

PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

VIMPAT
(lacosamide)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

Ref # 497-A

* Drugs that are listed in the target drug box include both brand and generic and all dosages forms and strengths unless otherwise stated

FDA-APPROVED INDICATIONS

Vimpat is indicated for the treatment of partial-onset seizures in patients 4 years of age and older.

As the safety of Vimpat injection in pediatric patients has not been established, Vimpat injection is indicated for the treatment of partial-onset seizures only in adult patients (17 years of age and 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 the treatment of partial-onset seizures
AND
 - The request is for the injectable formulation in a patient 17 years of age or older
OR
 - The request is for a non-injectable formulation in a patient 4 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. Vimpat is indicated for the treatment of partial-onset seizures in patients 4 years of age and older. As the safety of Vimpat injections in pediatric patients has not been established, Vimpat injection is indicated for the treatment of partial-onset seizures only in adult patients (17 years of age and older).¹⁻³

REFERENCES

1. Vimpat [package insert]. Smyrna, GA: UCB, Inc; November 2017.
2. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed November 2017.
3. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed November 2017.

Written by: UM Development (SE)
Date written: 12/2009
Revised: UM Development (KD) 04/2010 (CAS Adapted); (JK) 06/2011; (TM) 06/2012; (NB) 10/2012 (extended duration); (TM) 05/2013; (CT) 05/2014, 09/2014 (added new indication); (CF) 05/2015; (MS) 05/2016 (no clinical changes); (CT) 05/2017 (no clinical changes); (DS) 11/2017 (update to indication)
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CRITERIA FOR APPROVAL

1	Is the request for the injectable formulation of Vimpat (lacosamide)? [If no, then skip to question 3.]	Yes	No
2	Is the requested drug being prescribed for the treatment of partial-onset seizures in a patient 17 years of age or older? [No further questions.]	Yes	No
3	Is the requested drug being prescribed for the treatment of partial-onset seizures in a patient 4 years of age or older?	Yes	No

Mapping Instructions

Mapping Instructions			
	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
1.	Go to 2	Go to 3	
2.	Approve, 36 months	Deny	Your plan covers this drug when you meet all of these conditions: - You are 17 years of age or older - You have partial-onset seizures Your use of this drug does not meet the requirements. This is based on the information we have.
3.	Approve, 36 months	Deny	Your plan covers this drug when you meet all of these conditions: - You are 4 years of age or older - You have partial-onset seizures Your use of this drug does not meet the requirements. This is based on the information we have.