NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Darolutamide with androgen deprivation therapy and docetaxel for treating hormone-sensitive metastatic prostate cancer (TA903)

Published: June 2023

Summary

NICE has recommended darolutamide with docetaxel within its marketing authorisation, as an option for treating hormone-sensitive metastatic prostate cancer in adults. Darolutamide is only recommended if the company provides it according to the commercial arrangement.

We estimate that around:

- 6,040 adults with hormone-sensitive metastatic prostate cancer are eligible for treatment with darolutamide plus androgen deprivation therapy (ADT) and docetaxel each year based on expected population growth.
- around 1,510 adults will start treatment with darolutamide plus ADT and docetaxel each year by 2027/28 after adjusting for expected population growth.

Table 1 Estimated number of people in England receiving treatment with darolutamide plus ADT and docetaxel each year

	2023/24	2024/25	2025/26	2026/27	2027/28
Uptake %	10	18	25	25	25
People starting treatment with darolutamide plus ADT and docetaxel	593	1,042	1,496	1,504	1,510
People continuing treatment with darolutamide plus ADT and docetaxel from previous years	0	593	1,635	3,131	4,635
Total number of people	**593**	**1,635**	**3,131**	**4,635**	**6,145**
It is anticipated that people receive treatment for 41 months on average, so there will be people receiving treatment who started treatment in a previous year. The template includes the average treatment duration rather than applying discontinuation rates.					

This report is supported by a local resource impact template. This is because the company has a commercial arrangement which makes darolutamide available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

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

1 Darolutamide with androgen deprivation therapy and docetaxel

1.1 NICE has recommended darolutamide with docetaxel within its marketing authorisation, as an option for treating hormone-sensitive metastatic prostate cancer in adults. Darolutamide is only recommended if the company provides it according to the commercial arrangement.

1.2 Usual treatment for hormone-sensitive metastatic prostate cancer always includes ADT which may be given alone, or with docetaxel or enzalutamide. Darolutamide plus ADT and docetaxel would be another treatment option.

1.3 Clinical trial evidence shows that, compared with ADT and docetaxel, people taking darolutamide plus ADT and docetaxel live longer, and have longer before their cancer gets worse or stops responding to ADT.

1.4 Patient and clinical experts would welcome an additional treatment option for hormone-sensitive metastatic prostate cancer. The patient experts stated that an increasing number of people have metastatic prostate cancer at their initial diagnosis, which is associated with a worse prognosis.

1.5 A clinical expert noted that having darolutamide plus ADT and docetaxel in the hormone-sensitive metastatic stage limits treatment options in the hormone-relapsed metastatic stage. This is because an anti-androgen (apalutamide, darolutamide or enzalutamide) would have already been used in the hormone-sensitive metastatic stage, and NHS practice is to only use an anti-androgen once in the treatment pathway. The template reflects this in the subsequent treatment options.

2 Resource impact of the guidance

2.1 We estimate that:

- around 6,040 adults with hormone-sensitive metastatic prostate cancer are eligible for treatment with darolutamide plus ADT and docetaxel each year based on expected population growth.
- around 1,510 adults will start treatment with darolutamide plus ADT and docetaxel each year by 2027/28 after adjusting for expected population growth.

Table 2 Estimated number of people in England receiving treatment with darolutamide plus ADT and docetaxel using NICE assumptions

	2023/24	2024/25	2025/26	2026/27	2027/28
Uptake %	10	18	25	25	25
People starting treatment with darolutamide plus ADT and docetaxel	593	1,042	1,496	1,504	1,510
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2.2 This report is supported by a local resource impact template. This is because the company has a commercial arrangement which makes darolutamide available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

Savings and benefits

2.3 A patient expert explained that, apart from feeling weak for a few days after each docetaxel dose, darolutamide plus ADT and docetaxel was well tolerated and did not otherwise affect usual daily activities.

2.4 The use of darolutamide might also help to reduce visits to hospital for chemotherapy and make better use of clinical capacity as it is an oral medication which people can take at home.

3 Implications for commissioners and providers

3.1 Darolutamide is commissioned by NHS England. Providers are NHS hospital trusts.

3.2 Darolutamide falls within the programme budgeting category 02H – Cancers and Tumours, Cancer, Urological.

4 How we estimated the resource impact

The population

4.1 The Cancer Registration Statistics, England 2019 (C61, malignant neoplasm of prostate) estimated that in 2019 there were around 47,500 new cases of adults with prostate cancer in England. Applying population growth, this is expected to rise to 49,400 by 2027/28.

4.2 The National Prostate Cancer Audit: Annual Report 2021 estimated 13% of those diagnosed with prostate cancer had metastatic hormone-sensitive prostate cancer (mHSPC).

4.3 Of those with non-metastatic hormone-sensitive prostate cancer the company submission estimated 3.80% would progress to have metastatic hormone-sensitive prostate cancer.

4.4 Clinical experts estimated docetaxel would be suitable for 75% of these patients.

4.5 Table 3 shows the total number of people with hormone-sensitive metastatic prostate cancer who are eligible to start treatment each year with darolutamide.

Table 3 Number of people eligible to start treatment in England each year

Population	Proportion of previous row (%)	Number of people
Adult population forecast at 2027/28		46,263,200
Incidence of prostate cancer 2027/28[1]	0.11%	49,408
People diagnosed with metastatic hormone-sensitive prostate cancer (mHSPC)[2] **(A)**	13.00%	6,423
People diagnosed with non-metastatic hormone-sensitive prostate cancer (nmHSPC)[2]	87.00%	42,985
People diagnosed with nmHSPC who progress to have mHSPC[3] **(B)**	3.80%	1,633
Those with metastatic hormone-sensitive prostate cancer (mHSPC) **(A+B)** where docetaxel is suitable[4]	75.00%	6,042

[1] Cancer Registration Statistics, England 2019 (C61, malignant neoplasm of prostate)

[2] The National Prostate Cancer Audit: Annual Report 2021

[3] Company submission

[4] Clinical expert opinion

Assumptions

4.6 The resource impact template assumes that:

- Usual treatment for hormone-sensitive metastatic prostate cancer always includes androgen deprivation therapy (ADT), which may be given alone, or with docetaxel or enzalutamide.
- Treatment with darolutamide is to be maintained until disease progression or toxicity that is not tolerated. The average treatment duration with darolutamide is estimated to be 41 months. The template includes this average duration rather than applying discontinuation rates. The same approach is used for comparator treatments.
- Administration costs in clinic are based on the 2023-25 NHS Payment Scheme, 2023/24 prices workbook.
- Based on clinical trials data from TA712, people treated with ADT alone or docetaxel plus ADT may go on to receive enzalutamide plus ADT. The costs and treatment are shown in the resource impact template and can be amended on the unit cost tab.
- The recommended dose of darolutamide is 600 mg (two 300 mg film-coated tablets) taken orally, twice daily, equivalent to a total daily dose of 1,200 mg.
- Clinical opinion stated an ECG will be required before treatment with darolutamide. After treatment with docetaxel has finished additional blood tests may also be required at the standard 3-monthly assessments although many oncologists request them anyway to monitor the cancer. Any additional chemotherapy supervision appointments can be modelled in the template.

About this resource impact report

This resource impact report accompanies the NICE technology appraisal guidance on darolutamide with androgen deprivation therapy and docetaxel for treating hormone-sensitive metastatic prostate cancer and should be read with it. See terms and conditions on the NICE website.