

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

## Humira (adalimumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Humira 10 mg/0.2 mL prefilled syringe	2 syringes per 28 days
Humira 10 mg/0.1 mL prefilled syringe	2 syringes per 28 days
Humira pediatric Crohn's Disease starter pack 40 mg/0.8 mL prefilled syringe <sup>†</sup>	1 pack (28 day supply, one time fill)
Humira pediatric Crohn's Disease starter pack 80 mg/0.8 mL + 40 mg/0.4 mL prefilled syringe <sup>†</sup>	1 pack (28 day supply, one time fill)
Humira 20 mg/0.2 mL prefilled syringe	2 syringes per 28 days
Humira 20 mg/0.4 mL prefilled syringe	2 syringes per 28 days
Humira 40 mg/0.4 mL prefilled pen/syringe <sup>##*^\$†‡</sup>	2 pens/syringes per 28 days
Humira pediatric Crohn's Disease starter pack 80 mg/0.8 mL prefilled syringe <sup>†</sup>	1 pack (28 day supply, one time fill)
Humira 40 mg/0.8 mL prefilled pen <sup>##*^\$†‡</sup>	2 pens per 28 days
Humira 40 mg/0.8 mL prefilled syringe <sup>##*^\$†‡</sup>	2 syringes per 28 days
Humira Crohn's Disease/Ulcerative Colitis/Hidradenitis Suppurativa starter pack 40 mg/0.4 mL prefilled pen <sup>†*</sup>	1 pack (28 day supply, one time fill)
Humira Crohn's Disease/Ulcerative Colitis/Hidradenitis Suppurativa starter pack 40 mg/0.8 mL prefilled pen <sup>†*</sup>	1 pack (28 day supply, one time fill)
Humira Crohn's Disease/Ulcerative Colitis/Hidradenitis Suppurativa starter pack 80 mg/0.8 mL prefilled pen <sup>†*</sup>	1 pack (28 day supply, one time fill)
Humira Psoriasis/Uveitis starter pack 80 mg/0.8 mL + 40 mg/0.4 mL prefilled pen <sup>^‡</sup>	1 pack (28 day supply, one time fill)
Humira Psoriasis/Uveitis starter pack 40 mg/0.4 mL prefilled pen <sup>^‡</sup>	1 pack (28 day supply, one time fill)
Humira Psoriasis/Uveitis starter pack 40 mg/0.8 mL <sup>^‡</sup>	1 pack (28 day supply, one time fill)

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### Override Criteria

†Initiation of therapy for pediatric Crohn's Disease (CD): Depending on individual's weight, may approve one (1) pediatric or adult Crohn's Disease starter pack **OR** up to four (4) additional pens or syringes (40 mg) in the first month (28 days) of treatment.

\*Initiation of therapy for adult Crohn's Disease (CD) or Ulcerative Colitis (UC): May approve one (1) Crohn's Disease/Ulcerative Colitis starter pack **OR** up to four (4) additional pens, autoinjectors or syringes (40 mg) in the first month (28 days) of treatment.

¥In the treatment of Crohn's Disease (CD) or Ulcerative Colitis (UC): May approve up to an additional 2 (two) syringes, autoinjectors, or pens (40 mg) every 28 days if the individual has an inadequate response to standard maintenance dosing.

#In the treatment of Rheumatoid Arthritis (RA): May approve up to four (4) syringes autoinjectors or pens (40mg) (up to an additional two (2) syringes, autoinjectors or pens) every 28 days if the individual is unable to take concomitant methotrexate.

§ Initiation of therapy for adult Hidradenitis Suppurativa (HS): May approve 1 (one) Crohn's Disease/Ulcerative Colitis/Hidradenitis Suppurativa starter pack **OR** up to 4 (four) additional pens or syringes (40 mg) in the first month (28 days) of treatment. Maintenance therapy: May approve up to 2 (two) additional pens or syringes (40 mg) per each 28 days.

\*Initiation of therapy for Uveitis (UV): May approve up to 2 (two) additional pens or syringes (40 mg) in the first month (28 days) of treatment.

^Initiation of therapy for Plaque Psoriasis (Ps) (psoriasis vulgaris): May approve one (1) Psoriasis starter pack **OR** up to two (2) additional pens, autoinjectors or syringes (40 mg) in the first month (28 days) of treatment.

## **APPROVAL CRITERIA**

- I. Crohn's disease (CD) when each of the following criteria are met:
  - A. Individual is 6 years of age or older with moderate to severe CD; **AND**
  - B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants);

### **OR**

- II. Ulcerative colitis (UC) when each of the following criteria are met:
  - A. Individual is 18 years of age or older with moderate to severe UC; **AND**

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- B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants);

**OR**

III. Rheumatoid arthritis (RA) when each of the following criteria are met:

- A. Individual must be 18 years of age or older with moderate to severe RA; **AND**  
 B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [non-biologic disease modifying anti-rheumatic agents (DMARDs) (such as methotrexate, sulfasalazine, leflunomide, or hydroxychloroquine)] (ACR 2015);

**OR**

IV. Ankylosing spondylitis (AS) when each of the following criteria are met:

- A. Individual is 18 years of age or older with moderate to severe AS; **AND**  
 B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as NSAIDs or non-biologic disease modifying anti-rheumatic drugs (DMARDs) (such as sulfasalazine)];

**OR**

V. Polyarticular juvenile idiopathic arthritis (PJIA) when each of the following criteria are met:

- A. Individual is 2 years of age or older with moderate to severe PJIA; **AND**  
 B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [non-biologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate)] (ACR 2011).

**OR**

VI. Psoriatic arthritis (PsA) when each of the following criteria are met:

- A. Individual must be 18 years of age or older with moderate to severe PsA; **AND**  
 B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, or leflunomide)];

**OR**

VII. Plaque psoriasis (Ps) (psoriasis vulgaris) when each of the following criteria are met:

- A. Individual is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps (psoriasis vulgaris) with either of the following (AAD 2011):  
 1. Plaque Ps (psoriasis vulgaris) involving greater than five percent (5%) of body surface area (BSA); **OR**

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2. Plaque Ps (psoriasis vulgaris) involving less than or equal to five percent (5%) of BSA involving sensitive areas or areas that significantly impact daily function (such as fingernails, palms, soles of feet, head/neck, or genitalia);

**AND**

- B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as methotrexate, acitretin, or cyclosporine);

**OR**

- VIII. Non-infectious uveitis (UV) when each of the following criteria are met:
  - A. Individual has chronic, recurrent, treatment-refractory or vision-threatening disease; **AND**
  - B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as corticosteroids or immunosuppressive drugs (azathioprine, cyclosporine, or methotrexate)].

**OR**

- IX. Hidradenitis suppurativa (HS) when each of the following criteria are met:
  - A. Individual is 12 years of age or older; **AND**
  - B. Individual has moderate to severe HS (Hurley stage II or Hurley stage III disease); **AND**
  - C. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as oral antibiotics);

**OR**

- X. Sarcoidosis when each of the following criteria are met (Sweiss 2014):
  - A. Individual is 18 years of age or older; **AND**
  - B. Individual has chronic, progressive, treatment-refractory disease; **AND**
  - C. Individual has had an inadequate response to, is intolerant of, or has a contraindication to systemic corticosteroids; **AND**
  - D. Individual has had an inadequate response to, is intolerant of, or has a contraindication to nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate or azathioprine).

Humira (adalimumab) may **not** be approved for the following:

- I. In combination with other TNF antagonists, JAK inhibitors, or other biologic drugs (such

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as abatacept, anakinra, or vedolizumab); **OR**

II. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**

III. Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent, to evaluate for latent tuberculosis prior to initiating adalimumab.

**Note:**

TNFi have black box warnings for serious infections and malignancy. Individuals treated with TNFi are at increased risk for developing serious infections that may lead to hospitalization or death. Most individuals who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. TNFi should be discontinued if an individual develops a serious infection or sepsis. Individuals should be tested for latent tuberculosis (TB) before TNFi use and during therapy. Treatment for latent TB should be initiated prior to TNFi use. Risks and benefits of TNFi should be carefully considered prior to initiation of therapy in individuals with chronic or recurrent infection. Lymphoma and other malignancies have been reported in children and adolescents treated with TNFi. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL) have been reported in individuals treated with TNFi. Almost all cases had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNFi at or prior to diagnosis. It is uncertain whether HSTCL is related to the use of a TNFi or a TNFi in combination with these other immunosuppressants.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

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3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. NCCN Drugs & Biologics Compendium (NCCN Compendium®) 2016 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically. Accessed on: September 14, 2018.
6. Singh JA, Saag KG, Bridges SL et al. 2015 American College of Rheumatology Guideline for the treatment of rheumatoid arthritis. *Arthritis Rheum.* 2016;68:1-26.
7. Menter A, Korman NJ, Elmets CA et al for the American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. *J Am Acad Dermatol.* 2011; 65: 137-174.

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8. American Gastroenterological Association. Identification, assessment and initial medical treatment of ulcerative colitis Clinical Care Pathway. Available at <https://gastro.org/guidelines/ibd-and-bowel-disorders>. Accessed on: September 14, 2018.
9. American Gastroenterological Association. Identification, assessment and initial medical treatment of Crohn's disease Clinical Care Pathway. Available at <https://gastro.org/guidelines/ibd-and-bowel-disorders>. Accessed on: September 14, 2018.
10. Lichtenstein GR, Loftus EV, Isaacs KL et al. 2018 American College of Gastroenterology Guideline for the management of Crohn's disease in adults. *Am J Gastroenterol* 2018; 113:481–517.
11. Ward MM, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of America/ Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis Rheumatol*. 2016; 68(2):282-298.
12. Ringold S, Weiss PF, Beukelman T, et al. 2013 Update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. *Arthritis Rheum*. 2013; 65(10):2499-2512.
13. 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 & Research*. 2011; 63(4):465-482.
14. Levy-Clarke G, Jabs DA, Read RW, et al. Expert panel recommendations for the use of anti-tumor necrosis factor biologic agents in patients with ocular inflammatory disorders; American Uveitis Society subcommittee. *Ophthalmology*. 2014; 121(3):785-796.
15. Baughman RP, Drent M, et al. Infliximab therapy in patients with chronic sarcoidosis and pulmonary involvement. *Am J Respir Crit Care Med*. 2006; 174:795-802.
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