Hyrimoz™ (adalimumab-adaz) – New biosimilar approval

- On October 31, 2018, Sandoz announced the FDA approval of Hyrimoz (adalimumab-adaz), biosimilar to AbbVie's Humira (adalimumab).
    - This is the third FDA-approved biosimilar to Humira. The first was Amgen's Amjevita™ (adalimumab-atto) and the second was Boehringer Ingelheim's Cyltezo™ (adalimumab-adbm).
    - Hyrimoz, Amjevita, and Cyltezo share 7 of the 10 indications of Humira.

- Hyrimoz, Amjevita, Cyltezo 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 of age.
    - **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. 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.
    - **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.

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

- The approval of Hyrimoz is based on a review of analytical, non-clinical, pharmacokinetic and clinical data confirming that Hyrimoz is highly similar to Humira. An efficacy and safety similarity study conducted in patients with PsO demonstrated therapeutic equivalence between Hyrimoz and Humira.

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

- Other warnings and precautions of Hyrimoz 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 Hyrimoz use were infections (eg, upper respiratory, sinusitis), injection site reactions, headache, and rash.

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

Indication	Recommended Dose
Adult RA†, AS, and PsA	40 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

* Amjevita and Humira are also approved for 15 kg to < 30 kg: 20 mg every other week. Humira is approved for 10 kg to < 15 kg: 10 mg every other week.
† Some patients with RA not receiving methotrexate may benefit from increasing the frequency to 40 mg every week.
‡ Hyrimoz should only be continued in patients who have shown evidence of clinical remission by 8 weeks (Day 57) of therapy.

- Hyrimoz is intended for use under the guidance and supervision of a physician. A patient may self-inject Hyrimoz or a caregiver may inject Hyrimoz 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 additional indications.

- Sandoz announced a global resolution of all intellectual property-related litigation with AbbVie concerning all indications of Hyrimoz for the reference medicine. The license enables patient access in the U.S. to Hyrimoz as of September 30, 2023. Upon launch, Hyrimoz will be available as a 40 mg/0.8 mL single-dose pen (Sensoready® Pen) and a 40 mg/0.8 mL single-dose, 1 mL pre-filled glass syringe.

    — Amgen also announced a global settlement with AbbVie to resolve all pending litigation regarding Amjevita. Amgen expects to launch Amjevita in the U.S. on January 31, 2023.
    — Launch plans for Cyltezo are pending due to ongoing patent litigation.