PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**ANTICONVULSANTS**
BRAND NAME* **(generic)**	**ONFI (clobazam)**
	SYMPAZAN (clobazam)
Status: CVS Caremark Criteria	***Ref # 871-A***
Type: Initial Prior Authorization	***Ref # 718-A***

** Drugs that are listed in the target drug box include both brand and generic and all dosages forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

Onfi

Onfi (clobazam) is indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age or older.

Sympazan

Sympazan (clobazam) is indicated for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients 2 years of age or older.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in a patient 2 years of age or older

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Onfi and Sympazan are indicated for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age or older.[1-4]

REFERENCES

1. Onfi [package insert]. Deerfield, IL: Lundbeck Inc.; February 2021.
2. Sympazan [package insert]. Warren, NJ: Aquestive Therapeutics.; August 2020.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed May 4, 2021.
4. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed May 4, 2021.

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Sympazan); (CF) 05/2019 (no clinical changes, combined 718-A + 871-A, removed MDC from 718-A), (RP) 05/2020 (no clinical changes), (MAK) 05/2021 (no clinical changes)

Reviewed: Medical Affairs: (KP) 11/2011; (MG) 05/2012; (DC) 05/2013; (LMS) 05/2014; (DNC) 05/2015; (AM) 11/2018; (GAD) 05/2019; (CHART) 05/28/2020
External Review: 12/2011, 06/2012, 10/2013, 10/2014, 10/2015, 10/2016, 07/2017, 10/2018, 12/2018 (FYI), 10/2019, 10/2020, 08/2021

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in a patient 2 years of age or older?	Yes	No

Mapping Instructions (871-A)			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Approve, 36 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you meet all of these conditions: - You are 2 years of age or older - You have seizures associated with Lennox-Gastaut syndrome - You are taking the requested drug with another seizure drug Your request has been denied based on the information we have. [Short Description: No approvable diagnosis.]

Mapping Instructions (718-A)			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Approve, 12 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you meet all of these conditions: - You are 2 years of age or older - You have seizures associated with Lennox-Gastaut syndrome - You are taking the requested drug with another seizure drug Your request has been denied based on the information we have. [Short Description: No approvable diagnosis.]