NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Nivolumab with platinum- and fluoropyrimidine-based chemotherapy for untreated HER2-negative advanced gastric, gastro-oesophageal junction or oesophageal adenocarcinoma (TA857)

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Summary

NICE has recommended nivolumab with platinum- and fluoropyrimidine-based chemotherapy as an option for treating untreated HER2-negative, advanced or metastatic gastric, gastro-oesophageal junction or oesophageal adenocarcinoma in adults whose tumours express PD-L1 with a combined positive score (CPS) of 5 or more. Nivolumab is only recommended if the company provides it according to the commercial arrangement (see section 2 of the guidance).

By 2026/27 we estimate that:

- 2,300 people with untreated HER2-negative, advanced or metastatic gastric, gastro-oesophageal junction or oesophageal adenocarcinoma whose tumours express PD-L1 with a combined positive score (CPS) of 5 or more are eligible for treatment with nivolumab with chemotherapy after adjusting for expected population growth.
- 690 people will receive nivolumab with chemotherapy in 2026/27 after adjusting for expected population growth as shown in table 1.

Table 1 Estimated number of people in England receiving nivolumab with chemotherapy after adjusting for population growth

	2022/23	2023/24	2024/25	2025/26	2026/27
Uptake rate for nivolumab with chemotherapy (%)	16	20	30	30	30
Population receiving nivolumab with chemotherapy each year	340	450	680	680	690

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 with platinum- and fluoropyrimidine-based chemotherapy as an option for treating untreated HER2-negative, advanced or metastatic gastric, gastro-oesophageal junction or oesophageal adenocarcinoma in adults whose tumours express PD-L1 with a combined positive score (CPS) of 5 or more. Nivolumab is only recommended if the company provides it according to the commercial arrangement (see section 2 of the guidance).

1.2 Current practice is for people to receive treatment using either the platinum based chemotherapy XELOX (oxaliplatin plus capecitabine) or the platinum and fluoropyrimidine-based chemotherapy FOLFOX (oxaliplatin plus leucovorin and fluorouracil). This recommendation allows nivolumab to be added to these existing therapies.

1.3 The appraisal committee was shown evidence that the addition of nivolumab to the FOLFOX and XELOX regimens improved progression free survival and overall survival.

2 Resource impact of the guidance

2.1 By 2026/27 we estimate that:

- 2,300 people with untreated HER2-negative, advanced or metastatic gastric, gastro-oesophageal junction or oesophageal adenocarcinoma whose tumours express PD-L1 with a combined positive score (CPS) of 5 or more are eligible for treatment with nivolumab plus chemotherapy after adjusting for expected population growth.
- 690 people will receive nivolumab plus chemotherapy in 2026/27 after adjusting for expected population growth.

- There will be around 3,300 additional administrations per year as a result of the longer time on treatment when nivolumab is added to the chemotherapy regimens.

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 receive nivolumab with chemotherapy by financial year.

Table 2 Estimated number of people receiving nivolumab with chemotherapy using NICE assumptions after adjusting for population growth

	2022/23	2023/24	2024/25	2025/26	2026/27
Uptake rate for nivolumab with chemotherapy (%)	16	20	30	30	30
Population receiving nivolumab with chemotherapy each year	340	450	680	680	690

2.3 The number administrations per year and the relative complexity is based on uptake and the treatment duration observed in the company trial. Table 3 shows the number of administrations estimated per year for the entire eligible population by complexity of administration (based on HRG).

Table 3 Estimated number of administrations using NICE assumptions after adjusting for population growth

	Regimen	2022/23	2023/24	2024/25	2025/26	2026/27
SB14Z Deliver Complex Chemotherapy, including Prolonged Infusional Treatment, at First Attendance	Nivo+XELOX Nivo+FOLFOX FOLFOX	16,300	17,300	19,300	19,400	19,500
SB13Z Deliver More Complex Parenteral Chemotherapy, at First Attendance	XELOX	6,400	6,000	5300	5,300	5,400

2.4 This report is supported by a local resource impact template. Nivolumab has an agreed patient access scheme which makes it available with a commercial-in-confidence discount to the list price. The discounted price of nivolumab can be put into the template and other variables may be amended.

3 Implications for commissioners

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

3.2 The average time on treatment for nivolumab with chemotherapy compared with chemotherapy alone is longer and there will be more administrations required. Additionally adding nivolumab as a second intravenous infusion to the existing chemotherapy regimens increases the complexity of the administration. This represents an increase in required capacity to deliver chemotherapy.

3.3 Nivolumab plus chemotherapy falls within the programme budgeting category 02B, Cancer, upper GI.

4 How we estimated the resource impact

The population

4.1 By 2026/27 there will be around 5,300 diagnoses of gastric or gastro-oesophageal junction cancer each year in England, of these around 3,500 people (66.9%) will have stage III or IV disease on diagnosis. Around 1,700 people (33.1%) will have stage I or II disease of which 570 (33%) will progress to stage III disease, giving a total of 4,100 people with stage III or IV gastric or gastro-oesophageal junction cancer each year.

4.2 Of people with stage III or IV disease around 3,400 (82%) will have HER2 negative disease and of these around 1,600 (47.5%) will have first-line treatment. Around 1,000 people (60.4%) will have tumours that express PD-L1 with a combined positive score ≥5.

4.3 There will also be around 7,500 diagnoses of oesophageal cancer each year, of which 7,000 (93.0%) will have stage II, III or IV disease. Of these around 4,800 people (69%) will have adenocarcinoma. Around 4,000 (82%) of people with adenocarcinoma will have HER2 negative disease and of these around 2,200 (55.5%) will have first line treatment. Of these, around 1,300 people (60.4%) will have tumours that express PD-L1 with a combined positive score ≥5.

4.4 This gives a total eligible population of 1,000 people with gastric or gastro-oesophageal junction cancer and 1,300 with oesophageal cancer for an overall total of 2,300 people each year.

Table 4 Number of people eligible for treatment in England

	Population	Proportion of previous row (%)	Number of people in 2026/27
a	Adult population		46,263,200
b	Incidence of gastric or gastro-oesophageal junction cancer[1]	0.01	5,300
c	Proportion of people with stage III or IV disease on diagnosis[2]	66.9	3,500
d	Proportion of people with stage I or II disease on diagnosis[2]	33.1 of b	1,700
e	Proportion of people who progress to stage III disease[2]	33	570
f	Total treatable advanced or metastatic gastric or gastro-oesophageal junction cancer	c+e	4,100
g	Proportion of people with HER2 negative disease[3]	82	3,400
h	Proportion of people who receive first line therapy[4]	47.5	1,600
i	**Proportion of people whose tumours express PD-L1 with a combined positive score ⩾5[5]**	**60.4**	**1,000**
j	Incidence of oesophageal cancer[1]	0.02	7,500
k	Proportion of people with stage II, III or IV disease on diagnosis[2]	93.1	7,000
l	Proportion of people with adenocarcinoma[3]	69	4,800
m	Proportion of people with HER2 negative disease[3]	82	4,000
n	Proportion of people who receive first line treatment[6]	55.5	2,200
o	**Proportion of people whose tumours express PD-L1 with a combined positive score ⩾5[5]**	**60.4**	**1,300**
	Total number of people eligible for treatment with nivolumab with chemotherapy	**i+o**	**2,300**
	Total number of people estimated to receive nivolumab by 2025/26	**30**	**690**
	[1] Source: Cancer Registration Statistics, England 2020 - NHS Digital [2] Source: CRUK Early diagnosis Hub (shinyapps.io) [3] Source: Company submission [4] Source: Stomach cancer treatment statistics, Cancer Research UK [5] Source: Company trial data (955 of 1,581 people in the trial had CPS ≥5) [6] Source: Oesophageal cancer treatment statistics, Cancer Research UK		

Assumptions

4.5 The resource impact template assumes that:

- XELOX based regimens (XELOX and nivolumab plus XELOX) are administered every 3 weeks, FOLFOX based regimens (FOLFOX and nivolumab plus FOLFOX) are administered every 2 weeks.
- Nivolumab based regimens (nivolumab plus XELOX, nivolumab plus FOLFOX) and FOLFOX administration costs are based on HRG SB14Z Deliver Complex Chemotherapy, including Prolonged Infusional Treatment, at First Attendance.
- XELOX administration costs are based on SB13Z Deliver More Complex Parenteral Chemotherapy, at First Attendance.
- Uptake of XELOX and FOLFOX based regimens both with and without nivolumab are assumed to be equal so the two nivolumab regimens have 15% market share each and the two chemotherapy only regimens have 35% market share each at steady state from year 3 onwards. This may be different in practice with XELOX regimens possibly being favoured over FOLFOX because they require fewer administrations. This can be amended by users of the template to reflect local practice.
- Where proportions locally vary to the rates assumed in the template and in table 4, these can be amended in the resource impact template.

About this resource impact report

This resource impact report accompanies the NICE guidance on Nivolumab with platinum- and fluoropyrimidine-based chemotherapy for untreated HER2-negative advanced gastric, gastro-oesophageal junction or oesophageal adenocarcinoma and should be read with it.