NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Relugolix for treating hormone-sensitive prostate cancer [ID6187]

Final scope

Remit/evaluation objective

To appraise the clinical and cost effectiveness of relugolix within its marketing authorisation for treating hormone-sensitive prostate cancer.

Background

Prostate cancer is a condition in which tumours develop in the prostate, a gland in the male reproductive system. The exact cause is unknown but environmental and genetic factors are associated with an increased risk of developing prostate cancer.[1,2] Prostate cancer can be classified into localised, locally-advanced and metastatic, depending on whether, and how far the cancer has spread. Localised and locally-advanced prostate cancer can be further classified as being at low, intermediate or high risk of progression based on prostate-specific antigen concentration, Gleason score (based on a biopsy) and clinical stage. The description 'hormone-sensitive prostate cancer' refers to a population that includes people with prostate cancer who have not had androgen deprivation therapy, or whose disease is continuing to respond to androgen deprivation therapy.

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.[1] In England, in 2021, 43,378 people were diagnosed with prostate cancer.[3] The age standardised mortality rate for prostate cancer in 2020 was 44.8 for every 100,000 persons.[4]

For people with intermediate or high-risk localised or locally advanced prostate cancer, NICE clinical guideline 131 (NG131) recommends androgen deprivation therapy (also called hormone therapy) as part of their treatment.

For newly diagnosed metastatic prostate cancer, NG131 recommends starting docetaxel chemotherapy within 12 weeks of starting androgen deprivation therapy. The guideline recommends offering bilateral orchidectomy as an alternative to continuous gonadotropin-releasing hormone (GnRH) agonist therapy (a type of androgen deprivation therapy). For people who are willing to accept the adverse impact on overall survival and gynaecomastia (breast swelling) in the hope of retaining sexual function, the guideline recommends offering anti-androgen monotherapy with bicalutamide. NICE technology appraisal 404 recommends degarelix, a GnRH antagonist, for treating advanced hormone-dependent (hormone-sensitive) prostate cancer in people with spinal metastases. Additional options for treating hormone-sensitive metastatic prostate cancer in adults, in combination with androgen deprivation therapy, include enzalutamide (NICE technology appraisal 712), apalutamide (NICE technology appraisal 741; if docetaxel is not suitable), and darolutamide with docetaxel (NICE technology appraisal 903).

The technology

Relugolix (Orgovyx, Accord Healthcare Limited and Myovant Sciences) currently has a marketing authorisation in the UK for "the treatment of adult patients with advanced hormone sensitive prostate cancer."

Intervention(s)	Relugolix
Population(s)	People with hormone-sensitive prostate cancer
Subgroups	• People with advanced hormone-sensitive prostate cancer (locally advanced or metastatic, including biochemical relapse) • People with high-risk localised or locally advanced hormone sensitive prostate cancer in combination with radiotherapy • People with high-risk localised or locally advanced hormone sensitive prostate cancer requiring neo-adjuvant treatment prior to radiotherapy
Comparators	• Androgen deprivation therapy alone (including orchidectomy, GnRH agonists such as leuprorelin, goserelin, triptorelin, and buserelin, and GnRH antagonists such as degarelix)
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • response rate • prostate-specific antigen response • time to prostate-specific antigen progression • adverse effects of treatment • health-related quality of life.

Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. 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. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability and cost of biosimilar and generic products should be taken into account.
Other considerations	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.
Related NICE recommendations	**Related technology appraisals:** Darolutamide with androgen deprivation therapy and docetaxel for treating hormone-sensitive metastatic prostate cancer (2023) NICE technology appraisal guidance [TA903] Apalutamide with androgen deprivation therapy for treating hormone-sensitive metastatic prostate cancer (2021). NICE technology appraisal guidance [TA741]. Review date 2024. Abiraterone for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer (2021). NICE technology appraisal guidance [TA721]. Review date 2024. Enzalutamide for treating hormone-sensitive metastatic prostate cancer (2021). NICE technology appraisal guidance [TA712]. Review date 2024. **Related NICE guidelines:** Prostate cancer: diagnosis and management (2021). [NG131]. **Related interventional procedures:** Biodegradable spacer insertion to reduce rectal toxicity during radiotherapy for prostate cancer (2023). NICE interventional procedures guidance [IPG752].

	Focal therapy using high-intensity focused ultrasound for localised prostate cancer (2023). NICE interventional procedures guidance [IPG756]. Irreversible electroporation for treating prostate cancer (2023). NICE interventional procedures guidance [IPG768]. **Related diagnostic guidance:** MRI fusion biopsy in people with suspected prostate cancer (2023). NICE diagnostic guidance [DG53]. **Related quality standards:** Prostate cancer (2015) NICE quality standard [QS91].
Related National Policy	The NHS Long Term Plan (2019) NHS Long Term Plan NHS England (2018) NHS manual for prescribed specialist services (2018/2019) NHS England (2021) Clinical Commissioning Policy: External beam radiotherapy for patients presenting with hormone sensitive, low volume metastatic prostate cancer at the time of diagnosis NHS England (2016) Clinical Commissioning Policy Statement: Docetaxel in combination with androgen deprivation therapy for the treatment of hormone naïve metastatic prostate cancer NHS England (2013) 2013/14 NHS standard contract for cancer: chemotherapy (adult)

References

1. Cancer Research UK (2022) Prostate cancer risks and causes. Accessed November 2023.
2. Macmillan Cancer Support (2021) Potential causes of prostate cancer. Accessed November 2023.
3. NHS Digital (2023). Cancer Registrations Statistics, England 2021- First release, counts only. Accessed November 2023
4. NHS Digital (2022). Cancer registration statistics, England 2020. Accessed November 2023