

Clinical Policy Title:	clobazam
Policy Number:	RxA.429
Drug(s) Applied:	Sympazan®
Original Policy Date:	03/06/2020
Last Review Date:	12/11/2025
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. 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;

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Lennox-Gastaut Syndrome:

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met initial approval criteria.

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 March 24, 2025.
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 24, 2025.
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 March 24, 2025.
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>. Accessed March 24, 2025.

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	07/30/2020	09/14/2020

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>Approval duration updated from length of benefit to 12 months for commercial and for HIM updated to 12 months for Onfi® and Sympazan® both</p> <ol style="list-style-type: none"> 3. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 4. Reference reviewed and updated. 		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria 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
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 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): <ol style="list-style-type: none"> 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

<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 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
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 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	
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed prescriber criteria. 2. Updated continuation of therapy language. 3. References were reviewed and updated. 	03/24/2025	04/10/2025
Policy was reviewed.	12/11/2025	12/11/2025