

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Humira (adalimumab)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Actemra, Cimzia, Cosentyx, Enbrel, Kevzara, Olumiant, Otezla, Siliq and Xeljanz QUANTITY LIMIT— 4 per 28 days
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Humira (adalimumab) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ANKYLOSING SPONDYLITIS (AS)

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 must have tried and failed treatment with at least **two** of the following: Enbrel, Cimzia and Cosentyx. Treatment failure requires at least 12 weeks of therapy with each drug.
9. **Dosage allowed:** 40 mg subcutaneously every other week.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CROHN'S DISEASE (CD)

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:**
 - 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 member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, 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 with a diagnosis of moderately to severely HS as defined by The Physicians Global Assessment Tool (Hurley Stage II or III); AND
2. Medication must be prescribed by a dermatologist; 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 made documented lifestyle changes that would promote weight loss if member's body mass index (BMI) is greater than 25; AND
5. Member has a documented negative Urine Nicotine Test; AND
6. Member has tried at least a **four** week trial and has failed to respond to **both** of the following treatments:
 - a) Topical clindamycin and systemic tetracycline; AND
 - b) Systemic clindamycin and systemic rifampicin.
7. **Dosage allowed:** 160 mg initial dose, then 80 mg 2 weeks later (day 15), then 40 mg every week beginning on day 29.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, 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:** 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 member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, 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 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., 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 treatment with at least **two** of the following: Cimzia, Cosentyx, Enbrel, Otezla and Siliq. Treatment failure requires at least 12 weeks of therapy with each drug.

8. **Dosage allowed:** 80 mg initial dose, then 40 mg every other week starting 1 week after the initial dose.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease (e.g., documented member's BSA improvement, etc.).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

PSORIATIC ARTHRITIS (PsA)

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 or a dermatologist; AND
3. Member has a documented diagnosis of active psoriatic arthritis (PsA); 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 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.) **unless 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
6. Member must have tried and failed treatment with at least **two** of the following: Enbrel, Cimzia, Cosentyx, Otezla and Xeljanz. Treatment failure requires at least 12 weeks of therapy with each drug.
7. **Dosage allowed:** 40 mg subcutaneously every other week.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, 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 with moderately to severely active RA; AND
 2. 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
 3. Medication must be prescribed by or in consultation with a rheumatologist; AND
 4. Member must have a trial and failure of, or intolerance to methotrexate and **one** other non-biologic DMARD (i.e., hydroxychloroquine, sulfasalazine, and leflunomide) for 3 months per trial, either together or separately; AND
- Note:* only one non-biologic DMARD is required if member has a poor prognostic factor such as high swollen joint count, presence of early joint erosions, presence of autoantibodies (RF and/or ACPA).

5. Member has tried and failed treatment with at least **two** of the following: Actemra, Cimzia, Enbrel, Kevzara, Olumiant and Xeljanz. Treatment failure requires at least 12 weeks of therapy with each drug.
6. **Dosage allowed:** 40 mg subcutaneously every other week.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. 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 member meets all the reauthorization requirements above, 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:**
 - 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 member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

UVEITIS (noninfectious, chronic)

For **initial** authorization:

1. Medication must be prescribed by an ophthalmologist that is a uveitis specialist or an ocular immunologist; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Member has loss of visual acuity or has evidence of retinal involvement; AND
4. Member has tried at least a 4-week trial and has failed to respond to at least **one** of the following treatments:
 - a) Corticosteroids (prednisone, methylprednisolone, cortisone, etc.);

b) Systemic immunosuppressants (azathioprine, cyclosporine, etc.).

5. **Dosage allowed:** 80 mg as a single subcutaneous dose, then 40 mg every other week beginning 1 week after the initial dose.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Humira (adalimumab) not medically necessary for the treatment of the diseases that are not listed in this document.

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. <u>AS</u> : Removed list of symptoms of spondyloarthritis because imaging result should be sufficient. Removed peripheral arthritis requirement – not relevant for this diagnosis. <u>CD</u> : 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. <u>JIA</u> : Changed trials to require one non-biologic DMARD. Specified name to be pJIA. <u>PsA</u> : 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.). <u>PsO</u> : Removed rheumatologist from prescriber. Changed BSA to 3% or sensitive area involvement. Removed PASI score requirement. <u>RA</u> : 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. <u>UC</u> : 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.

References:

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