NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Pembrolizumab for untreated metastatic or unresectable recurrent head and neck squamous cell carcinoma (TA661)

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Summary

NICE has recommended pembrolizumab as an option for untreated metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC) in adults whose tumours express PD L1 with a combined positive score of 1 or more. See section 1 for further information.

We estimate that:

- 1,010 people with untreated metastatic or unresectable recurrent head and neck squamous cell carcinoma whose tumours express PD L1 with a combined positive score of 1 or more are eligible for treatment with pembrolizumab
- 760 people will receive pembrolizumab from year 2022/23 onwards once uptake has reached 75% as shown in table 1.

Table 1 Estimated number of people in England receiving pembrolizumab

	2020/21	2021/22	2022/23	2023/24	2024/25
Population receiving pembrolizumab each year	60[1]	420	760	760	760
1: Adjusted to reflect 2 months uptake in line with the NICE constitution that requires compliance with guidance recommendations within 3 months of guidance publication.					

This report is supported by a local resource impact template because the list price of pembrolizumab has a discount that is commercial in confidence. The discounted price of pembrolizumab can be put into the template and other variables may be amended.

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

1 Pembrolizumab

1.1 NICE has recommended pembrolizumab as an option for untreated metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC) in adults whose tumours express PD L1 with a combined positive score of 1 or more. This is only if:

- pembrolizumab is given as a monotherapy
- pembrolizumab is stopped at 2 years of uninterrupted treatment, or earlier if disease progresses, and
- the company provides pembrolizumab according to the commercial arrangement.

1.2 Treatment for HNSCC typically involves surgery and/or radiotherapy with curative intent, with systemic therapy in cases of advanced disease limited to a local region.

1.3 Treatment of metastatic or unresectable recurrent HNSCC depends on tumour location. If it starts in the oral cavity (mouth), it is usually first treated with cetuximab combination therapy (cetuximab with platinum and 5 fluorouracil (5-FU) chemotherapy). If it starts outside the oral cavity it is treated with chemotherapy (platinum and 5-FU) alone.

2 Resource impact of the guidance

2.1 We estimate that:

- 1,010 people with untreated metastatic or unresectable recurrent HNSCC whose tumours express PD L1 with a combined positive score of 1 or more are eligible for treatment with pembrolizumab
- 760 people will have pembrolizumab from year 2022/23 onwards once uptake has reached 75% as shown in table 1.

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 2 shows the number of people in England who are estimated to have pembrolizumab by financial year.

Table 2 Estimated number of people receiving pembrolizumab using NICE assumptions

	2020/21	2021/22	2022/23	2023/24	2024/25
Population receiving pembrolizumab each year	60[1]	420	760	760	760
1: Adjusted to reflect 2 months uptake in line with the NICE constitution that requires compliance with guidance recommendations within 3 months of guidance publication.					

2.3 This report is supported by a local resource impact template. This is because pembrolizumab has an agreed patient access scheme which makes it available with a commercial-in-confidence discount to the list price. The discounted price of pembrolizumab can be put into the template and other variables may be amended. For enquiries about the patient access scheme contact: keiron.hughes@merck.com.

Savings and benefits

2.4 As a monotherapy, pembrolizumab could reduce administration costs relative to current salvage chemotherapy options. This is modelled in the template.

2.5 Based on the resource impact model, pembrolizumab monotherapy requires around 12 days of intravenous infusions. Platinum (cisplatin) plus 5-fluorouracil and cetuximab requires around 35 days of chemotherapy administrations and platinum (cisplatin) and 5-fluorouracil requires around 52 days of chemotherapy administrations.

2.6 Clinical experts suggest that pembrolizumab is better tolerated than existing treatments, including cetuximab, which may cause rash, diarrhoea, and low magnesium.

3 Implications for commissioners

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

3.2 Pembrolizumab falls within the programme budgeting category 02A: Cancer, Head and Neck.

4 How we estimated the resource impact

The population

4.1 In 2017, around 9,200 new cases of adults with head and neck cancer were recorded in England (Office for National Statistics, 2017).

4.2 Table 3 shows the number of adults with untreated metastatic or unresectable recurrent HNSCC whose tumours express PD L1 with a combined positive score of 1 or more who are eligible for treatment with pembrolizumab.

Table 3 Number of people eligible for treatment in England

Population	Proportion of previous row (%)	Number of people
Adult population in England		44,022,560
Incidence of head and neck cancer[1]	0.02	9,200
People with squamous cell carcinoma[2]	90	8,300
People with stage I/II disease		
People diagnosed with stage I/II disease[3]	34.7	2,870
People who progress after surgery or radiotherapy for stage I/II disease and are suitable for active therapy for stage III/IV disease[4] **(A)**	49	1,410
People with stage III/IVa or IVb disease		
People with squamous cell carcinoma		8,300
People diagnosed with stage III or IVa or IVb disease[3]	60.2	4,980
People suitable for active therapy with stage III or IVa or IVb disease[4] (**B**)	53.4	2,660
Total people eligible to receive active therapy for stage III/IVa/IVb disease (**A+B**)		4,070
People with recurrent HNSCC who progress and are eligible for first-line treatment[4] (**C**)	40.6	1,650
People with stage IVc disease		
People with squamous cell carcinoma		8,300
People diagnosed with stage IVc disease[3]	4.3	360
People with metastatic HNSCC stage IVc disease suitable for first-line treatment[4] (**D**)	93	330
Total number of people with metastatic HNSCC stage I-IVc disease suitable for first-line treatment (**C+D**)		**1,980**
People with CPS ≥ 1[4]	85	1,680
People with performance status 0-1[5]	60	1,010
Total number of untreated people eligible for treatment with pembrolizumab		1,010
Total number of people estimated to have pembrolizumab each year from year 2022/23[5]	75	760

[1] Cancer registration statistics, England - Office for National Statistics

[2] Patient.co.uk

[3] Cancer Research UK

[4] Merck Sharp & Dohme company submission

[5] NHS England

Assumptions

4.3 The resource impact template assumes that:

- Uptake during the first year is expected to be 35%. This has been adjusted for 2020/21 to reflect 2 months uptake in line with the NICE constitution that requires compliance with guidance recommendations within 3 months of guidance publication. This will continue in 2021/22 until maximum uptake of 75% is achieved.
- Cetuximab with platinum and 5-FU chemotherapy or chemotherapy (platinum and 5-FU) alone are the only comparators for pembrolizumab.
- Treatment costs for cetuximab with platinum and 5-FU chemotherapy, and chemotherapy (platinum and 5-FU) alone include chemotherapy delivery costs of £479 on day 1 of every treatment cycle (Healthcare resource group SB14Z: Deliver Complex Chemotherapy, including Prolonged Infusional Treatment, at First Attendance) and £319 for each subsequent administration in the cycle (Healthcare resource group SB15Z Deliver Subsequent Elements of a Chemotherapy Cycle). Taken from NHS national tariff 2020/21.
- Treatment costs for pembrolizumab includes chemotherapy delivery costs of £160 on day 1 of every treatment cycle (Healthcare resource group SB12Z: Deliver simple parenteral chemotherapy at first Attendance) Taken from NHS national tariff 2020/21.
- There are no other additional costs needed to identify people with a combined positive score of 1 or more (CPS≥ 1) as this is assumed to be current practice already.

Other factors

4.4 The guidance recommends pembrolizumab is stopped at 2 years of uninterrupted treatment, or earlier if disease progresses. The

model uses average treatment costs for each year. This is assumed to account for any treatment costs extending over a year or under a year. Based on the economic model by the company the average length of a course of treatment with pembrolizumab is 11.58 cycles (7.99 months).

About this resource impact report

This resource impact report accompanies the NICE guidance on Pembrolizumab for untreated metastatic or unresectable recurrent head and neck squamous cell carcinoma and should be read with it.