NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Dabrafenib with trametinib for adjuvant treatment of resected BRAF V600 mutation-positive melanoma (TA544)

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Summary

NICE has recommended dabrafenib with trametinib for adjuvant treatment of stage III BRAF V600 positive melanoma. There are no existing treatments for stage III melanoma in the adjuvant setting. Post resection, people have routine surveillance to monitor the status of their disease.

We estimate that:

- 640 people per annum with BRAF V600 positive stage III melanoma are eligible for adjuvant treatment following a successful resection surgery.
- 575 people per annum will have dabrafenib with trametinib from year 2 onwards once uptake has reached 90% as shown in table 1.
- NICE uses 90% uptake where no alternative cancer treatments are available based on commissioner advice. NHSE is commissioner for cancer drugs.

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

	2018/19	2019/20	2020/21	2021/22	2022/23
Population having dabrafenib with trametinib each year	160	575	575	575	575

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 prices of dabrafenib and trametinib 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 Dabrafenib plus trametinib

1.1 NICE has recommended dabrafenib with trametinib as an option for the adjuvant treatment of resected stage III BRAF V600 mutation-positive melanoma in adults.

1.2 There are no existing treatments for stage III melanoma in the adjuvant setting. Post resection, people have routine surveillance to monitor the status of their disease.

1.3 Dabrafenib with trametinib addresses an unmet need and can reduce disease recurrence rates in people who have had a resection for stage III melanoma.

2 Resource impact of the guidance

2.1 We estimate that:

- 640 people with BRAF V600 positive stage III melanoma are eligible for treatment with dabrafenib plus trametinib as an adjuvant therapy each year.
- 575 people will have dabrafenib plus trametinib from year 2 onwards once uptake has reached 90%.

2.2 The current treatment and future uptake figure assumptions are based on clinical opinion, company estimates and commissioner input and are shown in the resource impact template. Table 2 shows the number of people in England who are estimated to have dabrafenib plus trametinib by financial year.

Table 2 Estimated number of people having dabrafenib plus trametinib using NICE assumptions

	2018/19	2019/20	2020/21	2021/22	2022/23
Population having dabrafenib with trametinib each year	160	575	575	575	575

2.3 This report is supported by a local resource impact template. The company has a commercial arrangement for each drug. This makes dabrafenib with trametinib available to the NHS with a discount. The size of the discount is commercial in confidence. The discounted price of dabrafenib with trametinib can be put into the template and other variables may be amended.

Savings and benefits

2.4 Dabrafenib with trametinib can reduce the rate of disease recurrence and delay disease recurrence in people with stage III melanoma who have undergone a resection.

2.5 Treating recurrent disease has worse outcomes as often disease recurrence will be at a more advanced stage and increases costs.

2.6 Reducing or delaying recurrence can reduce mortality, give more people more time without disease, improving their quality of life and reduce costs associated with treatment.

2.7 If 575 people per year choose dabrafenib with trametinib, it is expected that the number of people with disease recurrence could reduce from 280 to 100. The reduction will give savings in treatment costs avoided.

3 Implications for commissioners

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

3.2 Dabrafenib with trametinib falls within the programme budgeting category 02E cancers and tumours, skin.

4 How we estimated the resource impact

The population

4.1 Melanoma is one of the most common cancers with around 13,750 new cases each year in England. Dabrafenib with trametinib is recommended for use as an adjuvant therapy in people with BRAF V600 positive melanoma who have stage III disease.

Table 3 Number of people eligible for treatment in England

	Population	Proportion of previous row (%)	Number of people
	Total population		55,268,067
	Adult population		43,482,790
	Incidence of melanoma [1]	0.032	13,750
a	People with stage III melanoma on diagnosis[2]	6.7	920
	People with stage I or II melanoma on diagnosis[2]	90.9	12,500
b	People with stage I or II melanoma who recur to stage III[3]	6.0	750
a+b	Total people with stage III melanoma		1,670
	People with resectable stage III melanoma[4]	85.0	1,420
	People with stage III melanoma and BRAF V600 mutation positive disease[5]	45.0	640
	Total number of people eligible for treatment with dabrafenib plus trametinib	100.0	640
	Total number of people estimated to have dabrafenib with trametinib each year from year 2[6]	90.0	575
	[1] Source: ONS cancer registration statistics [2] Source: National cancer registration and analysis service – stage breakdown [3] Source: Company information [4] Source: Expert clinical opinion [5] Source: NICE TA396 [6] Source: NICE assumption reached in discussions with NHS England and company		

Assumptions

4.2 The resource impact template assumes that:

- the average treatment duration for dabrafenib with trametinib is 8.3 months.
- Uptake of dabrafenib with trametinib is assumed to reach 90% by year 2.
- People being treated with dabrafenib plus trametinib will undergo additional monitoring over and above the monitoring involved in routine surveillance.
- Rates of disease recurrence are assumed to be 44% in people undergoing routine surveillance and 34% in people who have dabrafenib plus trametinib.
- recurrence can be local or distant and distant recurrence is assumed to be more frequent in the routine surveillance population the rates of these can be amended in the template.

About this resource impact report

This resource impact report accompanies the NICE guidance on Dabrafenib with trametinib for adjuvant treatment of resected BRAF V600 mutation-positive melanoma and should be read with it.