REMICADE® (infliximab)

LENGTH OF AUTHORIZATION: UP TO ONE YEAR

REVIEW CRITERIA:

Rheumatoid Arthritis

- Patient must be 18 years of age or older
- Patient has a documented diagnosis of moderate to severe rheumatoid arthritis
- A negative tuberculin test (TB) prior to initiating therapy and results have been provided
- Patient has had an inadequate response, intolerance, or contraindication (clinical documentation must be submitted demonstrating response to previous therapies) to one or more non-biologic DMARDs (i.e., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) for at least 3 consecutive months AND
- Patient has had a trial of at least one of the preferred alternatives and experienced inadequate response or intolerance. If a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.

Ankylosing Spondylitis

- Patient must be 18 years of age or older
- Patient has a documented diagnosis of ankylosing spondylitis
- A negative tuberculin test (TB) prior to initiating therapy and results have been provided
- Patient has had an inadequate response, intolerance, or contraindication (clinical documentation must be submitted demonstrating response previous therapies) with the following:
  - One or more non-steroidal anti-inflammatory drugs – NSAIDs (trial at maximum dose for at least 2-3 weeks before considering them as failures) OR
  - Analgesic agents (acetaminophen or codeine) if NSAIDs do not completely control the pain OR
  - Sulfasalazine (if peripheral joint involvement is present) AND
  - Patient has had a trial of at least one of the preferred alternatives and experienced inadequate response or intolerance. If a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.

Crohn’s Disease

- Patient must be 6 years of age or older
- Patient has a documented diagnosis of moderate to severe Crohn’s disease
- A negative tuberculin test (TB) prior to initiating therapy and results have been provided
- Patient has inadequate responses, intolerance, or has contraindications to conventional therapy (clinical documentation must be submitted demonstrating response previous therapies):
  - Budesonide, mesalamine, or corticosteroids (i.e. prednisone, methylprednisolone) OR
Division: Pharmacy Policy
Subject: Prior Authorization Criteria

Original Development Date: 

- Non-biologic DMARDs (e.g. azathioprine, methotrexate, mercaptopurine) AND
- Patient has an inadequate response, intolerance, or has contraindications to Humira®

**Plaque Psoriasis**

- Patient must be 18 years of age or older; **AND**
- Patient has documented diagnosis of moderate to severe plaque psoriasis for at least 6 months with at least one of the following:
  - Incapacitation due to plaque location (e.g., head and neck, palms, soles, or genitalia); **OR**
  - Involvement of at least 10 percent of body surface area (BSA); **OR**
  - Psoriasis Area and Severity Index (PASI) score of 12 or greater; **AND**
- Patient is free of any clinically important active infections; **AND**
- Patient has a negative tuberculin test (TB) prior to initiating therapy and results have been provided; **AND**
- Patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of at least 1 systemic agent (e.g., immunosuppressives, retinoic acid derivatives, and/or methotrexate); **AND**
- Patient did not respond adequately (or is not a candidate) to a 3 month minimum trial of phototherapy (e.g., Psoralens with UVA light (PUVA) OR UVB with coal tar or dithranol **AND**
- Patient has had a trial of at least one of the preferred alternatives and experienced inadequate response or intolerance. If a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.

**Psoriatic Arthritis**

- Patient must be 18 years of age or older
- A negative tuberculin test (TB) prior to initiating therapy and results have been provided
- Patient has active psoriatic arthritis for at least 6 months defined as:
  - ≥ 3 swollen joints **AND**
  - ≥ 3 tender joints **AND**
- Patient has had an inadequate response, intolerance, or contraindication (clinical documentation must be submitted demonstrating response previous therapies) with the following:
  - One or more non-steroidal anti-inflammatory drugs –NSAIDs (trial at maximum dose for at least 2-3 weeks before considering them as failures) **AND**
  - One or more non-biologic disease modifying anti-rheumatic drugs DMARDs (i.e. methotrexate, sulfasalazine, leflunomide, cyclosporine) **AND**
  - Patient has had a trial of at least one of the preferred alternatives and experienced inadequate response or intolerance. If a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.
Ulcerative Colitis

- Patient must be 6 years of age or older
- Patient has a documented diagnosis of moderately to severely active ulcerative colitis (UC)
- A negative tuberculin test (TB) prior to initiating therapy and results have been provided
- Patient has demonstrated corticosteroid dependence OR
- Patient has had an inadequate response (clinical documentation must be submitted demonstrating response to previous therapies) or failed to tolerate oral mesalamine, oral corticosteroids (i.e., prednisone, dexamethasone, methylprednisolone), cyclosporine, azathioprine or 6-mecaptopurine (6-MTP) AND
- Patient has had an inadequate response, intolerance, or has contraindications to Humira®

DOSING:

Rheumatoid Arthritis:
3 mg/kg at: 0, 2 and 6 weeks, then every 8 weeks by intravenous infusion with methotrexate. May increase up to 10 mg/kg or 3 mg/kg every 4 weeks if incomplete response

Ankylosing Spondylitis:
5 mg/kg at: 0, 2 and 6 weeks, then every 6 weeks by intravenous infusion.

Crohn’s Disease:
5 mg/kg at: 0, 2 and 6 weeks, then every 8 weeks by intravenous infusion. Some adult patients who initially respond to treatment, may benefit from increasing the dose to 10 mg/kg if they later lose their response.

Plaque Psoriasis:
5 mg/kg at: 0, 2, and 6 weeks, then every 8 weeks by intravenous infusion.

Psoriatic Arthritis:
5 mg/kg at: 0, 2 and 6 weeks, then every 8 weeks by intravenous infusion

Ulcerative Colitis:
5 mg/kg at: 0, 2 and 6 weeks, then every 8 weeks by intravenous infusion.

CONTINUATION OF THERAPY:
- Documentation showing current patients are stable (have low disease activity or are in clinical remission) will be taken into consideration during the prior authorization review process regarding continuation of therapy with the same agent.