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

*FHK- Florida Healthy Kids

Amjevita (adalimumab-atto)

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 (RA): 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 (CD) or Ulcerative Colitis (UC): 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 CD or UC: 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 (Ps) (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.

APPROVAL CRITERIA

Requests for Amjevita (adalimumab-atto) may be approved for the following:

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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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);
   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 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

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);
   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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C. 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. 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 [nonbiologic disease modifying anti-rheumatic agents (DMARDs) (such as methotrexate, sulfasalazine, leflunomide, or hydroxychloroquine)] (ACR 2015);

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 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**

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. 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. 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 nonbiologic disease modifying anti-rheumatic agents (DMARDs) (such as sulfasalazine)];

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 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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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 [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, or leflunomide)];
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 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

VI. Psoriatic arthritis (PsA) when each of the following criteria are met:
A. Individual is18 years of age or older with moderate to severe PsA;
AND
B. Individual has had an inadequate response to, is intolerant of, or has had a contraindication to conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, or leflunomide)];
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 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

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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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**
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. 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%) body surface area (BSA); **OR**
   2. Plaque Ps (psoriasis vulgaris) involving less than or equal to five percent (5%) BSA involving sensitive areas or areas that significantly impact daily function (such as 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 acitretin, 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 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

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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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**
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. 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 immunosuppressants (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**

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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c. Pregnant or planning on becoming pregnant; **OR**
d. Serious infections or concurrent sepsis;

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 hidradenitis suppurativa (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);
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 the following:

I. In combination with other TNF antagonists, JAK inhibitors or other biologic drugs (such as, abatacept, anakinra, or vedolizumab); **OR**
II. Tuberculosis, other active serious infections, or a history of recurrent infections; **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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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-atto.

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 N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

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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.
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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-0347-19

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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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.
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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.