**MEDICATION POLICY:**
# Humira®

**Generic Name:** Adalimumab

**Therapeutic Class or Brand Name:** Humira®

**Applicable Drugs (if Therapeutic Class):** N/A

**GPI Code:** 6627001500

**Preferred:** N/A

**Non-preferred:** N/A

**Date of Origin:** 2/1/2013

**Date Last Reviewed / Revised:** 1/24/2019

## PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of one of the following conditions A through I AND must meet criteria listed under applicable diagnosis:

A. Active Ankylosing Spondylitis and criteria 1 and 2 are met:

1. Diagnosis must be established by a rheumatologist.
2. Minimum age requirement: 18 years old.

B. Moderately to Severely Active Rheumatoid Arthritis and criteria 1 through 3 are met:

1. History of treatment failure, intolerance, or contraindication to Methotrexate, or one other DMARD or second line drug (azathioprine, sulfasalazine, leflunomide, penicillamine, hydroxychloroquine, etc.).
2. Diagnosis must be established by a rheumatologist.
3. Minimum age requirement: 18 years old.

C. Moderately to Severely Active Polyarticular Juvenile Idiopathic Arthritis and criteria 1 through 3 are met:

1. History of treatment failure, intolerance, or contraindication to at least one DMARD (i.e. methotrexate, etc.).
2. Diagnosis must be established by a rheumatologist.
3. Minimum age requirement: 2 years old.

D. Active Psoriatic Arthritis and criteria 1 and 2 are met:

1. Diagnosis must be established by a rheumatologist or dermatologist.
2. Minimum age requirement: 18 years old.

E. Moderate to Severe Chronic Plaque Psoriasis and criteria 1 through 4 are met:

1. History of treatment failure, intolerance, or contraindication with phototherapy or photochemotherapy.
2. History of treatment failure, intolerance, or contraindication with at least one appropriate systemic agent (i.e. cyclosporine, methotrexate, acitretin, etc.).

3. Diagnosis must be established by a dermatologist or a rheumatologist.
4. Minimum age requirement: 18 years old.

F. Moderately to Severely Active Crohn's Disease and criteria 1 through 3 are met:
1. History of treatment failure, intolerance, or contraindication to conventional therapy (i.e. 5-aminosalicylates, antibiotics, methotrexate, 6-mercaptopurine, azathioprine, corticosteroids, budesonide, etc.).
2. Treatment must be prescribed by a gastroenterologist.
3. Minimum age requirement: 6 years old.

G. Moderately to Severely Active Ulcerative Colitis and criteria 1 through 3 are met:
1. History of treatment failure, intolerance, or contraindication to conventional therapy (i.e. 5-aminosalicylates, antibiotics, methotrexate, 6-mercaptopurine, azathioprine, corticosteroids, budesonide, etc.).
2. Treatment must be prescribed by a gastroenterologist.
3. Minimum age requirement: 18 years old.

H. Moderate to severe hidradenitis suppurativa and criteria 1 and 2 are met:
1. Treatment must be prescribed by a dermatologist.
2. Minimum age requirement: 12 years old.

I. Uveitis (non-infectious intermediate, posterior and panuveitis) and criteria 1 through 4 are met:
1. History of treatment failure, intolerance, or contraindication to corticosteroids (ophthalmic or systemic).
2. History of treatment failure, intolerance, or contraindication to at least one DMARD (i.e. azathioprine, cyclosporine, methotrexate, mycophenolate, etc.).
3. Diagnosis must be established by an ophthalmologist.
4. Minimum age requirement: 2 years old.

II. Absence of active serious infection or sepsis.

III. Negative TB skin test within the previous 12 months or history of treatment for latent TB infection.

IV. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

## EXCLUSION CRITERIA

- Coadministration of Humira® with another biologic DMARD, Otezla® (apremilast), or Xeljanz®/ XR (tofacitinib). Examples of biologic DMARDs include the following:
    - Actemra® (tocilizumab)
    - Cosentyx® (secukinumab)
    - Entyvio® (vedolizumab)
    - Kevzara® (sarilumab)
    - Kineret® (anakinra)
    - Orencia® (abatacept)
    - Rituxan® (rituximab)
    - Siliq™ (brodalumab)
    - Stelara® (ustekinumab)
    - Taltz® (Ixekizumab)
    - TNF inhibitors [Cimzia® (certolizumab pegol), Enbrel® (etanercept), Inflectra® (infliximab-dyyb), Remicade® (infliximab), Renflexis™ (infliximab-abda), Simponi®/Simponi® Aria® (golimumab)]
    - Tremfya™ (guselkumab)
    - Tysabri® (natalizumab)

## OTHER CRITERIA

- N/A

## QUANTITY / DAYS SUPPLY RESTRICTIONS

- Adult rheumatologic conditions (Ankylosing Spondylitis, Rheumatoid Arthritis, Psoriatic Arthritis):
    - Quantities of up to 2 of the 40mg pens or syringes every 28 days.
- Adult Plaque Psoriasis, Uveitis:
    - Quantities of up to 4 of the 40mg pens or syringes, or 1 x 80mg plus 2 x 40mg pens or syringes in the first 28 days, then in quantities of up to 2 of the 40mg pens or syringes every 28 days.
- Adult Inflammatory Bowel Disease (Crohn's Disease, Ulcerative Colitis):
    - Quantities of up to 6 of the 40mg or 3 of the 80mg pens or syringes in the first 28 days, then in quantities of up to 2 of the 40mg pens or syringes every 28 days.
- Hidradenitis suppurativa:

- Quantities of up to 6 of the 40mg or 3 of the 80mg pens or syringes in the first 28 days, then in quantities of up to 4 of the 40mg pens or syringes every 28 days.

- Polyarticular Juvenile Idiopathic Arthritis or Pediatric Uveitis
  - Quantities of up to 2 of the 10mg, 20mg or 40mg prefilled syringes every 28 days.
- Pediatric Crohn's Disease
  - 17kg to < 40kg: quantities of up to one (1) 80mg plus one (1) 40mg prefilled syringe for the first 28 days of therapy followed by 2 of the 20mg prefilled syringes every 28 days thereafter.
  - ≥ 40kg: quantities of up to three (3) 80mg for the first 28 days of therapy followed by two (2) 40mg prefilled syringes every 28 days thereafter.

## APPROVAL LENGTH

- **Authorization:** 1 year
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing improvement or maintenance with medication.

## APPENDIX

N/A

## REFERENCES

1. https://regence.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Cambia/Program_Summaries/dru444reg.pdf.
2. www.drugs.com.
3. https://npsonline.pti-nps.com.
4. http://www.rxabbvie.com/pdf/humira.pdf.

## HISTORICAL TRACKING OF CHANGES MADE TO POLICY

| Date | Notes/Changes |
|---|---|
| *1/24/2019* | 1. **Added** to "Quantities/Days Supply Restrictions" section to account for new NDC's for starter paks containing 80mg citrate-free formulation pens:<br>• Adult rheumatologic conditions (Ankylosing Spondylitis, Rheumatoid Arthritis, ~~Polyarticular Juvenile Idiopathic Arthritis,~~ Psoriatic Arthritis):<br>o Quantities of up to 2 of the 40mg pens or syringes every 28 days. |

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| | • Adult Plaque Psoriasis, Uveitis:<br>o Quantities of up to 4 of the 40mg pens or syringes, *or 1 x 80mg plus 2 x 40mg pens or syringes* in the first 28 days, then in quantities of up to 2 of the 40mg pens or syringes every 28 days.<br>• Adult Inflammatory Bowel Disease (Crohn's Disease, Ulcerative Colitis):<br>o Quantities of up to 6 of the 40mg *or 3 of the 80mg* pens or syringes in the first 28 days, then in quantities of up to 2 of the 40mg pens or syringes every 28 days.<br>• Hidradenitis suppurativa:<br>o Quantities of up to 6 of the 40mg *or 3 of the 80mg pens* or syringes in the first 28 days, then in quantities of up to 4 of the 40mg pens or syringes every 28 days.<br>• Polyarticular Juvenile Idiopathic Arthritis or Pediatric Uveitis<br>o Quantities of up to 2 of the 10mg, 20mg or 40mg prefilled syringes every 28 days.<br>• Pediatric Crohn's Disease<br>o 17kg to < 40kg: quantities of up to one (1) 80mg plus one (1) 40mg prefilled syringe for the first 28 days of therapy followed by 2 of the 20mg prefilled syringes every 28 days thereafter.<br>o ≥ 40kg: quantities of up to three (3) 80mg for the first 28 days of therapy followed by two (2) 40mg prefilled syringes every 28 days thereafter. |
| *12/14/2018* | 1. **Changed** obsolete URL in Reference #1 ("http://blue.regence.com/trgmedpol/drugs/dru081.pdf") to https://regence.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Cambia/Program_Summaries/dru444reg.pdf.<br>2. **Changed** under Prior Authorization section item H-2 age requirement for treatment of hidradentitis suppurativa from 18 to 12 years.<br>3. **Changed** under Prior Authorization section item I-4 minimum age requirement for treatment of uveitis from 18 to 2 years. |
| *11/21/2017* | 1. **Added** "Kevzara® (sarilumab)", "Siliq™ (brodalumab)", **and** "Tremfya™ (guselkumab)" **to list under Exclusion Criteria**.<br>2. **Added** "Inflectra® (infliximab-dyyb)" **and** "Renflexis™ (infliximab-abda)" following TNF Inhibitors to list under Exclusion Criteria. |
| *8/26/2016* | 1. **Changed** "I. D. Active Psoriatic Arthritis and criterion 1 is met:…" **to** "I. D. Active Psoriatic Arthritis and criteria 1 and 2 are met:…2. Minimum age requirement: 18 years old" **under Prior Authorization Criteria**. |

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| | 2. **Changed** "I. I. Active Uveitis and criteria 1 through 3 are met:…" **to** "I. I. Uveitis (non-infectious intermediate, posterior and panuveitis) and criteria 1 through 4 are met: …4. Minimum age requirement: 18 years old" **under Prior Authorization Criteria**.<br>3. **Changed** "IV. Refer to plan document for the list of preferred products. If Humira® is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product" **to** "IV. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s)" **under Prior Authorization Criteria**.<br>4. **Changed** "Coadministration of Humira® with …Xeljanz® (tofacitinib)..." **to** "Coadministration of Humira® with …Xeljanz®/ XR (tofacitinib)..." **under Exclusion Criteria**.<br>5. **Changed** "Cosentyx™" **to** "Cosentyx®" **under Exclusion Criteria**.<br>6. **Added** "Taltz® (Ixekizumab)" **to list under Exclusion Criteria**.<br>7. **Changed** "syringes or vials" **to** "pens or syringes" **under Quantity/Days Supply Restrictions**.<br>8. **Changed** "Plaque Psoriasis: Quantities of up to 4 of the 40mg pens or syringes in the first 28 days, then in quantities of up to 2 of the 40mg pens or syringes every 28 days;…Uveitis: Quantities of up to 2 of the 40mg pens or syringes every 28 days" **to** "Plaque Psoriasis, Uveitis: Quantities of up to 4 of the 40mg pens or syringes in the first 28 days, then in quantities of up to 2 of the 40mg pens or syringes every 28 days" **under Quantity/Days Supply Restrictions**.<br>9. **Removed table below from Appendix** (no longer needed since Uveitis is now FDA approved indication)**:** |

**Data Supporting Off-Label Indication: Uveitis**

| Study | Highlighted Details | Highlighted Findings |
|---|---|---|
| Díaz-Llopis et al. | - Prospective case series examining the efficacy of adalimumab in 131 patients with refractory uveitis and intolerance or failure to respond to prednisone and at least 1 other systemic immunosuppressive drug.<br>- Most common causes of uveitis included:<br>• Juvenile idiopathic arthritis in 39 patients (29.7%).<br>• Pars planitis in 16 patients (12.2%).<br>• Behçet's disease in 13 patients (9.9%).<br>• Idiopathic forms of uveitis in 27 patients (20.6%).<br>- Intervention:<br>• 40 mg adalimumab SC every other week for 6 months.<br>• Associated immunosuppressants were tapered after administering 3 adalimumab injections (week 6). | - At the end of the six month study period, anterior chamber and posterior chamber inflammation were statistically significantly improved ($p < 0.001$) by 1.26 points and 0.89 points respectively (measured on the Standardization of Uveitis Nomenclature Working Group grading scheme).<br>- Adverse events (treatment was not discontinued for these events):<br>• Injection site reaction<br>• Fatigue<br>• Hypertension<br>• Herpes zoster<br>• Infectious mononucleosis<br>• Reactivation of chronic hepatitis C virus infection |

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| | | Simonini et al. (2011) | - Open-label prospective, comparative, multicenter cohort study comparing adalimumab to infliximab in 33 patients with childhood refractory, vision-threatening, noninfectious active uveitis.<br>- Intervention:<br>• 17 children received infliximab 5mg/kg at weeks 0, 2, and 6, and then every 6-8 weeks for at least 1 year.<br>• 16 children received adalimumab 24 mg/m$^2$ every 2 weeks for at least 1 year.<br>- Causes of uveitis in infliximab treatment group:<br>• Juvenile idiopathic arthritis in 10 patients (58.8%).<br>• Early-onset sarcoidosis in 1 patient (5.9%).<br>• Behçet's disease in 1 patient (5.9%).<br>• Idiopathic uveitis in 5 patients (29.4%).<br>- Causes of uveitis in adalimumab treatment group:<br>• Juvenile idiopathic arthritis in 12 patients (75%).<br>• Behçet's disease in 1 patients (6.3%).<br>• Idiopathic uveitis in 3 patients (18.8%). | - There was no demonstrable difference between treatment groups in time to achieve remission and time to steroid discontinuation. However, at 40 months of follow-up, 9 (60%) of 15 children receiving adalimumab compared to 3 (18.8%) of 16 children receiving infliximab were still in remission on therapy ($p < 0.02$). |
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| Simonini et al. (2013) | - Open-label, comparative, multi-center, cohort study comparing adalimumab when used as first anti-TNFa therapy versus adalimumab used after the failure of a previous anti-TNFa (infliximab) in 26 patients with childhood refractory, non-infectious active uveitis.<br>- Intervention:<br>• 14 children (Group 1) received adalimumab 24 mg/m$^2$ every 2 weeks for at least 1 year, as first anti-TNFa choice.<br>• 12 children (Group 2) received adalimumab 24 mg/m$^2$ every 2 weeks for at least 1 year, as second anti-TNFa drug, due to the loss of efficacy of infliximab, administered after a period of at least 1 year.<br>- Causes of uveitis in Group 1:<br>• Juvenile idiopathic arthritis in 10 patients (71.4%).<br>• Behçet's disease in 1 patient (7.1%).<br>• Idiopathic uveitis in 3 patients (21.4%).<br>- Causes of uveitis in Group 2:<br>• Juvenile idiopathic arthritis in 7 patients (58.3%).<br>• Early-onset sarcoidosis in 1 patient (8.3%).<br>• Behçet's disease in 1 patient (8.3%).<br>• Idiopathic uveitis in 3 patients (25%). | - 17 children (12 in Group 1 and 5 in Group 2) were able to stop steroid administration during the first 6 months from the start of adalimumab, and all responders discontinued steroid before 1 year of treatment. However, Group 2 needed a longer time to discontinue steroids ($p < 0.001$) and showed a lower probability to steroid discontinuation during the first 12 months of treatment ($p < 0.004$).<br>- In long-term follow-up, Group 1 had higher probability of uveitis remission during the time of treatment on adalimumab ($p < 0.002$). |

10. **Removed**
"https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Humira%20RA,%20PA,%20AS%20&%20PP%202014-12-26.pdf",

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| | "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Humira%20Crohns%202014-12-26.pdf", **and** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Humira%20UC%202014-12-26.pdf" **from under References** (links no longer valid).<br>11. **Removed** "Díaz-Llopis M, Salom D, Garcia-de-Vicuña C, et al. Treatment of refractory uveitis with adalimumab: a prospective multicenter study of 131 patients. Ophthalmology. 2012 Aug;119(8):1575-81. doi: 10.1016/j.ophtha.2012.02.018. Epub 2012 Apr 21. PubMed PMID: 22525047; Simonini G, Taddio A, Cattalini M, et. al. Prevention of flare recurrences in childhood-refractory chronic uveitis: an open-label comparative study of adalimumab versus infliximab. Arthritis Care Res (Hoboken). 2011 Apr;63(4):612-8. doi: 10.1002/acr.20404. PubMed PMID: 21452272; Simonini G, Taddio A, Cattalini M, et. al. Superior efficacy of Adalimumab in treating childhood refractory chronic uveitis when used as first biologic modifier drug: Adalimumab as starting anti-TNF-a therapy in childhood chronic uveitis. Pediatr Rheumatol Online J. 2013 April 15; 11(1):16. doi: 10.1186/1546-0096-11-16. PubMed PMID: 23587261" **from under References** (no longer needed since Uveitis is now FDA approved indication). |
| Click or tap to enter a date. | 1.<br>2. |