HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

ADALIMUMAB (HUMIRA)

Generic	Brand	HICL	GCN	Exception/Other
ADALIMUMAB	HUMIRA HUMIRA PEDIATRIC	24800		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a member with a diagnosis of moderate to severe rheumatoid arthritis (RA) and does the request meet **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Prescribed by (or in consultation with) a rheumatologist
   - Trial with **ONE** of the following:
     - o At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
     - o Biologic agent approved for RA (e.g., Humira, Enbrel, Xeljanz)

   If yes, continue to #9.
   If no, continue to #2.

2. Is the request for a member with a diagnosis of psoriatic arthritis (PsA) and does the request meet **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Prescribed by (or in consultation with) a rheumatologist or dermatologist
   - Trial with **ONE** of the following:
     - o At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, or sulfasalazine
     - o Biologic agent approved for PsA (e.g., Humira, Enbrel, Xeljanz)

   If yes, continue to #9.
   If no, continue to #3.

3. Is the request for a member with a diagnosis of ankylosing spondylitis (AS) and does the request meet **ALL** of the following criteria?
   - Member is 18 years of age or older
   - Prescribed by (or in consultation with) a rheumatologist
   - Trial with **ONE** of the following:
     - o Prescription-strength NSAID (non-steroidal anti-inflammatory drug) such as: celecoxib, diclofenac, ibuprofen, naproxen, or meloxicam
     - o Biologic agent approved for AS (e.g., Humira, Enbrel)

   If yes, continue to #9.
   If no, continue to #4.

CONTINUED ON NEXT PAGE

ADALIMUMAB (HUMIRA)

INITIAL CRITERIA (CONTINUED)

4. Is the request for a member with a diagnosis of juvenile idiopathic arthritis (JIA) and does the request meet **ALL** of the following criteria?
   - Member is 2 years of age or older
   - Prescribed by (or in consultation with) a rheumatologist
   - Trial with **ONE** of the following:
     - o At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
     - o Biologic agent approved for JIA (e.g., Humira, Enbrel)

   If yes, continue to #9.
   If no, continue to #5.

5. Is the request for a member with a diagnosis of moderate to severe plaque psoriasis (PsO) and does the request meet **ALL** of the following criteria?
   - Member is 18 years of age or older
   - Prescribed by (or in consultation with) a dermatologist
   - Trial with **ONE** of the following:
     - o At least one course of systemic therapy for psoriasis such as: acitretin, cyclosporine, methotrexate, or oral methoxsalen plus UVA light (PUVA)
     - o Biologic agent approved for PsO (e.g., Humira, Enbrel)

   If yes, continue to #9.
   If no, continue to #6.

6. Is the request for a member with one of the following GI conditions and does the request meet **ALL** of the following criteria?
   - Moderate to severe Crohn's disease (CD) and the patient is 6 years of age or older OR moderate to severe ulcerative colitis (UC) and the patient is 18 years of age or older
   - Prescribed by (or in consultation with) a gastroenterologist
   - Trial with a biologic agent approved for the specific indication (e.g., Humira, Stelara [CD], Simponi [UC]) **OR** a trial with two of the following conventional therapies:
     - o Corticosteroids (such as prednisone, prednisolone, methylprednisolone, budesonide)
     - o 5-Aminosalicylates (such as sulfasalazine, mesalamine, olsalazine, balsalazide)
     - o Immunosuppressants/Immunomodulators (such as 6-mercaptopurine, azathioprine, methotrexate)

   If yes, continue to #9.
   If no, continue to #7.

CONTINUED ON NEXT PAGE

ADALIMUMAB (HUMIRA)

INITIAL CRITERIA (CONTINUED)

7. Is the request for a member with a diagnosis of moderate to severe hidradenitis suppurativa (HS) and does the request meet **ALL** of the following criteria?
   - Member is 12 years of age or older
   - Prescribed by (or in consultation with) a dermatologist

   If yes, continue to #9.
   If no, continue to #8.

8. Is the request for a member with a diagnosis of uveitis (non-infectious intermediate, posterior or panuveitis) and does the request meet **ALL** of the following criteria?
   - Member is 2 years of age or older
   - Prescribed by (or in consultation with) an ophthalmologist

   If yes, continue to #9.
   If no, do not approve. Please use status code #238 and the denial text provided.

   DENIAL TEXT (if diagnosis is not met): Per your health plan's Adalimumab (Humira) guideline, this medication is only covered for one of the following conditions: Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Plaque Psoriasis, Crohn's Disease, Ulcerative Colitis, Hidradenitis Suppurativa, Juvenile Idiopathic Arthritis, or Uveitis. Your provider did not indicate that you are being treated for any of these conditions and therefore your request was not approved.

   DENIAL TEXT (RA): Per your health plan's Adalimumab (Humira) guideline, this medication is only covered for moderate to severe Rheumatoid Arthritis (RA) when you meet all of the following conditions:
   - Member is 18 years of age or older
   - Prescribed by (or in consultation with) a rheumatologist
   - Trial with **ONE** of the following:
     - At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
     - Biologic agent approved for RA (e.g., Humira, Enbrel, Xeljanz), which also require prior authorization

   Your provider did not indicate that you **[specific criteria not met]**, and therefore your request was not approved.
   (Initial denial text continued on next page)

CONTINUED ON NEXT PAGE

ADALIMUMAB (HUMIRA)

INITIAL CRITERIA (CONTINUED)

DENIAL TEXT (PsA): Per your health plan's Adalimumab (Humira) guideline, this medication is only covered for Psoriatic Arthritis (PsA) when you meet all of the following conditions:

- Member is 18 years of age or older
- Prescribed by (or in consultation with) a rheumatologist or dermatologist
- Trial with one of the following:
  - At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, or sulfasalazine
  - Biologic agent approved for PsA (e.g., Humira, Enbrel, Xeljanz), which also require prior authorization

Your provider did not indicate that you **[specific criteria not met]**, and therefore your request was not approved.

DENIAL TEXT (AS): Per your health plan's Adalimumab (Humira) guideline, this medication is only covered for Ankylosing Spondylitis (AS) when you meet all of the following conditions:

- Member is 18 years of age or older
- Prescribed by (or in consultation with) a rheumatologist
- Trial with one of the following:
  - Prescription-strength NSAID (non-steroidal anti-inflammatory drug) such as: celecoxib, diclofenac, ibuprofen, naproxen, or meloxicam
  - Biologic agent approved for AS (e.g., Humira, Enbrel), which also require prior authorization

Your provider did not indicate that you **[specific criteria not met]**, and therefore your request was not approved.

DENIAL TEXT (JIA): Per your health plan's Adalimumab (Humira) guideline, this medication is only covered for Juvenile Idiopathic Arthritis (JIA) when you meet all of the following conditions:

- Member is 2 years of age or older
- Prescribed by (or in consultation with) a rheumatologist
- Trial with one of the following:
  - At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
  - Biologic agent approved for JIA (e.g., Humira, Enbrel), which also require prior authorization

Your provider did not indicate that you **[specific criteria not met]**, and therefore your request was not approved.

(Initial denial text continued on next page)

CONTINUED ON NEXT PAGE

ADALIMUMAB (HUMIRA)

INITIAL CRITERIA (CONTINUED)

DENIAL TEXT (PsO): Per your health plan's Adalimumab (Humira) guideline, this medication is only covered for moderate to severe plaque psoriasis (PsO) when you meet all of the following conditions:

- Member is 18 years of age or older
- Prescribed by (or in consultation with) a dermatologist
- Trial with one of the following:
  - At least one course of systemic therapy for psoriasis such as: acitretin, cyclosporine, methotrexate, or oral methoxsalen plus UVA light (PUVA)
  - Biologic agent approved for PsO (e.g., Humira, Enbrel), which also require prior authorization

Your provider did not indicate that you **[specific criteria not met]**, and therefore your request was not approved.

DENIAL TEXT (CD): Per your health plan's Adalimumab (Humira) guideline, this medication is only covered for moderate to severe Crohn's disease (CD) when you meet all of the following conditions:

- Member is 6 years of age or older
- Prescribed by (or in consultation with) a gastroenterologist
- Trial with a biologic agent approved for CD (e.g., Humira, Stelara), which also require prior authorization, or a trial with two of the following conventional therapies:
  - Corticosteroids (such as prednisone, prednisolone, methylprednisolone, budesonide)
  - 5-Aminosalicylates (such as sulfasalazine, mesalamine, olsalazine, balsalazide)
  - Immunosuppressants/Immunomodulators (such as 6-mercaptopurine, azathioprine, methotrexate)

Your provider did not indicate that you **[specific criteria not met]**, and therefore your request was not approved.

DENIAL TEXT (UC): Per your health plan's Adalimumab (Humira) guideline, this medication is only covered for moderate to severe ulcerative colitis (UC) when you meet all of the following conditions:

- Member is 18 years of age or older
- Prescribed by (or in consultation with) a gastroenterologist
- Trial with a biologic agent approved for UC (e.g., Humira, Simponi), which also require prior authorization, or a trial with two of the following conventional therapies:
  - Corticosteroids (such as prednisone, prednisolone, methylprednisolone, budesonide)
  - 5-Aminosalicylates (such as sulfasalazine, mesalamine, olsalazine, balsalazide)
  - Immunosuppressants/Immunomodulators (such as 6-mercaptopurine, azathioprine, methotrexate)

Your provider did not indicate that you **[specific criteria not met]**, and therefore your request was not approved.

(Initial denial text continued on next page)

CONTINUED ON NEXT PAGE

INITIAL CRITERIA (CONTINUED)

DENIAL TEXT (HS): Per your health plan's Adalimumab (Humira) guideline, this medication is only covered for moderate to severe Hidradenitis Suppurativa (HS) when you meet all of the following conditions:

- Member is 12 years of age or older
- Prescribed by (or in consultation with) a dermatologist

Your provider did not indicate that you **[specific criteria not met]**, and therefore your request was not approved.

DENIAL TEXT (UVEITIS): Per your health plan's Adalimumab (Humira) guideline, this medication is only covered for Uveitis (non-infectious intermediate, posterior and panuveitis) in patients at least 2 years of age when prescribed by (or in consultation with) an ophthalmologist. Your provider did not indicate that you **[specific criteria not met]**, and therefore your request was not approved.

9. **Approve for 12 months by HICL up to 13 fills.** (Humira is hard-coded with a quantity of two pens/syringes (two 40 mg doses) per 28 days, and one starter kit per year.)
   NOTE: Please enter 'F' in the restriction field with a Max Quantity if the request is for one of the following diagnoses. (If a second PA is needed, please enter a start dates 3 weeks after the initial PA.)
   - **RA: Please enter an override for #4 per 28 days.**
   - **CD or UC: Please approve #6 per 28 days for 28 days, and a second PA for 11 months.**
   - **HS: Please approve #6 per 28 days for 28 days, and a second PA for #4 per 28 days for 11 months.**
   - **PsO or Uveitis: Please approve #4 per 28 days for 28 days, and a second PA for 11 months.**

   Please use status code #056 and the approval text provided.
   APPROVAL TEXT (for requests with starter kit): Your request for Humira has been approved for a 12-month period for a quantity of **[one Starter kit or up to [# pens/syringes for the first month, and then two or four pens/syringes]** per 28 days for the next 11 months.

   APPROVAL TEXT: Your request for Humira has been approved for a quantity of **[two or four pens/syringes]** per 28 days for a 12-month period.

CONTINUED ON NEXT PAGE

ADALIMUMAB (HUMIRA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the request meet **ALL** of the following criteria?
   - Prescribed for one of the following diagnoses: rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, chronic plaque psoriasis, Crohn's disease, ulcerative colitis, hidradenitis suppurativa or uveitis (non-infectious intermediate, posterior or panuveitis)
   - Prescribed by (or in consultation with) a dermatologist, rheumatologist, gastroenterologist or ophthalmologist
   - Documentation that the patient experienced improvement while on therapy

   If yes, **approve for 12 months by HICL up to 13 fills.** Please use status code #056 and the approval text provided.

   If the request is for RA or for HS, please enter an override for four pens or syringes (providing up to four 40 mg doses) per 28 days. **(NOTE: Please enter 'F' in the restriction field with a Max Quantity)**

   APPROVAL TEXT (PSO, JIA, AS, PSA, CD, UC or Uveitis; Qty of two pens/syringes per 28 days): Your request for Humira has been approved for a quantity of two **[pens/syringes]** per 28 days for a 12-month period.

   APPROVAL TEXT (RA or HS; Qty of four pens/syringes per 28 days): Your request for Humira has been approved for a quantity of four **[pens/syringes]** per 28 days for a 12-month period.

   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Adalimumab (Humira) guideline, authorization for renewal requires that you meet **ALL** of the following conditions:
   - Prescribed for one of the following diagnoses: rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, chronic plaque psoriasis, Crohn's disease, ulcerative colitis, hidradenitis suppurativa, or uveitis (non-infectious intermediate, posterior or panuveitis)
   - Prescribed by (or in consultation with) a dermatologist, rheumatologist, gastroenterologist, or ophthalmologist
   - Your provider indicates that you have experienced improvement while on therapy

   Your provider did not indicate that **[specific criteria not met],** and therefore your request was not approved.

CONTINUED ON NEXT PAGE

ADALIMUMAB (HUMIRA)

RATIONALE
To ensure appropriate diagnostic, utilization and safety criteria are used to determine the medical necessity of requests for adalimumab (Humira).

FDA APPROVED INDICATIONS
HUMIRA is indicated for reducing 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 and psoriatic arthritis. HUMIRA can be used alone or in combination with methotrexate or other DMARDs.

HUMIRA is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

HUMIRA is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in children 6 years of age and older and in adults with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. HUMIRA is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.

HUMIRA is indicated for the treatment of adults with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.

HUMIRA is indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical functions in patients with psoriatic arthritis. Humira can be used alone or in combination with DMARDs.

HUMIRA is indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. HUMIRA can be used alone or in combination with methotrexate.

HUMIRA is indicated for inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had 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.

HUMIRA is indicated for the treatment of moderate to severe hidradenitis suppurativa.

HUMIRA is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients.

Dosing:
Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis
40 mg every other week. Some patients with RA not receiving methotrexate may benefit from increasing the frequency to 40 mg every week.

CONTINUED ON NEXT PAGE

ADALIMUMAB (HUMIRA)

Juvenile Idiopathic Arthritis
10 kg (22 lbs) to <15 kg (33 lbs): 10 mg every other week
15 kg (33 lbs) to <30 kg (66 lbs): 20 mg every other week
≥30 kg (66 lbs): 40 mg every other week

Plaque Psoriasis
80 mg initial dose followed by 40 mg every other week starting one week after initial dose.

Hidradenitis Suppurativa
- Initial dose (Day 1): 160 mg (four 40 mg injections in 1 day or two 40 mg injections per day for 2 consecutive days),
- Next dose two weeks later (Day 15): 80 mg
- Two weeks later (Day 29): Maintenance dose of 40 mg every week

Uveitis
80 mg initial dose followed by 40 mg every other week starting one week after initial dose.

Adult Crohn's Disease and Ulcerative Colitis
- Initial dose (Day 1): 160 mg (four 40 mg injections in one day or two 40 mg injections per day for two consecutive days)
- Next dose two weeks later (Day 15): 80 mg
- Two weeks later (Day 29): Begin a maintenance dose of 40 mg every other week

For patients with Ulcerative Colitis, only continue Humira in patients who have shown evidence of clinical remission by eight weeks (Day 57) of therapy.

Pediatric Crohn's Disease:
17 kg (37 lbs) to < 40 kg (88 lbs):
- Initial dose (Day 1): 80 mg
- Second dose two weeks later (Day 15): 40 mg
- Two weeks later (Day 29): Begin a maintenance dose of 20 mg every other week.

≥ 40 kg (88 lbs):
- Initial dose (Day 1): 160 mg
- Second dose two weeks later (Day 15): 80 mg
- Two weeks later (Day 29): Begin a maintenance dose of 40 mg every other week

CONTINUED ON NEXT PAGE

ADALIMUMAB (HUMIRA)

DOSAGE FORMS AND STRENGTHS

80 mg/0.8 mL in a single - use prefilled pen
80 mg/0.8 mL in a single-use prefilled glass syringe
40 mg/0.8 mL in a single-use prefilled pen
40 mg/0.4 mL in a single-use prefilled pen
40 mg/0.8 mL in a single-use prefilled glass syringe
40 mg/0.4 mL in a single-use prefilled glass syringe
20 mg/0.4 mL in a single-use prefilled glass syringe
20 mg/0.2 mL in a single-use prefilled glass syringe
10 mg/0.2 mL in a single-use prefilled glass syringe
10 mg/0.1 mL in a single-use prefilled glass syringe

REFERENCES

- Humira (adalimumab) [prescribing information]. North Chicago, IL. October 2018.
- Felson D, Anderson J, Boers M, et al. American College of Rheumatology preliminary definition of improvement in rheumatoid arthritis. Arthritis Rheum 1995; 38:727-35.
- Mease P, Gladman D, Ritchlin C, et al. Adalimumab for the treatment of patients with moderately to severely active psoriatic arthritis. Arthritis and Rheumatism 2005; 52:3279-89.
- Braun J, Davis J et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with ankylosing spondylitis. Ann Rheum Dis. 2006; 65(3):316-20.
- Hanauer SB, Sandborn WJ, Rutgeerts P, et al. Human Anti-Tumor Necrosis Factor Monoclonal Antibody (Adalimumab) in Crohn's Disease: the CLASSIC-I Trial. Gastroenterology. 2006; 130: 323-333.
- Colombel JF, Sandborn WJ, Rutgeerts P, et al. Adalimumab for Maintenance of Clinical Response and Remission in Patients With Crohn's Disease: The CHARM Trial. Gastroenterology. 2007; 132: 53-65.

Created: 09/14
Effective: 05/01/19 Client Approval: 04/10/19 P&T Approval: 03/04/19