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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Amjevita (adalimumab-atto)

CG-DRUG-64, CG-DRUG-65

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

Medications	Quantity Limit
Amjevita 20 mg/0.4 mL prefilled syringe	2 syringes per 28 days
Amjevita (adalimumab-atto) 40 mg/0.8 mL prefilled syringe#* ¥^	2 syringes per 28 days
Amjevita (adalimumab-atto) 40 mg/0.8 mL prefilled SureClick® autoinjector#* ¥^	2 autoinjectors per 28 days

Override Criteria

#In the treatment of Rheumatoid Arthritis: May approve up to 4 (four) syringes, autoinjectors, or pens (40mg/0.8 mL) [up to an additional 2 (two) syringes, autoinjectors, or pens] every 28 days if the individual is unable to take concomitant methotrexate.

*Initiation of therapy for adult Crohn's Disease or Ulcerative Colitis: May approve up to 4 (four) additional pens, autoinjectors, or syringes (40 mg/0.8 mL) in the first month (28 days) of treatment.

¥In the treatment of Crohn's Disease or Ulcerative Colitis: May approve up to an additional 2 (two) syringes, autoinjectors, or pens (40 mg/0.8 mL) every 28 days if the individual has an inadequate response to standard maintenance dosing.

^Initiation of therapy for Plaque Psoriasis (Psoriasis Vulgaris): May approve up to 2 (two) additional pens, autoinjectors, or syringes (40 mg/0.8 mL) in the first month (28 days) of treatment.

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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APPROVAL CRITERIA

I. Diagnosis of Crohn's Disease:
   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-Aminosalicylic acid products, sulfasalazine, systemic corticosteroids, or immunosuppressants) or has lost response to or is intolerant to infliximab and Amjevita (adalimumab-atto) is used for one of the following:
      1. To reduce signs or symptoms; **OR**
      2. To induce or maintain clinical remission;

   AND
   D. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to ONE (1) preferred biologic agent [Current preferred biologics include - Humira (adalimumab), Inflectra (infliximab-dyyb), Renflexis (infliximab-abda)] unless the following criteria are met:
      1. Individual has been receiving and is maintained on a stable dose of Amjevita (adalimumab-atto); **OR**
      2. The preferred agent is not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Amjevita (adalimumab-atto) does; **OR**
      3. The preferred agent is not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
         a. Known hypersensitivity to any active or inactive component which is not also associated with Amjevita (adalimumab-atto); **OR**
         b. Individual's age; **OR**
         c. Pregnant or planning on becoming pregnant; **OR**
         d. Serious infections or concurrent sepsis; OR
      4. The preferred agent(s) do not have activity against a concomitant clinical condition and Amjevita (adalimumab-atto) does. Examples include but may not be limited to the following:
         a. Concomitant Psoriasis: TNFi (agents FDA-approved for both indications) or Stelara are preferred; **OR**
         b. Concomitant Rheumatoid Arthritis: TNFi agents are preferred;

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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OR

II. Diagnosis of Ulcerative Colitis:
   A. Individual is 18 years of age or older; **AND**
   B. Individual has a diagnosis of with moderately to severely active UC; **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 Amjevita (adalimumab-atto) is used for one of the following:
      1. To reduce signs or symptoms; **OR**
      2. To induce or maintain clinical remission;

   AND

   D. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to ONE (1) preferred biologic agent [Current preferred biologics include - Humira (adalimumab), Inflectra (infliximab-dyyb), Renflexis (infliximab-abda)] unless the following criteria are met:
      1. Individual has been receiving and is maintained on a stable dose of Amjevita (adalimumab-atto); **OR**
      2. The preferred agent is not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Amjevita (adalimumab-atto) does; **OR**
      3. The preferred agent is not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
         a. Known hypersensitivity to any active or inactive component which is not also associated with Amjevita (adalimumab-atto); **OR**
         b. Individual's age; **OR**
         c. Pregnant or planning on becoming pregnant; **OR**
         d. Serious infections or concurrent sepsis; **OR**
      4. The preferred agent(s) do not have activity against a concomitant clinical condition and Amjevita (adalimumab-atto) does. Examples include but may not be limited to the following:
         a. Concomitant Psoriasis: TNFi (agents FDA-approved for both indications) or Stelara are preferred; **OR**
         b. Concomitant Rheumatoid Arthritis: TNFi agents are preferred.

OR

III. Diagnosis of Rheumatoid Arthritis:
   A. Individual must be 18 years of age or older; **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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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);

AND

E. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – Enbrel (etanercept), Humira (adalimumab)] unless the following criteria are met:
   1. Individual has been receiving and is maintained on a stable dose of Amjevita (adalimumab-atto); **OR**
   2. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
      a. Known hypersensitivity to any active or inactive component which is not also associated with Amjevita (adalimumab-atto); **OR**
      b. Individual's age; **OR**
      c. Pregnant or planning on becoming pregnant; **OR**
      d. Serious infections or concurrent sepsis; **OR**
   3. The preferred agent(s) do not have activity against a concomitant clinical condition and Amjevita (adalimumab-atto) does. An example includes but may not be limited to the following:
      a. Concomitant Crohn's disease: TNFi (agents FDA-approved for both indications) are preferred;

OR

IV. 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**
   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);

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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E. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – Enbrel (etanercept), Humira (adalimumab)] unless the following criteria are met:
   1. Individual has been receiving and is maintained on a stable dose of Amjevita (adalimumab-atto); **OR**
   2. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Amjevita (adalimumab-atto) does; **OR**
   3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
      a. Known hypersensitivity to any active or inactive component which is not also associated with Amjevita (adalimumab-atto); **OR**
      b. Individual's age; **OR**
      c. Pregnant or planning on becoming pregnant; **OR**
      d. Serious infections or concurrent sepsis;

OR

V. 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;

AND

E. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – Enbrel (etanercept), Humira (adalimumab)] unless the following criteria are met:
   1. Individual has been receiving and is maintained on a stable dose of Amjevita (adalimumab-atto); **OR**
   2. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Amjevita (adalimumab-atto) does; **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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3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
    a. Known hypersensitivity to any active or inactive component which is not also associated with Amjevita (adalimumab-atto); **OR**
    b. Individual's age; **OR**
    c. Pregnant or planning on becoming pregnant; **OR**
    d. Serious infections or concurrent sepsis;

OR

VI. 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);

AND

- E. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – Enbrel (etanercept), Humira (adalimumab)] unless the following criteria are met:
    1. Individual has been receiving and is maintained on a stable dose of Amjevita (adalimumab-atto); **OR**
    2. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Amjevita (adalimumab-atto) does; **OR**
    3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
        a. Known hypersensitivity to any active or inactive component which is not also associated with Amjevita (adalimumab-atto); **OR**
        b. Individual's age; **OR**
        c. Pregnant or planning on becoming pregnant; **OR**
        d. Serious infections or concurrent sepsis; **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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4. The preferred agent(s) do not have activity against a concomitant clinical condition and Amjevita (adalimumab-atto) does. Examples include but may not be limited to the following:
   a. Concomitant Crohn's Disease: TNFi (agents FDA-approved for both indications) or Stelara are preferred; OR
   b. Concomitant Ulcerative Colitis: TNFi (agents FDA-approved for both indications) are preferred;

OR

VII. 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; **OR**
      2. Plaque psoriasis (psoriasis vulgaris) involving less than or equal to 5% of body surface area involving sensitive areas or areas that would significantly impact daily function (such as 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**
      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 acitretin, cyclosporine, or methotrexate);

   AND

   E. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – Enbrel (etanercept), Humira (adalimumab)] unless the following criteria are met:
      1. Individual has been receiving and is maintained on a stable dose of Amjevita (adalimumab-atto); **OR**
      2. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Amjevita (adalimumab-atto)does; **OR**
      3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
         a. Known hypersensitivity to any active or inactive component which is not also associated with Amjevita (adalimumab-atto); **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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b. Individual's age; **OR**
c. Pregnant or planning on becoming pregnant; **OR**
d. Serious infections or concurrent sepsis; **OR**

4. The preferred agent(s) do not have activity against a concomitant clinical condition and Amjevita (adalimumab-atto) does. Examples include but may not be limited to the following:
   a. Concomitant Crohn's Disease: TNFi (agents FDA-approved for both indications) or Stelara are preferred; **OR**
   b. Concomitant Ulcerative Colitis: TNFi (agents FDA-approved for both indications) are preferred;

OR

VIII. 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]);

AND

C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to the preferred biologic agent [Current preferred biologic includes – Humira (adalimumab)] unless the following criteria are met:

1. Individual has been receiving and is maintained on a stable dose of Amjevita (adalimumab-atto); **OR**
2. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Amjevita (adalimumab-atto) does; **OR**
3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
   a. Known hypersensitivity to any active or inactive component which is not also associated with Amjevita (adalimumab-atto); **OR**
   b. Individual's age; **OR**
   c. Pregnant or planning on becoming pregnant; **OR**
   d. Serious infections or concurrent sepsis;

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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IX. Diagnosis of Hidradenitis suppurativa:
- A. Individual is 18 years of age or older; **AND**
- B. Individual has moderate to severe hidradenitis suppurativa (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); **AND**
- D. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to the preferred biologic agent [Current preferred biologic includes – Humira (adalimumab)] unless the following criteria are met:
  1. Individual has been receiving and is maintained on a stable dose of Amjevita (adalimumab-atto); **OR**
  2. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Amjevita (adalimumab-atto) does; **OR**
  3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
     a. Known hypersensitivity to any active or inactive component which is not also associated with Amjevita (adalimumab-atto); **OR**
     b. Individual's age; **OR**
     c. Pregnant or planning on becoming pregnant; **OR**
     d. Serious infections or concurrent sepsis.

Amjevita (adalimumab-atto) 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: anakinra, abatacept, 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-atto; **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: Amjevita (adalimumab-atto) 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 Amjevita should be considered prior to initiating in individuals with chronic or recurrent infection. Amjevita is not indicated for the use in pediatric individuals due to reports of lymphoma and other malignancies developing 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

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.
CRX-ALL-0276-18

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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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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