

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

**Abiraterone (originator and generics) for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer (review of TA721) [ID6378]**

**Final scope**

**Remit/evaluation objective**

To appraise the clinical and cost effectiveness of abiraterone within its marketing authorisation for treating newly diagnosed high risk metastatic hormone-naïve prostate cancer.

**Background**

Prostate cancer is a condition in which tumours develop in the prostate, a gland in the male reproductive system.<sup>1</sup> The exact cause is unknown but environmental and genetic factors are associated with an increased risk of developing prostate cancer.<sup>2</sup>

The incidence of prostate cancer increases with age and is higher in people of black African-Caribbean family origin and people with a family history of the condition.<sup>2</sup> 54,628 people were diagnosed with prostate cancer in England during 2023<sup>3</sup>. Between 2020 to 2021, 19% of people diagnosed in England had metastatic disease, that is, disease that has spread to other parts of the body (for example, the bones).<sup>4</sup>

[NICE guideline \(NG\)131](#) recommends androgen deprivation therapy (luteinising hormone-releasing hormone agonist therapy, bicalutamide monotherapy or bilateral orchidectomy) for people whose prostate cancer is sensitive to such hormonal therapy. For metastatic (or advanced) hormone sensitive prostate cancer, NICE technology appraisal guidance (TA)[995](#) recommends relugolix as an alternative androgen deprivation therapy. Docetaxel can also be added within 12 weeks of starting androgen deprivation therapy. Newer hormonal treatments, enzalutamide, apalutamide and darolutamide (with docetaxel) are also recommended as treatment options with androgen deprivation therapy in people with metastatic prostate cancer (NICE TA[712](#), [741](#) and [903](#) respectively). However, apalutamide is only recommended if docetaxel is not suitable. Abiraterone (originator) with prednisone or prednisolone and androgen deprivation therapy is not recommended for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer (NICE TA[721](#)).

**The technology**

Abiraterone (Zytiga, J&J Innovative Medicines) has a UK marketing authorisation for treating newly diagnosed high risk metastatic hormone sensitive prostate cancer in adults in combination with androgen deprivation therapy. Generic versions of abiraterone are also available.

<b>Intervention(s)</b>	Abiraterone with prednisolone and androgen deprivation therapy
<b>Population(s)</b>	Adults with newly diagnosed high risk metastatic hormone-naïve prostate cancer
<b>Comparators</b>	<p>Traditional standard of care treatments:</p> <ul style="list-style-type: none"> <li>• androgen deprivation therapy alone (including orchidectomy, luteinising hormone-releasing hormone agonist therapy or monotherapy with bicalutamide)</li> <li>• relugolix</li> <li>• docetaxel with androgen deprivation therapy</li> </ul> <p>Novel hormonal agents:</p> <ul style="list-style-type: none"> <li>• enzalutamide with androgen deprivation therapy</li> <li>• apalutamide with androgen deprivation therapy</li> <li>• darolutamide with docetaxel and androgen deprivation therapy</li> <li>• darolutamide with androgen deprivation therapy (subject to NICE evaluation)</li> </ul>
<b>Outcomes</b>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> <li>• overall survival</li> <li>• progression-free survival</li> <li>• response rate</li> <li>• adverse effects of treatment</li> <li>• health-related quality of life.</li> </ul>

<p><b>Economic analysis</b></p>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost comparison may be carried out.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.</p> <p>The availability and cost of biosimilar and generic products should be taken into account.</p>
<p><b>Other considerations</b></p>	<p>Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.</p>
<p><b>Related NICE recommendations</b></p>	<p><b>Related technology appraisals:</b></p> <p><a href="#">Relugolix for treating hormone-sensitive prostate cancer</a> (2024). NICE Technology appraisal guidance [TA995]</p> <p><a href="#">Darolutamide with androgen deprivation therapy and docetaxel for treating hormone-sensitive metastatic prostate cancer</a> (2023). NICE Technology appraisal guidance [TA903]</p> <p><a href="#">Apalutamide with androgen deprivation therapy for treating hormone-sensitive metastatic prostate cancer</a> (2021). NICE Technology appraisal guidance [TA741]. Review date 2024.</p> <p><a href="#">Abiraterone for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer</a> (2021). NICE Technology appraisal guidance [TA721]. Review date 2024.</p> <p><a href="#">Enzalutamide for treating hormone-sensitive metastatic prostate cancer</a> (2021). NICE Technology appraisal guidance [TA712].</p> <p><b>Related technology appraisals in development:</b></p> <p><a href="#">Darolutamide with androgen deprivation therapy for treating hormone-sensitive metastatic prostate cancer</a>. NICE Technology appraisal guidance [TSID 12045].</p>

	<p><a href="#">Niraparib with abiraterone acetate and prednisone for treating hormone-sensitive metastatic prostate cancer</a>. NICE Technology appraisal guidance [TSID 12044].</p> <p><b>Related NICE guidelines:</b></p> <p><a href="#">Prostate cancer: diagnosis and management</a> (2019). NICE guideline [NG131].</p> <p><b>Related quality standards:</b></p> <p><a href="#">Prostate cancer</a> (2015). NICE quality standard [QS91].</p>
<b>Related National Policy</b>	<p>The NHS Long Term Plan, 2019. <a href="#">NHS Long Term Plan</a>. NHS England (2018/2019) <a href="#">NHS manual for prescribed specialist services (2018/2019)</a> Specialist cancer services (adults) [section 105].</p> <p>Department of Health (2016) <a href="#">Department of Health and Social Care, NHS Outcomes Framework 2016-2017</a> Domains 1-5.</p> <p>NHS England (2013) <a href="#">NHS England B14/S/a 2013/14 NHS standard contract for cancer: specialised kidney, bladder and prostate cancer services (adult)</a>.</p> <p>NHS England (2016) <a href="#">Clinical Commissioning Policy Statement: Docetaxel in combination with androgen deprivation therapy for the treatment of hormone naïve metastatic prostate cancer</a></p>

## References

1. Cancer Research UK (2019) [What is prostate cancer?](#) Accessed July 2023.
2. Macmillan Cancer Support (2021) [Potential causes of prostate cancer](#). Accessed July 2023.
3. National Prostate Cancer Audit (2024) [NPCA Quarterly Report January 2021 to December 2023](#)
4. National Prostate Cancer Audit (2024) [State of the Nation Report Infographic](#).