Clinical Policy: Sonidegib (Odomzo)

Reference Number: CP.PHAR.272
Effective Date: 05/12
Last Review Date: 08/17 Revision_Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for sonidegib (Odomzo®).

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® that Odomzo is **medically necessary** when one of the following criteria is met:

I. Initial Approval Criteria

A. Basal Cell Carcinoma (must meet all):

1. Diagnosis of basal cell carcinoma (BCC);
2. Member meets a or b:
   a. FDA approved use:
      i. Locally advanced disease and (a or b):
         a) Disease has recurred following surgery or radiation therapy;
         b) Member is not a candidate for surgery or radiation therapy;
   b. Off-label NCCN recommended use: metastatic disease;
3. Prescribed dose does not exceed 200 mg/day;
4. If applicable, pregnancy has been ruled out.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

A. Basal Cell Carcinoma (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member has responded positively to therapy (e.g., no disease progression or unacceptable toxicity);
3. Prescribed dose does not exceed 200 mg/day.

Approval duration: 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:
Sonidegib is an inhibitor of the Hedgehog pathway which binds to and inhibits Smoothened, a transmembrane protein involved in Hedgehog signal transduction.

Formulations:
Odomzo: 200 mg capsules for oral administration

FDA Approved Indications:
Odomzo is a hedgehog pathway inhibitor/oral capsule formulation indicated for:

- Treatment of adult patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.

Appendices

Appendix A: Abbreviation Key
BCC: basal cell carcinoma
FDA: Food and Drug Administration
NCCN: National Comprehensive Care Network

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date
Policy split from CP.PHAR.99 Erivedge and Odomzo. Criteria: removed age restriction; removed pregnancy and drug interaction safety criteria. Background: added formulations.	06/16	08/16
Maximum dose, confirmation of pregnancy status and efficacy statement added. Reasons to discontinue removed. Approval periods increased from 3/6 to 6/12 months.	07/17	08/17

References

1. Odomzo Prescribing Information. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; February 2017. Available at https://www.odomzo.com/themes/custom/odomzo/global/pdfs/pi.pdf. Accessed July 5, 2017.

2. Sonidegib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed July 5, 2017.
3. Basal cell skin cancer (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed July 5, 2017.

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.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs and Medicare coverage articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.