

## 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 <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

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. Member 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. Medication must be prescribed by a rheumatologist; 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 inflammation of one or both of the sacroiliac joints; AND
6. Member shows at least **one** of the following signs or symptoms of Spondyloarthritis:
  - a) Arthritis;
  - b) Elevated serum C-reactive protein;
  - c) Inflammation at the tendon, ligament or joint capsule insertions;
  - d) Positive HLA-B27 test;
  - e) Limited chest expansion;
  - f) Morning stiffness for 1 hour or more; AND
7. Member meets at least **one** of the following scenarios:
  - a) Member has Axial (spinal) disease;
  - b) Member has peripheral arthritis without axial involvement and has tried and failed treatment with methotrexate or sulfasalazine. Treatment failure requires at least 3 months of therapy without an adequate response; AND
8. Member has tried and failed to respond to treatment with at least **two** prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response; AND
9. Member must have tried and failed treatment with at least **two** of the following: Enbrel, Cimzia and Cosentyx. Treatment failure requires at least for 12 weeks of therapy with each drug.
10. **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 retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. 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.***

## CROHN'S DISEASE (CD)

For **initial** authorization:

1. Member is 6 years of age or older with moderate to severe active CD; 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. Medication must be prescribed by a gastroenterologist; AND
4. Member has had a documented trial and inadequate response to at least **one** of the following: 6-mercaptopurine, azathioprine, methotrexate or corticosteroids; OR
5. Member has severe disease, as indicated by at least **one** of the following:
  - a) Esophageal or gastroduodenal disease;
  - b) Extensive small-bowel disease involving more than 100 cm;
  - c) History of colonic resection;
  - d) History of two or more small-bowel resections;
  - e) Perianal or rectal disease.
6. **Dosage allowed:** Adult dose: 160 mg subcutaneously on day one, then 80 mg 2 week later, then 40 mg every other week beginning on day 29; Pediatric dose: 17 kg (37 lbs.) to < 40 kg (88 lbs.) induction dose: 80 mg initially on Day and 40 mg two weeks later (Day 15), maintenance: 20 mg every other week; ≥ 40 kg (88 lbs.): 160 mg initially on Day 1 (given in one day or split over two consecutive days) 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. Member must be retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. 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.***

## HIDRADENITIS SUPPURATIVA (HS)

For **initial** authorization:

1. Member is 18 years of age or older with a diagnosis of moderate to severe 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), an interferon-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 (given as four 40 mg injections on day 1 or given as two 40 mg injections per day over 2 consecutive days), 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 retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. 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.***

## JUVENILE IDIOPATHIC ARTHRITIS (JIA)

For **initial** authorization:

1. Member must be 2 years of age or older with moderate to severe active JIA; 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. Medication must be prescribed by a rheumatologist; AND
4. Member must have tried and failed treatment with **both** Enbrel and Actemra. Treatment failure requires at least for 12 weeks of therapy with each drug; AND
5. Member shows at least **one** of the following signs or symptoms:
  - a) Four or fewer joints involved with inadequate response to systemic corticosteroids (prednisone, cortisone, methylprednisolone, etc.) AND systemic immunosuppressants (azathioprine, cyclosporine, etc.) AND NSAID treatment for at least 12 weeks;
  - b) Five or more joints involved AND inadequate response to methotrexate;
  - c) Sacroiliitis AND inadequate response to methotrexate;
  - d) Uveitis with inadequate response to systemic corticosteroids (prednisone, cortisone, methylprednisolone, etc.) AND systemic immunosuppressants (i.e., azathioprine, cyclosporine, etc.) AND topical ophthalmic corticosteroids (i.e., prednisolone, fluoromethalone, dexamethasone, etc.).
6. **Dosage allowed:** For members 10 to < 15 kg: inject 10 mg subcutaneously every other week;  
For members 15 to < 30 kg: inject 20 mg subcutaneously every other week;  
For members ≥ 30 kg: inject 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 retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. 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.***

## PLAQUE PSORIASIS (PsO)

For **initial** authorization:

1. Member must be 18 years of age or older; 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. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member has PsO involves 10% or more of the body surface area (BSA); AND
5. Member's Psoriasis Area and Severity Index (PASI) score is greater than or equal to 12; AND
6. 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; tanning beds emit mostly UVA light and therefore would not meet this criteria);
  - c) At least a 4 week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene); AND
7. Member has tried and failed to respond to treatment with traditional first-line oral/systemic therapies (i.e., cyclosporine, methotrexate, acitretin) for at least a 12 week trial; AND
8. Member has tried and failed treatment with at least **two** of the following: Cimzia, Cosentyx, Enbrel, Otezla and Siliq. Treatment failure requires at least for 12 weeks of therapy with each drug.
9. **Dosage allowed:** Inject 80 mg subcutaneously, 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 retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease (e.g., documented member's PASI score 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. 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. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member meets at least **one** of the following scenarios:
  - a) Member has predominantly axial disease (i.e., sacroiliitis or spondylitis) as indicated by radiographic evidence;
  - b) Member has shown symptoms of predominantly axial disease (i.e., sacroiliitis or spondylitis) for more than 3 months (i.e., limited spinal range of motion, spinal morning stiffness for more than 30 minutes) AND has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response;
  - c) Member has predominately non-axial disease (e.g., peripheral synovitis or dactylitis or nail involvement) and has tried and failed to respond to treatment with at least 8-week trial of methotrexate and NSAID taken at the maximum recommended dosages (if unable to tolerate or has contraindication to methotrexate than 8-week trial of sulfasalazine or azathioprine or cyclosporine); AND

5. 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 for 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 retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. 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.***

## RHEUMATOID ARTHRITIS (RA)

For **initial** authorization:

1. Member must be 18 years of age or older with moderate to severe active RA; 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. Medication must be prescribed by a rheumatologist; AND
4. Medication must be used in combination with methotrexate, or if intolerant to methotrexate, another immunosuppressant (i.e., azathioprine, hydroxychloroquine, cyclosporine, etc.); AND
5. Member must have tried and failed treatment with at least **two** non-biologic DMARDs (i.e., methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented contraindication to all non-biologic DMARDs. Treatment trial duration with each non-biologic DMARD agent must have been at least 12 weeks; AND
6. 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 for 12 weeks of therapy with each drug.
7. **Dosage allowed:** 40 mg subcutaneously every other week. Prior to any dosages or dosing frequencies greater than listed, medical necessity documentation must be supplied to justify coverage.

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

For **reauthorization**:

1. Member must be retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. 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.***

## ULCERATIVE COLITIS (UC)

For **initial** authorization:

1. Member is 18 years of age or older with moderate to severe active UC; 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. Medication must be prescribed by a gastroenterologist; AND
4. Member have had a documented history of an inadequate response with, lost response to, or were intolerant to **one** of the following:
  - a) Immunomodulator (e.g., 6-mercaptopurine, azathioprine);
  - b) Corticosteroids (or demonstrated dependence on corticosteroids);

c) Salicylates (e.g., Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, etc.).

5. **Dosage allowed:** Inject 160 mg subcutaneously on day one, then 80 mg 2 week later, then 40 mg every other 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 retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. 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.***

## **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 retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. 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 following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:**

- Active infections
- Asthma
- Cellulitis
- Dissecting scalp cellulitis
- For use in combination with other TNF-inhibitors (i.e., Kineret, Enbrel, Remicade)
- Giant-cell arteritis
- Guttate psoriasis
- Infectious uveitis



- Lupus perino
- Osteoarthritis
- Recurrent pregnancy loss
- Relapsing polychondritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis (other than ankylosing spondylitis)
- Takayasu's arteritis
- Vogt-Koyanagi

DATE	ACTION/DESCRIPTION
<b>05/08/2017</b>	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.
<b>02/26/2019</b>	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.

References:

1. Humira [prescribing information]. North Chicago, IL; AbbVie Inc.: January, 2019.
2. US Food and Drug Administration Drug Safety Data.  
[http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/125261s114lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125261s114lbl.pdf) (October 14, 2014).
3. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2008 May;58(5):826-50.
4. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. *J Am Acad Dermatol.* 2008 May;58(5):851-64.
5. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 4. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. *J Am Acad Dermatol.* 2009 Sep;61(3):451-85. Epub 2009 Jun 3.
6. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. *J Am Acad Dermatol.* 2011 Feb 7. [Epub ahead of print].
7. DeWitt EM, Kimura Y, Beukelman T, et al; Juvenile Idiopathic Arthritis Disease-specific Research Committee of Childhood Arthritis Rheumatology and Research Alliance. Consensus treatment plans for new-onset systemic juvenile idiopathic arthritis. *Arthritis Care Res (Hoboken).* 2012 Jul;64(7):1001-10. doi: 10.1002/acr.21625. PubMed PMID: 22290637; PubMed Central PMCID: PMC3368104.
8. Medscape; Juvenile Idiopathic Arthritis Treatment & Management Author: David D Sherry, MD; Chief Editor: Lawrence K Jung, MD.
9. Singh, J., et al., (2012). 2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Anti-rheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research*, 64(5), 625-639, May 2012.

10. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. *Arthritis Care Res. (Hoboken)*. 2011 Apr;63(4):465-82.
11. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 Recommendations for the Use of Non- biologic and Biologic Disease-Modifying Anti-rheumatic Drugs in Rheumatoid Arthritis. *Arthritis Care & Research. Arthritis Rheum* 2008;59(6):762-84.
12. Lichtenstein GR, Hanauer SB, Sandborn WJ, Practice Parameters Committee of American College of Gastroenterology. Management of Crohn's disease in adults. *American Journal of Gastroenterology* 2009;104(2):465-83; quiz 464, 484. DOI: 10.1038/ajg.2008.168. (Reaffirmed 2014 Oct).
13. Terdiman JP, Gruss CB, Heidelbaugh JJ, Sultan S, Falck-Ytter YT; AGA Institute Clinical Practice and Quality Management Committee. American Gastroenterological Association Institute guideline on the use of thiopurines, methotrexate, and anti-TNF- $\alpha$  biologic drugs for the induction and maintenance of remission in inflammatory Crohn's disease. *Gastroenterology*. 2013 Dec;145(6):1459-63.
14. Sandborn, W., Binion, D., Persley, K., Atreja, A., & Kosinski, L. (2014). AGA Institute Guidelines for the Identification, Assessment and Initial Medical Treatment in Crohn's Disease: Clinical Decision Support Tool. AGA Institute. Retrieved August 14, 2015, from [www.gastro.org/IBDcarepathway](http://www.gastro.org/IBDcarepathway).
15. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. *Arch Dermatol*. 2012 Jan;148(1):95-102.
16. Callhoff J, et al. Efficacy of TNF $\alpha$  blockers in patients with ankylosing spondylitis and non-radiographic axial spondyloarthritis: a meta-analysis. *Ann Rheum Dis*. 2015; 74:1241.
17. Lovell DJ, et al. Adalimumab with or without methotrexate in juvenile rheumatoid arthritis. *N Engl J Med*. 2008; 359:810.
18. Bissonnette R, et al. Efficacy and safety of adalimumab in patients with plaque psoriasis who have shown an unsatisfactory response to etanercept. *J Am Acad Dermatol*. 2010; 63:228.
19. Mease PJ, et al. Adalimumab for the treatment of patients with moderately to severely active psoriatic arthritis: results of a double-blind, randomized, placebo-controlled trial. *Arthritis Rheum*. 2005; 52:3279.
20. Weinblatt ME, et al. Adalimumab, a fully human anti-tumor necrosis factor alpha monoclonal antibody, for the treatment of rheumatoid arthritis in patients taking concomitant methotrexate: the ARMADA trial. *Arthritis Rheum*. 2003; 48:35.
21. Singh JA, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016 Jan;68(1):1-26.

Effective date: 04/01/2019

Revised date: 02/26/2019