Briviact® (brivaracetam) – Expanded indication

- On May 14, 2018, UCB announced the FDA approval of Briviact (brivaracetam) tablets and oral solution, for the treatment of partial-onset seizures in patients 4 years of age and older.
    - Previously, Briviact was approved for the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy.
    - As the safety of Briviact injection in pediatric patients has not been established, Briviact injection is indicated for the treatment of partial-onset seizures only in adult patients (16 years of age and older).
    - Briviact is a schedule V controlled substance.
- Epilepsy is a chronic neurological disorder of the brain. It is estimated that nearly 470,000 children in the U.S. under the age of 18 have epilepsy.
- The safety and effectiveness of Briviact tablets and oral solution have been established in pediatric patients 4 years to less than 16 years of age.
    - Use of Briviact in these age groups is supported by evidence from adequate and well-controlled studies of Briviact in adults with partial-onset seizures, pharmacokinetic data from adult and pediatric patients, and safety data in 149 pediatric patients 4 years to less than 16 years of age.
- The most common adverse reactions with Briviact use in pediatric patients are similar to those seen in adults: somnolence/sedation, dizziness, fatigue, and nausea/vomiting.
- The recommended dosage of Briviact in pediatric patients aged 4 years to less than 16 years is based on body weight and is administered orally twice daily.
    - When initiating treatment, gradual dose escalation is not required.
    - Dosage should be adjusted based on clinical response and tolerability.
    - Consult the Briviact drug label for further dosing recommendations for pediatric patients, adult patients, and intravenous dosing.