Idacio® (adalimumab-aacf) – New biosimilar approval

- On December 14, 2022, Fresenius Kabi announced the FDA approval of Idacio (adalimumab-aacf), a biosimilar to AbbVie's Humira® (adalimumab).
    - Amgen's Amjevita™ (adalimumab-atto) was the first biosimilar to Humira and was approved on September 23, 2016.
    - Additional biosimilars to Humira include Boehringer Ingelheim's Cyltezo® (adalimumab-adbm); Sandoz's Hyrimoz® (adalimumab-adaz); Samsung Bioepis/Organon's Hadlima (adalimumab-bwwd); Pfizer's Abrilada™ (adalimumab-afzb); Mylan's Hulio® (adalimumab-fkjp); and Coherus' Yusimry™ (adalimumab-aqvh).
    - In addition, Cyltezo was granted *interchangeable status* on October 15, 2021. One-year of interchangeability status is granted from time of first commercial marketing.
    - Licensing agreements have been signed with AbbVie allowing launch of Amjevita on January 31, 2023, Cyltezo on July 1, 2023, Hyrimoz on July 1, 2023, Hadlima on July 1, 2023, Abrilada on July 1, 2023, Hulio in July 2023, and Yusimry on July 1, 2023.
- Idacio is a citrate-free formulation of adalimumab.
- Idacio, Hadlima, Yusimry, Hulio, Abrilada, Amjevita, Cyltezo, Hyrimoz, and Humira share the following indications: rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult and pediatric Crohn's disease (CD), ulcerative colitis (UC), and plaque psoriasis (PsO).
- In addition, Humira is also approved for UC in pediatric patients 5 years and older, hidradenitis suppurativa and uveitis.
- Similar to Amjevita, Cyltezo, Hyrimoz, Abrilada, Hulio, Yusimry, Hadlima, and Humira, Idacio carries a boxed warning for serious infections and malignancy.
- Warnings and precautions of Idacio include hypersensitivity reactions, hepatitis B virus reactivation, neurologic reactions, hematological reactions, increased risk of infection when used with Kineret® (anakinra), heart failure, autoimmunity, immunizations, and increased risk of infection when used with Orencia® (abatacept).
- The most common adverse reactions (> 10%) with Idacio use were infections (eg, upper respiratory, sinusitis), injection site reactions, headache and rash.
- The recommended dose of Idacio administered by subcutaneous (SC) injection is as follows:

Indication	Recommended Dose
Adult RA*, PsA, AS	40 mg every other week
JIA (≥ 2 years of age) ≥ 30 kg (66 lbs)	40 mg every other week
Adult CD and UC	Day 1: 160 mg Day 15: 80 mg Day 29 and maintenance: 40 mg every other week§
Pediatric CD (≥ 6 years of age) ≥ 40 kg (88 lbs)	Day 1: 160 mg Day 15: 80 mg Day 29 and maintenance: 40 mg every other week

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Adult PsO	Day 1: 80 mg Day 8 and maintenance: 40 mg every other week

*Some patients with RA not receiving methotrexate may benefit from increasing the frequency to 40 mg every week or 80 mg every other week
§Idacio should only be continued in UC if patients have shown clinical remission by 8 weeks (day 57).

- Idacio is intended for use under the guidance and supervision of a physician. A patient may self-inject Idacio, or a caregiver may inject Idacio using either the pen or prefilled syringe if a physician determines that it is appropriate, and with medical follow-up, as necessary, after proper training in SC injection technique.
- Consult the Humira drug label for dosing recommendations for its additional indications.
- Per a licensing agreement signed with AbbVie, Fresenius Kabi may launch Idacio in July 2023. Idacio will be available as a 40 mg/0.8 mL prefilled pen and prefilled syringe.