Protocol for cannabidiol (Epidiolex®)
Updated July 2021
Approved January 2019

Addendum:

a. Addition of new indication for Tuberous Sclerosis Complex (TSC) – July 2020

b. Eligibility age changed from 2 to 1 year old

Background:

Epidiolex is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients 1 year of age and older. Cannabidiol is a marijuana derivative; however, it lacks the psychoactive properties that are commonly associated with delta-9-tetrahydrocannabinol (THC).

Criteria for approval:

1. *Patient is 1 year of age or older*; **AND**
2. Patient has a diagnosis of seizures associated with **Lennox-Gastaut syndrome** (LGS) or **Dravet syndrome** (DS) or ***Tuberous Sclerosis Complex*** *(TSC)*; **AND**
3. Seizures has been inadequately controlled by trial of at least **two** antiepileptic drugs (e.g., clobazam, valproate, levetiracetam, topiramate, etc.) and has documentation that confirm at least 8 drop seizures for LGS or at least 4 convulsive seizures for DS while on antiepileptic treatment or at least 8 seizures per month for TSC; **AND**
4. Medication is prescribed by or in consultation with a neurologist; **AND**
5. Patient's serum transaminases (ALT and AST) and total bilirubin is evaluated prior to starting treatment (copies of lab will be required prior to approval)
6. ALT and AST and total bilirubin is monitored at 1 (one) month, 3 months, and 6 months after initiation of therapy

Approval Duration: 12 months

References:

1. Epidiolex® [package insert]. Greenwich Biosciences, Inc., Carlsbad 92008. July 2020
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2016. Updated periodically
3. Devinsky O, Patel AD, Cross JH, et al. Effect of Cannabidiol on Drop Seizures in the Lennox-Gastaut Syndrome. N Engl J Med 2018;378:1888-97
4. Wirrell EC, Laux L, Donner E, Jette N, Knupp K, Meskis MA, et al. Optimizing the Diagnosis and Management of Dravet Syndrome: Recommendations From a North American Consensus Panel. Pediatric Neurology. 2017;68