Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

REMICADE® (infliximab)

GPI CODING:

52505040002120

DESCRIPTION:

Remicade is a tumor necrosis factor (TNF) blocker FDA-approved for the treatment of adult and pediatric Crohn's disease, adult and pediatric ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and chronic plaque psoriasis. Remicade may also be used for juvenile idiopathic arthritis, reactive arthritis, and arthritis associated with inflammatory bowel disease.

APPROVAL DURATION:

Approval duration: 3 years

CRITERIA FOR REMICADE

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 other serious infection
   E. Patients who have not had a tuberculin skin test or a CDC-recommended equivalent, to rule out latent tuberculosis
   F. Use of Remicade in combination with other TNF blockers, Kineret (anakinra), or Orencia (abatacept)

II. Moderate to Severe Rheumatoid Arthritis
   A. Patient must be 18 years of age or older **AND**
   B. Patient is currently receiving methotrexate or another immunosuppressive agent that has also been demonstrated to prevent the development of human anti-chimeric antibodies (ie, azathioprine, cyclosporine, or sulfasalazine) **OR**
   C. Patient has a documented contraindication or another clinical reason for not receiving methotrexate or another immunosuppressive agent **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. Juvenile Idiopathic Arthritis
   A. Patient has moderately to highly active arthritis **AND**
   B. Patient has had an inadequate response to methotrexate or leflunomide or such therapy is contraindicated or not tolerated **AND**
   C. Patient has had an inadequate response to Enbrel (etanercept) and Humira (adalimumab), or such therapy is contraindicated or not tolerated

IV. 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

V. Ulcerative Colitis
   A. Patient is 6 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)

VI. 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)

VII. 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 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

VIII. Reactive Arthritis (Reiter's Syndrome) and Arthritis Associated with Inflammatory Bowel Disease
- A. Patient is 18 years of age or older

IX. Chronic 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: **AND**
  1. Patient has greater than 10% of body surface area with plaque psoriasis
  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)

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)