Amjevita™ (adalimumab-atto) – New Biosimilar Approval

- On September 23, 2016, the FDA approved Amgen's Amjevita (adalimumab-atto), the fourth biosimilar approved by the FDA. Amjevita is biosimilar to AbbVie's Humira® (adalimumab) and shares 7 of the 10 indications for Humira.

- Both Amjevita and Humira are approved for:

  - **Rheumatoid arthritis (RA)**: reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA.
  - **Juvenile idiopathic arthritis (JIA)**: reducing signs and symptoms of moderately to severely active polyarticular JIA in patients ≥ 4 years of age. In contrast, Humira is approved for JIA in patients ≥ 2 years old.
  - **Psoriatic arthritis (PsA)**: reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA.
  - **Ankylosing spondylitis (AS**): reducing signs and symptoms in adult patients with active AS.
  - **Adult Crohn's disease (CD)**: reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active CD who have had an inadequate response to conventional therapy. Amjevita is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to Remicade® (infliximab).
  - **Ulcerative colitis (UC)**: inducing and sustaining clinical remission in adult patients with moderately to severely active UC who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine (6-MP).
  - **Plaque psoriasis (PsO)**: treatment of adult patients with moderate to severe chronic PsO who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.

- In addition, Humira is also approved for pediatric CD, hidradenitis suppurativa, and uveitis.

- A biosimilar product is a biological agent that is considered highly similar to an already-approved biological drug, known as the reference product. Biological products are generally derived from a living organism and can come from many sources, including humans, animals, microorganisms or yeast.

  - A biosimilar product must show no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.
  - In addition, a biosimilar product may only be approved for the indication(s) and condition(s) that have been FDA approved for the reference product, and must have the same mechanism(s) of action, route(s) of administration, dosage form(s) and strength(s) as the reference product.

- Amjevita is approved as a biosimilar to Humira, ***not*** as an interchangeable product.

- The approval of Amjevita is based on a review of analytical, non-clinical, pharmacokinetic and clinical data confirming that Amjevita is highly similar to Humira. Two efficacy and safety similarity studies conducted in patients with chronic PsO and RA demonstrated comparable clinical efficacy between Amjevita and Humira.

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- The FDA approval follows a unanimous (26-0) vote by the FDA's Arthritis Advisory Committee to recommend use of Amjevita in 7 indications of Humira.

- Similar to Humira, Amjevita carries a boxed warning for serious infections and malignancies.

- Other warnings and precautions of Amjevita include hypersensitivity reactions, hepatitis B virus reactivation, neurologic reactions, hematological reactions, use with Kineret® (anakinra) or Orencia® (abatacept), heart failure, autoimmunity, and immunizations.

- The most common adverse reactions (> 10%) with Amjevita use were infections (eg, upper respiratory, sinusitis), injection site reactions, headache and rash.

- The recommended dose of Amjevita administered by subcutaneous injection is as follows:

Indication	Recommended Dose
Adult RA, AS, and PsA	40 mg every other week
JIA (weight 15 kg to < 30 kg)	20 mg every other week
JIA (weight ≥ 30 kg)	40 mg every other week
Adult CD and UC	Day 1: 160 mg Day 15: 80 mg Day 29 & Maintenance Dose: 40 mg every other week
Adult PsO	Day 1: 80 mg Day 8 & Maintenance Dose: 40 mg every other week

- Dosing of Humira for its additional indications can be found in its drug label.

- The launch plans for Amjevita are pending due to ongoing patent litigation. Upon launch, Amjevita will be available as 40 mg/0.8 mL and 20 mg/0.4 mL single-dose prefilled syringes and as 40 mg/0.8 mL single-dose prefilled SureClick® auto-injectors.