NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

Relugolix for treating hormone-sensitive prostate cancer

1 Recommendations

1.1 Relugolix is recommended, within its marketing authorisation, as an option for treating prostate cancer in adults:

- with advanced hormone-sensitive prostate cancer
- alongside radiotherapy for high-risk localised or locally advanced hormone-sensitive prostate cancer
- as neoadjuvant treatment before radiotherapy for high-risk localised or locally advanced hormone-sensitive prostate cancer.

Why the committee made this recommendation

Hormone-sensitive (also called hormone-dependent) prostate cancer is usually treated with androgen deprivation therapy (ADT) such as leuprolide. This may be used alone, or with chemotherapy, radiotherapy or androgen receptor inhibitors. Relugolix is an ADT.

Clinical trial evidence suggests that relugolix is better at reducing testosterone to levels that stop cancer growth in the long term, and reduces the risk of serious cardiovascular events, compared with leuprolide. An indirect treatment comparison suggests that relugolix works as well as other ADTs, but this is uncertain.

The cost-effectiveness estimates are within the range that NICE considers an acceptable use of NHS resources. So, relugolix is recommended.

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2 Information about relugolix

Marketing authorisation indication

2.1 Relugolix (Orgovyx, Accord) is indicated for:

- 'the treatment of adult patients with advanced hormone-sensitive prostate cancer'
- 'the treatment of high-risk localised and locally advanced hormone dependent prostate cancer in combination with radiotherapy'
- 'neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced hormone dependent prostate cancer'.

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the summary of product characteristics for relugolix.

Price

2.3 The proposed list price for relugolix per pack of 30 tablets is commercial in confidence until the guidance is published.

2.4 Costs may vary in different settings because of negotiated procurement discounts.

3 Committee discussion

The evaluation committee considered evidence submitted by Accord, a review of this submission by the external assessment group (EAG), and responses from stakeholders. See the committee papers for full details of the evidence.

The condition

Details of condition

3.1 Hormone-sensitive (also called hormone-dependent) prostate cancer is a cancer that continues to respond to androgen deprivation therapy (ADT). Advanced hormone-sensitive prostate cancer includes cancer that has

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progressed after radical treatment or has a significant risk of progression, or increases risk of death. The patient experts explained that the experience of living with advanced hormone-sensitive prostate cancer varies from person to person. They explained that initial diagnosis causes fear, distress and anxiety for people and their families. The committee concluded that advanced hormone-sensitive prostate cancer can have a substantial effect on quality of life.

Unmet need

3.2 Treatment options for advanced hormone-sensitive prostate cancer depend on several factors such as:

- how advanced the prostate cancer is (localised, locally advanced or metastatic)
- the aggressiveness of the cancer as indicated by Gleason score
- the level of prostate-specific antigen (PSA) in the blood
- the individual's age
- overall health.

Other considerations include previous treatments, individual preference and the potential side effects of existing treatments. The clinical experts explained that the main aim of treatment for advanced hormone-sensitive prostate cancer is to extend life while maintaining quality of life. They commented that ADT reduces circulating testosterone levels and is an effective treatment option for advanced hormone-sensitive prostate cancer. But they noted that currently available ADT drug treatments are given as injections, and are associated with cardiovascular events, initial testosterone surge and prolonged time to testosterone recovery after stopping treatment. The patient experts explained that current ADT drug treatments are also associated with injection site reactions, including infections and swollen and sore injection sites. The patient and clinical experts explained that avoiding injections could greatly improve physical and mental wellbeing, and improve quality of life for people with advanced hormone-sensitive prostate cancer. They agreed that, because relugolix is

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an oral treatment, it may be more convenient for some people than injectable ADT drug treatments. The clinical and patient experts also highlighted that relugolix is associated with faster testosterone recovery times after stopping treatment and reduced risk of cardiovascular events, which may be beneficial for some people. The committee concluded that people with the condition, and their families and healthcare professionals would welcome an additional treatment option for advanced hormone-sensitive prostate cancer.

Clinical management

Population and prescribing setting

3.3 The marketing authorisation indications for relugolix are for:

- advanced hormone-sensitive prostate cancer
- high-risk localised and locally advanced hormone-dependent prostate cancer, in combination with radiotherapy
- high-risk localised or locally advanced hormone-dependent prostate cancer, as neoadjuvant treatment before radiotherapy.

For the second population in the marketing authorisation, the committee considered that relugolix could be used with radiotherapy for treating either high-risk localised or locally advanced hormone-sensitive prostate cancer. In its submission, the company defined advanced hormone-sensitive prostate cancer as high-risk localised, locally advanced, or metastatic prostate cancer including biochemically relapsed cancer. The clinical experts agreed with the company's definition. They clarified that high-risk localised or locally advanced hormone-sensitive prostate cancer would be classified by a Cambridge Prognostic Group score of 4 or 5. The company also explained that it expected relugolix to be used in a primary care setting. The clinical experts commented that relugolix might be started in secondary care but it is likely that it would mostly be used in primary care. The committee questioned whether relugolix would replace ADT in all 3 populations included in the marketing authorisation. The

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clinical experts explained that when ADT is an option in those populations, relugolix would be used as an alternative. They also clarified that some people with biochemically relapsed cancer are not always offered ADT initially. For example, people with oligometastatic disease (fewer than 5 lesions) are usually offered stereotactic radiotherapy, and are then offered ADT if the cancer relapses. The committee noted that relugolix would likely be used mostly in a primary care setting. The committee thought the company's definition of advanced hormone-sensitive prostate cancer was appropriate, and that having another ADT option for each of the 3 populations in the marketing authorisation would offer increased treatment choice.

Treatment pathway

3.4 NICE's guideline on prostate cancer recommends that people with high-risk localised or locally advanced hormone-sensitive prostate cancer are normally offered ADT or radiotherapy. ADT includes surgery to remove both testicles (orchidectomy) and drug treatments such as gonadotrophin-releasing hormone (GnRH) agonists (leuprorelin, triptorelin, goserelin, buserelin). People with hormone-sensitive metastatic prostate cancer are usually offered:

- ADT alone
- ADT with docetaxel with or without prednisolone
- ADT with docetaxel and darolutamide (see NICE's technology appraisal guidance on darolutamide with androgen deprivation therapy and docetaxel for treating hormone-sensitive metastatic prostate cancer)
- ADT with enzalutamide (see NICE's technology appraisal guidance on enzalutamide for treating hormone-sensitive metastatic prostate cancer)
- ADT with apalutamide, if docetaxel is not suitable (see NICE's technology appraisal guidance on apalutamide with androgen deprivation therapy for treating hormone-sensitive metastatic prostate cancer)

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- degarelix for people with spinal metastases (see NICE's technology appraisal guidance on degarelix for treating advanced hormone-dependent prostate cancer, from now TA404).

Comparators

3.5 In NICE's final scope, the relevant comparators listed were ADT alone including orchidectomy, GnRH agonists such as leuprorelin, goserelin, triptorelin and buserelin, and GnRH antagonists such as degarelix for the subgroup of people with spinal metastases. The company explained multiple GnRH agonists are licensed in England and it was appropriate to assume they have equal efficacy and safety, based on clinical opinion and in line with TA404. The committee noted that the company used a blended comparator of 3 GnRH agonists (47% leuprorelin, 33% goserelin and 20% triptorelin) based on Prescription Cost Analysis data for England. The EAG highlighted that GnRH agonists are prescribed for conditions other than prostate cancer, so it was uncertain if the proportions of GnRH agonists used in the blended comparator represented NHS practice for treating advanced hormone-sensitive prostate cancer. It also explained there are price differences between the GnRH agonists, so it is important to also consider comparisons of relugolix with the most and least expensive GnRH agonist. The committee concluded that the appropriate comparators for decision making in this evaluation were the company's blended comparator, the least and most expensive GnRH agonist, and degarelix for the spinal metastases subgroup.

Clinical effectiveness

Clinical trial

3.6 The main source of clinical-effectiveness evidence for relugolix was HERO, a multicentre, open-label, phase 3 trial. HERO included people aged 18 and over with androgen-sensitive (hormone-sensitive) advanced prostate cancer eligible for at least 1 year of continuous ADT. The primary outcome of HERO was the 'sustained castration rate', defined as the cumulative probability of testosterone suppression to less than 50 ng/dL.

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The key secondary outcomes that informed the economic model were time to PSA progression and adverse events including major adverse cardiovascular events (MACE). People were randomly assigned in a 2:1 ratio to either relugolix (n=624) or leuprolide (n=310). The HERO results showed that 96.7% of people who had relugolix reached and maintained sustained testosterone suppression below 50 ng/dL from week 5 (day 29) to week 49 (day 337; 95% confidence interval [CI] 94.9% to 97.9%). Results also suggested a 54% reduction in the risk of MACE for relugolix compared with leuprolide (hazard ratio [HR)] 0.46; 95% CI 0.24 to 0.88). The company also presented a post-hoc subgroup analysis of the incidence of MACE in people with or without a self-reported medical history of MACE. The results suggested that for people with a history of MACE, the odds of having a MACE after 48 weeks were 5.8 times greater with leuprolide compared with relugolix (odds ratio [OR] 5.8; 95% CI 1.5 to 23.3). For people without a medical history of MACE there was no statistically significant difference (OR 1.5; 95% CI 0.7 to 3.4). The committee concluded that the evidence suggested that relugolix is more effective at reaching and maintaining sustained testosterone suppression below 50 ng/dL and reducing the risk of MACE compared with leuprolide.

Generalisability

3.7 The committee was aware that the marketing authorisation indication for relugolix includes use with or before radiotherapy for high-risk localised or locally advanced hormone-sensitive prostate cancer (see section 3.3). It noted that the company did not present clinical or cost-effectiveness evidence specific to using relugolix in these 2 populations. The company clarified that the HERO results were generalisable to the whole population included in the marketing authorisation indication. This is because the licence was based on the HERO data (see section 3.6) that included a subgroup of people with high-risk localised or locally advanced hormone-sensitive prostate cancer. It explained that the rate of MACE with relugolix, used with or before radiotherapy, was unlikely to differ for people with high-risk localised or locally advanced prostate cancer. The

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EAG explained that differences in risk of progression, duration of treatment and costs in the adjuvant and neoadjuvant settings may affect the cost-effectiveness results. So, the EAG thought that generalising the results from HERO to high-risk localised or locally advanced prostate cancer, for treatment with or before radiotherapy, was uncertain. The clinical experts clarified that in clinical practice ADT duration may vary between high-risk localised, locally advanced, metastatic or biochemically relapsed cancer. But, they would expect similar clinical effectiveness across the populations while continuing ADT. They explained that in HERO around 30% of people had locally advanced hormone-sensitive prostate cancer, which was in line with what they would expect in NHS clinical practice and National Prostate Cancer Audit data. So, they thought the results from HERO could be generalised to the high-risk localised or locally advanced populations, for treatment with or before radiotherapy. The committee concluded that relugolix's efficacy for high-risk localised or locally advanced hormone-sensitive prostate cancer with or before radiotherapy was likely to be similar to that for advanced hormone-sensitive prostate cancer.

Indirect treatment comparisons

3.8 HERO only provided a head-to-head comparison between relugolix and leuprolide. There were no head-to-head comparisons between relugolix and other comparators. So, the company did a series of network meta-analyses (NMAs) comparing the clinical effectiveness of relugolix with all ADTs. The NMAs were done for 2 outcomes: testosterone suppression to below 50 ng/dL and MACE. The EAG explained that 5 studies (HERO [Shore et al. 2020], Klotz et al. [2008], Heyns et al. [2003], Silva et al. [2012] and Tanaka et al. [2007]) were used to inform the NMA of testosterone suppression, and 3 studies (HERO, Klotz et al. [2008], Margel et al. [2019]) were used to inform the NMA of MACE. The EAG noted inconsistencies in how the company identified and selected studies for inclusion in the NMA, which led to some studies being excluded that could have provided relevant data. Specifically, the EAG thought that

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excluding a phase 2 study comparing relugolix with leuprolide (C27002; ClinicalTrials.gov, NCT02083185), and a phase 3 study comparing degarelix with goserelin (ClinicalTrials.gov, NCT00946920), was inappropriate. It asked for these to be included in the NMAs. The company provided the results of the NMA for testosterone suppression with and without the inclusion of study C27002. It also provided sensitivity analyses excluding degarelix because the trial (Klotz et al. [2008]) included all stages of disease, not just spinal metastatic disease for which degarelix is recommended in TA404. The committee noted that the company's original NMA for testosterone suppression (without study C27002) suggested relugolix had a statistically significant benefit for achieving testosterone suppression to below 50 ng/dL compared with leuprolide and goserelin. For other comparators, there were no statistically significant differences. It further noted that in the company's updated NMA (with study C27002) there were no statistically significant differences between relugolix and any of the comparators. In the sensitivity analyses in which degarelix was removed from the network, the only statistically significant difference in testosterone suppression was between relugolix and leuprolide. The company did not include C27002 in the NMA of MACE because the study did not report MACE outcomes. The committee noted that the ClinicalTrials.gov record for C27002 reported the incidence of cardiovascular events in keeping with the company's definition of MACE and cardiovascular-related events. The company provided results of the NMA for MACE with and without Margel et al. (2019), because the control arm was a non-specific GnRH agonist treatment. Both the primary NMA and sensitivity analysis results for MACE suggested no statistically significant difference in MACE or cardiovascular-related events between relugolix versus the other comparators.

The committee agreed with the inconsistencies highlighted by the EAG. The committee also noted that the company fitted a random effects model for MACE and testosterone suppression but did not provide the results using a fixed effects model. The committee would have liked to see the

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results of the NMAs using both random and fixed effects models. But it noted it would expect the fixed effects model to provide narrower credible intervals and so the difference between the results using random and fixed effects models would likely be small. It also would have preferred all relevant studies to be included in the NMAs for each outcome, but noted the model assumed equivalent efficacy between comparators for testosterone suppression. The committee recalled the substantial heterogeneity between studies included in the NMAs. It also recalled that the HERO trial showed a statistically significant reduction in the risk of MACE with relugolix compared with leuprolide. The committee concluded that the results of the indirect treatment comparisons were uncertain, and it would consider results from the NMAs and HERO in its decision making.

Risk of MACE

3.9 The relative effect of relugolix on the risk of MACE was the main driver of results in the company's economic model. In its base case, the company assumed a relative risk of MACE of 0.38 with relugolix. It explained the definition of MACE in the HERO trial included all-cause mortality, so it adjusted the relative risk of MACE from HERO (see section 3.6) to exclude non-cardiovascular fatal events to avoid double-counting. The EAG noted uncertainty over the relative effects of relugolix and comparators on the incidence of MACE. The EAG explained that the estimates differed between the evidence sources and methods of analysis. Differences in the relative risk of MACE may have been due to the definitions of MACE used, populations and treatment doses. The committee noted the different results presented:

- HERO showed a 54% reduction in risk of MACE with relugolix compared with leuprolide (HR 0.46; 95% CI 0.2429 to 0.8821).
- A meta-analysis of 10 studies by Cirne et al. (2022), which included C27002, compared GnRH antagonists (degarelix and relugolix) with GnRH agonists (including leuprorelin and goserelin). It reported a risk ratio of 0.57 (95% CI 0.39 to 0.81).

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- Point estimates of relative risk from the company NMAs varied between 0.42 and 0.84.

The clinical experts estimated that in clinical practice they would expect around a 50% reduction in the risk of MACE with relugolix. They also explained that people should ideally have a cardiovascular risk assessment before starting ADT, but that this rarely occurs in clinical practice. So, an ADT option that reduces the risk of cardiovascular events would be welcomed. To help quantify the uncertainty, the EAG provided threshold analyses which varied the relative risk of MACE for relugolix from 0.9 to 1.0. The committee understood there may be multiple reasons that different evidence sources provided different estimates of the risk of MACE with relugolix. These included different definitions of MACE and heterogeneity between studies. The committee recalled the various estimates of the relative risk of MACE with relugolix from HERO, the company NMA and Cirne et al. It also recalled the threshold analyses provided by the EAG, which reassured the committee that relugolix remained cost effective even at relative risks close to 1. Based on the evidence provided and clinical expert testimony, the committee concluded that relugolix is likely to reduce the risk of MACE compared with the GnRH agonists used in clinical practice. But, the exact relative risk of MACE with relugolix remained uncertain.

Economic model

The company's modelling approach

3.10 The company presented an economic model comparing relugolix with GnRH agonists. The model was based on a Markov model that included 2 sub-models for people with previous MACE and no previous MACE. Each sub-model had 10 health states and an absorbing death state. This resulted in a model with 22 health states. The model assumed a starting age of 71 years based on the mean age from HERO, had a lifetime horizon (26 years) and a 3-month cycle length. The EAG explained that the model used a set of tunnel states, one for each of the 22 health states.

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The EAG considered the company's health state transition approach appropriate but noted that the model was very complex, with a large number of health states, and multiple tunnel states. The committee questioned the validity of transitioning from the locally advanced prostate cancer or biochemically relapsed health states directly to a metastatic hormone-relapsed prostate cancer health state. The clinical experts explained that the transitions depend on how the metastatic disease after biochemical relapse is detected. They clarified that metastatic lesions can be detected earlier than before because of advanced imaging technology. The clinical experts agreed that the company's model structure appropriately captured all the relevant health states for advanced hormone-sensitive prostate cancer. The committee concluded that the company's model structure captured relevant health states and was appropriate for decision making.

Spinal metastases

3.11 Degarelix is only recommended in England and Wales for advanced hormone-sensitive prostate cancer in a subgroup of people with spinal metastases (TA404). The company presented subgroup analyses comparing relugolix with degarelix in people with metastatic hormone-sensitive prostate cancer. It assumed that the results of this comparison would be the same in people with spinal metastases because of a lack of data specific to people with spinal metastases from HERO and other sources. The EAG noted that TA404 explored the additional risks of spinal compression in this subgroup. The committee considered the validity of using metastatic hormone-sensitive prostate cancer to represent the cost effectiveness of relugolix in people with spinal metastases. Prostate cancer with spinal metastases is often severe and debilitating and has a high risk of spinal cord compression which can lead to severe nerve problems. The clinical experts explained that approximately 15% of people who have advanced prostate cancer develop spinal metastases with spinal cord compression. The clinical experts clarified that they would expect relugolix and degarelix to provide similar testosterone suppression

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for people with and without spinal metastases. It concluded that it was appropriate to use cost-effectiveness results for relugolix compared with degarelix in people with metastatic hormone-sensitive prostate cancer as a proxy for people with spinal metastases.

Subsequent treatments

3.12 The company's model included medication and administration costs for subsequent treatments after disease progression. People with non-metastatic hormone-relapsed prostate cancer continued to have ADT indefinitely, with the addition of an androgen receptor inhibitor (ARI) (apalutamide, darolutamide or enzalutamide). People whose disease progressed to metastatic hormone-relapsed prostate cancer were also assumed to continue to have ADT indefinitely, with the addition of an ARI or chemotherapy (abiraterone, cabazitaxel with prednisolone, dexamethasone, docetaxel, enzalutamide, or radium-223). Clinical opinion received by the EAG suggested that enzalutamide is not used for non-metastatic hormone-relapsed prostate cancer in the NHS. So, the EAG used 50% apalutamide and 50% darolutamide as subsequent treatments in its base case. The NHS England Cancer Drugs Fund (CDF) clinical lead agreed with the EAG's approach of using only apalutamide and darolutamide as subsequent treatments for non-metastatic hormone-relapsed prostate cancer. The CDF clinical lead clarified that in clinical practice, 80% of people have darolutamide and 20% have apalutamide. The committee noted that scenario analyses varying the subsequent treatment costs had a minimal effect on the cost-effectiveness results. It concluded that for non-metastatic hormone-relapsed prostate cancer, 80% of people should have darolutamide and 20% of people should have apalutamide as subsequent treatments in the model. For metastatic hormone-relapsed prostate cancer, abiraterone, cabazitaxel with prednisolone, dexamethasone, docetaxel, enzalutamide, and radium-223 in equal proportions were appropriate.

History of MACE

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3.13 In its model, the company included a proportion of people with a previous history of MACE at baseline. The company assumed that 30.4% had a history of MACE based on a pooled analysis of 6 randomised clinical trials reported by Albertsen et al. (2014). The company explained that HERO excluded people with a history of MACE in the 6 months before the trial. So, it considered the proportion of people in HERO with a previous MACE (37.7%) may not represent clinical practice. The EAG thought the company's approach of choosing a lower estimate from Albertsen et al. was not appropriate. The EAG preferred to use HERO as the source of baseline history of MACE because it was consistent with other baseline characteristics and clinical outcomes informing the model. The clinical expert noted that only 3 out of 6 studies included in Albertsen et al. reported MACE, and the definitions of MACE varied between the trials. The committee concluded that it was more appropriate and consistent to use HERO data as the source for the baseline history of MACE to inform the model.

Risk of MACE carry-over period

3.14 The company's model assumed that the risk of MACE for people who had a GnRH agonist was higher than for people who had relugolix, and that this increased risk continued for a period after stopping the GnRH agonist. This was based on clinical opinion that time until testosterone recovery could be used to approximate the carry-over period for risk of MACE. The company estimated the duration of the carry-over period for a continuing increased risk of MACE using the mean time to testosterone recovery after stopping GnRH agonist treatment (6.8 months) from Nam et al. (2018). The EAG thought that the evidence for assuming a carry-over period for a continuing increased risk of MACE based on an increased time to testosterone recovery was weak. So, the EAG preferred not to include a carry-over period in its base case. The clinical experts explained that testosterone recovery takes on average 9 to 12 months in people who have stopped treatment with an injectable GnRH agonist. They explained that they would also expect an increased risk of MACE during that period

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of continued testosterone suppression. The committee recognised there is evidence for delayed testosterone recovery after treatment with GnRH agonists and that this is reduced with relugolix. But it recalled it had not seen any evidence to suggest there is a continued increased risk of MACE after stopping treatment with GnRH agonists. The committee noted there was uncertainty around the carry-over period and concluded the model should not include a period of increased risk of MACE after stopping treatment with GnRH agonists.

End of life care costs

3.15 The company used estimates of costs for end of life care for people with cancer by Addicott and Dewar (2008) and it updated these costs to 2021 to 22 prices (£7,071). The EAG explained that the Addicott and Dewar estimate was based on a small sample and was out of date. The EAG thought that costs provided by Georghiou et al. (2012), reported in the Personal Social Services Research Unit Costs of Health and Social Care 2022 manual (£13,113), were more appropriate. The company agreed with using the updated costs provided by the EAG. The committee noted that using Addicott and Dewar's estimate or estimates from Georghiou et al. (2012) had a relatively minor impact on the cost-effectiveness results. The committee concluded that the EAG's approach of using the more recent estimates of costs for end of life care was more appropriate.

Cost-effectiveness estimates

Committee's preferred assumptions

3.16 The committee's preferred assumptions included:

- using darolutamide (80%) and apalutamide (20%) as subsequent treatments for non-metastatic hormone-relapsed prostate cancer (see section 3.12)
- using abiraterone, cabazitaxel with prednisolone, dexamethasone, docetaxel, enzalutamide, and radium-223 in equal proportions as

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subsequent treatments for metastatic hormone-relapsed prostate cancer (see section 3.12)

- using the proportion of people with a history of prior MACE at baseline from the HERO trial (37.7%; see section 3.13)
- not including a carry-over period for risk of MACE after stopping GnRH agonist treatment (see section 3.14)
- using end of life care costs from Georghiou et al. (2012; see section 3.15).

Acceptable ICER

3.17 The committee noted that there was some uncertainty in the modelling of relugolix, in particular:

- the company's approach to the NMAs was uncertain (see section 3.8)
- the company's model structure was very complex (see section 3.10).

The committee noted that when using list prices for all treatments to represent primary care costs, and considering its preferences, the cost-effectiveness estimates for both the company's and the EAG's base cases were below £20,000 per quality adjusted life year (QALY). The committee considered relugolix to be a cost-effective use of NHS resources. So, the committee recommended it for routine use in the NHS.

Equality

3.18 The committee noted that African or Caribbean groups were not represented in the HERO trial as specified subgroups. It heard that baseline risks of MACE for African or Caribbean people with cardiovascular risk factors and advanced prostate cancer may lead to different outcomes. The committee discussed the equality issue raised and agreed that its recommendations do not have a different impact on people protected by equality legislation. The committee considered that there were no equalities issues that could be addressed by its recommendation.

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Innovation

3.19 The committee considered whether relugolix was innovative. The patient and clinical experts considered that relugolix is an oral treatment that provides an alternative to injectable ADTs. The committee acknowledged the benefits offered by relugolix and that people value an oral treatment, but it noted that it had not been presented with evidence of any additional benefits that were not captured in the QALY estimates. The committee concluded that the benefits of relugolix were adequately captured in the model.

Other factors

3.20 NICE's methods on conditions with a high degree of severity did not apply.

Conclusion

Recommendation

3.21 The committee agreed that its preferred cost-effectiveness estimates were within the range considered an acceptable use of NHS resources. So, it concluded that relugolix is recommended.

4 Implementation

4.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 3 months of its date of publication.

4.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide

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funding and resources for it within 2 months of the first publication of the final draft guidance.

4.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has advanced hormone-sensitive prostate cancer and the healthcare professional responsible for their care thinks that relugolix is the right treatment, it should be available for use, in line with NICE's recommendations.

5 Evaluation committee members and NICE project team

Evaluation committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by committee B.

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each evaluation committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

Baljit Singh

Chair, technology appraisal committee B

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser and a project manager.

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