



**pan-Canadian Oncology Drug Review  
Stakeholder Feedback on a pCODR Expert  
Review Committee Initial Recommendation  
(Patient Advocacy Group)**

**Sonidegib (Odomzo) for Basal Cell Carcinoma**

**Canadian Skin Patient Alliance**

April 29, 2021

### 3 Feedback on pERC Initial Recommendation

Name of the Drug and Indication(s):	Odomzo for treatment of locally advanced basal cell carcinoma (laBCC)
Eligible Stakeholder Role	Patient organization
Organization Providing Feedback	Canadian Skin Patient Alliance

\* CADTH may contact this person if comments require clarification. Contact information will not be included in any public posting of this document by CADTH.

#### 3.1 Comments on the Initial Recommendation

a) Please indicate if the stakeholder agrees, agrees in part, or disagrees with the initial recommendation:

Agrees                       Agrees in part                       Disagrees

*Please explain why the stakeholder agrees, agrees in part or disagrees with the initial recommendation. If the stakeholder agrees in part or disagrees with the initial recommendation, please provide specific text from the recommendation and rationale. Please also highlight the applicable pERC deliberative quadrants for each point of disagreement. The points are to be numbered in order of significance.*

1. Despite its rarity, the impacts of this cancer on patients should not be understated. Basal cell carcinoma (BCC) comprises 80 per cent of non-melanoma cancers. It can recur in the same or other places on the skin. Within 5 years of diagnosis, 35-50 per cent of BCC patients develop a new skin cancer. Although not as deadly as melanoma, an untreated BCC can continue to grow and spread to nearby areas, to the bone or to other tissues beneath the skin.<sup>1</sup>
2. Based on correspondence with Save Your Skin Foundation, the CSPA understands that the annual incidence rate for locally advanced BCC is less than 600 people - people for whom alternative interventions such as surgery and radiation have usually failed or would not be recommended. At the CSPA, we are very aware of the impacts on a patient of a visual disease such as skin cancers and other diseases. Patients often report to us that they have lower self-esteem and increased mental health burdens, which are exacerbated by society dismissing their disease as “just a rash”. For skin patients, disorders like locally advanced BCC are so much more than that. For BCC patients for whom existing treatment options such as surgery or radiation would result in irreversible changes to their appearance - and how they are treated at home, at work, at school, or by their friends, family and the public - is not optimal healthcare.
3. Patients deserve to have access to new treatments that can promote a longer time free of cancer progression. Patients respond to different interventions - including medications - differently. It is important that skin cancer patients in Canada have access to multiple treatment options in order to optimize their health outcomes and support their quality of life.

<sup>1</sup> Canadian Cancer Society’s Advisory Committee on Cancer Statistics. *Canadian Cancer Statistics 2014*. Toronto, ON: Canadian Cancer Society; 2014. [May 2014]

4. The Save Your Skin Foundation (SYSF), which is an Affiliate Member of the CSPA, provided a patient input submission to pCODR in relation to this treatment and indication. The CSPA has corresponded with SYSF to understand the rationale of pCODR's draft recommendation and to discuss the ramifications of this decision on patients in Canada living with locally advanced BCC.

- b) Please provide editorial feedback on the initial recommendation to aid in clarity. Is the initial recommendation or are the components of the recommendation (e.g., clinical and economic evidence) clearly worded? Is the intent clear? Are the reasons clear?

Page Number	Section Title	Paragraph, Line Number	Comments and Suggested Changes to Improve Clarity

### 3.2 Comments Related to Eligible Stakeholder Provided Information

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- |  |  |
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CADTH welcomes comments and feedback from all eligible stakeholders with the expectation that even the most critical feedback be delivered respectfully and with civility.

### A. Application of Early Conversion

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## B. Guidance on Scope of Feedback for Early Conversion

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## 2 Instructions for Providing Feedback

- The following stakeholders are eligible to submit feedback on the initial recommendation:
  - The sponsor and/or the manufacturer of the drug under review;
  - Patient groups who have provided input on the drug submission;
  - Registered clinician(s) who have provided input on the drug submission; and
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**Sonidegib (Odomzo) for Basal Cell Carcinoma**

**Melanoma Network of Canada**

**April 29, 2021**

### 3 Feedback on pERC Initial Recommendation

Name of the Drug and Indication(s):	Odomzo (sonidegib) for the treatment of adult patients with histologically confirmed laBCC that is not amenable to radiation therapy or curative surgery
Eligible Stakeholder Role	Patient Advocacy Organization
Organization Providing Feedback	Melanoma Network of Canada

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One of our primary objectives at Melanoma Network of Canada is to help patients access effective and safe treatments in a timely manner. We disagree with the recommendation of pERC as we do not feel it aligns with patient needs for treatment options. Having spoken to several of our supporting clinicians as well about this decision, the following comments were received back:

1. Elena Netchiporouk, MD, MSc, FRCPC -Assistant Professor of Dermatology, Junior scientist IDIGH, McGill University Health Center. 'I fully support Odomzo. I run a rare disease clinic at the Montreal General Hospital where I follow several patients with Gorlin syndrome. Having only one Hh poses significant limitations given vismodegib side effects profile and risk of developing drug resistance. I look forward being able to help my patients with addition of Odomzo to the therapeutic arsenal of advanced or difficult to manage BCCs'.
2. Yves Poulin, MD. FRCPC, Dermatologist, Quebec City 'I want to lend my support for the approval of Odomzo 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'.
3. Katharine Xing - Medical Oncologist – BC Cancer Agency – 'This is really too bad that sonidegib had a negative pCODR review! We were just discussing this during our last tumour group meeting last week that this would be a good addition to the armamentarium'.
4. Ivan V. Litvinov, Dermatologist – Montreal "I am sorry that the recommendation was not a positive one' There needs to be a dermatologist on the panel.
5. Philip Champion- Medical Oncologist – PEI "It is disappointing not to have access to all the drugs that show benefit. It is particularly difficult to produce high quality trial data to meet their standards, for rare diseases."

We observed the following statements directly from the report:

- **Unmet need and requirement for more options:** "pERC agreed with the Clinical Guidance Panel (CGP), the registered clinicians, and the patient groups that there is a need for effective treatment options for patients with laBCC".
- **Good overall safety profile:** "Overall, pERC agreed that sonidegib is reasonably safe with no unexpected or unmanageable toxicities, and that its safety profile is consistent with other Hedgehog (Hh) inhibitors".

- **Unmet need and requirement for more options as well as an oral option for elderly patients unable to travel distances:** “The committee agreed with the Clinical Guidance Panel (CGP) that IaBCC commonly develops in the elderly population, which increases the potential for treatment toxicity due to the presence of significant comorbid illnesses and can lead to significant morbidity in patients”.
- **Unmet need and requirement for more options as well as an oral option for elderly patients unable to travel distances. Comparative studies are not always available due to timing, and rare disease profile:** “pERC concluded that sonidegib aligned with patient values of delaying progression, causing potentially less scarring or disfigurement, oral option, manageable side effect profile, and no apparent detriment in quality of life. However, pERC noted that the impact of sonidegib on patient outcomes and quality of life compared with vismodegib is uncertain”.

We believe the threshold has been attained that this therapy need only demonstrate efficacy and safety, not necessarily superiority, or even equivalence, to existing options. The CGP states the following:

“Based on clinical experience and response data from the ERIVANCE and BOLT trials, sonidegib is expected to be at least as efficacious as vismodegib. Sonidegib may also provide an alternative toxicity profile that may be suitable for some patients when vismodegib is not well tolerated. Overall, due to longer-term data and clinical experience with vismodegib, vismodegib would still be the preferred treatment in this patient population and sonidegib would be used as an alternative option”. (Table 3, *CADTH Clinical Guidance Panel Response to Provincial Advisory Group Implementation Questions*).

It is Melanoma Network of Canada’s position that the efficacy of sonidegib is supported by the trial results which met with the pERC’s own definition of clinical benefit, the experience of patients who provided feedback for our submission, and the desire of contributing clinicians to make sonidegib available to patients who need it.

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			Our comments are indicated above and reflect the concerns we have with the recommendation. The report does not indicate significant concerns, but instead appears to indicate that there is efficacy and a high degree of safety and that this drug therapy also provides another option for patients and clinicians which is desperately needed. If it is deemed to be at least as good as existing options, consideration should be given for approval.

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**Save Your Skin Foundation**

April 29, 2021

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Organization Providing Feedback	Save Your Skin Foundation

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9	Review Committee		Unfortunate that there are no dermatologists or oncologists that focus on skin cancer on this review committee
			More treatments options are needed in the Locally advanced BCC – For patients that fail the current treatment there are no additional options and patients are having to travel to the USA for treatment
5	Overall clinical benefit		At present, we only have access to the hedgehog inhibitor vismodegib. There is evidence that sonidegib is slightly more efficacious with a better side effect profile. A recent review article in JEADV (DOI: 10.1111/jdv.16230) contrasts the two sonic hedgehog inhibitors currently available. It is clear from this review article that there is a slight advantage to sonedegib.
8	Economic evaluation		The rarity of this condition speaks volumes in terms of need for additional therapies, but also stresses that this will not be in major burden on funding organizations (i.e., provincial cancer boards).

Please see accompanying document.

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