Remicade® (infliximab)
MEDICARE Prior Authorization Form

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

Complete Patient and Physician information (PLEASE PRINT)

STEP 1

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

Remicade is exclusively provided by Modern Health Specialty Pharmacy Phone: 800-228-3643

STEP 2

Complete the Clinical Assessment:

Please attach all relevant medical records and test results

Diagnosis	PRIOR AUTHORIZATION **REQUIRED** IF PRESCRIBED FOR: ☐ Rheumatoid arthritis (in combination with methotrexate) ☐ Failure of at least one "disease modifying anti-rheumatic drug" (DMARD) *Please state which and provide documentation:* _____ PA **NOT REQUIRED** IF PRESCRIBED FOR ANY OTHER FDA APPROVED INDICATION ☐ Other Indication *(please state):* _____
Physician Specialty FOR RA ONLY	☐ Rheumatology ☐ Other (please state): _____
Patients should not receive live vaccine(s) while taking Remicade	
For Medicare Part D Members, Prior Authorization is only required for the diagnosis of Rheumatoid Arthritis	
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: Remicade® (infliximab) Strength _____ Sig _____ Qty _____ Refills _____
	We will not process incomplete forms. **If we do not receive the completed form and all relevant medical records and test results within 6 calendar days of this request, it will be denied.**

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

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. 01/23/14

STEP 4 **Fax completed form, all records & test results to RMHP Pharmacy Help Desk ONLY: 970-248-5034**

Name of Person filling out form: _____

Rocky Mountain Health Plans Use ONLY

Remember: PA in Facets also has to be entered for the facility.

Pharmacy Technician initials _____ Date Initiated _____

RMHP Formulary Coverage Policy

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

Remicade® (infliximab)

CLASSIFICATION

- Immunological Agent, Tumor Necrosis Factor Inhibitor

DESCRIPTION

- Infliximab is a chimeric human-murine immunoglobulin (IgG1– kappa) monoclonal antibody demonstrating anti-tumor necrosis factor (TNF) activity. This unique mechanism makes infliximab a useful addition in treating inflammatory conditions where TNF activity is correlated with disease severity such as Crohn's disease, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, and ulcerative colitis.
- Infliximab neutralizes the biological activity of TNF-alpha; by binding to the soluble and transmembrane forms of TNF-alpha, it inhibits the binding of TNF-alpha to its receptors. Biological activities attributed to TNF-alpha include induction of proinflammatory cytokines, such as interleukin-1 (IL-1) and interleukin-6 (IL-6); enhancement of leukocyte migration by increasing endothelial layer permeability and expression of adhesion molecules by endothelial cells and leukocytes; stimulation of neutrophil and eosinophil functions; and induction of acute phase and other liver proteins.
- In patients with moderate-to-severe Crohn’s disease (draining enterocutaneous fistulae) infliximab is reserved for cases refractory to conventional treatment (e.g. optimal therapy with prednisone, azathioprine, mercaptopurine, aminosalicylates).
- In patients with moderately to severely active rheumatoid arthritis. Infliximab should be given in combination with methotrexate.
- In patients with chronic, extensive and/or disabling plaque psoriasis who are candidates for systemic therapy, infliximab is reserved for when other systemic therapies are medically less appropriate.
- In patients with ulcerative colitis, infliximab is used when patients who did not adequately respond to conventional therapy.

FORMULARY COVERAGE

Prior authorization: Required
Good Health Formulary: Tier 6
Commercial Formulary: Tier 6
Medicare Part D coverage: Tier 5

COVERAGE CRITERIA

For *Medicare Part D Members*, prior authorization for Remicade® (infliximab) is required ONLY for the diagnosis of moderate to severe Rheumatoid Arthritis.
Coverage criteria include:

- Documentation of failure of at least one Disease Modifying Anti-Rheumatic Drug for RA required.
- Provider Specialty is limited to Rheumatology
- Must be given in combination with methotrexate

Remicade® (infliximab) meets the definition of **medical necessity** for any FDA approved indication, not otherwise excluded from Part D, including the following:

- Ankylosing spondylitis
- Fistulizing Crohn's disease
- Crohn's disease (Moderate to Severe), in patients with an inadequate response to conventional therapy
- Plaque psoriasis, chronic (Severe)
- Psoriasis with arthropathy
- Rheumatoid arthritis (Moderate to Severe), in combination with methotrexate
- Ulcerative colitis, in patients with an inadequate response to conventional therapy

Remicade® (infliximab) is considered **experimental** for the following:

- Adult onset Still's disease, Arthropathy in Crohn's disease, Behcet's syndrome Celiac disease (refractory), Congestive heart failure, Gastrointestinal tract transplantation (Transplanted organ rejection), Giant cell arteritis, Graft versus host disease, Hidradenitis (suppurativa, Severe, refractory), Inflammatory bowel disease, Juvenile idiopathic arthritis (Severe, Refractory to other therapies), Kawasaki disease (Refractory), Necrobiosis lipoidica diabeticorum, Polymyalgia rheumatica (Newly diagnosed), Psoriasis (minor to moderate), Pyoderma gangrenosum, Rheumatoid arthritis (Monotherapy), SAPHO syndrome (Severe, Refractory), Sarcoidosis, Subcorneal pustular dermatosis, Synovitis, Uveitis, (Refractory; Adjunct), Wegener's granulomatosis (Refractory, in combination with corticosteroids)

Required Provider Specialty:

- **For RA only**: Approval is limited to Rheumatology
- For all other indications: Preferred provider specialty includes Rheumatology, Gastroenterology, or Dermatology

DOSAGE/ADMINISTRATION:

Adult Dosing:

- Ankylosing spondylitis: 5 mg/kg IV over at least 2 hr given at week 0, 2 and 6 then every 6 weeks thereafter
- Crohn's disease, Fistulizing: induction, 5 mg/kg IV over at least 2 hr at weeks 0, 2 and 6 followed by maintenance therapy
- Crohn's disease, Fistulizing: maintenance, 5 mg/kg IV over at least 2 hr every 8 weeks
- Crohn's disease (Moderate to Severe), In patients with an inadequate response to conventional therapy: induction, 5 mg/kg IV over at least 2 hr at weeks 0, 2, and 6 followed by maintenance therapy
- Crohn's disease (Moderate to Severe), In patients with an inadequate response to conventional therapy: maintenance, 5 mg/kg IV over at least 2 hr every 8 weeks
- Plaque psoriasis, chronic (Severe): 5 mg/kg IV over at least 2 hr at weeks 0, 2, and 6 then every 8 weeks thereafter
- Psoriasis with arthropathy: 5 mg/kg IV over at least 2 hr given at week 0, 2 and 6 then every 8 weeks; may be given with or without methotrexate
- Rheumatoid arthritis (Moderate to Severe), In combination with methotrexate: 3 mg/kg IV over at least 2 hr given at weeks 0, 2, and 6 then every 8 weeks in combination with methotrexate; may increase dose up to 10 mg/kg IV OR give 3 mg/kg IV every 4 weeks in patients with an incomplete response
- Ulcerative colitis, In patients with an inadequate response to conventional therapy: induction, 5 mg/kg IV over at least 2 hr at weeks 0, 2, and 6 followed by maintenance therapy

- Ulcerative colitis, In patients with an inadequate response to conventional therapy: maintenance, 5 mg/kg IV over at least 2 hr every 8 weeks

Pediatric dosing:

- Safety and effectiveness not established in pediatric patients with ulcerative colitis and plaque psoriasis or in children less than 6 yr of age with Crohn's disease
- Crohn's disease (Moderate to Severe), In patients with an inadequate response to conventional therapy: (6 years and older) induction, 5 mg/kg IV over at least 2 hr at weeks 0, 2, and 6 followed by maintenance therapy
- Crohn's disease (Moderate to Severe), In patients with an inadequate response to conventional therapy: (6 years and older) maintenance, 5 mg/kg IV over at least 2 hr every 8 weeks

Notes:

- Concomitant use of anakinra or live vaccines is not recommended
- Infusion reaction:
    - mild to moderate: slow or temporarily withhold; reinitiated at a slower infusion rate and/or administer antihistamines, acetaminophen, and/or corticosteroids
    - severe: permanently discontinue infliximab therapy
- Pediatric patients should be brought up-to-date on all immunization requirements, when possible, prior to beginning treatment with infliximab

PRECAUTIONS:

- Black Box Warning
    - Patients treated with infliximab are at increased risk for infections, some progressing to serious infections leading to hospitalization or death. These infections have included bacterial sepsis, tuberculosis, invasive fungal and other opportunistic infections. Evaluate for latent tuberculosis and treat if necessary prior to initiation of therapy. Lymphoma and other malignancies, some fatal, have been reported in pediatric patients treated with infliximab. Rare postmarketing cases of hepatosplenic T-cell lymphoma, usually fatal, have been reported in patients with Crohn's disease and ulcerative colitis treated with infliximab. All of these hepatosplenic T-cell lymphomas with infliximab have occurred in patients on concomitant treatment with azathioprine or 6-mercaptopurine. Auto-antibody formation has occurred; may develop into lupus-like syndrome; discontinue therapy if symptoms of lupus-like syndrome occur.
- Contraindications
    - Heart failure, moderate to severe; doses greater than 5 mg/kg should not be administered
    - Hypersensitivity to infliximab, murine proteins, or any other component of the product
- Other precautions
    - Consult package insert or prescribing information

Billing/Coding information

CPT Coding:

96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Each additional hour (list separately in addition to code for primary)
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to code for primary procedure)

HCPCS Coding:

J1745	Injection, infliximab, 10 mg
J9250	Methotrexate sodium, 5 mg
J9260	Methotrexate sodium, 50 mg

COST

- AWP (April 2010): Remicade 100mg vial for IV injection (1): $752.57
- AWP (January 2012): Remicade 100mg vial for IV injection (1): $852.10

COMMITTEE APPROVAL:

- September 2003

GUIDELINE UPDATE INFORMATION:

April 2010	Medical Policy created
November 2011	Medical Policy updated

REFERENCES:

- DRUGDEX®, accessed 04/05/2010, 11/21/11
- Product Information: REMICADE® IV injection, infliximab IV injection. Centocor Ortho Biotech, Inc., Malvern, PA, 2009.