Humira® (adalimumab) – Expanded indication

- On October 16, 2018, the FDA approved AbbVie's Humira (adalimumab) for the treatment of moderate to severe hidradenitis suppurativa (HS) in patients ≥ 12 years of age.
    - Previously, Humira was approved for the treatment of moderate to severe HS with dosing recommendations only provided for adult patients.
- Humira is also FDA-approved for the following conditions: rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult and pediatric Crohn's disease, ulcerative colitis, plaque psoriasis, and uveitis.
- Use of Humira in pediatric patients ≥ 12 years of age for HS is supported by evidence from adequate and well-controlled studies of Humira in adult HS patients.
    - Additional population pharmacokinetic modeling and simulation predicted that weight-based dosing of Humira in pediatric patients ≥ 12 years of age can provide generally similar exposure to adult HS patients.
    - The course of HS is sufficiently similar in adult and adolescent patients to allow extrapolation of data from adult to adolescent patients.
- Humira carries a boxed warning for serious infections and malignancy.
- The recommended dose of Humira for adolescent patients ≥ 12 years of age and weighing ≥ 30 kg with HS is weight-based:
    - 30 kg (66 lbs) to < 60 kg (132 lbs): 80 mg initially on day 1; 40 mg on day 8; and subsequent doses are 40 mg every other week
    - ≥ 60 kg (132 lbs): 160 mg initially on day 1 (given in one day or split over two consecutive days); 80 mg on day 15; 40 mg on day 29; and subsequent doses are 40 mg every week
- The recommended dose of Humira for adult patients with HS is an initial dose of 160 mg (given in one day or split over two consecutive days), followed by 80 mg two weeks later (day 15). Begin 40 mg weekly dosing two weeks later (day 29).
- Refer to the Humira drug label for dosing recommendations for all other indications.

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