

Specialty Pharmacy Program

Remicade® (infliximab)

DESCRIPTION

Remicade is a tumor necrosis factor (TNF) blocker indicated for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, and plaque psoriasis.

APPROVAL DURATION

Approval duration: lifetime

APPROVAL CRITERIA

- I. None of the following are present:
 - A. Hypersensitivity to any murine proteins or other components of the product.
 - B. Moderate to severe (NYHA Class III/IV) Congestive Heart Failure (CHF).
 - C. Individuals with CHF who develop new symptoms or worsening symptoms of pre-existing CHF.
 - D. Tuberculosis or a history of recurrent infection, current chronic infection, or clinically important infection.
 - E. Patients who have not had a tuberculin skin test (TST), or a CDC-recommended equivalent, to rule out latent tuberculosis.
 - F. Using Remicade in combination with other TNF blockers, Kineret (anakinra), or Orencia (abatacept).
- II. Rheumatoid Arthritis
 - A. Patient must be 18 years of age or older AND
 - B. Patient must have symptoms of moderately to severely active rheumatoid arthritis (RA) as defined in the table below.

Mild	No radiographic evidence of destructive changes; evidence of osteoporosis may be present (Mild RA is not an approved indication)
Moderate*	No joint deformities, although limitation of joint mobility may be present; radiographic evidence of osteoporosis with or without slight bone or cartilage destruction; extra-articular soft tissue lesions may be present
Moderate to Severe*	Markedly swollen and painful joints; significant joint involvement; ESR (erythrocyte sedimentation rate) near 10mm, frequent anemia; fatigue; functionally limited
Severe*	Radiographic evidence of cartilage and bone destruction, in addition to osteoporosis; joint deformity; extensive muscle atrophy; extra-articular soft tissue lesions may be present
Terminal	Fibrous or bony ankylosis; criteria for Stage 3 present (end stage)

* RA must be moderate to severe for approval.

- C. Patient is currently on methotrexate (if patient is intolerant to methotrexate, in combination with another immunosuppressive agent that has also been demonstrated to prevent the development of human anti-chimeric antibodies [HACA], i.e. azathioprine, cyclosporine, or sulfasalazine), AND
- D. Patient has had an inadequate response to one or more nonbiologic disease modifying anti-rheumatic agents (DMARDs), or such therapy is contraindicated or not tolerated:
 - 1. Auranofin (Ridaura)
 - 2. Azathioprine (Imuran)
 - 3. Cyclophosphamide (Cytoxan or Neosar)
 - 4. Cyclosporine (Neoral or Sandimmune)

5. Gold sodium thiomalate (Myochrysine)
6. Hydroxychloroquine (Plaquenil)
7. Leflunomide (Arava)
8. Methotrexate
9. Minocycline (Minocin or Dynacin)
10. Penicillamine (Cuprimine, Depen)
11. Sulfasalazine (Azulfidine, Azulfidine EN-tabs)

III. Crohn's Disease (CD)

- A. Patient is 6 years of age or older AND
- B. Patient has moderately to severely active CD AND
- C. Patient has one or more of the following symptoms; AND
 1. abdominal pain
 2. bleeding
 3. diarrhea
 4. extra-intestinal manifestations (arthritis, uveitis, iritis, pyoderma gangrenosum, erythema nodosum, or spondylitis)
 5. internal fistulae
 6. intestinal obstruction
 7. perianal disease
 8. megacolon
 9. weight loss
- D. Patient has had an inadequate response to conventional therapy, or such therapy is contraindicated or not tolerated; OR
 1. 5-Aminosalicylates
 - i. Sulfasalazine (Azulfidine, Azulfidine EN-tabs)
 - ii. Mesalamine (Asacol, Pentasa, Lialda, Apriso)
 2. Systemic corticosteroids (eg, prednisone)
 3. Azathioprine (Imuran)
 4. 6-Mercaptopurine
 5. Methotrexate
 6. Cyclosporine (Neoral, Sandimmune)
 7. Antibiotics (eg, metronidazole)
- E. Patient has fistulizing Crohn's disease with draining enterocutaneous or rectovaginal fistulas, of at least 3 months duration OR
- F. Patient has fistulizing or moderately to severely active Crohn's disease and has responded to previous therapy with infliximab.

IV. Ulcerative Colitis

- A. Patient is 18 years of age or older AND
- B. Patient has signs and symptoms of moderately to severely active ulcerative colitis; AND
- C. Patient has had an inadequate response to conventional therapy.
 1. Sulfasalazine (Azulfidine, Azulfidine EN-tabs)
 2. Mesalamine (Asacol, Pentasa, Apriso, Lialda, Rowasa, Canasa)
 3. Azathioprine (Imuran)
 4. 6-Mercaptopurine
 5. Budesonide (Entocort EC)

V. Active Ankylosing Spondylitis (Adult)

- A. Patient is 18 years of age or older AND
- B. Patient has signs and symptoms of active ankylosing spondylitis; AND
- C. Patient has had an inadequate response to conventional treatment, or such therapy is contraindicated or not tolerated:
 1. Non-steroidal anti-inflammatory drugs (ibuprofen, naproxen, others)
 2. Methotrexate
 3. Sulfasalazine (Azulfidine, Azulfidine EN-tabs)

VI. Active Psoriatic Arthritis (Adult)

- A. Patient is 18 years of age or older AND
- B. Patient has active arthritis, with at least 5 swollen joints and 5 tender joints AND
- C. Patient has arthritis in any of the following distributions, AND:
 - 1. Distal interphalangeal joint involvement
 - 2. Polyarticular arthritis, without rheumatoid nodules
 - 3. Arthritis mutilans
 - 4. Asymmetric arthritis
 - 5. Ankylosing spondylitis-like arthritis
- D. Patient has had an inadequate response to one or more nonbiologic disease modifying anti-rheumatic agents (DMARDs), or such therapy is contraindicated or not tolerated: AND
 - 1. Auranofin (Ridaura)
 - 2. Azathioprine (Imuran)
 - 3. Cyclophosphamide (Cytoxan or Neosar)
 - 4. Cyclosporine (Neoral or Sandimmune)
 - 5. Gold sodium thiomalate (Myochrysine)
 - 6. Hydroxychloroquine (Plaquenil)
 - 7. Leflunomide (Arava)
 - 8. Methotrexate
 - 9. Minocycline (Minocin or Dynacin)
 - 10. Penicillamine (Cuprimine, Depen)
 - 11. Sulfasalazine (Azulfidine, Azulfidine EN-tabs)
- E. None of the following are present:
 - 1. Currently receiving systemic psoriasis therapy (except for methotrexate) or immunosuppressive therapy.
 - 2. Pregnant women or nursing mothers.

VII. Extensive or Disabling Treatment Resistant Plaque Psoriasis (Adult)

- A. Patient is 18 years of age or older; AND
- B. Patient has a diagnosis of moderate to severe plaque psoriasis with either of the following:
 - 1. Patient has greater than 10% of body surface area with plaque psoriasis OR
 - 2. Less than or equal to 10% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia) AND
- C. Patient has had an inadequate response to systemic therapies, or such therapy is contraindicated or not tolerated.
 - 1. Methotrexate
 - 2. Acitretin (Soriatane)
 - 3. Cyclosporine (Neoral, Sandimmune)

VI. Reactive Arthritis (Reiter's Syndrome) and Arthritis Associated with Inflammatory Bowel Disease

- A. Patient is 18 years of age or older.