NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Trametinib in combination with dabrafenib for treating unresectable or metastatic melanoma (TA396)

Published: June 2016

Summary

Trametinib in combination with dabrafenib is recommended, within its marketing authorisation, as an option for treating unresectable or metastatic melanoma in adults with a BRAF V600 mutation only when the company provides trametinib and dabrafenib with the discounts agreed in the patient access schemes.

It is estimated that 1,170 people with advanced, metastatic melanoma are eligible for treatment with trametinib with dabrafenib. It is estimated that around 1,000 people will have trametinib with dabrafenib from year 5 onwards.

The number of people in England estimated to have trametinib with dabrafenib each year based on the uptake in the resource impact assumptions is shown in table 1.

Table 1 Estimated number of people in England having trametinib with dabrafenib

	2016/17	2017/18	2018/19	2019/20	2020/21
Population having trametinib with dabrafenib each year	146	417	625	834	1042

This report is supported by a local resource impact template because the list prices of dabrafenib and trametinib have discounts that are commercial in confidence. The discounted price of trametinib with dabrafenib can be put into the template and other variables may be amended.

This technology is commissioned by NHS England. Providers are NHS hospital trusts.

1 Introduction

1.1 This report looks at the resource impact of implementing the NICE guidance on trametinib in combination with dabrafenib for treating unresectable or metastatic melanoma in England.

1.2 The guidance states that:

- trametinib in combination with dabrafenib is recommended, within its marketing authorisation, as an option for treating unresectable or metastatic melanoma in adults with a BRAF V600 mutation only when the company provides trametinib and dabrafenib with the discounts agreed in the patient access schemes

1.3 The Department of Health and Novartis have agreed that trametinib with dabrafenib will be available to the NHS with a patient access scheme which makes it available with a discount. The size of the discount is commercial in confidence. It is the responsibility of the company to communicate details of the discount to the relevant NHS organisations. Any enquiries from NHS organisations about the patient access scheme should be directed to Novartis on 01276 692 255 or 01276 698 557, email hta.phgbfr@novartis.com.

1.4 This report is supported by a resource impact template. The template aims to help organisations in England, Wales and Northern Ireland plan for the financial implications of implementing the NICE guidance by amending the variables.

1.5 This technology is commissioned by NHS England. Providers are NHS hospital trusts.

2 Background and epidemiology of unresectable or metastatic melanoma

2.1 There were 12,993 new diagnoses of melanoma registered in England in 2014.

A mutated form of the BRAF gene (called BRAF V600) is found in about 45% of melanomas. The mutated gene means that the cells produce too much BRAF protein, leading to uncontrolled cell division and growth of the tumour.

Treatment options for advanced (unresectable or metastatic) melanoma depend on the person's BRAF mutation status and their treatment history. In clinical practice, for people with BRAF mutation-positive advanced melanoma, a BRAF inhibitor is the usual first-line treatment; ipilimumab may be considered for first-line use in a subgroup of patients who are relatively well and in whom the disease is not progressing rapidly.

Table 2 Number of people eligible for treatment in England and estimated number treated from 2020/21

Population	Proportion	Number of people
Total population		53,865,817
Annual incidence of melanoma	0.024%	12,993
Stage III and IV melanomas	20%	2,599
BRAF V600 mutation positive melanomas	45%	1,169
Number treated with dabrafenib and trametinib as a first line treatment[a]		550
Number treated with dabrafenib and trametinib as a second line treatment[a]		492

[a] Estimate taken from expert clinical opinion. Future uptake is uncertain, can be amended in the resource impact template and is explored within the sensitivity analysis in the template.

2.2 Therefore it is estimated that approximately 1,200 people are eligible for treatment with trametinib with dabrafenib each year.

2.3 From year 5 it is estimated that around 1,000 people will have treatment with trametinib with dabrafenib each year once uptake has reached the level estimated by clinical experts.

3 Assumptions made

3.1 The resource impact template makes the following assumptions:

- All people with unresectable or metastatic BRAF V600 mutation positive melanoma will have dabrafenib, vemurafenib or trametinib with dabrafenib as either first or second line therapy.
- Trametinib with dabrafenib will displace dabrafenib and vemurafenib monotherapy.
- The treatment length of trametinib with dabrafenib is around 12 four-week cycles.
- Estimates of first and second line treatment based on expert clinical opinion indicate uptake of trametinib with dabrafenib will increase from 146 in year one to 1,042 by year five. Please refer to the resource impact template for further details.
- The number of people who are treated with dabrafenib with trametinib is subject to a part year effect in year 1 (2016/17).

4 Resource impact

4.1 The list prices of trametinib and dabrafenib have discounts that are commercial in confidence. The discounted prices of trametinib and dabrafenib can be put into the template to calculate the resource impact of the guidance.

4.2 The current treatment and future uptake figure assumptions are based on expert clinical opinion and are shown in the resource impact template. Table 3 shows the number of people that are estimated to have trametinib with dabrafenib by financial year.

Table 3 Population estimated to have trametinib with dabrafenib in England using NICE assumptions

	2016/17	2017/18	2018/19	2019/20	2020/21
Population having trametinib with dabrafenib each year	146	417	625	834	1042

5 Savings and benefits

5.1 Trametinib with dabrafenib has better clinical effectiveness than vemurafenib and dabrafenib monotherapies without any increase in adverse effects or toxicity.

6 Implications for commissioners

6.1 Trametinib with dabrafenib falls within programme budgeting code 02X.

About this resource impact report

This resource impact report accompanies the NICE technology appraisal guidance on trametinib in combination with dabrafenib for treating unresectable or metastatic melanoma (TA396) and should be read in conjunction with it. See terms and conditions on the NICE website.

This report is written in the following context

This report represents the view of NICE, which was arrived at after careful consideration of the available data and through consulting healthcare professionals. The report is an implementation tool and focuses on the recommendations that were considered to have a significant impact on national resource use.

Assumptions used in the report are based on assessment of the national average. Local practice may be different from this, and the impact should be estimated locally.

Implementation of the guidance is the responsibility of local commissioners and providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this costing tool should be interpreted in a way that would be inconsistent with compliance with those duties.