

PROVINCIAL FUNDING SUMMARY

Vismodegib (Erivedge) for Advanced Basal Cell Carcinoma

pERC Recommendation: Recommends with condition on the cost-effectiveness being improved to an acceptable level For further details, please see pERC Final Recommendation

Notification to Implement Issued by pCODR: January 27, 2014

This information is current as of January 26, 2015. The use of this document is directed by <u>pCODR's</u> Terms of Use.

Note: Funding criteria as listed on the decision date. Please refer to the provincial drug programs for the most recent funding criteria and program eligibility.

PROVINCE	STATUS	DECISION DATE	FUNDING CRITERIA
ВС	Funded	Oct 1, 2014	For patients with metastatic basal cell carcinoma or locally advanced basal cell carcinoma who are inappropriate for surgery and radiation therapy and who have ECOG 0-2. A BCCA "Compassionate Access Program" request with appropriate clinical information for each patient must be approved prior to treatment.

1



PROVINCE	STATUS	DECISION DATE	FUNDING CRITERIA
АВ	Funded	Jun 20, 2014	For the treatment of metastatic basal cell carcinoma (BCC) or locally advanced BCC (including patients with basal cell nevus syndrome, i.e., Gorlin syndrome) in patients who meet the following criteria: - patients must have measurable metastatic disease or locally advanced disease; AND - patients' disease must be considered inoperable or inappropriate for surgery; AND - patients' disease must be considered inappropriate for radiotherapy, AND - patient is 18 year of age or older, AND - patient has an EGOG≤2 Dose is 150 mg orally once daily taken until disease progression or unacceptable toxicity. Physicians must provide rationale for why surgery AND radiation cannot be considered - must include a surgical consult note that provides a preoperative/surgical evaluation why surgery is not appropriate for the patient; AND - a consult note as to why radiation therapy is not appropriate for the patient: AND - both of the above evaluations must come from a physician who is not the ordering physician, AND - the chart must include confirmation that the patient has been discussed at a multi-disciplinary cancer
			conference (MCC) or equivalent. Note: considered inoperable or inappropriate for surgery for at least ONE of the following reasons: - technically not possible to perform surgery due to size/location/invasiveness of BCC (either lesion too large or can be several small lesions making surgery not feasible) OR - recurrence of BCC after two or more surgical procedures and curative resection unlikely; OR - substantial deformity and/or morbidity anticipated from surgery Note: considered inappropriate for radiation for at least ONE of the following reasons: - contraindication to radiation (e.g. Gorlin syndrome) OR - prior radiation lesion: OR - suboptimal outcomes expected due to size/location/invasiveness of BCC Note: patients preference for oral therapy will not be considered * Prescribing limited to named physicians WHO ARE REGISTERED IN EPPP PROGRAM WITH A SPECIFIC PRESCRIBER ID NUMBER.



PROVINCE	STATUS	DECISION DATE	FUNDING CRITERIA
SK	Funded	Jul 18, 2014	Approved for the following indications: • Treatment of metastatic basal cell cancer (BCC) in patients with ECOG ≤2 • Treatment of locally advanced BCC (including basal cell nevus syndrome or Gorlin syndrome, 18 years of age or older) in patients with ECOG ≤2, who are inappropriate for surgery or radiotherapy, based on a multi-disciplinary team decision that included surgeons, dermatologists, radiation oncologists, and medical oncologists
МВ	Funded	Jul 1, 2014	For patients with metastatic basal cell carcinoma (BCC) or with locally advanced BCC (including patients with basal cell nevus syndrome, ie. Gorlin syndrome) who have measurable metastatic disease or locally advanced disease, which is considered inoperable or inappropriate for surgery and inappropriate for radiotherapy AND - With measurable disease (at least one lesion > 10 mm) that is considered inoperable or inappropriate for surgery or radiation, as determined and documented by at least two specialist physicians AND - Patients 18 years of age or older AND - Patient has ECOG = or < 2
ON	Funded	Apr 16, 2014	 Initial Requests: For patients with metastatic basal cell carcinoma (BCC) or with locally advanced BCC (including patients with basal cell nevus syndrome, i.e. Gorlin syndrome) who have measurable metastatic disease or locally advanced disease, which is considered inoperable or inappropriate for surgery* AND inappropriate for radiotherapy**; AND Patient 18 years or age or older; AND Patient has ECOG ≤ 2 Dose: 150 mg orally once daily taken until disease progression or unacceptable toxicity. Approval Duration: 1 year Physicians must provide rationale for why surgery AND radiation cannot be considered The request must include a surgical consult note that provides a preoperative/surgical evaluation why
			surgery is not appropriate for the patient; AND • A consult note as to why radiation therapy is not appropriate for the patient • Both of the above evaluations must come from a physician who is not the requesting physician. • Please confirm this patient has been discussed at a multi-disciplinary cancer conference (MCC) or equivalent *Considered inoperable or inappropriate for surgery for one of the following reasons:



PROVINCE	STATUS	DECISION DATE	FUNDING CRITERIA
			- Technically not possible to perform surgery due to size/location/invasiveness of BCC (either lesion too large or can be several small lesions making surgery not feasible) - Recurrence of BCC after two or more surgical procedures and curative resection unlikely - Substantial deformity and/or morbidity anticipated from surgery **Considered inappropriate for radiation for one of the following reasons: - Contraindication to radiation (e.g. Gorlin syndrome) - Prior radiation to lesion - Suboptimal outcomes expected due to size/location/invasiveness of BCC Note: Patient preference for oral therapy will not be considered
NS	Funded	Dec 29, 2014	Vismodegib may be used for the treatment of locally advanced BCC (including basal cell nevus syndrome i.e. Gorlin syndrome who are 18 years of age and older) in patients with ECOG PS≤2 who are inappropriate for surgery and radiotherapy based on a discussion/evaluation with other members of the multi-disciplinary team.



PROVINCE	STATUS	DECISION DATE	FUNDING CRITERIA
NB	Funded	Jun 25, 2014	Initial Requests: For patients with metastatic basal cell carcinoma (BCC) or with locally advanced BCC (including patients with basal cell nevus syndrome, i.e. Gorlin syndrome) who have measurable metastatic disease or locally advanced disease, which is considered inoperable or inappropriate for surgery ¹
			AND inappropriate for radiotherapy ² AND • Patient 18 years or age or older; AND • Patient has ECOG ≤ 2 • Patient preference for oral therapy will not be considered Information Required Physicians must provide rationale for why surgery¹ AND radiation² cannot be considered • The request must include a surgical consultation
			report that provides a preoperative/surgical evaluation why surgery is not appropriate for the patient; AND • A consultation report as to why radiation therapy is not appropriate for the patient • Both of the above evaluations must come from a physician who is not the requesting physician • Confirmation that the patient has been discussed at a multi-disciplinary cancer conference or equivalent (e.g. Regional Tumour Board).
			Renewal criteria: The physician has confirmed that the patient has not experienced disease progression while on Erivedge therapy.
			Clinical Notes: ¹Considered inoperable or inappropriate for surgery for one of the following reasons: - Technically not possible to perform surgery due to size/location/invasiveness of BCC (either lesion too large or can be several small lesions making surgery not feasible) - Recurrence of BCC after two or more surgical procedures and curative resection unlikely - Substantial deformity and/or morbidity anticipated from surgery
			 ²Considered inappropriate for radiation for one of the following reasons: Contraindication to radiation (e.g. Gorlin syndrome) Prior radiation to lesion o Suboptimal outcomes expected due to size/location/invasiveness of BCC
			Dose: 150mg orally once daily taken until disease progression or unacceptable toxicity. Claim Notes: Initial approval duration: 1 year Renewal approval duration: 1 year



PROVINCE	STATUS	DECISION DATE	FUNDING CRITERIA
NL	Funded	Oct 1, 2014	For patients with metastatic basal cell carcinoma (BCC) or with locally advanced BCC (including patients with basal cell nevus syndrome, i.e. Gorlin syndrome) who have measurable metastatic disease or locally advanced disease, which is considered inoperable or inappropriate for surgery and inappropriate for radiotherapy; AND • Patient 18 years or age or older; AND • Patient has ECOG ≤ 2
PEI	Under provincial consideration*		

*Under provincial consideration means that the province is reviewing pCODR's recommendation. This may include the province working with the drug manufacturer to reach an agreement for a drug product that both parties can accept, in particular in cases where the pCODR Expert Review Committee has recommended that the drug be funded only on the condition of cost-effectiveness being improved to an acceptable level. This may occur before or after the pan-Canadian Pricing Alliance negotiations. Please contact the specific provincial drug program and/or cancer agency in your province for information about the status of a given drug product.