



**Complete Patient and Physician information (PLEASE PRINT)**

STEP  
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI Number

**If Applicable:** Pharmacy Name: \_\_\_\_\_  
Pharmacy Phone: \_\_\_\_\_

**Complete the Clinical Assessment:**

STEP  
2

Diagnosis	<input type="checkbox"/> Active Rheumatoid Arthritis (moderate to severe) <input type="checkbox"/> Active Polyarticular Juvenile Idiopathic Arthritis (moderate to severe) <input type="checkbox"/> Psoriatic Arthritis	<input type="checkbox"/> Chronic Plaque Psoriasis (moderate to severe) <input type="checkbox"/> Ankylosing Spondylitis <input type="checkbox"/> Active Crohn's Disease (moderate to severe)
Clinical Consideration	For Crohn's Disease, patients should have moderate to severely active disease and be refractory to conventional therapy. <input type="checkbox"/> Patient has tried conventional therapy. Please indicate which: _____	
Physician Specialty	<input type="checkbox"/> Rheumatology <input type="checkbox"/> Dermatology <input type="checkbox"/> Gastroenterology <input type="checkbox"/> Physician experienced with Humira therapy <input type="checkbox"/> Other (please state): _____	
Supporting Documentation	Diagnosis: ICD-9/10 Code #/ Description / J Code (required):	
	Please attach a copy of the prescription or provide ALL of the information below: Humira® (adalimumab)	
	Strength _____ Sig _____ Qty _____ Refills _____	
<p><i>*Please attach all relevant medical records and test results*</i></p> <p><b>We will not process incomplete forms.</b></p> <p><b>If we do not receive the completed form &amp; all relevant medical records &amp; test results within 10 calendar days of this request, it will be denied.</b></p>		

STEP  
3

**I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)**

\_\_\_\_\_  
Prescriber Signature

\_\_\_\_\_  
Date

STEP  
4

**Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:  
970-248-5034**

Name of Person filling out form: \_\_\_\_\_

Pharmacy Technician initials \_\_\_\_\_ Date Initiated \_\_\_\_\_

**Confidentiality Notice:**

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 01/09/12

## RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

### Humira® (adalimumab)

#### CLASSIFICATION

- Antirheumatic, Tumor Necrosis Factor Inhibitor

#### DESCRIPTION

- Adalimumab binds specifically to TNF-alpha and blocks its interaction with the p55 and p75 cell surface TNF receptors. Adalimumab lyses surface TNF expressing cells in vitro in the presence of complement. Adalimumab does not bind or inactivate lymphotoxin (TNF-beta). Adalimumab also modulates biological responses that are induced or regulated by TNF, including changes in the levels of adhesion molecules responsible for leukocyte migration. Adalimumab decreases C-reactive protein, erythrocyte sedimentation rate, IL-6, and matrix metalloproteinases MMP-1 and MMP-3.
- Adalimumab does not possess nonhuman or artificially fused human sequences, suggesting a low propensity for immunogenicity
- The rationale for use of adalimumab is based on cumulative evidence that the pleotropic cytokine TNF-alpha plays a major role in numerous events in inflammatory synovitis and articular matrix degradation; TNF-alpha is overproduced in rheumatoid joints, principally by macrophages
- Advantages over infliximab include subcutaneous administration and a potentially lower risk of allergic phenomena (adalimumab is a fully-human antibody). Although infliximab is approved only for concomitant use with methotrexate, this does not preclude its use as monotherapy. Infliximab may offer an advantage of less frequent dosing. Like adalimumab, etanercept is given subcutaneously, and can be self-administered by the patient; a disadvantage of etanercept is the usual requirement of more frequent dosing (eg, twice weekly).

#### FORMULARY COVERAGE

Prior authorization: Required

Good Health Formulary: Tier 5

Commercial Formulary: Tier 6

Medicare Part D coverage: Tier 5

#### COVERAGE CRITERIA

Humira® (adalimumab) meets the definition of **medical necessity** for the following:

- Ankylosing spondylitis
- Crohn's disease (Moderate to Severe), for induction or maintenance *in patients with an inadequate response to conventional therapy or prior TNF inhibitors*
- Juvenile idiopathic arthritis, alone or with methotrexate, children aged 4 to 17 years
- Plaque psoriasis (Moderate to Severe), Chronic
- Psoriasis with arthropathy, alone or with DMARDs
- Rheumatoid arthritis (Moderate to Severe), alone or with DMARDs

Humira® (adalimumab) is considered **experimental** for the following:

- Any condition or diagnosis that is not FDA approved or Compendia supported.

Required Provider Specialty:

- Approval is limited to Rheumatology, Gastroenterology, or Dermatology

## DOSAGE/ADMINISTRATION:

### Note:

- Evaluate patients for latent tuberculosis (tuberculin skin test) prior to therapy; treatment of latent infection should be started prior to adalimumab therapy

### Adult Dosing:

- Ankylosing spondylitis: 40 mg subQ every other week alone or in combination with NSAIDs, glucocorticoids, methotrexate or other DMARDs
- Crohn's disease (Moderate to Severe), In patients with an inadequate response to conventional therapy: 160 mg subQ at week 0 (may administer as 4 injections in 1 day or 2 injections daily for 2 consecutive days), 80 mg subQ at week 2 (Day 15), then 40 mg subQ every other week starting at week 4 (Day 29)
- Plaque psoriasis (Moderate to Severe), Chronic: initial, 80 mg subQ, followed by 40 mg subQ every other week starting one week after the initial dose
- Psoriasis with arthropathy: 40 mg subQ every other week alone or in combination with other disease-modifying antirheumatic drugs
- Rheumatoid arthritis (Moderate to Severe): 40 mg subQ every other week; other disease-modifying antirheumatic drugs (DMARDs) may be continued during therapy; may increase to 40 mg subQ every week in patients not receiving concomitant methotrexate

### Pediatric Dosing:

- Crohn's disease (Moderate to Severe), In patients with an inadequate response to conventional therapy: (40 kg or greater): 160 mg subQ loading dose once at wk 0 and 2 followed by a maintenance dosage of 80 mg subQ once every other wk for 48 wk (starting on week 4) was used in a clinical trial: (40 kg or less): 80 mg subQ loading dose once at wk 0 and 2 followed by a maintenance dosage of 40 mg subQ once every other wk for 48 wk (starting on week 4) was used in a clinical trial
- Juvenile idiopathic arthritis, age 4 to 17 years: Weight 15 kg (33 pounds) to less than 30 kg (66 pounds): 20 mg subQ every other week: Weight 30 kg (66 pounds) or greater: 40 mg subQ every other week – Concomitant methotrexate, glucocorticoids, salicylates, NSAIDs, or analgesics may be continued
- *All juvenile idiopathic arthritis patients should be brought up to date with current immunizations prior to initiating adalimumab therapy*

## PRECAUTIONS:

- **BLACK BOX WARNING:**
  - Serious Infections: Patients treated with adalimumab are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Adalimumab should be discontinued if a patient develops a serious infection or sepsis. Reported infections include:
    - Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent tuberculosis before adalimumab use and during therapy. Treatment for latent infection should be initiated prior to adalimumab use.
    - Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Empiric antifungal therapy

should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.

- Bacterial, viral and other infections due to opportunistic pathogens.
- The risks and benefits of treatment with adalimumab should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with adalimumab, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.
- Malignancies
  - Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor (TNF) blockers, of which adalimumab is a member (Prod Info HUMIRA® subcutaneous injection, 2009).
- Anaphylaxis and angioneurotic edema have been reported; requires discontinuation of therapy
- Autoantibody formation, including lupus-like syndrome; has occurred; discontinue therapy if symptoms occur
- CNS demyelinating disorders, new onset or worsening of preexisting condition may occur
- Concomitant use with anakinra is not recommended
- Concomitant use with live vaccine not recommended
- Congestive heart failure, new-onset or worsening; has been reported; monitoring recommended; discontinuation may be necessary
- Hematologic abnormalities (e.g. pancytopenia, aplastic anemia) have occurred and may require discontinuation of therapy
- Hepatitis B, chronic carriers; increased risk of reactivation, some cases fatal, including several months after therapy termination; monitoring recommended; discontinuation and supportive treatment may be necessary
- Latex sensitivity: needle cover of prefilled syringe contains latex

## Billing/Coding information

### CPT Coding:

96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
-------	---

### HCPCS Coding:

J0135	Adalimumab (Humira®) Injection 20 mg
-------	--------------------------------------

### ICD-9 Diagnoses Codes That Support Medical Necessity:

555.0 – 555.9	Crohn's disease
696.0	Psoriatic arthropathy
696.1	Other psoriasis
714.0 – 714.2	Rheumatoid arthritis
714.30 – 714.33	Juvenile chronic polyarthritis
714.4	Chronic postrheumatic arthropathy
714.81	Other specified inflammatory polyarthropathies
714.89	Other
714.9	Unspecified inflammatory polyarthropathy
720.0	Ankylosing spondylitis

## **COST**

- AWP (April 2010): Humira® 40mg/0.8ml syringe (2): \$1,828.76
- AWP (November 2011): Humira® 40mg/0.8ml syringe (2): \$2,151.23

## **COMMITTEE APPROVAL:**

- February 2003

## **GUIDELINE UPDATE INFORMATION:**

April 2010	Policy created
November 2011	Medical policy updated

## **REFERENCES:**

- DRUGDEX®, accessed 04/05/2010
- Product Information: HUMIRA® solution for subcutaneous injection, adalimumab solution for subcutaneous injection. Abbott Laboratories, North Chicago, IL, 2008.