ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Urgent**[1] ☐ **Non-Urgent**

Requested Drug Name: Humira® (adalimumab)

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit: ☐ New Request ☐ Reauthorization

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Humira® (adalimumab)

Diagnosis (documentation supportive of diagnosis required)

☐ Active Rheumatoid Arthritis (moderate to severe)
☐ Active polyarticular Juvenile Idiopathic Arthritis (moderate to severe)
☐ Psoriatic Arthritis
☐ Chronic Plaque Psoriasis (moderate to severe)
☐ Ankylosing Spondylitis
☐ Active adult Crohn's Disease (moderate to severe) in adults with an inadequate response to conventional therapy
☐ Active pediatric Crohn's Disease (moderate to severe) in children ≥ 6 years of age with an inadequate response to corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate)
☐ Ulcerative Colitis (moderate to severe) in adults with an inadequate response to other immunosuppressants (e.g., corticosteroids, azathioprine, and 6-mercaptopurine)

Physician Specialty

☐ Rheumatology
☐ Dermatology
☐ Gastroenterology
☐ Other (please state): _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	

Product will be delivered to: ☐ Patient's Home ☐ Physician Office Other:

Prescriber or Authorized Signature: Date:

Dispensing Pharmacy Name and Phone Number:

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request

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 (e.g. twice weekly).
- Adalimumab is indicated for 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 rheumatoid arthritis*. May be used alone or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs.
- Adalimumab is indicated as monotherapy or with methotrexate to reduce signs and symptoms of *moderately to severely active polyarticular juvenile idiopathic arthritis* in children 2 years of age or older.
- Adalimumab is indicated for use in adults with *psoriatic arthritis* to reduce signs and symptoms of active arthritis, inhibit the progression of structural damage and improve physical function
- Adalimumab is indicated for 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.
- Adalimumab is indicated for reducing signs and symptoms in adults with active ankylosing spondylitis.
- Adalimumab is indicated as induction and maintenance treatment in adult patients with *moderately to severely active Crohn's disease* who have inadequately responded to conventional therapy; also indicated to reduce the signs and symptoms and induce clinical remission in these patients if they have lost response to or are intolerant to infliximab therapy. It is also indicated as induction and maintenance treatment in *children 6 years of age or older with moderately to severely active Crohn's disease* who have inadequately responded to corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate).

- Adalimumab is indicated for induction and maintenance of clinical remission in adult patients with *moderately to severely active ulcerative colitis* who have inadequately responded to immunosuppressant therapy (e.g., corticosteroids, azathioprine, or 6-mercaptopurine). Effectiveness has not been demonstrated in patients who lost response to or were intolerant to tumor necrosis factor (TNF) blockers.

FORMULARY COVERAGE

Prior authorization: Required
Good Health Formulary: Tier 4
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
- Adult Crohn's disease (moderate to severe), for induction and maintenance ***in adults with an inadequate response to conventional therapy or prior TNF inhibitors***
- Pediatric Crohn's disease (moderate to severe), for induction and maintenance ***in children 6 years of age or older with an inadequate response to corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate)***
- Juvenile idiopathic arthritis, alone or with methotrexate, in children ≥ 2 years of age
- Chronic plaque psoriasis (moderate to severe)
- Psoriasis with arthropathy, alone or with DMARDs
- Rheumatoid arthritis (moderate to severe), alone or with DMARDs
- Ulcerative Colitis (moderate to severe) ***in adults with an inadequate response to other immunosuppressants (e.g., corticosteroids, azathioprine, and 6-mercaptopurine).***
  Documentation of inadequate response to at least one other immunosuppressant required
  - **For patients with Ulcerative Colitis only:**
    - When criteria are met, initial approval will be given for 2 months only. Renewal will require evidence of clinical remission. Subsequent approvals will be given in 12 month increments.
    - Only continue HUMIRA in patients who have shown evidence of clinical remission by eight weeks (Day 57) of therapy.

Supporting documentation from the patient's medical record about the patient's diagnosis and prior therapy(s) when applicable (e.g. Crohn's and UC) is required. For all indications EXCEPT Ulcerative Colitis, when criteria are met, approvals are given in 12 month increments.

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:

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; other agents may be continued during adalimumab treatment (e.g., methotrexate, glucocorticoids, NSAIDs, analgesics, other nonbiologic DMARDs).
- **Chronic plaque psoriasis (Moderate to Severe):** Initially 80 mg subQ, followed by 40 mg subQ every other week starting one week after the initial dose. Controlled clinical studies have not evaluated the use of adalimumab for moderate to severe chronic plaque psoriasis beyond 1 year
- **Psoriatic arthritis**: 40 mg administered subQ every other week. Treatment with other medications such as methotrexate, glucocorticoids, NSAIDs, analgesics, and other nonbiologic DMARDs may be continued during therapy with adalimumab.
- **Rheumatoid arthritis (Moderate to Severe):** Usual dose: 40 mg subQ every other week; other agents may be continued during adalimumab treatment (e.g., methotrexate, glucocorticoids, NSAIDs, analgesics, other DMARDs). Maintenance dose for monotherapy: Increasing to adalimumab 40 mg subQ once weekly may provide greater benefit. Treatment with adalimumab has been given for up to 4 years.
- **Crohn's disease (Moderate to Severe), in adults with an inadequate response to conventional therapy:** 160 mg subQ at week 0 (may be administered as 4 injections of 40 mg in 1 day or 2 injections of 40 mg daily for 2 consecutive days), followed by 80 mg subQ at week 2, then maintenance therapy with 40 mg subQ every other week starting at week 4. Clinical studies have not evaluated the use of adalimumab in this patient population beyond 1 year. Aminosalicylates and corticosteroids may be continued during adalimumab therapy. Azathioprine, 6-mercaptopurine, or methotrexate may be continued if necessary.
- **Ulcerative colitis (Moderately to Severe) in adults refractory to prior immunosuppressant(s):** 160 mg subQ on day 1 (may administer as 4 injections of 40 mg in one day or as 2 injections of 40 mg 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). **Only continue adalimumab therapy past week 8 when there is evidence of clinical remission.** Aminosalicylates and corticosteroids may be continued during adalimumab therapy. Azathioprine and 6-mercaptopurine may be continued if necessary.

Pediatric Dosing (Safety and efficacy of adalimumab in pediatric patients has not been established for indications other than juvenile idiopathic arthritis and moderate to severe Crohn's disease):

- **Juvenile idiopathic arthritis** (2 years of age or older):
  - Weight 10 kg (22 lbs.) to less than 15 kg (33 lbs.): 10 mg subQ every other week
  - Weight 15 kg (33 lbs.) to less than 30 kg (66 lbs.): 20 mg subQ every other week
  - Weight 30 kg (66 lbs.) 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.*
- **Pediatric Crohn's disease (Moderate to Severe), in children $\geq$ 6 years of age with an inadequate response to conventional therapy:**
  - ***Weight $\geq$ 40 kg (88 lbs):***

        - *Initial dose*: 160 mg subQ at week 0 (may be administered as 4 injections of 40 mg in 1 day or 2 injections of 40 mg daily for 2 consecutive days), followed by 80 mg subQ at week 2 (2 injections of 40 mg in 1 day)
        - *Maintenance dose:* 40 mg subQ every other week starting at week 4 (day 29)
    - ***Weight 17 kg (37 lbs.) to less than 40 kg (88 lbs.):***
        - *Initial dose:* 80 mg subQ at week 0 (2 injections of 40 mg in 1 day), followed by 40 mg subQ at week 2 (day 15)
        - *Maintenance dose:* 20 mg subQ every other week starting at week 4 (day 29)

PRECAUTIONS:

BLACK BOX WARNING: Serious Infections and Malignancy

- 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, leukemia, breast, colon, prostate, lung, skin): have been reported in adults. Patients with rheumatoid arthritis and other chronic inflammatory disease, particularly those with highly active disease and chronic exposure to immunosuppressant therapies, are at higher risk for developing lymphomas than the general population.
- Lymphoma and other malignancies, some fatal, have been reported in children, adolescents, and young adults.

Precautions:

- Anaphylaxis and angioneurotic edema have been reported and should it occur, requires discontinuation of therapy.
- Autoantibody formation has occurred and may develop into lupus-like syndrome. Discontinue therapy if symptoms occur.
- Demyelinating disorders (e.g., CNS including multiple sclerosis and optic neuritis and peripheral including Guillain-Barre syndrome); new onset or worsening of preexisting condition may occur.
- Concomitant use with abatacept, anakinra, or live vaccines is not recommended.
- Juvenile rheumatoid arthritis patients should be brought up-to-date on all immunization requirements, when possible, prior to beginning treatment with adalimumab.

- Congestive heart failure, new-onset or worsening has been reported. Monitoring is 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 is recommended. Discontinuation and supportive treatment may be necessary.
- Latex sensitivity: needle cover of prefilled syringe contains latex
- Melanoma and nonmelanoma skin cancers have been reported.
- Elderly patients > 65 years of age, patients with co-morbid conditions, and/or patients on concomitant immunosuppressants have increased risk of serious infections.
- Hepatosplenic T-cell lymphoma, usually fatal, has been reported, primarily in adolescent and young adult males with Crohn's disease or ulcerative colitis. Most cases have occurred with concomitant use of azathioprine or 6-mercaptopurine.
- History of opportunistic infection: risk for serious infection; monitor and discontinue if serious infection develops. Travel or residence in areas of endemic TB or mycoses; risk for serious infection; monitoring recommended; discontinue if serious infection develops.
- Do not initiate adalimumab if active infection, including localized infection.
- If chronic or recurrent infection or if conditions that predispose patients to infection, there is risk for serious infection. Monitor and discontinue if serious infection develops.

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

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
- AWP (October 2012): Humira® 40mg/0.8ml syringe (2): $2,458.34
- AWP (February 2014): Humira® 40mg/0.8ml syringe (2): $3,003.12

COMMITTEE APPROVAL:

- February 2003

GUIDELINE UPDATE INFORMATION:

April 2010	Policy created
November 2011	Coverage policy updated
October 2012	Coverage policy updated - addition of Ulcerative Colitis indication
May 2014	Coverage Policy updated
May 2015	Coverage policy updated – addition of pediatric Crohn’s disease indication and lower age limit for JIA

REFERENCES:

- DRUGDEX®, accessed 04/05/2010, 5/18/2014, 05/21/2015
- Product Information: HUMIRA® solution for subcutaneous injection, adalimumab solution for subcutaneous injection. Abbott Laboratories, North Chicago, IL, 2008.
- Product Information: HUMIRA® solution for subcutaneous injection, adalimumab solution for subcutaneous injection. Abbott Laboratories, North Chicago, IL. Revised 9/2012.
- Product Information: HUMIRA® solution for subcutaneous injection, adalimumab solution for subcutaneous injection. Abbott Laboratories, North Chicago, IL. Revised 12/2014.