

## Engagement Report

### Topic details

<b>Title of policy or policy statement:</b>	Clinical Commissioning Policy: Vismodegib for adults with either Gorlin syndrome or non-Gorlin syndrome related multiple basal cell carcinomas (Adults)
<b>Programme of Care:</b>	Cancer
<b>Clinical Reference Group:</b>	Chemotherapy
<b>URN:</b>	1905

### 1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered.

### 2. Background

This policy proposition recommends that vismodegib is made routinely available for the treatment of adults with either Gorlin syndrome or non-Gorlin syndrome related multiple basal cell carcinomas (BCC). Vismodegib is an oral, targeted cancer medicine and the treatment is not licensed in this indication.

BCC is the most common form of skin cancer. People with multiple BCC develop lesions frequently and at different sites in the body. The most common treatment for multiple BCC is surgery, however, these procedures can be potentially disfiguring and have an impact on the patient's quality of life. A subgroup of patients with multiple BCCs are those with Gorlin syndrome (also known as basal cell nevus syndrome). This is a dominantly inherited genetic disorder in which people develop BCCs from an early age (teens or 20s), as well as other abnormalities such as cysts in the jaw bone and benign ovarian tumours.

This policy proposition is specifically for the treatment of adults who have multiple lesions (a minimum of 6) where surgery could result in significant disfiguration.

This policy proposition has been developed by a Policy Working Group established in line with standard processes and involved clinical members, Public Health England and patient and public voice representatives.

### 3. Engagement

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to 'make arrangements' to involve the public in commissioning. Full guidance is available

in the Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

The policy proposition underwent stakeholder testing for a period of 2 weeks from 2<sup>nd</sup> July 2020 to 16<sup>th</sup> July 2020. The comment from stakeholders have then been shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the proposition might be recommended.

Respondents were asked the following questions:

- Do you support the proposal for vismodegib to be available for adult patients with Gorlin Syndrome and multiple basal cell carcinomas through routine commissioning based on the evidence review and within the criteria set out in this document?
- Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details.
- Do you agree with the definition of locally advanced basal cell carcinoma used in the policy?
- Do you agree with the estimated eligible patient population as outlined in the policy proposition?
- Do you believe that there are any potential positive and/or negative impacts on patient care as a result of making this treatment option available?
- Do you have any further comments on the proposal?

#### **4. Engagement Results**

There were eight responses to engagement, of which (i) five responses were from individual clinicians; (ii) two responses were from individual members of the public; and (iii) one response was submitted by a pharmaceutical company on behalf the license holder.

Of the 8 responses received, all respondents fully supported the draft policy proposition. Furthermore, all eight respondents supported the draft Equality Health Impact Assessment and agreed that the Patient Impact Form represented a true reflection of the patient and carers lived experience of this condition.

However, respondents queried the following:

- Whether the definition of basal cell carcinoma needs to be expanded to include that these cancers are not amenable for curative radiotherapy.
- To clarify that the proposed use of the vismodegib in this indication is an off-label use of the medicine.
- Whether the policy could be expanded to include: (i) the treatment of single BCCs on the eyelid, especially if covering and involving the medial canthus; and (ii) patients with inoperable or locally advanced BCCs that are not suitable for radiotherapy.
- The pharmaceutical company queried the inclusion of the Pregnancy and Prevention Programme within the policy as this was likely to change over the

coming months. The company suggested the exclusion criteria be altered to reference the Summary of Product Characteristics (SmPC) only with no specific details.

The Programme of Care agreed that the proposition offers a clear and positive impact on patient treatment, by potentially making a new treatment available which widens the range of treatment options without disrupting current care or limiting patient choice, and therefore further public consultation was not required. This decision has been assured by the Patient Public Voice Advisory Group.

## 5. How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group and the Cancer National Programme of Care (NPoC). NHS England's response to feedback from engagement can be found in Table 1 below.

<b>Keys themes in feedback</b>	<b>NHS England Response</b>
Definition of basal cell carcinoma	The PWG agree that people with Gorlin syndrome are unable to have radiotherapy, however, people with multiple BCCs (non-Gorlins) could potentially have radiotherapy. The challenge in treating these patients with radiotherapy lies in the size and number of the BCCs which can result in overlapping treatment fields. For this reason, no change is recommended to the definition of BCC.
Off label use of vismodegib	The policy proposition already states that the use of vismodegib in this indication is off-label.
Expanding the use of the treatment	Both the treatment of single BCCs and inoperable/locally advanced BCCs are outside the scope of this policy proposition.
Pregnancy Prevention Programme	Vismodegib is a teratogenic medicine and for this reason, details of the Pregnancy Prevention Programme were included in the policy. The PWG note the feedback that the Pregnancy Prevention Programme may be altered and therefore the policy will be amended to ensure the Summary of Product Characteristics is followed for advice on the management of contraception and pregnancy.

## **6. Has anything been changed in the policy proposition as a result of the stakeholder testing?**

As a result of stakeholder testing, the section on 'Eligibility Criteria' in the policy proposition has been amended to:

- Clarify that vismodegib is a teratogenic medicine. A definition of teratogenic has also been added to the 'Definitions' section of the policy.
- Remove the details of the Pregnancy Prevention Programme and to refer to the Summary of Product Characteristics for details on contraception and pregnancy. The policy states that these guidelines must be followed.

## **7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?**

None.