PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Adalimumab (Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, Yusimry)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Humira, a tumor necrosis factor (TNF) blocker was originally approved in 2002 for the treatment of rheumatoid arthritis. Since then, the FDA has granted approval for a variety of indications. Multiple biosimilars have been approved for Humira including Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflym and Yusimry. They are indicated for some, but not all, of the same indications as Humira.

Adalimumab is a monoclonal antibody produced by recombinant DNA technology. It 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. Adalimumab is administered by subcutaneous injection.

Adalimumab (Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, Yusimry) 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 has had back pain for 3 months or more that began before the age of 50; AND
5. Current imaging results show an inflammation of one or both of the sacroiliac joints (sacroiliitis); AND
6. 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
7. If the request is for a non-preferred adalimumab product, member has tried and failed three (3) preferred adalimumab products (see appendix for preferred and non-preferred products); AND
8. Member has had a negative tuberculosis test within the past 12 months.
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. If the request is for Humira, member has had a trial of Hadlima, Hyrimoz and Hulio, where applicable, or acceptable clinical reason must be provided as to why Hadlima, Hyrimoz and Hulio cannot be used; AND
2. 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. If the request is for Humira, Hadlima or Hulio, member is 6 years of age or older; OR
2. If the request is for Hyrimoz, member is 18 years of age or older; AND
3. Medication must be prescribed by or in consultation with a gastroenterologist; AND
4. Member has a diagnosis of moderately to severely active CD; AND
5. 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
6. 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; AND
7. If the request is for a non-preferred adalimumab product, member has tried and failed three (3) preferred adalimumab products (see appendix for preferred and non-preferred products)
8. Member has had a negative tuberculosis test within the past 12 months.
9. **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 (Humira, Hadlima, Hulio Only):
      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.

8. If the request is for a non-preferred adalimumab product, member has tried and failed three (3) preferred adalimumab products (see appendix for preferred and non-preferred products); AND
9. Member has had a negative tuberculosis test within the past 12 months.
10. **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 (Humira only):

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

For **reauthorization**:
1. If the request is for Humira, member has had a trial of Hadlima, Hyrimoz and Hulio, where applicable, or acceptable clinical reason must be provided as to why Hadlima, Hyrimoz and Hulio cannot be used; AND
2. 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. If the request is for Humira, Hadlima or Hulio, member must be 2 years of age or older; OR
2. If the request is for Hyrimoz, member must be 4 years of age or older; AND
3. Medication must be prescribed by or in consultation with a rheumatologist; AND
4. Member has a diagnosis of moderately to severely active pJIA; AND
5. Member has had an adequate trial and failure of at least **ONE** non-biologic DMARD (e.g., methotrexate, leflunomide, etc.) for 8 weeks, unless not tolerated or contraindicated; AND
6. Member must have tried and failed treatment with ActemraTreatment failure requires at least 12 weeks of therapy with each drug; AND
7. If the request is for a non-preferred adalimumab product, member has tried and failed three (3) preferred adalimumab products (see appendix for preferred and non-preferred products); AND
8. Member has had a negative tuberculosis test within the past 12 months.
9. **Dosage allowed/Quantity limit(t)aqlCd[M) e(non)}1.1 (t)7**

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For **reauthorization**:
1. If the request is for Humira, member has had a trial of Hadlima, Hyrimoz and Hulio, where applicable, or acceptable clinical reason must be provided as to why Hadlima, Hyrimoz and Hulio cannot be used; AND
2. 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. Member has tried and failed to respond to treatment with at least **ONE** 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., anlowi.9 (nl)2.6 (ow)2.efaVnlci5stri (e.gg7967c -

5. If the request is for a non-preferred adalimumab product, member has tried and failed three (3) preferred adalimumab products (see appendix for preferred and non-preferred products); 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. If the request is for Humira, member has had a trial of Hadlima, Hyrimoz and Hulio, where applicable, or acceptable clinical reason must be provided as to why Hadlima, Hyrimoz and Hulio cannot be used; AND
2. 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

6. If the request is for a non-

For **reauthorization**:

1. If the request is for Humira, member has had a trial of Hadlima, Hyrimoz and Hulio, where applicable, or acceptable clinical reason must be provided as to why Hadlima, Hyrimoz and Hulio cannot be used; AND
2. 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 Adalimumab (Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, Yusimry) 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

42.