Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	NA	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†	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†	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#*^§†‡	2 pens/syringes per 28 days
Humira pediatric Crohn's Disease starter pack 80 mg/0.8 mL prefilled syringe†	1 pack (28 day supply, one time fill)
Humira 40 mg/0.8 mL prefilled pen#*^§†‡	2 pens per 28 days
Humira 40 mg/0.8 mL prefilled syringe#*^§†‡	2 syringes per 28 days
Humira Crohn's Disease/Ulcerative Colitis/ Hidradenitis Suppurativa starter pack 40 mg/0.4 mL prefilled pen†*	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†*	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†*	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^‡	1 pack (28 day supply, one time fill)
Humira Psoriasis/Uveitis starter pack 40 mg/0.4 mL prefilled pen^‡	1 pack (28 day supply, one time fill)
Humira Psoriasis/Uveitis starter pack 40 mg/0.8 mL^‡	1 pack (28 day supply, one time fill)

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

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 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. ǂInitiation 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

Initial requests for Humira (adalimumab) may be approved for the following:

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 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**
   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);

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

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 2019).

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 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 2019):
      1. Plaque Ps (psoriasis vulgaris) involving greater than three percent (3%) of body surface area (BSA); **OR**
      2. Plaque Ps (psoriasis vulgaris) involving less than or equal to three percent (3%) of BSA involving sensitive areas or areas that significantly impact daily function (such as fingernails, palms, soles of feet, head/neck, or genitalia);

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

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).

Continuation requests for Humira (adalimumab) may be approved if the following criterion is met:

I. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

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

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

I. All other indications not included above; **OR**
II. In combination with other TNF antagonists, apremilast, JAK inhibitors, or other biologic drugs (such as abatacept, anakinra, or vedolizumab); **OR**
III. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**
IV. Prior to initiating therapy, 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 (unless switching therapy from another targeted immune modulator and no risk factors).

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.

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

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