that are continuing therapy with biologics.

\* If the screening testing for TB is positive, there must be testing to confirm there is no active disease. Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

\*\* Risk factors for TB include: Persons with close contact to people with infectious TB disease; persons who have recently immigrated from areas of the world with high rates of TB (e.g., Africa, Asia, Eastern Europe, Latin America, Russia); children less than 5 years of age who have a positive TB test; groups with high rates of TB transmission (e.g., homeless persons, injection drug users, persons with HIV infection); persons who work or reside with people who are at an increased risk for active TB (e.g., hospitals, long-term care facilities, correctional facilities, homeless shelters).

For all indications: Member cannot use the requested medication concomitantly with any other biologic DMARD or targeted synthetic DMARD.

#### **VI. DOSAGE AND ADMINISTRATION**

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. For rheumatoid arthritis, member must initiate treatment with every other week dosing.

#### **VII. APPENDICES**

##### **Appendix A: Examples of Contraindications to Methotrexate**

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or currently planning pregnancy
10. Renal impairment
11. Significant drug interaction



### **Appendix B: Examples of Conventional Therapy Options for CD**

1. Mild to moderate disease – induction of remission:
  - a. Oral budesonide
  - b. Alternatives: metronidazole, ciprofloxacin, rifaximin
2. Mild to moderate disease – maintenance of remission:
  - a. Azathioprine, mercaptopurine
  - b. Alternatives: oral budesonide, methotrexate intramuscular (IM) or subcutaneous (SC), sulfasalazine
3. Moderate to severe disease – induction of remission:
  - a. Prednisone, methylprednisolone intravenous (IV)
  - b. Alternatives: methotrexate IM or SC
4. Moderate to severe disease – maintenance of remission:
  - a. Azathioprine, mercaptopurine
  - b. Alternative: methotrexate IM or SC
5. Perianal and fistulizing disease – induction of remission
  - a. Metronidazole ± ciprofloxacin, tacrolimus
6. Perianal and fistulizing disease – maintenance of remission
  - a. Azathioprine, mercaptopurine
  - b. Alternative: methotrexate IM or SC

### **Appendix C: Examples of Conventional Therapy Options for UC**

1. Mild to moderate disease – induction of remission:
  - a. Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa), balsalazide, olsalazine
  - b. Rectal mesalamine (e.g., Canasa, Rowasa)
  - c. Rectal hydrocortisone (e.g., Colocort, Cortifoam)
  - d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission:
  - a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine
  - b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission:
  - a. Prednisone, hydrocortisone IV, methylprednisolone IV
  - b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission:
  - a. Azathioprine, mercaptopurine
  - b. Alternative: sulfasalazine
5. Pouchitis: Metronidazole, ciprofloxacin
  - a. Alternative: rectal mesalamine

### **Appendix D: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin.**

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or currently planning pregnancy
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

### **APPENDIX E: Risk factors for Articular Juvenile Idiopathic Arthritis**

1. Positive rheumatoid factor
2. Positive anti-cyclic citrullinated peptide antibodies
3. Pre-existing joint damage

## VIII. REFERENCES

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