

Clinical Policy: Oxcarbazepine Extended-Release (Oxtellar XR)

Reference Number: CP.CPA.136

Effective Date: 11.16.16

Last Review Date: 11.19

Line of Business: Commercial

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Oxcarbazepine (Oxtellar XR[®]) is an antiepileptic drug.

FDA Approved Indication(s)

Oxtellar XR is indicated for the treatment of partial-onset seizures in patients 6 years of age and older.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Oxtellar XR is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Partial Seizures (must meet all):

1. Diagnosis of partial seizures;
2. Age \geq 6 years;
3. Failure of oxcarbazepine at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed the following (a or b):
 - a. Adults: 2,400 mg per day;
 - b. Children 6 to 17 years of age: 1,800 mg per day.

Approval duration: Length of Benefit

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

II. Continued Therapy

A. Partial Seizures (must meet all):

1. Currently receiving medication via Centene benefit or documentation supports that member is currently receiving Oxtellar XR for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed the following (a or b):

- a. Adults: 2,400 mg per day;
- b. Children 6 to 17 years of age: 1,800 mg per day.

Approval duration: Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2):

- 1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 months (whichever is less); or
- 2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
oxcarbazepine (Trileptal®)	<p>Adolescents and children 2 – 16 years: 8 – 10 mg/kg/day PO (generally 600 mg/day or less) BID. For patients less than 20 kg, a starting dose of 16 – 20 mg/kg may be considered. The target dose should be achieved over 2 – 4 weeks. Dosage must be individualized. Suggested target maintenance dose for children aged 2 to younger than 4 years is 60 mg/kg/day PO. Suggested target maintenance doses for children 4 – 16 years are weight-based: 900 mg/day PO for those 20 – 29 kg; 1,200 mg/day PO for those 29.1 – 39 kg; 1,800 mg/day PO for those greater than 39 kg.</p> <p>Adults and adolescents > 16 years: 300 mg PO BID, may be increased by a maximum of 600 mg/day at weekly intervals up to 1,200 mg/day</p>	<p>Children: 1,800 mg/day</p> <p>Adults: 1,200 mg/day</p>

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity to oxcarbazepine or to any of its components
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Partial seizures	<p>Adults: The recommended daily dose is 1,200 mg to 2,400 mg per day, given once daily. Initiate treatment at a dose of 600 mg per day given once daily for one week. Subsequent dose increases can be made at weekly intervals in 600 mg per day increments to achieve the recommended daily dose.</p> <p>Children (6 to 17 years old): Initiate treatment at a daily dose of 8 mg/kg to 10 mg/kg once daily, not to exceed 600 mg per day in the first week. Increase in weekly increments of 8 – 10 mg/kg once daily, not to exceed 600 mg to achieve daily target dose as follows: 20 – 29 kg: 900 mg per day, 29.1-39 kg: 1,200 mg per day, greater than 39 kg: 1,800 mg per day</p>	<p>Adults: 2,400 mg/day Children: 1,800 mg/day</p>

VI. Product Availability

Extended-release tablets: 150 mg, 300 mg, and 600 mg

VII. References

1. Oxtellar XR Prescribing Information. Rockville, MD: Supernus Pharmaceuticals, Inc.; December 2018. Available at <https://www.oxtellarxr.com/>. Accessed August 1, 2019.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed August 1, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Minor changes to verbiage and grammar. References updated.	01.10.17	11.17
4Q 2018 annual review: no significant changes; added age requirement; used generic name of the redirection drug instead of the brand name; updated continued therapy language to include continuity of care for partial seizures; references reviewed and updated.	07.05.18	11.18
No significant changes: updated FDA approved indication language to reflect use as monotherapy (previously approved only for use as adjunctive therapy).	12.17.18	
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.01.19	11.19

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members

and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.