



RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Odomzo is used in the treatment of locally advanced basal cell carcinoma that has recurred following surgery or radiation therapy, or in patients who are not candidates for surgery or radiation therapy. It works by inhibiting a molecular pathway, called the Hedgehog pathway, which is active in basal cell cancers. By suppressing this pathway, Odomzo may stop or reduce the growth of cancerous lesions (1).

Skin cancer is the most common cancer and basal cell carcinoma accounts for approximately 80 percent of non-melanoma skin cancers. Basal cell carcinoma starts in the top layer of the skin called the epidermis and usually develops in areas that have been regularly exposed to the sun and other forms of ultraviolet radiation. Locally advanced basal cell skin cancer refers to basal cancers that have not spread to other parts of the body, but cannot be curatively treated with local treatments, specifically surgery and radiation (2).

Regulatory Status

FDA-approved indication: Odomzo is a hedgehog pathway inhibitor 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 (1).

Odomzo carries a boxed warning that its use can result in embryo-fetal death or severe birth defects. Pregnancy status must be determined prior to initiation of treatment in females of reproductive potential. Females should be advised of the need to use effective contraception during treatment with Odomzo and for at least 20 months after the last dose. Males should be advised of the potential risk of Odomzo exposure through semen (1).

Patients should be instructed not to donate blood or blood products while receiving Odomzo and for at least 20 months after the last dose of Odomzo (1).

Patients that experienced treatment resistance to vismodegib have been shown to have the same resistance to Odomzo (sonidegib) (3).

Safety and effectiveness of Odomzo have not been established in pediatric patients (1).



**BlueCross
BlueShield**

Federal Employee Program.

ODOMZO
(sonidegib)

Summary

Odomzo is a hedgehog pathway inhibitor indicated for the treatment of adults with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, who are not candidates for radiation and have not been previously treated with vismodegib. Odomzo carries a boxed warning that its use can result in embryo-fetal death or severe birth defects. Females should be advised of the need for contraception, males should be advised of the potential risk of Odomzo exposure through semen. Patients should be instructed to not donate blood or blood products while receiving Odomzo and for at least 20 months after the last dose of Odomzo. Patients may continue Odomzo until disease progression or unacceptable toxicity has occurred. Safety and effectiveness have not been established in pediatric patients (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Odomzo while maintaining optimal therapeutic outcomes.

References

1. Odomzo [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; August 2023.
2. Peggy A Wu. Epidemiology, pathogenesis, and clinical features of basal cell carcinoma. UpToDate. Updated on March 10, 2021.
3. Danial C, Sarin K, Oro A, et al. An Investigator-Initiated Open-Label Trial of Sonidegib in Advanced Basal Cell Carcinoma Patients Resistant to Vismodegib. *Clin Cancer Res*. 2016; 22: 1325-1329.
4. NCCN Drugs & Biologics Compendium® Sonidegib 2024. National Comprehensive Cancer Network, Inc. Accessed on April 23, 2024.