NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Ribociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer (TA496)

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Summary

NICE has recommended ribociclib as an option for treating hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer in post-menopausal women.

We estimate that:

- 7,500 women with HR-positive, HER2-negative, locally advanced or metastatic breast cancer are eligible for treatment with ribociclib per year.
- 900 women will have ribociclib from year 3 onwards once uptake of CDK inhibitor therapy has reached 50%. Of these 50%, 30% of women are assumed to take ribociclib from 2019/20 onwards as shown in table 1.

Table 1 Estimated number of women in England having ribociclib

	2017/18	2018/19	2019/20	2020/21	2021/22
Population having ribociclib each year	180	550	910	910	910

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

1.1 NICE has recommended ribociclib as an option for treating hormone receptor-positive (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer in post-menopausal women.

1.2 NICE recommends endocrine therapy (such as aromatase inhibitors) as the first line treatment for the majority of women with metastatic HR-positive HER2-negative breast cancer.

1.3 The evidence presented to the appraisal committee by Novartis showed that combining ribociclib (a CDK inhibitor) with letrozole (an aromatase inhibitor) gave a gain in progression survival when compared with letrozole alone.

2 Resource impact of the guidance

2.1 We estimate that:

- 7,500 women with HR-positive HER2-negative metastatic breast cancer are eligible for treatment with ribociclib each year.
- 900 women will have ribociclib from year 3 onwards once uptake of CDK inhibitors has reached 50% and 30% of these women take ribociclib.

2.2 The current treatment and future uptake figure assumptions are based on clinical expert opinion and submissions received by the manufacturer and are shown in the resource impact template. Table 2 shows the number of women in England who are estimated to have ribociclib by financial year.

Table 2 Estimated number of women having ribociclib using NICE assumptions

	2017/18	2018/19	2019/20	2020/21	2021/22
Population having ribociclib each year	180	550	910	910	910

2.3 This report is supported by a local resource impact template. Ribociclib has a patient access scheme, agreed between the Department of Health and Novartis, which makes it available with a commercial-in-confidence discount to the list price. The discounted price of ribociclib can be put into the template and other variables may be amended. For enquiries about the patient access scheme contact commercial.team@novartis.com

3 Implications for commissioners

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

3.2 Ribociclib falls within the programme budgeting category 02F cancer, breast.

4 How we estimated the resource impact

The population

4.1 The annual incidence of breast cancer is 0.08% (approximately 45,800 women per year in England).

- 90% of these women will have invasive disease.
- 95% of these women will have early and locally advanced disease.

- 70% of women with early and locally advanced disease will survive to disease progression.
- 35% of these women will progress to advanced disease which means that around 9,600 women in England each year progress to advanced or metastatic disease.
- In addition to this, 5% of women will have advanced disease at diagnosis which is around 2,100 women in England for a total of around 11,600 women per year in England with advanced disease.
- 64% of women with advanced disease will have hormone receptor positive, human epidermal growth factor receptor 2 negative disease and will be eligible for treatment with a CDK inhibitor.

Table 3 Number of women eligible for treatment in England

Population	Proportion of previous row (%)	Number of women
Total population		54,786,327
Incidence of breast cancer[1]	0.08	45,800
Women with invasive disease[2] (a)	90	41,200
Women with early and locally advanced disease[2]	95	39,100
Women who survive until disease progression[2]	70	27,400
Women with advances or metastatic disease[2] (b)	35	9,600
Plus: Women with advanced or metastatic disease at diagnosis[2] (5% of a) (c)	5	2,100
Total number of women with advanced or metastatic disease (b+c)		11,600
Women with hormone receptor positive human epidermal growth factor receptor 2 negative disease who are eligible for treatment with CDK inhibitor[3]	64	7,500
Total number of women estimated to have a CDK inhibitor each year from year 3[4]	50	3,700
Post-menopausal women[1]	81	3,000
Total number of women estimated to have ribociclib each year from year 3[4]	30	910

[1] Source: Cancer registration statistics England, 2015

[2] Source: Company submissions

[3] Source: De Koven et al, 2012, Howlader et al, 2014

[4] Source: Combination of clinical opinion and company market share projections

Assumptions

4.2 The resource impact template assumes that:

- No chemotherapy is given as a first line treatment for advanced or metastatic breast cancer
- Endocrine therapy is given as the first line treatment

- Letrozole is the only aromatase inhibitor used in the template both as monotherapy and in combination with a CDK inhibitor.
- The market share of the CDK inhibitors in post-menopausal women is 70% for palbociclib and 30% for ribociclib. This is based on clinical expert opinion and information received from NHS England.
- The resource impact template uses the maximum dose for ribociclib this is the 600mg per day dose, for which the pack size is 63 200mg tablets. Novartis also has smaller pack sizes for 400mg per day and 200mg per day doses which contain 42 and 21 tablets respectively. Using the smaller doses will reduce the cost of treatment with ribociclib.

Other factors

4.3 Treating women with ribociclib will delay the use of subsequent therapies when compared with letrozole monotherapy as progression-free survival is greater.

About this resource impact report

This resource impact report accompanies the NICE guidance on Ribociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer and should be read with it.