NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Nivolumab for adjuvant treatment of invasive urothelial cancer at high risk of recurrence (TA817)

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Summary

NICE has recommended nivolumab as an option for the adjuvant treatment of muscle-invasive urothelial carcinoma that is at a high risk of recurrence after radical resection in adults whose tumours express PD-L1 at a level of 1% or more only if:

- adjuvant treatment with platinum-based chemotherapy is unsuitable, and
- the company provides nivolumab according to the commercial arrangement

We estimate that:

- 310 people with urothelial carcinoma are eligible for treatment with nivolumab each year after adjusting for population growth
- 260 people will receive nivolumab from year 2023/24 onwards once uptake has reached 85% as shown in table 1
- 6,800 additional appointments for administering nivolumab will be needed from 2025/26 as shown in table 2. This is approximately 12 per 100,000 population.

Table 1 Estimated number of people in England receiving nivolumab

	2022/23	2023/24	2024/25	2025/26	2026/27
Uptake rate for nivolumab (%)	43	85	85	85	85
Eligible population	300	300	305	310	310
Population receiving nivolumab each year	130	257	260	260	260

Table 2 Estimated additional appointments needed in England

	2022/23	2023/24	2024/25	2025/26	2026/27
Additional appointments	3,400	6,700	6,700	6,800	6,800

This report is supported by a local resource impact template because the list price of nivolumab has a discount that is commercial in confidence. The

discounted price of nivolumab 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

1.1 NICE has recommended nivolumab as an option for the adjuvant treatment of muscle-invasive urothelial cancer that is at high risk of recurrence after radical resection in adults whose tumours express PD-L1 at a level of 1% or more. It is recommended only if:

- adjuvant treatment with platinum-based chemotherapy is unsuitable, and
- the company provides nivolumab according to the commercial arrangement.

1.2 Current treatment options for high-risk muscle invasive urothelial cancer includes neoadjuvant platinum-based chemotherapy, followed by surgery. If neoadjuvant platinum-based chemotherapy was not given before surgery, adjuvant platinum-based chemotherapy may be offered after surgery. Evidence for platinum chemotherapy after surgery shows it is suitable for upper tract urothelial cancer, which is a small number of people.

1.3 Despite resection, the disease can recur. The patient experts explained that for some people platinum-based chemotherapy is not well tolerated, leading to some people being unwilling to take it. Clinical experts explained some people are not fit enough to have platinum-based chemotherapy or they have toxicity concerns.

1.4 The clinical and patient experts noted that nivolumab was generally well tolerated and that the short infusion time of the treatment compared to chemotherapy was an advantage. The clinical experts explained that treating the disease at an early stage with immunotherapy had the potential to significantly improve outcomes and increase the number of patients which achieve a cure.

2 Resource impact of the guidance

2.1 We estimate that:

- 310 people with urothelial carcinoma are eligible for treatment with nivolumab each year after adjusting for population growth
- 260 people will receive nivolumab from year 2023/24 onwards once uptake has reached 85% as shown in table 3
- 6,800 additional appointments for administering nivolumab will be needed from 2025/26 as shown in table 4. This is approximately 12 per 100,000 population.

2.2 The current treatment and future uptake figure assumptions are based on clinical expert opinion and are shown in the resource impact template. Table 3 shows the number of people in England who are estimated to receive nivolumab by financial year.

Table 3 Estimated number of people receiving nivolumab using NICE assumptions

	2022/23	2023/24	2024/25	2025/26	2026/27
Uptake rate for nivolumab (%)	43	85	85	85	85
Eligible population	300	300	305	310	310
Population receiving nivolumab each year	130	257	260	260	260

Table 4 Estimated additional appointments needed in England

	2022/23	2023/24	2024/25	2025/26	2026/27
Additional appointments	3,400	6,700	6,700	6,800	6,800

2.3 This report is supported by a local resource impact template. Nivolumab has a commercial arrangement which makes nivolumab available to the NHS with a discount. The size of the discount is commercial in confidence. The discounted price of nivolumab can be put into the template and other variables may be amended. It is the company's responsibility to let relevant NHS organisations know details of the discount.

3 Implications for commissioners

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

3.2 Although chemotherapy infusion time is shorter with nivolumab (around 30 minutes) compared with adjuvant platinum-based chemotherapy (over 60 minutes), for people for whom adjuvant platinum-based chemotherapy is not appropriate, the alternative is best supportive care. There will therefore be a capacity impact on chemotherapy units for people who receive nivolumab. The resource impact template allows commissioners to assess the resource impact of any additional attendances required at provider services for reimbursement.

3.3 Nivolumab falls within the programme budgeting category 2H 'Cancers and Tumours – Urological'.

4 How we estimated the resource impact

The population

4.1 In 2019, around 10,600 cases of bladder cancer were recorded in England. [Cancer Registration Statistics 2019 England - NHS Digital]. Urothelial cancer accounts for around 90% of bladder cancer cases in England [Cancer Research UK: Types of bladder cancer]. This is currently around 9,500 cases, predicted to increase to 9,900 cases per year after adjusting for population growth.

Table 5 Number of people eligible for treatment in England

Population	Proportion of previous row (%)	Number of people
Total population		54,786,327
Adult population (adjusted for predicted growth each year)		46,263,200
Incidence of bladder cancer[1]	0.02	10,600
People who have urothelial cancer[2]	90	9,900
People with tumour cell PD-L1 expression ≥ 1%[3]	39.77	3,900
People who have stage II-IV[4]	54.5	2,100
People who receive surgery[5]	24	500
People who have a high risk of recurrence[6]	80	400
People for whom adjuvant platinum-based chemotherapy is inappropriate[7] **Eligible population**	75	**310**
Total number of people estimated to receive nivolumab in 2023/24[7]	85	**257**
Total number of people estimated to receive nivolumab each year from year 2024/25 after adjusting for population growth[8]	85	**260**

[1] Cancer Registration Statistics, England 2019 - NHS Digital; ICD10 Code C66,C67,D09.1

[2] Cancer Research UK: Types of bladder cancer

[3] Company submission, based on data from CheckMate 274

[4] National Cancer Registration and Analysis Service. NCRAS: Survival by stage. 2019. Available at: http://www.ncin.org.uk/publications/survival_by_stage [Accessed 19 February 2021].

[5] Cancer Research UK; Weighted calculation depending on each stage people received surgery [stages II-IV only]

[6] Company submission

[7] Company submission based on expert opinion

[8] NHSE & I and company submission

Assumptions

4.2 The resource impact template assumes that:

- People receive around 18 cycles of nivolumab. This is based on the median treatment duration included in the published committee papers for this topic

- Treatment is assumed to be given in 2-week cycles as per the trial
- Uptake of nivolumab in 2022/23 is adjusted by 50% for a part year effect from when the guidance is published
- 100% of the eligible population are expected to currently receive best supportive care
- 85% of people receive nivolumab in future practice once peak uptake is reached.

About this resource impact report

This resource impact report accompanies the NICE guidance on [insert guidance title and embed hyperlink, for example http://www.nice.org.uk/guidance/TA/DG/MTXXX] and should be read with it.