

The following policy is for medication that falls under the Medicare Part D benefit only.

**Prior Authorization Group:** REMICADE Policy

**Drug(s):** REMICADE (infliximab)

**Covered Uses:** All FDA-approved indications not otherwise excluded from Part D. Indicated for moderate to severe ulcerative colitis.

**Required Medical Information:** Tuberculosis (TB) test result. Chart notes including physical exam findings, number of swollen or tender joints, duration of morning stiffness, other symptoms, requested dose and frequency and expected duration of therapy.

For Crohn's disease: Documentation must include assessment of growth, nutrition, extraintestinal complications, therapy-induced complications and functional ability. For psoriasis: %BSA (Body Surface Area) involvement current and with extension of therapy, previous and current therapies and responses, quality of life assessments at baseline and current, chart notes indicating relevant information

**Age Restrictions:** Restricted to 18 years of age and older, except for Crohn's which is restricted to 6 years and older.

**Prescriber Restrictions:** Restricted to rheumatologists, immunologists, dermatologists, gastroenterologists, colorectal surgeons

**Other Criteria:**

- Must be screened for immunologic and infectious diseases including hepatitis and TB.
- May be used without prior methotrexate (MTX) trial if the member has acute, aggressive, very rapidly progressive intense inflammatory symmetrical arthritis diagnosis as defined by their rheumatologist.

Indicated for Crohn's disease when all of the following are met:

- intolerance to conventional therapy (i.e.: corticosteroids, anti-inflammatory aminosalicylates such as mesalamine, 6-mercaptopurine and sulfasalazine),
- clinical signs and symptoms outlined in Crohn's Disease Activity Index (CDAI) such as frequent liquid stools 4/day, severity grade and frequency of abdominal pain, presence of an abdominal mass, general well-being, extra-intestinal symptoms (arthralgia, uveitis, erythema, stomatitis, abscess, fever 37.5° C in the last week), taking opiates or diphenoxylate/atropine for diarrhea, anemia, and weight loss greater than 10%;
- fistulizing Crohn's disease for at least 3 months and location of fistula identified.
- Requests for Wegener's granulomatosis will be reviewed on a case-by-case basis.
- Requests for pyoderma gangrenosum with coexisting inflammatory bowel disease will be reviewed on a case-by-case basis.

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For treatment of moderate to severe active adult RA as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit (Active Daily Living) ADLs, the following criteria must be met:

- Failed to respond to other DMARDs (Disease-Modifying Anti-Rheumatic Drugs) (see table 1) and a 2-month trial of 12.5mg/week of methotrexate before infliximab is covered. ACR (American College of Rheumatology) response of less than 20 after 7.5-20mg of methotrexate for 2 months).
- In the event the member has contraindications or intolerance to methotrexate, the member must have failed to respond to other DMARDs.

For the treatment of moderate to severe psoriatic arthritis as indicated by 3 or more tender joints AND 3 or more swollen joints on 2 separate occasions at least 1 month apart, the following criteria must be met:

- Must have had an inadequate response to NSAIDs, and
- Failed to respond to an adequate trial of at least one DMARDs as listed in table 1.

Treatment for plaque psoriasis will be considered medically necessary when ALL of the following criteria are met:

- Members with severe psoriasis or those with functional disability and/or intractable recalcitrant psoriasis that interferes with ADLs due to the affected areas (e.g. hands and/or feet).
- Severe chronic plaque psoriasis with 10% BSA involvement or involvement of the palms, soles of feet and scalp for at least 1 yr.
- Treatment with phototherapy or photochemotherapy was not effective or contraindicated.
- An appropriate treatment trial was not effective or contraindicated with at least two of the following agents: methotrexate, oral retinoids, cyclosporine.
- And who have functional impairment related to symptomatology of psoriasis.

Initial authorization period will be allowed for up to 3 months.

Continuation of therapy will require documentation of improved patient status in the monitoring parameters of the following:

- Improvement of clinical signs/symptoms of psoriasis (eg. itching, redness, scaling, psoriatic body surface area coverage).

Table 1

DMARDs	Minimum Time Required for Adequate Trial
Hydroxychloroquine	2 months

The following policy is for medication that falls under the Medicare Part D benefit only.

Sulfasalazine	1 month
Methotrexate	2 months
Injectable gold	3 months
Oral gold	4 months
Azathioprine	2 months
Penicillamine	3 months

**Exclusion Criteria:**

- History of Lupus or multiple sclerosis.
- Not evaluated for latent TB infection with a TB skin test and treatment of the infection prior to therapy if indicated.
- Not indicated for members with OA (Osteoarthritis), JRA (Juvenile Rheumatoid Arthritis).
- Pre-existing or recent-onset CNS demyelinating disorders.
- Concomitant therapy with Rituxan and other DMARDs or biologic therapies other than methotrexate.
- Members who have not had plaque psoriasis for more than one year (when prescribed for psoriasis) or have another form of psoriasis other than chronic plaque psoriasis (e.g. guttate, erythrodermic or pustular psoriasis as the sole or predominant form).
- Active infection or a history of chronic or recurrent infections.
- Members who are receiving concurrent treatment with immunosuppressive therapies or have a history of malignancy.
- Frequency less than every 8 weeks except for induction regimen at 0, 2, and 6 weeks (for Crohn's).
- Not covered for members who are being treated for psoriasis and have arthropathies such as PSA, unless consult with rheumatologist.
- Members with CHF with NYHA class III/IV at doses of greater than 5mg/kg.
- For ankylosing spondylitis: No trial and failure of physiotherapy.
- Duration greater than 1 yr in pediatric CD Dosing greater than 5mg/kg and/or more frequently than every 8 weeks for UC, psoriasis, pediatric Crohn's, or PSA after induction regimen at 0,2, and 6 wks.
- Dosing greater than 5mg/kg and/or more frequently than every 6 weeks.
- Members with Wegener's granulomatosis prior to conventional treatment failure.

**Coverage Duration:** Initial approval for 3 months with extensions of up to 6 months intervals.