SONIDEGIB

Generic	Brand	HICL	GCN	Exception/Other
SONIDEGIB	ODOMZO	42369		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced basal cell carcinoma (BCC) and has the following criteria been met?
   - This is a recurrence of BCC after the patient has already had surgery or radiation therapy or the patient is not a candidate for surgery or radiation therapy

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at end of the guideline.

2. Has the patient obtained the following tests prior to initiating therapy?
   - Baseline serum creatinine kinase (CK) level
   - Baseline serum creatinine
   - Pregnancy status of females of reproductive potential

   If yes, **approve for 12 months by HICL with a quantity limit of #1 capsule per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at end of the guideline.

DENIAL TEXT: Our guideline for **SONIDEGIB** requires a diagnosis of locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or that the patient not be a candidate for surgery or radiation therapy. In addition, the patient must have obtained baseline serum creatine kinase (CK) and serum creatinine levels, and females of reproductive potential must verify their pregnancy status prior to initiating therapy.

RATIONALE

Promote appropriate utilization of Sonidegib based on FDA approved indication.

Skin cancer is the most common cancer and basal cell carcinoma accounts for approximately 80 percent of non-melanoma skin cancers. The vast majority of patients can be successfully managed with a variety of simple procedures, such as cryotherapy, curettage and electrodesiccation, topical treatments (5-fluorouracil, imiquimod), or simple surgical excision. When lesions are more advanced, Mohs micrographic surgery, more extensive surgical resection, or radiation therapy generally are generally sufficient to control locoregional disease. The use of systemic therapy is limited to patients with distant metastases or locally advanced disease that cannot be adequately managed with surgical or radiotherapeutic techniques.

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RATIONALE (CONTINUED)
The Hedgehog (Hh) signaling pathway plays a key role in directing growth and patterning during embryonic development and is required in vertebrates for the normal development of many structures, including the skin. Signaling in this pathway is initiated by the cell surface receptor smoothened homolog (SMO). In adults, this pathway normally is inhibited by another cell surface receptor, the patched homolog 1 (PTCH1). In the pathogenesis of basal cell carcinoma, either SMO or PTCH1 could have a mutation resulting in aberrant cell proliferation.

Odomzo works by binding to and inhibiting SMO protein, thereby blocking activation of the Hh pathway and the proliferation of tumor cells. It offers an alternative to Erivedge (vismodegib) with a similar safety profile for patients who have a recurrence of BCC following surgery or radiation therapy, or for those patients who are not candidates for surgery or radiation.

The safety and effectiveness of Odomzo was evaluated in a single clinical trial conducted in patients with locally advanced basal cell carcinoma (laBCC) or metastatic basal cell carcinoma who received Odomzo 200 mg orally, once daily, until disease progression or intolerable toxicity. A total of 66 patients randomized to Odomzo 200 mg daily had laBCC and were followed for at least 12 months unless discontinued earlier. Seventy-six percent of patients had prior therapy for treatment of BCC; this included surgery (73%), radiotherapy (18%), and topical/photodynamic therapies (21%). Approximately half of these patients (56%) had aggressive histology. The ORR was 58% (95% confidence interval: 45, 70), consisting of 3 (5%) complete responses and 35 (53%) partial responses. Among the 38 patients with an objective response, 7 (18%) patients experienced subsequent disease progression with 4 of these 7 patients having maintained a response of 6 months or longer. The remaining 31 patients (82%) have ongoing responses ranging from to 1.9+ to 18.6+ months and the median duration of response has not been reached.

The most common adverse effects seen while using Odomzo were muscle spasms, alopecia, dysgeusia, fatigue, nausea, musculoskeletal pain, diarrhea, decreased weight, decreased appetite, myalgia, abdominal pain, headache, pain, vomiting, and pruritus. It is recommended that baseline serum CK and creatinine levels be obtained prior to initiating Odomzo, periodically during treatment, and as clinically indicated (e.g., if muscle symptoms are reported). Obtain serum creatinine and CK levels at least weekly in patients with musculoskeletal adverse reactions with concurrent serum CK elevation greater than 2.5 times ULN until resolution of clinical signs and symptoms. Depending on the severity of symptoms, temporary dose interruption or discontinuation may be required for musculoskeletal adverse reactions or serum CK elevation.

There is a **black box warning** for embryo-fetal death and severe birth defects. Pregnancy Category D.

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DOSAGE
Odomzo is taken as a single 200 mg capsule, once daily, on an empty stomach, at least 1 hour before or 2 hours after a meal. Odomzo therapy should be continued until disease progression or unacceptable toxicity.

FDA APPROVED INDICATION
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.

REFERENCES

- Odomzo [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals, Corp. July 2015.
- FDA [Online Press Release]. Available at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm455862.htm Updated: July 24, 2015.
- UpToDate, Inc. Systemic treatment of advanced cutaneous squamous and basal cell carcinomas. UpToDate [database online]. Waltham, MA. Available at http://www.uptodate.com/home/index.html. Updated July 28, 2015.
- Hedgehog Signaling Pathway. CST Cell Signaling Technology. 2015. Available at: http://www.cellsignal.com/contents/science-cst-pathways-stem-cell-markers/hedgehog-signaling-pathway/pathways-hedgehog. Accessed August 24, 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/16
Created: 10/15
Client Approval: 11/15
P&T Approval: 11/15