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 (Preferred Product) Alternative preferred product includes Enbrel QUANTITY LIMIT— 4 per 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	**Click Here**

Humira (adalimumab) is a **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), or a chest x-ray) within 6 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 45; 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 without an adequate response.
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 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), or a chest x-ray) within 6 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), or a chest x-ray) within 6 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), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. 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.).
5. **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 (PP)

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), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member has PP 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 of an immunosuppressant (i.e. cyclosporine, methotrexate, acetretin) for at least a 12 week trial.
8. **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.

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), or a chest x-ray) within 6 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 without an adequate response;
   c) Member has predominately non-axial disease and has tried and failed to respond to treatment with at least an 8 week trial of methotrexate and NSAID taken at the maximum recommended dosages.
5. **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), or a chest x-ray) within 6 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.
6. **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), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a gastroenterologist; AND
4. Member has had a trial and inadequate response to at least **one** of the following:
   a) 6-mercaptopurine;
   b) Azathioprine;
   c) Oral corticosteroids (i.e. prednisone, cortisone, methylprednisolone, etc.);
   d) Salicylates (i.e. 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), or a chest x-ray) within 6 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 four week trial and has failed to respond to at least **one** of the following treatments:
   a) Corticosteroids (prednisone, methylprednisolone, cortisone, etc.);
   b) Systemic immunosuppresants (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
05/12/2017	New policy for Humira created. For diagnosis of CD: Remicade removed from criteria requirements. For HS diagnosis: prescribed by a dermatologist requirement added. For diagnosis of PP: immunosuppressive drug criteria separated from phototherapies and topical agents trials; Psoriasis Area and Severity Index (PASI) score requirement added. For diagnosis of RA: non-biologic DMARDS listed and criterion added to use drug in combination with methotrexate, or if intolerant to methotrexate, use another immunosuppressant. List of diagnoses considered not medically necessary added.

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