NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Neratinib for extended adjuvant treatment of hormone receptor-positive, HER2-positive early stage breast cancer after adjuvant trastuzumab (TA612)

Published: November 2019

Summary

NICE has recommended neratinib for hormone receptor positive, HER2 positive early stage breast cancer (see section 1.1 for conditions).

We estimate that:

- 500 people with early breast cancer are eligible for treatment with neratinib
- 400 people will have neratinib from year 3 onwards once uptake has reached 80% as shown in table 1.

Table 1 Estimated number of people in England having neratinib

	2019/20	2020/21	2021/22	2022/23	2023/24
Population having neratinib each year	50	170	400	400	400

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

1.1 NICE has recommended neratinib as an option for the extended adjuvant treatment of hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-positive early stage breast cancer in adults who completed adjuvant trastuzumab-based therapy less than 1 year ago only if:

- trastuzumab is the only HER2-directed adjuvant treatment they have had, and
- if they had neoadjuvant chemotherapy-based regimens, they still had residual invasive disease in the breast or axilla following the neoadjuvant treatment, and
- the company provides neratinib according to the commercial arrangement.

1.2 Current adjuvant treatments are HER2-directed therapies (either trastuzumab or trastuzumab in combination with pertuzumab) with chemotherapy. Neratinib is a HER2-directed oral treatment with a marketing authorisation in a new place in early breast cancer pathway. It is given in the extended adjuvant setting after 1 year of treatment with trastuzumab

1.3 Neratinib has a high rate of diarrhoea as an adverse event, but clinical experts advised the committee that the symptoms could be managed with prophylaxis and diarrhoeal treatments in most cases.

2 Resource impact of the guidance

2.1 We estimate that:

- 500 people with early breast cancer are eligible for treatment with neratinib
- 400 people will have neratinib from year 3 onwards once uptake has reached 80%.

2.2 The current treatment and future uptake figure assumptions are based on company supplied data and are shown in the resource impact template. Table 2 shows the number of people in England who are estimated to have neratinib by financial year.

Table 2 Estimated number of people having neratinib using NICE assumptions

	2019/20	2020/21	2021/22	2022/23	2023/24
Population having neratinib each year	50	170	400	400	400

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

Savings and benefits

2.4 Clinical trial evidence shows women who have treatment with neratinib have less risk of disease recurrence than women who have treatment with standard care.

2.5 Based on list price, the average saving per person is around £1,800 per year in associated costs of disease recurrence. These savings have been built into the resource impact model. However, neratinib is associated with higher treatment and monitoring costs so this saving simply reduces the total cost of using neratinib.

3 Implications for commissioners

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

3.2 Neratinib falls within the programme budgeting category 02F cancers and tumours, cancer - breast.

4 How we estimated the resource impact

The population

4.1 There are around 45,800 cases of breast cancer each year in England, around 36,600 of these cases will be invasive breast cancer, and 34,400 will be stage I, II or III at diagnosis. Around 24,100 of women with stage I, II or III breast cancer on diagnosis will survive to disease progression and about 19,500 will have surgery. Of these around 18,000 will be tested for HER2 status and of these around 2,700 will have HER2 positive disease.

4.2 Around 1,800 women with HER2-positive disease will also have hormone receptor-positive disease and of these around 1,250 will have node positive disease of which around 60 will be treated with trastuzumab with the remaining node positive population having trastuzumab in combination with pertuzumab. The remaining 550 women with node-negative disease will have trastuzumab in the adjuvant setting. Of women who have a course of adjuvant trastuzumab, around 500 will have a full year of treatment and be eligible for neratinib.

Table 3 Number of people eligible for treatment in England

	Population	Proportion of previous row (%)	Number of people
a	Total population		54,786,327
b	Adult population		43,752,473
c	Incidence of breast cancer[1]	0.1	45,800
d	Proportion of women with invasive disease[2]	80	36,600
e	Proportion of women with early cancer (stage I, II or III) at diagnosis[3]	94	34,400
f	Proportion of women who survive to disease progression[4]	70	24,100
g	Proportion of women who have surgery[5]	81	19,500
h	Proportion of women who are tested for human epidermal growth factor receptor 2 (HER2)[6]	92	18,000
i	Proportion of women tested who have HER2 positive disease[6]	15	2,700
j	Proportion of women who have HER2+ and hormone receptor positive disease[10]	66	1,800
k	Proportion of women with lymph node negative disease[7]	31 of j	550
l	Proportion of women with lymph node positive disease[7]	69 of j	1,250
m	Proportion of women with node positive disease who have trastuzumab in the adjuvant setting[8]	5 of l	60
n	Total number of women who have trastuzumab in the adjuvant setting	k+m	610
o	Women who have a full year treatment cycle of trastuzumab and are eligible for treatment with neratinib[9]	81.2	500
p	Total number of people estimated to have neratinib each year from year 3[8]	80	400

[1] Source: https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/bulletins/cancerregistrationstatisticsengland/2017

[2] Source: https://www.breastcancer.org/symptoms/types/idc

[3] Source: http://www.ncin.org.uk/publications/survival_by_stage

[4] Source: https://www.nice.org.uk/guidance/ta495/resources

[5] Source: https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/breast-cancer

[6] Source: https://www.nice.org.uk/guidance/ta424/resources

[7] Source: https://www.nice.org.uk/guidance/ta569/resources

[8] Source: Clinical opinion

[9] Source: Webster et al; 2012, NJC

[10] Source: Company submission

5 Other considerations

5.1 Treatment with neratinib requires additional monitoring which will be done in GP practices, the additional GP appointments have not been included in the resource impact model as GP practices are reimbursed based on list size and not activity. A full course of treatment with neratinib would involve on average 11 GP monitoring appointments.

About this resource impact report

This resource impact report accompanies the NICE guidance on Neratinib for extended adjuvant treatment of hormone receptor-positive, HER2-positive early stage breast cancer after adjuvant trastuzumab and should be read with it.