Hulio® (adalimumab-fkjp) – New biosimilar approval

- On July 6, 2020, the FDA approved Mylan's Hulio (adalimumab-fkjp), a biosimilar to AbbVie's Humira® (adalimumab).
    - Hulio is the sixth FDA-approved biosimilar to Humira.
    - Amgen's Amjevita™ (adalimumab-atto) was the first biosimilar to Humira and was approved on September 23, 2016. The second biosimilar to Humira was Boehringer Ingelheim's Cyltezo® (adalimumab-adbm), approved on August 25, 2017. The third biosimilar to Humira was Sandoz's Hyrimoz™ (adalimumab-adaz), approved on October 31, 2018. Samsung Bioepis/Merck's Hadlima™ (adalimumab-bwwd) received FDA approval on July 23, 2019. The fifth biosimilar to Humira was Pfizer's Abrilada™ (adalimumab-afzb), approved on November 18, 2019.
    - Licensing agreements have been signed with AbbVie allowing launch of Amjevita on January 31, 2023, Cyltezo on July 1, 2023, Hyrimoz on September 30, 2023, Hadlima after June 30, 2023, Abrilada on November 20, 2023 and Hulio on July 31, 2023.

- Hulio, Abrilada, Amjevita, Cyltezo, Hyrimoz, Hadlima, and Humira share the following indications: rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult Crohn's disease (CD), ulcerative colitis (UC), and plaque psoriasis (PsO).

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

- Similar to Amjevita, Cyltezo, Hyrimoz, Hadlima, Abrilada, and Humira, Hulio carries a boxed warning for serious infections and malignancy.

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

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

- The recommended dose of Hulio administered by subcutaneous (SC) injection is as follows:

Indication	Recommended Dose
Adult RA*, PsA, AS	40 mg every other week
JIA (≥ 4 years of age) 15 kg to < 30 kg ≥ 30 kg	 20 mg every other week 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[§]
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.
[§]Hulio should only be continued in UC if patients have shown clinical remission by 8 weeks (day 57).

- Hulio is intended for use under the guidance and supervision of a physician. A patient may self-inject Hulio or a caregiver may inject Hulio if a physician determines that it is appropriate, and with medical follow-up, as necessary, after proper training in SC injection technique.

Continued . . .

- Consult the Humira drug label for dosing recommendations for additional indications.
- Per a licensing agreement signed with AbbVie, Mylan will launch Hulio on July 31, 2023. Hulio will be available as a 40 mg/0.8 mL prefilled syringe and pen, and as 20 mg/0.4 mL prefilled syringe.

optumrx.com