Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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Humira (adalimumab)

CG-DRUG-65

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)

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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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)
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): 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. **Individual has been on Humira (adalimumab) in the past 180 days (medication samples/ coupons/ discount cards are excluded from consideration as a trial); OR**

II. Diagnosis of Crohn's Disease:

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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A. Individual is 6 years of age or older; **AND**
B. Individual has a diagnosis of moderately to severely active Crohn's disease; **AND**
C. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy [such as 5-ASA products, sulfasalazine, systemic corticosteroids, or immunosuppressants] or has lost response to or is intolerant to infliximab or infliximab-dyyb, and Humira (adalimumab) is used for one of the following:
   1. To reduce signs or symptoms; **OR**
   2. To induce or maintain clinical remission;

OR

III. Diagnosis of Ulcerative Colitis:
A. Individual is 18 years of age or older; **AND**
B. Individual has a diagnosis of moderately to severely active ulcerative colitis; **AND**
C. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as 5-Aminosalicylic acid products, sulfasalazine, systemic corticosteroids, or immunosuppressive drugs), and Humira (adalimumab) is used for one of the following:
   1. To reduce signs or symptoms; **OR**
   2. To induce or maintain clinical remission;

OR

IV. Diagnosis of Rheumatoid Arthritis:
A. Individual must be 18 years of age or older; **AND**
B. Individual must have moderately to severely active rheumatoid arthritis; **AND**
C. Agent is used for **any** of the following reasons:
   1. To reduce signs or symptoms; **OR**
   2. To induce or maintain clinical response; **OR**
   3. To inhibit the progression of structural damage; **OR**
   4. To improve physical function; **AND**
D. Individual has failed to respond to, is intolerant of, or has a medical contraindication to one or more non-biologic disease-modifying anti-rheumatic agents (DMARDs);

OR

V. Diagnosis of Ankylosing Spondylitis:
A. Individual is 18 years of age or older; **AND**
B. Individual has active ankylosing spondylitis; **AND**
C. Agent is used to reduce signs or symptoms of the disease; **AND**

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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D. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as NSAIDs or non-biologic; DMARDs);

OR

VI. Diagnosis of Juvenile Idiopathic Arthritis:
- A. Individual has a diagnosis of moderate to severely active juvenile idiopathic arthritis; **AND**
- B. Individual is 2 years of age or older; **AND**
- C. Agent is used for **any** of the following reasons:
  1. To reduce signs or symptoms; **OR**
  2. To induce or maintain clinical response; **AND**
- D. Individual has failed to respond to, is intolerant of, or has a medical contraindication to one or more non-biologic DMARDs.

OR

VII. Diagnosis of Psoriatic Arthritis:
- A. Individual must be 18 years of age or older; **AND**
- B. Individual has active psoriatic arthritis; **AND**
- C. Agent is used for **any** of the following reasons:
  1. To reduce signs or symptoms; **OR**
  2. To induce or maintain clinical response; **OR**
  3. To inhibit the progression of structural damage; **OR**
  4. To improve physical function; **AND**
- D. Individual has failed to respond to, is intolerant of, or has had a medical contraindication to conventional therapy (such as non biologic DMARDs);

OR

VIII. Diagnosis of Plaque Psoriasis (Psoriasis Vulgaris):
- A. Individual is 18 years of age or older; **AND**
- B. Individual has a diagnosis of chronic moderate to severe (that is, extensive or disabling) plaque psoriasis (psoriasis vulgaris) with either of the following:
  1. Plaque psoriasis (psoriasis vulgaris) involving greater than 5% of body surface area (BSA); **OR**
  2. Plaque psoriasis (psoriasis vulgaris) involving less than or equal to 5% of BSA involving sensitive areas or areas that would significantly impact daily function (such as fingernails, palms, soles of feet, head/neck, or genitalia);

AND

- C. Agent is used for **any** of the following reasons:
  1. To reduce signs or symptoms; **or**

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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2. To induce or maintain clinical response; **AND**

D. Individual has failed to respond to, is intolerant of, or has a medical contraindication to phototherapy or other systemic therapies (such as methotrexate, acitretin, or cyclosporine);

OR

IX. Diagnosis of Non-infectious Uveitis:

A. Individual has chronic, recurrent, treatment-refractory or vision-threatening disease; **AND**

B. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as corticosteroids or immunosuppressive drugs [for example, azathioprine, cyclosporine, or methotrexate]).

OR

X. Diagnosis of Hidradenitis Suppurativa:

A. Individual is 18 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 failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as oral antibiotics).

Humira (adalimumab) may **not** be approved for an individual with any of the following:

I. In combination with other TNF antagonists; **OR**
II. In combination with tofacitinib citrate; **OR**
III. In combination with the following non-TNF immunomodulatory drugs: abatacept, anakinra, or vedolizumab; **OR**
IV. Tuberculosis, invasive fungal infection, other active serious infections, or a history of recurrent infections; **OR**
V. Individual has not had a tuberculin skin test, or a CDC-recommended equivalent, to evaluate for latent tuberculosis prior to initiating adalimumab; **OR**
VI. When the above approval criteria are not met and for all other indications.

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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Note: Humira (adalimumab) has a black box warning related to the increased risk of developing serious infections that could result in hospitalization or death. Individuals should be closely monitored for the development of infection during and after treatment with discontinuation of therapy if the individual develops a serious infection or sepsis. Reported infections include: Tuberculosis, invasive fungal infections (including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis), and infections (bacterial, viral, or other) due to opportunistic pathogens (including Legionella and Listeria). The risks and benefits of treatment with Humira should be considered prior to initiating in individuals with chronic or recurrent infection. Lymphoma and other malignancies, some fatal, have been reported in children and adolescents treated with tumor necrosis factor (TNF) blockers.

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

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Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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