# Prior Authorization Criteria for the Use of Humira (adalimumab)

Humira (adalimumab) is a recombinant human IgG1 monoclonal antibody specific for human tumor necrosis factor (TNF). Humira is indicated for the following conditions:

1. **Rheumatoid Arthritis**—Reducing the signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Humira can be used alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARD’s).

2. **Psoriatic Arthritis**—Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis. Humira can be used alone or in combination with DMARD’s.


4. **Crohn’s Disease in Adults**—Reducing signs and symptoms and inducing and maintaining clinical remission in adults patients with moderately to severely active Crohn’s Disease who have had an inadequate response to conventional therapy. Reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.

5. **Crohn’s Disease in children**—Reducing signs and symptoms and inducing and maintaining clinical remissions in patients 6 years of age and older with moderately or severely active Crohn’s disease who have had inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate.

6. **Juvenile Idiopathic Arthritis**—Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.

7. **Plaque Psoriasis**—For treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy.

8. **Ulcerative Colitis**—Inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have an inadequate response to immunosuppressants such as...
corticosteroids, azathioprine or 6-mercaptopurine (6-MP). The effectiveness of Humira has not been established in patients who have lost response to or were intolerant to TNF blockers.

9. **Hidradenitis suppurativa**—the treatment of moderate to severe hidradenitis suppurativa.

The following criteria, documented with office notes, must be met for prior authorization of Humira for **Rheumatoid Arthritis, Psoriatic Arthritis, and Ankylosing Spondylitis**:

- Prescribed by a rheumatologist
  
  - Documented presence of moderately to severe active rheumatoid arthritis
  
  - Documented presence of active arthritis in patients with psoriatic arthritis
  
  - Documented presence of active ankylosing spondylitis

**IN ADDITION**

- The patient must be at least 18 years old.
- For Rheumatoid Arthritis, the patient must have failed therapy on one or more DMARD (see list below)
- Humira can be administered alone or in combination with Methotrexate and other DMARD’s.

The following criteria, documented with office notes, must be met for prior authorization of Humira for **Crohn’s Disease**:

- Prescribed by a specialist
  
  - Documented presence of moderately to severely active Crohn’s disease
  
  - Documented trial and failure and/or intolerance to conventional therapy-----medical records must be submitted. (adults). For pediatric patients (6 years of age and up)—documented inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine or methotrexate.

**IN ADDITION**

- The patient must be at least 6 years old.
- Humira will be approved for a period of one year; the use of Humira in Crohn’s disease beyond one year has not been evaluated in controlled clinical studies.
- During treatment of Crohn’s Disease with Humira, concomitant aminosalicylates, corticosteroids, and/or immunomodulatory agents may be continued.

The following criteria, documented with office notes, must be met for prior authorization of Humira for **Ulcerative Colitis**:

- Prescribed by a specialist
  
  - Documented presence of moderately to severely active ulcerative colitis
  
  - Documented trial and inadequate response to immunosuppressants (corticosteroids, azathioprine, 6-MP). The medication must appear on the member’s prescription claims history. The trial and clinical results must be documented in medical records submitted with prior authorization.

**IN ADDITION**

- The patient must be at least 18 years old.
- Humira will be approved for a period of 2 months. Humira should only be continued in patients who have shown evidence of clinical remission by 8 weeks. A new prior authorization may be submitted at
This time for further therapy. Medical records documenting evidence of clinical remission must be submitted along with the prior authorization request.

- Azathioprine and 6-MP may be continued during the treatment with Humira, if necessary.

The following criteria, documented with office notes, must be met for prior authorization of Humira for Juvenile Idiopathic Arthritis:

- Prescribed by a rheumatologist
- Documented presence of Juvenile Idiopathic Arthritis
- The child is 2 years of age or older
  - the Humira is given alone or in combination with methotrexate

The following criteria, documented with office notes, must be met for prior authorization of Humira for the treatment of Plaque Psoriasis.

- Prescribed by a dermatologist
- All of the following are documented by submitted office notes:
  - Presence of chronic plaque psoriasis—greater than or equal to one year
  - Minimum body surface area involvement with plaque psoriasis of greater than or equal to 15%
  - Member has tried a systemic therapy (eg, methotrexate, azathioprine, cyclosporine, acitretin (Soriatane), tacrolimus (Prograf), etanercept (Enbrel), infliximab (Remicade), mycophenolate mofetil (Cellcept), OR phototherapy (eg, ultraviolet B [UVB]) OR oral methoxsalen plus UVA light [PUVA] for psoriasis for a minimum of a 3 month period, and has failed therapy or has been intolerant.
  - The use of Humira in moderate to severe chronic plaque psoriasis beyond one year has not been evaluated in controlled clinical studies.

The following criteria, documented with office notes, must be met for prior authorization of Humira for the treatment of Hidradenitis Suppurativa:

- Presence of moderate to severe hidradenitis suppurativa in members, 18 years of age and older, documented in submitted medical records. (ICD-10 L73.2).

Quantity Limits

The recommended dose of Humira (adalimumab) for the treatment of Rheumatoid Arthritis, Psoriatic Arthritis, and Ankylosing Spondylitis is 40 mg, administered subcutaneously, every other week. A quantity limit of 1 package, containing 2 syringes, per month will be enforced.

Some patients with Rheumatoid Arthritis not taking concomitant Methotrexate may need to increase the dosing frequency to 40 mg every week. The need for this dosing schedule must be noted in physician’s notes and submitted along with the prior authorization. The patient must have received Humira 40 mg every other week for a minimum of 12 weeks before consideration of coverage of increased dosing frequency. If approved, 4 syringes per month may be obtained.

The recommended regimen of Humira (adalimumab) for Crohn’s Disease for adults is 160 mg initially at week 0 (dose can be administered as four injections in one day, or two injections per day for two consecutive days), 80 mg at week 2, followed by a maintenance dose of 40 mg every other week beginning at week 4. The patient may obtain one “Humira Starter Kit” which contains 6 syringes of 40 mg. Thereafter, the patient may obtain 2 syringes of 40 mg per month.
The recommended regimen of Humira in pediatric patients with Crohn’s Disease is 17 kg to less than 40 kg—initial dose (day 1) 80 mg (2x40 mg injections in one day), second dose two weeks later (day 15), 40 mg, two weeks later (day 29), maintenance dose of 20 mg every other week. For patients 40 kg or more, initial dose (day 1) is 160 mg (4 of the 40 mg injections in 1 one day or 2 of the 40 mg injections per day for 2 consecutive days). Second dose is 2 weeks later (day 15), 80 mg (2 of the 40 mg injections) in one day, two weeks later (day 29), maintenance dose of 40 mg every other week.

The recommended dose of Humira for the treatment of Juvenile Idiopathic Arthritis is weight-based. For those patients between the weights of 10 kg and less than 15 kg, 10 mg every other week, for those 15- to less than 30 kg, the recommended dose is 20 mg every other week, for those patients 30 kg or greater, the recommended dose is 40 mg every other week. Based on these dosing recommendations, the patient may receive either 2 of the 20 mg syringes per month OR 2 of the 40 mg syringes per month.

In the treatment of Plaque Psoriasis, the recommended dose is an initial dose of 80 mg (2 of the 40 mg syringes), one week later, 40 mg, thereafter, 40 mg every other week. The use of Humira in moderate to severe chronic plaque psoriasis beyond one year has been evaluated in controlled clinical studies. Based on these dosing recommendations, if the prior authorization request is approved, the member may obtain 4 of the 40 mg syringes for the first month, 2 of the 40 mg syringes thereafter for a period of 11 months.

For Ulcerative Colitis, 160 mg (4x40 mg syringes in one day or 2x40 mg syringes per day for 2 consecutive days) is initially administered on Day 1, followed by 80 mg two weeks later (Day 15). Two weeks later (Day 29) continue with a dose of 40 mg every other week. Based on these dosing recommendations, if the prior authorization request is approved, the member may obtain 7 of the 40 mg syringes the 1st month, 2 of the 40 mg syringes thereafter. Humira should only be continued in patients who have shown evidence of clinical remission by eight weeks (day 57) of therapy. Please see criteria for length of authorization.

For Hidradenitis Suppurativa, 160 mg (4x40 mg syringes on day 1 or as 2x40 mg syringes on days 1 and 2), two weeks later (day 15), 80 mg (2x40 mg syringes), third, on day 29, 40 mg once a week. Based on these dosing recommendations, if the prior authorization request is approved, the member may obtain 6 of the 40 mg syringes for the first fill, Subsequent fills receive 4x40 mg syringes per 30 days.

Continued authorization or re-authorization (after the initial 6 month period) shall be reviewed at least annually, and clinical documentation indicating that there is disease stability or improvement must be provided for diagnoses of ankylosing spondylitis, chronic plaque psoriasis, juvenile idiopathic arthritis, psoriatic arthritis, rheumatoid arthritis, ulcerative colitis, or Crohn’s disease.

When approved, Humira must be obtained through our specialty pharmacy.