NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Nivolumab with ipilimumab for untreated advanced renal cell carcinoma (TA780)

Published: March 2022

Summary

NICE has recommended nivolumab with ipilimumab within its marketing authorisation, as an option for untreated advanced renal cell carcinoma in adults. See the full recommendation wording in section 1.

We estimate that:

- around 1,950 adults with untreated advanced renal cell carcinoma are eligible for treatment with nivolumab with ipilimumab
- around 490 adults will start treatment with nivolumab with ipilimumab from year 2022/23 onwards. This is based on the current number of people receiving treatment in the cancer drugs fund (CDF); 25% of the eligible population. This number is expected to remain constant over 5 years as shown in table 1.

Table 1 Estimated number of people in England starting treatment with nivolumab with ipilimumab each year

	2022/23	**2023/24**	**2024/25**	**2025/26**	**2026/27**
Uptake %	25	25	25	25	25
People starting treatment with nivolumab with ipilimumab	490	490	490	490	490
Total number of people	**490**	**490**	**490**	**490**	**490**
It is anticipated people continue treatment for 18.13 months on average and therefore there will also be people receiving treatment who started treatment in the previous year**.**					

This report is supported by a local resource impact template because the list prices of nivolumab and ipilimumab have discounts that are commercial in confidence. The discounted prices of nivolumab and ipilimumab 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 Nivolumab with ipilimumab

1.1 NICE has recommended nivolumab with ipilimumab within its marketing authorisation, as an option for untreated advanced renal cell carcinoma in adults:

- whose disease is intermediate or poor risk as defined in the International Metastatic Renal Cell Carcinoma Database Consortium criteria and
- only if the company provides nivolumab with ipilimumab according to the commercial arrangement.

1.2 This appraisal reviews the additional evidence collected as part of the Cancer Drugs Fund managed access agreement for nivolumab with ipilimumab for untreated advanced renal cell carcinoma (NICE technology appraisal guidance 581).

1.3 For intermediate- or poor-risk advanced renal cell carcinoma, tyrosine kinase inhibitors such as pazopanib, sunitinib, tivozanib and cabozantinib are current standard care available in routine commissioning in the NHS. They can cause adverse effects such as fatigue, hand and foot syndrome, and chronic diarrhoea, which can substantially affect quality of life.

1.4 NICE have also recommended the combination of avelumab and axitinib for use within the Cancer Drugs Fund for this indication.

1.5 The aim of treatment is to prevent the growth and survival of cancer cells within the tumour. Treatment aims to prolong survival and maintain a good quality of life by controlling the disease and relieving symptoms.

2 Resource impact of the guidance

2.1 We estimate that:

- around 1,950 adults with untreated advanced renal cell carcinoma are eligible for treatment with nivolumab with ipilimumab
- around 490 adults will start treatment with nivolumab with ipilimumab from year 2022/23 onwards. This is based on the current number of people receiving treatment in the CDF; 25% of the eligible population. This number is expected to remain constant over 5 years as shown in table 2.

2.2 The current treatment and future uptake figure assumptions are based on Blueteq CDF data (current uptake) and clinical expert opinion (future uptake) and are shown in the resource impact template. This is not anticipated to increase once the treatment leaves the CDF. Table 2 shows the number of people in England who are estimated to receive nivolumab with ipilimumab by financial year.

Table 2 Estimated number of people in England starting treatment with nivolumab with ipilimumab using NICE assumptions

	2022/23	2023/24	2024/25	2025/26	2026/27
Uptake %	25	25	25	25	25
People starting treatment with nivolumab with ipilimumab	490	490	490	490	490
Total number of people	**490**	**490**	**490**	**490**	**490**
It is anticipated people continue treatment for 18.3 months on average and therefore there will also be people receiving treatment who started treatment in the previous year**.**					

2.3 This report is supported by a local resource impact template because the company has a commercial arrangement (simple discount patient access scheme). This makes nivolumab and

ipilimumab available to the NHS with a discount. The size of the discounts are commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

Savings and benefits

2.4 Clinical experts explained that in their experience, nivolumab with ipilimumab is well tolerated and has a preferable adverse event profile compared with tyrosine kinase inhibitors.

3 Implications for commissioners and providers

3.1 Nivolumab with ipilimumab is commissioned by NHS England and Improvement. Providers are NHS hospital trusts

3.2 Nivolumab with ipilimumab will now be available through routine commissioning. The technology was previously funded from the Cancer Drugs Fund, but this will stop from 90 days after the publication of the guidance.

3.3 Nivolumab with ipilimumab falls within the programme budgeting category 2H: Cancer, Urological.

4 How we estimated the resource impact

The population

4.1 In 2019, around 10,200 adults were diagnosed with kidney cancer in England (Cancer Registration Statistics, England 2019).

4.2 Of these, Cancer Research UK estimated around 80% have kidney cancer that is renal cell carcinoma and the National Cancer Registration and Analysis Service estimated 42% would be advanced or metastatic renal cell carcinoma.

4.3 75% of these patients will receive first line systemic therapy based on the company's submission for TA417.

4.4 Using the baseline characteristics from the company's checkmate 214 trial approximately 76% will have disease that is intermediate or poor risk.

4.5 Table 3 shows the number of people eligible for treatment with nivolumab with ipilimumab.

Table 3 Number of people eligible for treatment in England

Population	Proportion of previous row (%)	Number of people
Adult population		44,263,393
Incidence of kidney cancer[1]	0.02%	10,181
Proportion of kidney cancer that is renal cell carcinoma[2]	80%	8,145
Proportion with advanced or metastatic renal cell carcinoma[3]	42%	3,421
Proportion of patients who will receive first line systemic therapy[4]	75%	2,566
Proportion with advanced renal cell carcinoma with clear cell disease who are intermediate or poor risk[5]	76%	1,950

[1] Cancer Registration Statistics, England 2019
[2] Cancer Research UK
[3] National Cancer Registration and Analysis Service
[4] TA417
[5] Company checkmate 214

Assumptions

4.6 The resource impact template shows the impact on routine commissioning resulting from nivolumab with ipilimumab moving from the CDF into routine commissioning. It is assumed that the number of people currently receiving comparator treatments in routine commissioning and the CDF will not change.

4.7 While people have been treated with nivolumab with ipilimumab in the CDF the impact of a reduction in subsequent treatments has already been realised within routine commissioning. There will be no further impact on subsequent treatment once nivolumab with

ipilimumab moves into routine commissioning due to no expected increase in the use of nivolumab with ipilimumab.

4.8 The resource impact template assumes that:

- Current NHS treatment for untreated advanced renal cell carcinoma with intermediate to poor risk is usually sunitinib, pazopanib, cabozantinib or tivozanib (within routine commissioning) or nivolumab with ipilimumab (which is currently funded by the CDF) or avelumab with axitinib (which is currently funded by the CDF).
- Estimated usage of avelumab with axitinib remains the same but there is uncertainty whether or not it will be recommended for routine use in the NHS in the future.
- The uptake of nivolumab with ipilimumab and the comparator treatments is assumed to stay the same as current practice.
- Unit costs of current treatments funded within the CDF are not included in the resource impact template. This is so the template shows the impact on routine commissioning. This can be amended locally.
- Nivolumab with ipilimumab has a recommended dose of nivolumab 3 mg/kg in combination with ipilimumab 1 mg/kg every three weeks for 12 weeks followed by nivolumab 480mg every 4 weeks.
- The mean treatment duration for people starting treatment with nivolumab with ipilimumab is 18.13 months however ipilimumab is only used for the first 12 weeks of this.
- Administration costs in clinic are based on the 2021/22 National Tariff Payment System.
- People receiving nivolumab with ipilimumab are likely to be receiving treatment for longer than comparators. For people treated with nivolumab with ipilimumab in the CDF the impact of an increase in administrations has already been realised within routine commissioning. There will be no further impact on

administrations once nivolumab with ipilimumab moves into routine commissioning due to no expected increase in the use of nivolumab with ipilimumab.

- The cost of adverse events is not included in the resource impact template because there is not expected to be significant difference between adverse events costs for nivolumab with ipilimumab and comparator treatments.

About this resource impact report

This resource impact report accompanies the NICE guidance on Nivolumab with ipilimumab for untreated metastatic renal cell carcinoma and should be read with it. See terms and conditions on the NICE website.