Epidiolex® (cannabidiol) – New and expanded indications

- On July 31, 2020, the FDA approved Greenwich Biosciences' Epidiolex (cannabidiol) for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS) or tuberous sclerosis complex (TSC) in patients 1 years of age and older.
    - Previously, Epidiolex was only approved for the treatment of seizures associated with LGS or DS in patients ≥ 2 years of age.
- The safety and effectiveness of Epidiolex for the treatment of seizures associated with LGS, DS, or TSC have been established in patients 1 year of age and older. The use of Epidiolex in these indications is supported by adequate and well-controlled studies in patients 2 years of age and older with LGS and DS and in patients 1 year of age and older with TSC.
- The effectiveness of Epidiolex for the treatment of seizures associated with TSC was demonstrated in a randomized, double-blind, placebo-controlled trial in 224 patients aged 1 to 65 years. The primary efficacy measure was the change in seizure frequency of TSC-associated seizures over the 16-week treatment period compared with baseline.
    - The median percentage change from baseline in the frequency of TSC-associated seizures was significantly greater for patients treated with Epidiolex vs. placebo (-43% vs. -20%; $p < 0.01$, respectively).
- The recommended dosage of Epidiolex for the treatment of seizures associated with LGS, DS or TSC is 2.5 mg/kg by mouth twice daily.
    - For LGS or DS, after one week, the dosage can be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day).
    - For TSC, the dose may be increased weekly in increments of 2.5 mg/kg twice daily as tolerated to a maintenance dosage of 12.5 mg/kg twice daily.
    - Refer to the Epidiolex prescribing information for further dosing instructions.