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

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.

[§]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 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 4 (four) additional pens or syringes (40 mg) in the first month (28 days) of treatment.

[‡]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.

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

APPROVAL CRITERIA

Requests for Amjevita (adalimumab-atto) 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 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

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
   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

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

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

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

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

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)] (ACR 2019);

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);

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

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

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%) body surface area (BSA); **OR**
2. Plaque Ps (psoriasis vulgaris) involving less than or equal to three percent (3%) 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 – Cosentyx (secukinumab), 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

VIII. Non-infectious uveitis (UV) when each of the following criteria are met:

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

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

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

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 agents (DMARDs) (such as methotrexate or azathioprine);

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

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 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).

Requests for Amjevita (adalimumab-atto) may **not** be approved for the following:

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. 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.

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

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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.