

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

**Prior Authorization Group: HUMIRA**

**Drug(s):** HUMIRA (adalimumab)

**Covered Uses:** All FDA-approved indications not otherwise excluded from Part D. All criteria in "other criteria" section must be met for coverage.

**Required Medical Information:** Tuberculosis (TB) test result. For arthritis: 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 inadequate response to or intolerance to conventional therapy. Assessment of growth, nutrition, extraintestinal complications, therapy-induced complications and functional ability must also be documented as well as clinical signs and symptoms as outlined in Crohn's Disease Activity Index (CDAI).

**Age Restrictions:** Restricted to 18 years of age and older, except for Juvenile Rheumatoid Arthritis (JRA) which is restricted to 4 years and older.

**Prescriber Restrictions:** Restricted to rheumatologists, immunologists, dermatologists, gastroenterologists, and 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 disease as defined by their rheumatologist.

For the treatment of **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 greater than 4 times/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 greater than 37.5 °C in the last week), taking opiates or diphenoxylate/atropine for diarrhea, anemia, and weight loss greater than 10%
- Assessment of growth, nutrition, extraintestinal complications, therapy-induced complications and functional ability

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

- Failed to respond to other disease-modifying anti-rheumatic drugs (DMARDs) including a 2 month trial of MTX before coverage (American College of

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Rheumatology (ACR) response of less than 20 after 7.5-20mg of MTX for 2 months).

- In the event the member has contraindications or intolerance to MTX, the member must have failed to respond to other DMARDs.

For the treatment of moderate to severe **polyarticular-course juvenile chronic Rheumatoid arthritis** as indicated by 5 swollen joints and three or more joints with limitation of motion, pain, tenderness or both, or persistent symptoms in oligoarticular disease, the following criteria must be met:

- Failed to respond to an adequate trial of at least one DMARD.

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 Non Steroidal Anti-inflammatory Drugs (NSAIDs), and failed to respond to an adequate trial of at least one DMARD.

For the treatment of **plaque psoriasis** the following criteria must be 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 year.
- Treatment with phototherapy or photochemotherapy was not effective or contraindicated.
- An appropriate treatment trial of methotrexate was not effective or contraindicated. If methotrexate is contraindicated, an appropriate trial of oral retinoids or cyclosporine is required.
- And who have functional impairment related to symptomatology of psoriasis.

For Crohn's Disease: Initial authorization period will be allowed for up to 3 months. Documentation of clinical response must be submitted prior to continuation of therapy and may be approved up to a maximum of 6 months. Increase in dose and/or frequency of administration requires a new prior authorization.

For psoriasis: Initial authorization period will be allowed for up to 3 months. Continuation of therapy will be allowed for up to 6 months and will require documentation of improved patient status in the monitoring parameters of all of the following:

- At least a 50% improvement of clinical signs/symptoms of psoriasis (eg. itching, redness, scaling, psoriatic body surface area coverage) at three months and 75% improvement at six months.
- Quality of life assessments - improved per patient and/or physician.
- **Exclusion Criteria**: Humira will not be covered for the following:

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- Not covered if member has not been evaluated for latent TB infection with a TB skin test and if TB infection has not been treated prior to therapy if indicated.
- Members at risk for infection or who have an active infections including chronic or localized infections
- Not covered for a diagnosis of osteoarthritis
- Members who have another form of psoriasis other than chronic plaque psoriasis (e.g. guttate, erythrodermic or pustular psoriasis as the sole or predominant form).
- Members who have not had plaque psoriasis for more than one year (when prescribed for psoriasis).
- Caution should be used in members who have a history of significant hematologic abnormalities.
- Not covered for concomitant therapy with Rituxan or biologic therapies other than MTX.
- Frequency/dose greater than 40mg every other week is not covered except for the initial 2-week induction period only for Crohn's Disease.
- Not covered for members who are being treated for psoriasis and have arthropathies such as PSA, unless consult with rheumatologist.
- Not covered for Ulcerative Colitis.
- Members who have a history of or currently have Lupus, malignancy, clinically significant chronic or recurrent infections, or CNS demyelinating disorder will be reviewed on a case-by-case basis.

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