

Pre - PA Allowance

None

Prior-Approval Requirements

Age 1 year of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Seizures associated with Lennox-Gastaut syndrome (LGS)
 - a. Prescriber will not exceed the FDA labeled dose of 20mg/kg/day
2. Seizures associated with Dravet syndrome (DS)
 - a. Prescriber will not exceed the FDA labeled dose of 20mg/kg/day
3. Seizures associated with tuberous sclerosis complex (TSC)
 - a. Prescriber will not exceed the FDA labeled dose of 25mg/kg/day

AND ALL of the following

- a. Serum transaminases (ALT and AST) and total bilirubin levels must be obtained prior to starting therapy and monitored periodically throughout therapy
- b. Patient is on **TWO** concomitant anti-seizure medications **OR** has had an inadequate treatment response, intolerance, or contraindication to **TWO** of the following medications:
 - a. Clobazam
 - b. Valproate / Valproic acid (i.e. Depakote, Depacon)
 - c. Lamotrigine
 - d. Levetiracetam
 - e. Banzal (rufinamide)
 - f. Topiramate
 - g. Felbamate
 - h. Stiripentol (Dravet syndrome **only**)

Prior - Approval Limits

Quantity

Diagnosis	Maximum daily dose
Lennox-Gastaut syndrome (LGS)	20 mg/kg/day
Dravet syndrome (DS)	
Tuberous sclerosis complex (TSC)	25 mg/kg/day

Duration 12 months

Prior – Approval *Renewal* Requirements

Age 1 year of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Seizures associated with Lennox-Gastaut syndrome (LGS)
 - a. Prescriber will not exceed the FDA labeled dose of 20mg/kg/day
2. Seizures associated with Dravet syndrome (DS)
 - a. Prescriber will not exceed the FDA labeled dose of 20mg/kg/day
3. Seizures associated with tuberous sclerosis complex (TSC)
 - a. Prescriber will not exceed the FDA labeled dose of 25mg/kg/day

AND the following:

- a. Serum transaminases (ALT and AST) and total bilirubin levels are monitored periodically throughout therapy

Prior - Approval *Renewal* Limits

Same as above