Crysvita® (burosumab-twza) – Expanded indication

- On September 30, 2019, Ultragenyx and Kyowa Kirin announced the FDA approval of Crysvita (burosumab-twza), for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older.
    - Crysvita was previously approved for this indication in adult and pediatric patients 1 year of age and older.
- The safety and effectiveness of Crysvita in patients 6 months to 1 year and adolescents are supported by evidence from the studies in pediatric patients 1 year to less than 13 years of age with additional modeling and simulation of adult and pediatric pharmacokinetic and pharmacodynamic data to inform dosing.
- The recommended starting dose of Crysvita in pediatric patients who weigh less than 10 kg is 1 mg/kg of body weight rounded to the nearest 1 mg, administered subcutaneously every two weeks. For patients who weigh more than 10 kg, the starting dose regimen is 0.8 mg/kg of body weight rounded to the nearest 10 mg, administered every two weeks. The minimum starting dose is 10 mg up to a maximum dose of 90 mg.
    - The dose may be increased up to approximately 2 mg/kg (maximum 90 mg) administered every two weeks to achieve normal serum phosphorus.
    - Refer to the Crysvita drug label for additional dosing and administration recommendations.