Clinical Policy: Sonidegib (Odomzo)

Reference Number: CP.PHAR.272
Effective Date: 05.01.12
Last Review Date: 05.21
Line of Business: Commercial, HIM, Medicaid Revision Log

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

Description

Sonidegib (Odomzo®) is a hedgehog pathway inhibitor.

FDA Approved Indication(s)

Odomzo is indicated for the 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.

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 Odomzo is **medically necessary** when the following criteria are met:

I. **Initial Approval Criteria**
   A. **Basal Cell Carcinoma** (must meet all):
      1. Diagnosis of locally advanced BCC;
      2. Prescribed by or in consultation with an oncologist;
      3. Age ≥ 18 years;
      4. Member meets one of the following (a, b, or c):
         a. Member has disease that recurred following surgery;
         b. Member has disease that recurred following radiation;
         c. Member is not a candidate for surgery or radiation;
      5. Odomzo is prescribed as a single agent;
      6. Request meets one of the following (a or b):*
         a. Dose does not exceed 200 mg (one tablet) per day;
         b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

      **Prescribed regimen must be FDA-approved or recommended by NCCN*

      Approval duration:
      Medicaid/HIM – 6 months
      Commercial – 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, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Basal Cell Carcinoma

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Odomzo for BCC 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, request meets one of the following (a or b):*
   a. New dose does not exceed 200 mg (one tablet) per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 12 months
Commercial – 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 6 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, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

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

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindication/Boxed Warnings
- Contraindication(s): none reported
- Boxed warning(s): embryo-fetal toxicity

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
BCC	200 mg PO QD	200 mg/day

VI. Product Availability

Capsules: 200 mg

VII. References

1. Odomzo Prescribing Information. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; May 2019. Available at https://www.odomzo.com/themes/custom/odomzo/global/pdfs/pi.pdf. Accessed February 2, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 2, 2021.
3. National Comprehensive Cancer Network Guidelines. Basal Cell Skin Cancer Version 2.2021. Available at www.nccn.org. Accessed February 12, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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
2Q 2018 annual review; policies combined for HIM and Medicaid; Commercial line of business added; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; added continuity of care statement; references reviewed and updated.	02.13.17	05.18
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.04.19	05.19
2Q 2020 annual review: no significant changes; HIM nonformulary language removed; reference reviewed and updated.	02.11.20	05.20
2Q 2021 annual review: added BCC criteria for diagnosis of locally advanced BCC, previous surgery or radiation therapy if eligible, and use as a single agent, as these criteria are supported by the FDA label and/or NCCN; references for HIM line of business off-label use revised from HIM.PHAR.21 to HIM.PA.154; reference reviewed and updated.	02.02.21	05.21

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.

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