CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Humira (adalimumab)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Humira, a tumor necrosis factor (TNF) blocker was originally approved in 2002 for the treatment of rheumatoid arthritis. Since then, it has gained additional indications for psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis, juvenile idiopathic arthritis, ulcerative colitis, hidradenitis suppurativa, and certain types of uveitis. It is a monoclonal antibody produced by recombinant DNA technology. Humira is administered by subcutaneous injection.
Humira specifically binds to TNF-alpha and blocks its interaction with TNF receptors. TNF is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Elevated concentrations of TNF are found in the synovial fluid of patients with RA, JIA, PsA, and AS and play an important role in both the pathologic inflammation and the joint destruction that are hallmarks of these diseases. Increased concentrations of TNF are also found in psoriasis plaques.

Humira (adalimumab) will be considered for coverage when the following criteria are met:

Ankylosing Spondylitis

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of active ankylosing spondylitis (AS); AND
4. Member must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Member has had back pain for 3 months or more that began before the age of 50; AND
6. Current imaging results show an inflammation of one or both of the sacroiliac joints (sacroiliitis); AND
7. Member has tried and failed to respond to treatment with at least two NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response; AND
8. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be another TNF inhibitor (same class as Humira);
9. **Dosage allowed/Quantity limit:** 40 mg subcutaneously every other week (2 syringes/pens per 28 days).

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease (ie. decreased morning stiffness, tenderness or inflammatory back pain, improved quality of life, etc).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Crohn's Disease

For **initial** authorization:
1. Member is 6 years of age or older with moderately to severely active CD; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
4. Member has had a documented trial and inadequate response, or intolerance to at least **one** of the following conventional therapies: a 4-week trial of a corticosteroid OR a 12-week trial of 6-mercaptopurine, azathioprine, or methotrexate; OR
5. Member has severe disease that requires immediate use of a biologic agent, as indicated by **one** of the following:
   a) Extensive small bowel disease involving more than 100 cm;
   b) History of bowel or colon resection and is at high risk for CD recurrence (e.g., smoker, <30 years old, 2 or more resections, penetrating/fistulizing disease, etc.);
   c) Fistulizing disease.
6. **Dosage allowed/Quantity limit:**
   a) Adults: 160 mg subcutaneously on day one, then 80 mg 2 week later (day 15), then 40 mg every other week beginning on day 29;
   b) Pediatrics:
      i. 17 kg (37 lbs) to < 40 kg (88 lbs): Induction: 80 mg on day 1 and 40 mg two weeks later (day 15); maintenance: 20 mg every other week;
      ii. ≥ 40 kg (88 lbs.): Induction: 160 mg on day 1 and 80 mg two weeks later (day 15); maintenance: 40 mg every other week.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement in signs and symptoms of CD (defined as mucosal healing, fewer flare-ups of symptoms, improved quality of life, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Hidradenitis Suppurativa (HS)

For **initial** authorization:
1. Member is 12 years of age or older; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has a documented diagnosis of moderate to severe HS with Hurley stage II or III disease; AND
4. Member has been counseled on weight loss if they are overweight or obese; AND
5. Member is a non-smoker or has been counseled on smoking cessation and advised to quit; AND
6. Member has tried and failed at least one of the following options:
   a) Topical clindamycin x 12 weeks and an oral tetracycline x 12 weeks (sequential or concomitant)
   b) Oral clindamycin plus rifampicin x 8-12 weeks; AND
7. Must have a documented negative tuberculosis test within 12 months prior to starting therapy.

8. **Dosage allowed/Quantity limit:**
   Adults: 160 mg initial dose, then 80 mg 2 weeks later (day 15), then 40 mg every week or 80 mg every other week beginning on day 29.
   Adolescents:

Body Weight of Adolescent Patients (12 years of age and older)	Recommended Dosage
30 kg (66 lbs) to less than 60 kg (132 lbs)	• Day 1: 80 mg • Day 8 and subsequent doses: 40 mg every other week
60 kg (132 lbs) and greater	• Day 1: 160 mg (given in one day or split over two consecutive days); • Day 15: 80 mg • Day 29 and subsequent doses: 40 mg every week or 80 mg every other week

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must include documentation of a positive clinical response such as reduced count of total abscesses and inflammatory nodules or reduction of skin pain.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

For **initial** authorization:
1. Member must be 2 years of age or older with moderately to severely active pJIA; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
4. Member has had an adequate trial and failure of a non-biologic DMARD (e.g., methotrexate, leflunomide, etc.) for 8 weeks, unless not tolerated or contraindicated; AND
5. Member must have tried and failed treatment with both Enbrel and Actemra. Treatment failure requires at least 12 weeks of therapy with each drug.
6. **Dosage allowed/Quantity limit:**
   10 kg (22 lbs) to < 15 kg (33 lbs): 10 mg subcutaneously every other week;
   15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg subcutaneously every other week;
   ≥ 30 kg (66 lbs): 40 mg subcutaneously every other week.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Plaque Psoriasis (PsO)

For **initial** authorization:
1. Member must be 18 years of age or older; AND

2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has clinical documentation of moderate to severe plaque psoriasis characterized by 3% or more of body surface area (BSA) or disease affecting sensitive areas (e.g., hands, feet, face, genitals, etc.); AND
4. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Member has tried and failed to respond to treatment with <u>at least one</u> of the following:
   a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
   b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments);
   c) At least a 4-week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene, tacrolimus, pimecrolimus); AND
6. Member has tried and failed, or unable to tolerate a systemic non-biologic DMARD (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks; AND
7. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be another TNF inhibitor (same class as Humira);
8. **Dosage allowed/Quantity limit:** 80 mg initial dose, then 40 mg every other week starting 1 week after the initial dose.

If all the above requirements are met, the medication will be approved for 12 months.

For **<u>reauthorization</u>**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease (e.g., documented member's BSA improvement, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Psoriatic Arthritis (PsA)

For **<u>initial</u>** authorization:
1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist or a dermatologist; AND
3. Member has a documented diagnosis of active psoriatic arthritis (PsA); AND
4. Member has met a 4-week trial of an NSAID taken at maximally tolerated dose AND a 3-month trial of a non-biologic DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) <u>unless</u> one of the following situations is met:
   a) Non-biologic DMARD is not required for:
      i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and non-biologic DMARD are not required for:
      i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life); AND
5. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be another TNF inhibitor (same class as Humira); AND
6. Member has had a negative tuberculosis test within the past 12 months.
7. **Dosage allowed/Quantity limit:** 40 mg subcutaneously every other week (2 syringes/pens per 28 days).

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease (ie. decreased joint swelling and pain, improved skin appearance, improved quality of life, etc).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Rheumatoid Arthritis (RA)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of moderately to severely active RA; AND
4. Member must have a trial and failure of, or intolerance to methotrexate for at least 3 months;
   Note: If methotrexate is contraindicated, one of the following conventional DMARDs must be trialed instead: leflunomide, sulfasalazine, or hydroxychloroquine; AND
5. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be another TNF inhibitor (same class as Humira); AND
6. Member has had a negative tuberculosis test within the past 12 months.
7. **Dosage allowed/Quantity limit:** 40 mg subcutaneously every other week.
   If remain uncontrolled, and if not also on methotrexate, may increase to 40 mg every week or 80 mg every other week.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes demonstrate improvement of RA signs and symptoms (e.g. fewer number of painful and swollen joints, achievement of remission, slowed progression of joint damage, etc.)

If all the above requirements are met, the medication will be approved for an additional 12 months.

Ulcerative Colitis (UC)

For **initial** authorization:
1. Member is 5 years of age or older with moderately to severely active UC; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
4. Member must have a documented trial and inadequate response with one of the following:
   a) 3 months of 6-mercaptopurine or azathioprine;
   b) 30 days of Corticosteroid (e.g., budesonide, prednisone, methylprednisolone, etc.);
   c) 3 months of 5-aminosalicylate (e.g., Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, etc.).
5. **Dosage allowed/Quantity limit:**
   a) Adults (18 or older): 160 mg subcutaneously on day 1, then 80 mg 2 weeks later (day 15), then 40 mg every other week beginning on day 29.
   b) Pediatric 20 kg (44 lbs) to less than 40 kg (88 lbs): 80 mg subcutaneously on day 1, 40 mg on day 8, 40 mg on day 15. Starting on day 29, give 40 mg every other week or 20 mg every week.
   c) Pediatric 40 kg (88 lbs) and greater: 160 mg subcutaneously on day 1, 80 mg on day 8, 80 mg on day 15. Starting on day 29, give 80 mg every other week or 40 mg every week.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement in signs and symptoms of UC (defined as clinical remission, decrease in rectal bleeding, decreased corticosteroid use, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Uveitis

For **initial** authorization:
1. Member is 2 years of age or older; AND
2. Medication must be prescribed by an ophthalmologist or rheumatologist; AND
3. Member has a documented diagnosis of non-infectious intermediate, posterior, or panuveitis; AND
4. Member has had a trial and failure of both of the following (unless contraindicated or intolerable):
   a) Corticosteroid (e.g. prednisone, methylprednisolone)
   b) Systemic immunosuppressant (e.g. mycophenolate mofetil, methotrexate, etc.); AND
5. Must have a documented negative tuberculosis test within 12 months prior to starting therapy.
6. **Dosage allowed/Quantity limit:**
   Adults: 80 mg as a single subcutaneous dose, then 40 mg every other week beginning 1 week after the initial dose.
   Pediatrics:

Pediatric Weight (2 Years of Age and older)	Recommended Dosage
10 kg (22 lbs) to less than 15 kg (33 lbs)	10 mg every other week
15 kg (33 lbs) to less than 30 kg (66 lbs)	20 mg every other week
30 kg (66 lbs) and greater	40 mg every other week

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must document positive clinical response such as fewer flares, decreased or discontinued corticosteroid use, improved or stabilized visual acuity, or improved vitreous haze grade.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Humira (adalimumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/08/2017	New policy for Humira created. Policies SRx-0041, SRx-0042, and SRx-0043 archived. For diagnosis of CD: Remicade was removed from criteria requirements. For HS diagnosis: prescribed by a dermatologist requirement was added. For diagnosis of PP: immunosuppressive drug criterion was separated from phototherapies and topical agents' trials; Psoriasis Area and Severity Index (PASI) score requirement was added. For diagnosis of RA: non-biologic DMARDS were listed and criterion was added to use drug in combination with methotrexate, or if intolerant to methotrexate, use

	another immunosuppressant. List of diagnoses considered not medically necessary was added.
02/26/2019	Medication status changed to non-preferred. Actemra, Cimzia, Cosentyx, Enbrel, Kevzara, Olumiant, Otezla, Siliq and Xeljanz added to trial agents list. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. References added. Symptoms of back pain for AS extended till before age of 50. Other drugs options allowed for PsA if there is an intolerance or contraindication to methotrexate.
11/13/2019	Age coverage for diagnosis of HS expanded; it's now approved for 12 years old and older.
11/22/2020	Replaced list of excluded diagnoses with the generic statement. Updated references. For all diagnoses: Removed repeat TB in reauth for all diagnoses. AS: Removed list of symptoms of spondyloarthritis because imaging result should be sufficient. Removed peripheral arthritis requirement – not relevant for this diagnosis. CD: Specified length of trials for conventional therapies, previously not specified. For severe disease, removed esophageal/gastroduodenal disease, specified that history of colonic resection must also be high risk for recurrence. JIA: Changed trials to require one non-biologic DMARD. Specified name to be pJIA. PsA: Added requirement of diagnosis of PsA. Changed the trial section to be 4 weeks of an NSAID AND 3 months of a DMARD unless other circumstances apply (e.g., concomitant axial disease, severe PsA, etc.). PsO: Removed rheumatologist from prescriber. Changed BSA to 3% or sensitive area involvement. Removed PASI score requirement. RA: Changed the trials to require methotrexate as one of the non-biologic DMARD trials; only one trial is needed if member has poor prognostic factors. Removed concurrent use with methotrexate. UC: Specified the length of trials for conventional therapies (previously not specified).
05/04/2021	For Ulcerative Colitis (UC), age limit expanded to 5 years of age or older (previously 18 or older). Dosage allowed section updated.
12/20/2021	Transferred to new template. Uveitis: Added references. Added age limit. Added pediatric dosing. Added diagnosis specifying type of uveitis. Added rheumatology as a specialist (FOCUS guideline). Changed the immunosuppressant examples to the most common ones with greatest evidence. Removed "loss of visual acuity or has evidence of retinal involvement." Changed trial of one to trial of both (Rosenbaum et al), removed trial duration. Created specific renewal criteria. Reduced initial auth duration from 12 months to 6 months. HS: Added references. Corrected adult dosing, added pediatric dosing. Removed PGA from diagnosis. Changed "negative urine nicotine test" to non-smoker status or smoking cessation education/counseling. Changed trial drug options to one or the other rather than both. Simplified the statement regarding weight loss. Changed the trial durations, 4 weeks was incorrect. Created specific renewal criteria. Reduced initial auth duration from 12 months to 6 months. RA: Removed Xeljanz, Olumiant from try first options per recent JAK inhibitor label changes; also changed from other specific drug names to say 2 preferred biologics one of which is a TNF inhibitor. Added additional reference. Edited the terminology "non-biologic" DMARD to "conventional" DMARD (JAK inhibitors are non-biologic DMARDs). Changed from requiring 2 csDMARD to just 1. Added complete dosing options per label. PsA: c

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