

## **NHS ENGLAND SPECIALISED SERVICES CLINICAL PANEL REPORT**

Date: December 2019

Intervention: Vismodegib

Indication: Multiple basal cell carcinoma (adults)

ID: 1905

Gateway: 2 Round 2

Programme: Cancer

CRG: Chemotherapy

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### **Information provided to the panel**

Clinical Panel Report from Gateway 1

Clinical Panel Report from Gateway 2 Round 1

Evidence Review undertaken by Solutions for Public Health

Clinical Priorities Advisory Group Summary Report

Policy Proposition

Blueteq® Form

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### **Key elements discussed**

This proposition is for routine commissioning of off-label use for this intervention. It was last considered by Panel in October with numerous changes requested.

The Clinical Panel reviewed each of the required amendments in turn.

The title of the proposition was discussed and that there should be an amendment.

The policy proposition is for adults as the drug is contraindicated in children. The wording in the proposition needs to be clear that the marketing authorisation does not recommend use in children.

The Panel discussed the statement that said this proposition is for those patients with a minimum of 6 BCCs at presentation. They considered this potentially confusing – presentation to whom? This is at the point of consideration for surgery/therapy.

The numbers of eligible patients for this treatment was discussed at length. Substantial concern from Clinical Panel that the estimated number of eligible patients stated in the proposition could seriously underestimate the actual demand for treatment. Extrapolation of data from the Cancer Drugs Fund may not necessarily take into account the actual prescribing practice and change in usage. This proposition should be recommended as an interim policy and subject to annual review and for a maximum of 100 patients per year and if this number is exceeded the access criteria would need to be reviewed and the policy return to annual prioritisation. This can be tested during the stakeholder testing phase of the proposition's development.

The flow chart was discussed and requires some minor modification.

The Blueteq form was discussed. The revisions already undertaken were agreed although the Panel considered further amendment was required regarding the debilitating element of surgery.

The definition of locally advanced disease needs to be checked as the Panel were unsure about accuracy.

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## **Recommendation**

Clinical Panel recommended that this proposition is amended as requested before progressing to stakeholder testing.

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## **Why the panel made these recommendations**

The Clinical Panel considered that the proposition had been substantially revised since the previous consideration but requires some further revisions to provide clarity.

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## **Documentation amendments required**

Policy Proposition:

- Page 2 – proposition title to be amended to ‘Vismodegib for patients with Gorlin Syndrome and multiple basal cell carcinoma subject to specific criteria (adults)’. The bluteq form needs to reflect this also.
- Page 3 Para 2 of the summary – this is contraindicated in children and therefore the wording needs to be modified to include wording from the marketing authorisation.
- Page 3 – this should state at the decision to treat with surgery/therapy. Remove ‘at presentation’.
- Page 12 - Flow chart - the box at the bottom of the chart should state ‘vismodegib +/- surgery’.
- In definitions section of the proposition, ‘locally advanced disease’ needs checking, correcting and referencing. CET to assure any changes.

Blueteq® form:

- wording regarding disfigurement needs adding in section 2 - with the potential for ‘substantial’ disfigurement.
- Q1 and 2 to be changed to:

Q1: I confirm the patient has:

Option 1 Gorlin Syndrome

Option 2  $\geq 6$  operable clinically evident non-locally advanced, non-metastatic multiple BCC

with surgically eligible tumours of 3 lesions  $\geq 5$ mm diameter, of which  $\geq 1$  is histopathologically confirmed.

Q2: I confirm that up front surgical intervention alone has the potential for substantial disfigurement

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Declarations of Interest of Panel Members: None.

Panel Chair: James Palmer, Medical Director

## Post Panel notes and amendments:

### Policy Proposition:

1. Page 2 – proposition title to be amended to 'Vismodegib for patients with Gorlin Syndrome and multiple basal cell carcinoma subject to specific criteria (adults)'. The blueteq® form needs to reflect this also: **Complete.**
2. Page 3 Para 2 of the summary – this is contraindicated in children and therefore the wording needs to be modified to include wording from the marketing authorisation: **Complete; however, this is contested by the Clinical Lead for the following reason:**  
**This is more applicable to locally advanced BCCs. You can have 6 BCCs removed without substantial disfigurement depending where they are and their size. The point of the application is to help people who need multiple surgery/intervention over the years, which cumulatively can lead to disfigurement. Leaving this in implies that removal of one BCC would lead to substantial disfigurement.**
3. Page 3 – this should state at the decision to treat with surgery/therapy. Remove 'at presentation': **Complete and reflected in the inclusion criteria.**
4. Page 12 - Flow chart - the box at the bottom of the chart should state 'vismodegib +/- surgery: **Complete.**
5. In definitions section of the proposition, 'locally advanced disease' needs checking, correcting and referencing. CET to assure any changes: **Complete.**

Blueteq® Form- changes as requested above: **This will be completed in time for publication of the policy to ensure alignment with the eligibility criteria in the policy proposition.**