Clinical Policy Title:	stiripentol
Policy Number:	RxA.104
Drug(s) Applied:	Diacomit®
Original Policy Date:	02/07/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Seizures associated with Dravet Syndrome (must meet all):

1. Diagnosis of seizures associated with Dravet syndrome;
2. Will be used as adjunctive therapy with at least one other antiepileptic drug;
3. Hematologic testing was obtained prior to starting treatment to monitor for neutropenia and thrombocytopenia.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Seizures associated with Dravet Syndrome (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Wirrell EC, Laux L, Jette N, et al. Optimizing the diagnosis and management of Dravet syndrome: recommendations from a North American consensus panel. Pediatr Neurol. 2017; 68: 18-34. Available at: https://pubmed.ncbi.nlm.nih.gov/28284397/. Accessed August 28, 2024.
2. National Institute for Health and Care Excellence (NICE). Epilepsies: diagnosis and management. Available at: https://www.nice.org.uk/guidance/CG137/chapter/Appendix-EPharmacological-treatment. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
1. Criteria added to initial and continued therapy: Hematologic testing should be obtained prior to starting treatment and every 6 months	4/30/2020	5/20/2020

to monitor for neutropenia and thrombocytopenia. 2. Updated References		
Policy was reviewed: 1. Policy title table was updated: Line of business policy applies was updated to All lines of business. 2. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance.	01/14/2021	03/09/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A, I.A.1: Updated indication from Dravet syndrome to Seizures associated with Dravet syndrome. 2. Continued Therapy Approval Criteria, II.A: Updated indication from Dravet syndrome to Seizures associated with Dravet syndrome. 3. Continued Therapy Approval Criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance”…". 4. References were reviewed and updated.	11/24/2021	1/17/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.3: Updated age criteria from 2 years of age to 6 months of age. 2. Initial Approval Criteria, I.A.4: Updated to include new weight criteria Member’s weight ≥ 7 kg. 3. References were reviewed and updated.	9/15/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed weight restriction. 4. Removed dose restrictions.	08/28/2024	09/13/2024

5. Removed reference to Appendix B. 6. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 7. Removed other reauthorization requirements including positive response to therapy. 8. Updated approval duration verbiage. 9. References were reviewed and updated.		