Lyrica® (pregabalin) – Expanded indication

- On May 23, 2019, the FDA approved Pfizer's Lyrica (pregabalin) capsules and oral solution as adjunctive therapy for the treatment of partial-onset seizures in patients 1 month of age and older.
    - Lyrica was previously approved for this indication in patients 4 years of age and older.
- Lyrica is also approved for the management of neuropathic pain associated with diabetic peripheral neuropathy; postherpetic neuralgia; fibromyalgia; and neuropathic pain associated with spinal cord injury.
- The approval of Lyrica's expanded indication was based on a double-blind study in 140 children 1 month to less than 4 years of age with partial-onset seizures. Lyrica 7 mg/kg/day and 14 mg/kg/day were compared vs. placebo.
    - A significant improvement in partial-onset seizure rate was observed for the Lyrica 14 mg/kg/day group vs. placebo. The median percent change from baseline in seizure frequency was 70.0% with Lyrica 14 mg/kg/day vs. 22.2% with placebo ($p = 0.0223$).
    - Patients treated with Lyrica 7 mg/kg/day did not show improvement vs. placebo.
- The recommended initial dosage for Lyrica for partial-onset seizures in pediatric patients 1 month to less than 4 years of age is 3.5 mg/kg/day. The maximum dosage is 14 mg/kg/day. The dose should be administered in 3 divided doses.
    - Refer to the Lyrica drug label for dosing for all its other indications.