Clinical Policy Title:	clobazam
Policy Number:	RxA.429
Drug(s) Applied:	Sympazan®
Original Policy Date:	03/06/2020
Last Review Date:	4/1/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Lennox-Gastaut Syndrome (must meet all)**:**

1. Diagnosis of LGS;
2. Prescribed by or in consultation with a neurologist;
3. Trial and failure of one agent for LGS (e.g., clobazam tablets or oral suspension, clonazepam, valproic acid [divalproex], lamotrigine, rufinamide, topiramate, felbamate), unless contraindicated, or clinically significant adverse effects are experienced;
4.

Initial Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

1. Member is currently receiving medication or has been treated with this medication within the past 90 days, excluding manufacturer samples. .

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Hancock EC, Cross JH. Treatment of Lennox-Gastaut syndrome. Cochrane Database Syst Rev. 2013 Feb 28;(2). Available at: https://pubmed.ncbi.nlm.nih.gov/23450537/. Accessed April 24, 2023.
2. Epilepsies: diagnosis and management. National Institute for Health and Care Excellence (NICE) website. Available at: https://www.nice.org.uk/guidance/ng217. Updated April 2022. Accessed March 15, 2022.
3. Wirrell EC. Treatment of Dravet syndrome. Can J Neurol Sci. 2016; 43 Suppl 3: S13-8. Available at: https://www.ncbi.nlm.nih.gov/pubmed/27264138. Accessed April 26, 2023.
4. Wilfong A, Nordli DR, and Dashe JF. Lennox-Gastaut syndrome (2023). UpToDate. Accessed April 1st, 2024. https://www.uptodate.com/contents/lennox-gastaut-syndrome
5.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020

Policy was reviewed. 1. Clinical Policy table updated. 2. Initial Therapy and Continued Therapy Approval duration updated from length of benefit to 12 months for commercial and for HIM updated to 12 months for Onfi® and Sympazan® both 3. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 4. Reference reviewed and updated.	07/30/2020	09/14/2020
Policy was reviewed: 1. Initial Approval Crtieria and Continued Therapy Approval Criteria were updated to remove HIM approval duration.. 2. Continued Therapy Approval Criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…”. 3. References were reviewed and updated.	07/05/2021	09/14/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.6: Updated dosing criteria Dose does not exceed 40 mg per day to Dose does not exceed as following (a or b): a. Weighing 30 kg or less: 20 mg/day orally. b. Weighing more than 30 kg: 40 mg/day orally. 2. Initial Approval Criteria, I.A.4 and I.B.4, updated from “…unless all contraindicated” to just “unless contraindicated.” 3. Initial Approval Criteria, I.A.5, I.B.5, and I.C.4, updated from “medial justification supports…” to “trial of generic clobazam tablets and oral suspension unless intolerable (e.g., contraindications to excipients in generic formulations, etc);” 4. Continued Therapy Approval Criteria, II.A.3: Updated dosing criteria for LGS from general to weight based dosing. 5. References were reviewed and updated.	03/16/2022	07/18/2022

Policy was reviewed: 1. Initial Approval Criteria I.A.4: Updated to remove verbiage preferred. 2. References were reviewed and updated.	04/26/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. I.A.3: Revised to 1 drug trial, added rufinamide per treatment algorithm (UpToDate) 2. Removed drugs that no longer require a PA (Onfi) 3. Updated continued therapy approval criteria 4. Removed trial and failure of clobazam tablets or oral suspension	4/1/2024	