Tofidence™ (tocilizumab-bavi) – New biosimilar approval

- On September 29, 2023, Biogen announced the FDA approval of Tofidence (tocilizumab-bavi), biosimilar to Genentech's Actemra® (tocilizumab).
    - Tofidence is the first FDA-approved biosimilar to Actemra.
- Tofidence and Actemra share the following indications:
    - Adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs)
    - Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (PJIA)
    - Patients 2 years of age and older with active systemic juvenile idiopathic arthritis (SJIA).
- Actemra is also indicated for:
    - Treatment of giant cell arteritis in adult patients
    - Slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease
    - Treatment of chimeric antigen receptor T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients 2 years of age and older
    - Treatment of coronavirus disease 2019 in hospitalized adult patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation.
- In addition, Actemra may be administered as an intravenous (IV) infusion and subcutaneous (SC) injection in some indications whereas Tofidence may only be administered IV for its approved indications.
- The approval of Tofidence is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Actemra.
- Tofidence has been approved as a biosimilar to Actemra, *not as* an interchangeable product.
- Tofidence and Actemra carry a boxed warning for risk of serious infections.
- Warnings and precautions for Tofidence include gastrointestinal perforations, hepatotoxicity, changes in laboratory parameters, immunosuppression, hypersensitivity reactions including anaphylaxis, demyelinating disorders, active hepatic disease and impairment, and vaccinations.
- The most common adverse reactions (≥ 5%) with Tofidence use were upper respiratory tract infections, nasopharyngitis, headache, hypertension, increased alanine transaminase.
- The recommended dosage of Tofidence for adult patients with RA given as a 60-minute single IV drip infusion is 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response.
- The recommended dosage of Tofidence for PJIA patients given once every 4 weeks as a 60-minute single IV drip infusion is patients < 30 kg: 10 mg/kg and ≥ 30 kg: 8 mg/kg.

Continued . . .

- The recommended dosage of Tofidence for SJIA patients given once every 2 weeks as a 60-minute single IV drip infusion is patients < 30 kg: 12 mg/kg and ≥ 30 kg: 8 mg/kg.
- For the treatment of RA, PJIA, and SJIA, when transitioning from IV therapy with Tofidence to SC therapy with another tocilizumab product, the first SC dose should be administered instead of the next scheduled IV dose.
    - Refer to the Tofidence drug label for additional dosing details.
- Biothera's launch plans for Tofidence are pending. Tofidence will be available as single-dose vials containing 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL solution.

Optum