

Specialty Pharmacy Program

Humira® (adalimumab)

DESCRIPTION

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

APPROVAL DURATION AND QUANTITY LIMITS

Approval duration: lifetime

Quantity limits:

Every other week dosing: 2 vials per 28 days OR

- Moderate to Severe Rheumatoid Arthritis:
 - Once weekly dosing if patient is not taking concomitant methotrexate: 4 vials per 28 days
- Crohn's Disease:
 - Induction dose of 160 mg with an 80 mg dose at week two, followed by maintenance dose of 40 mg every other week beginning at week four
 - One Humira Pen – Crohn's Disease Starter Package (1 kit = 6 doses) one time only
- Chronic Moderate to Severe Plaque Psoriasis
 - Induction dose of 80 mg one time only as initial dose, followed by 40 mg every other week starting one week after initial dose
- Pediatric patients (20 mg/ 0.4 ml, 1 kit = 2 doses)
 - Every other week dosing: 2 vials per 28 days

APPROVAL CRITERIA

- I. None of the following are present:
 - A. Tuberculosis or a history of recurrent infection, chronic current infection, or clinically important infection.
 - B. Patients who have not had a tuberculin skin test (TST), or a CDC-recommended equivalent, to rule out latent tuberculosis.
 - C. Latex allergy as Humira prefilled syringe cover contains latex.
 - D. Individuals with moderate to severe congestive heart failure (CHF) or patients who develop new symptoms or worsening symptoms of pre-existing CHF.
 - E. Using Humira 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 on the next page.

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 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. Psoriatic Arthritis

A. Patient is 18 years of age or older AND

B. Patient has active arthritis, with at least 3 swollen joints and 3 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 nonbiologic 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)

E. None of the following are present:

1. Currently receiving systemic psoriasis therapy (except for methotrexate, glucocorticoids, salicylates, non-steroidal anti-inflammatory drugs, or analgesics), immunosuppressive therapy, or Kineret (anakinra).
2. Pregnant women or nursing mothers

- IV. Active Ankylosing Spondylitis
 - A. Patient is 18 years of age or older AND
 - B. 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)
- V. Crohn's Disease (CD)
 - A. Patient is 18 years of age or older AND
 - B. Patient has had an inadequate response to conventional therapy, or such therapy is contraindicated or not tolerated:
 - 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)
- VI. Chronic Moderate to Severe Plaque Psoriasis
 - 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. Disease is not controlled with topical therapy; AND
 - D. 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)
- VII. Diagnosis of Juvenile Idiopathic Arthritis (JIA):
 - A. Patient has a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; AND
 - B. Patient is at least 4 years of age.