

## 14.02 Vismodegib

### Capsule, 150 mg,

### Erivedge<sup>®</sup>, Roche Products Pty Ltd.

#### 1. Purpose of Application

- 1.1 To request changes to the current initial and continuing restrictions of vismodegib to relax the requirement of a letter from a surgically qualified clinician and/or a radiation oncologist for patients with metastatic basal cell carcinoma.

#### 2. Suggested listing

- 2.1 Suggestions and additions proposed by the Secretariat to the current listing are added in italics and suggested deletions are crossed out with strikethrough.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
VISMODEGIB 150 MG CAPSULE, 28	1	3	ERIVEDGE	Roche Products Pty Limited

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Severity:</b>	Metastatic or locally advanced
<b>Condition:</b>	Basal cell carcinoma
<b>PBS Indication:</b>	Metastatic or locally advanced basal cell carcinoma
<b>Treatment phase:</b>	Initial
<b>Restriction Level / Method:</b>	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	The condition must be inappropriate for surgery,  AND  The condition must be inappropriate for curative radiotherapy,  AND  Patient must not receive more than 16 weeks of treatment under this restriction.

<p><b>Prescriber Instructions</b></p>	<p>The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> <li>a) A completed authority prescription form; and</li> <li>b) a completed Basal Cell Carcinoma Initial PBS Authority Application Form - Supporting Information Form; and</li> <li>c) A histological confirmation of BCC <i>and whether the condition is metastatic or locally advanced</i>; and</li> <li>d) A letter from a surgically qualified clinician demonstrating inappropriateness for surgery <i>for patients with locally advanced BCC</i>; and</li> <li>e) A letter from a radiation oncologist demonstrating inappropriateness for curative radiotherapy <i>for patients with locally advanced BCC</i>; and</li> <li>f) A signed patient acknowledgement.</li> </ul> <p>The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.</p> <p><b>Inappropriate for surgery is defined as:</b></p> <ul style="list-style-type: none"> <li>i/ Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or</li> <li>ii/ Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or</li> <li>iii/ Medical contraindication to surgery</li> </ul> <p><b>Inappropriate for curative radiotherapy is defined as:</b></p> <ul style="list-style-type: none"> <li>i/ Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or</li> <li>ii/ Limitations due to location of tumour; or</li> <li>iii/ Limitations due to cumulative prior radiotherapy dose; or</li> <li>iv/ Progressive disease despite prior irradiation of locally advanced BCC.</li> </ul>
<p><b>Administrative Advice</b></p>	<p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a></p> <p>Applications for authority to prescribe should be forwarded to:</p> <p>Department of Human Services          Prior Written Approval of Complex Drugs          Reply Paid 9826          GPO Box 9826          HOBART TAS 7001</p> <p>No increase in the maximum quantity or number of units may be authorised.</p> <p>No increase in the maximum number of repeats may be authorised.</p> <p>Special Pricing Arrangements apply.</p>
<p><b>Cautions:</b></p>	<p>Vismodegib is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 9 months and 2 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.</p>

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### **3. Background**

- 3.1 Clinicians had reported to the Secretariat that the criteria required to be submitted to the Department of Human Services for approval of PBS subsidised treatment were onerous for patients with metastatic basal cell carcinoma (BCC) where surgery and radiotherapy are not appropriate. A request was made to members of the PBAC that the PBAC approve a change in the wording of the Prescriber Instructions to remove the requirement for written confirmation from a surgeon AND radiation oncologist in patients with metastatic BCC disease confirming that they are or remain not suited to curative resection nor curative radiotherapy for continuing treatment.
- 3.2 The rationale for this change was that the presence of metastatic disease implies that they are not, and will not become, suited to surgery and radiation therapy, and confirmation from both a surgically qualified clinician and a radiation oncologist in such patients was a waste of resources for both patients and clinicians.

### **4. PBAC Outcome**

- 4.1 The PBAC recommended the proposed new wording for both the initial and continuing treatment to remove the requirement for written confirmation from a surgeon AND radiation oncologist in patients with metastatic BCC disease.
- 4.2 The PBAC agreed with the advice from clinicians that the provision of a letter from both a surgically qualified clinician and a radiation oncologist in patients with metastatic disease was not a good use of resources for both patients and clinicians.
- 4.3 The PBAC agreed that the wording changes as provided by the Secretariat would remove the need to obtain a letter from both a qualified clinician and a radiation oncologist in patients with metastatic disease.
- 4.4 The PBAC noted that no other changes to the current restriction were requested or approved.

#### **Outcome:**

Recommended

### **5. Recommended listing**

- 5.1 Amend existing listing as follows:

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## 6. Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

## **7. Sponsor's Comment**

Roche welcomes the pragmatic decision-making of the PBAC, enabling better continuity of care for patients with metastatic basal cell carcinoma.