

Putting NICE guidance into practice

Resource impact report: Darolutamide with androgen deprivation therapy for treating hormone-relapsed non- metastatic prostate cancer (TA660)

Published: November 2020

Summary

NICE has recommended darolutamide with androgen deprivation therapy (ADT), within its marketing authorisation, as an option for treating hormone-relapsed prostate cancer in adults at high risk of developing metastatic disease in adults only if the company provides darolutamide according to the commercial arrangement.

We estimate that:

- 600 people with hormone-relapsed prostate cancer at high risk of developing metastatic disease are eligible for treatment with darolutamide each year
- 480 people will commence treatment with darolutamide each year from 2023/24 onwards once uptake has reached 80% as shown in table 1. Around 850 people will have darolutamide as a second or third-year treatment by year 2024/25.

Table 1 Estimated number of people in England receiving darolutamide

Population receiving darolutamide each year	2020/21	2021/22	2022/23	2023/24	2024/25
First year	40 ¹	260	370	480	480
Second and third year	0	40	300	630	850
Total	40	300	670	1,110	1,330

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 darolutamide has a discount that is commercial in confidence. The discounted price of darolutamide can be put into the template and other variables may be amended.

This technology is commissioned by NHS England. Providers are NHS trust hospitals.

1 Darolutamide

- 1.1 NICE has recommended darolutamide with androgen deprivation therapy (ADT), within its marketing authorisation, as an option for treating hormone-relapsed prostate cancer in adults at high risk of developing metastatic disease in adults only if the company provides darolutamide according to the commercial arrangement.
- 1.2 Current treatment for hormone-relapsed non-metastatic prostate cancer is to continue treatment with androgen deprivation therapy, even though the cancer may not be responding to it
- 1.3 Darolutamide prolongs the time until metastasis develop, which is expected to have a positive impact on patients' lives.

2 Resource impact of the guidance

- 2.1 We estimate that:
- 600 people with hormone-relapsed prostate cancer at high risk of developing metastatic disease are eligible for treatment with darolutamide each year.
 - 480 people commence treatment with darolutamide each year from 2023/24 onwards once uptake has reached 80%. Around 850 people will have darolutamide as a second or third-year treatment by year 2024/25.
- 2.2 The current treatment and future uptake figure assumptions are based on the company submission and NHS England 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 darolutamide by financial year.

Table 2 Estimated number of people receiving darolutamide using NICE assumptions

Population receiving darolutimde each year	2020/21	2021/22	2022/23	2023/24	2024/25
First year	40 ¹	260	370	480	480
Second and third year	0	40	300	630	850
Total	40	300	670	1,110	1,330
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. Darolutamide has an agreed patient access scheme which makes it available with a commercial-in-confidence discount to the list price. The discounted price of darolutamide can be put into the template and other variables may be amended. For enquiries about the patient access scheme contact: access.team@bayer.com.

3 Implications for commissioners

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

3.2 Darolutamide falls within the programme budgeting category PBC02H: Cancer, Urological.

4 How we estimated the resource impact

The population

4.1 In 2017, around 41,200 new cases of adults with prostate cancer were recorded in England ([Office for National Statistics, 2017](#)).

4.2 Table 3 shows the number of adults with hormone-relapsed prostate cancer at high risk of developing metastatic disease who are eligible for treatment with darolutamide.

Table 3 Number of people eligible for treatment in England

Population	Proportion of previous row (%)	Number of people
Adult population		44,022,560
Incidence of prostate cancer ¹	0.09	41,200
Proportion of people who have hormone-relapsed prostate cancer ²	15	6,180
Proportion of people who have hormone-relapsed non-metastatic prostate cancer ²	16	990
Proportion of people with hormone-relapsed non-metastatic prostate cancer that are at high risk of developing metastatic disease therefore eligible for treatment with darolutamide ³	60	600
Total number of people estimated to commence treatment with darolutamide each year from year 2023/24 ³	80	480
<p>¹ Office for National Statistics, 2017</p> <p>² Company submission: Kirby M, Hirst C, Crawford ED. Characterising the castration-resistant prostate cancer population: a systematic review. <i>Int J Clin Pract.</i> 2011;65(11):1180-92.</p> <p>³ NHS England clinical experts and company submission</p>		

Assumptions

4.3 The resource impact template assumes that:

- Uptake during the first year is expected to be 40%. 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 and 2022/23 until maximum uptake of 80% is achieved.
- The comparator treatments are androgen deprivation therapy (ADT) alone. The ADT drugs are also used in combination with darolutamide.
- Using darolutamide has no incremental effect on the treatment or administration costs of ADT when used alone or in addition to

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darolutamide. Therefore, the relevant costs considered in the model are for darolutamide only.

- The treatment cost for darolutamide include an oral administration cost of £128 per cycle (Healthcare resource group: SB11Z Deliver Exclusively Oral Chemotherapy). Taken from [NHS national tariff 2020/21](#).
- The average length of a course of treatment is not known. However, based on [The New England Journal of Medicine, 2019](#), the metastasis-free survival was 40.4 months on darolutamide plus ADT. This has been rounded down to 3 years for simplicity and used in the template.

About this resource impact report

This resource impact report accompanies the NICE guidance on [Darolutamide with androgen deprivation therapy for treating non-metastatic hormone-relapsed prostate cancer](#) and should be read with it.

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