

**NATIONAL INSTITUTE FOR HEALTH AND CARE  
EXCELLENCE**

**Final draft guidance**

**Olaparib with abiraterone for untreated  
hormone-relapsed metastatic prostate cancer**

**1 Recommendations**

Olaparib with abiraterone and prednisone or prednisolone is recommended, within its marketing authorisation, as an option for untreated hormone-relapsed metastatic prostate cancer in adults who cannot have or do not want chemotherapy. It is only recommended if the company provides it according to the commercial arrangements (see section 2).

**Why the committee made these recommendations**

Usual treatment for untreated hormone-relapsed metastatic prostate cancer is abiraterone or enzalutamide.

Clinical trial evidence shows that olaparib with abiraterone and prednisone or prednisolone increases how long people live and how long they have before their cancer gets worse compared with abiraterone alone. Olaparib with abiraterone and prednisone or prednisolone has not been directly compared with enzalutamide.

The cost-effectiveness estimates are within the range that NICE considers an acceptable use of NHS resources. So, olaparib with abiraterone and prednisone or prednisolone is recommended.

## 2 Information about olaparib with abiraterone

### Marketing authorisation indication

- 2.1 Olaparib (Lynparza, AstraZeneca) with abiraterone and prednisone or prednisolone is indicated for ‘the treatment of adult patients with metastatic castration-resistant prostate cancer in whom chemotherapy is not clinically indicated’.

### Dosage in the marketing authorisation

- 2.2 The dosage schedule is available in the [summary of product characteristics](#) for olaparib with abiraterone and prednisone or prednisolone.

### Price

- 2.3 The list price for olaparib is £2,317.50 per pack of 56 tablets, each containing 100 mg or 150 mg of the active ingredient (excluding VAT; BNF online, accessed December 2023). The list price for abiraterone is £2,735 for a pack of 56 x 500 mg tablets (excluding VAT; BNF online, accessed December 2023).
- 2.4 The company has a commercial arrangement. This makes olaparib with abiraterone 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.

## 3 Committee discussion

The [evaluation committee](#) considered evidence submitted by AstraZeneca, 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

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3.1 Hormone-relapsed metastatic prostate cancer (also known as metastatic castration-resistant prostate cancer) is a cancer that has spread beyond the prostate and no longer responds to androgen deprivation therapy (ADT). The patient experts explained that people may experience more significant symptoms when hormone resistance occurs, and the condition becomes more aggressive. For example, people may experience pain, tiredness, anaemia, weight loss and reduced appetite. The risk of prostate cancer increases with age, usually developing in people aged 50 years and over. Prostate cancer is also more common in people of Black African ethnicity, people with a family history of prostate cancer and people with a homologous recombination repair (HRR) mutation. People of Ashkenazi Jewish ethnicity have a greater risk of having a breast cancer gene (BRCA) mutation and so a higher risk of developing prostate cancer. People with advanced or metastatic prostate cancer have a poor prognosis. The patient experts explained that people with prostate cancer and their families are disappointed that there is no curative treatment. They also explained that there is a need for new treatments that improve quality and length of life. They explained that olaparib with abiraterone and prednisone or prednisolone (from now, referred to as olaparib with abiraterone) offers people another treatment choice at this point in the pathway and a better chance of surviving for longer. The patient experts added that, for people with hormone-relapsed metastatic prostate cancer and their carers, ease of administration is a key factor in choosing a treatment. This oral combination could allow people to administer treatment in the comfort of their own home. The committee concluded that there is an unmet need for effective and easy to administer treatments for people with hormone-relapsed metastatic prostate cancer.

## **Clinical management**

### **Treatment options**

3.2 People with newly diagnosed hormone-sensitive non-metastatic prostate cancer are normally offered ADT or radical therapy such as surgery or

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radiotherapy. If the disease progresses with ADT, it is known as hormone relapsed. Treatment with ADT continues, either alone or with the novel hormonal agents darolutamide or apalutamide. People with newly diagnosed hormone-sensitive metastatic prostate cancer are usually offered:

- ADT alone
- ADT with docetaxel with or without prednisolone (from now, referred to as docetaxel)
- ADT with enzalutamide (see [NICE's technology appraisal guidance on enzalutamide for treating hormone-sensitive metastatic prostate cancer](#)), or
- if docetaxel is not suitable, ADT with apalutamide (see [NICE's technology appraisal guidance on apalutamide with androgen deprivation therapy for treating hormone-sensitive metastatic prostate cancer](#)).

First-line treatment options for hormone-relapsed metastatic prostate cancer for whom chemotherapy is not yet indicated include:

- abiraterone with prednisolone or prednisone (from now, referred to as abiraterone) or enzalutamide, if neither has been used before (see [NICE's technology appraisal guidance on enzalutamide](#) and on [abiraterone](#) for treating hormone-relapsed metastatic prostate cancer before chemotherapy is indicated), or
- 'watchful waiting'.

People who had a novel hormonal agent, such as darolutamide, enzalutamide, abiraterone or apalutamide, when their cancer was hormone sensitive or non-metastatic, would not have it again if their cancer becomes hormone relapsed and metastatic. After this, further treatment options include:

- docetaxel (for the first time, or again in people who had docetaxel when their cancer was hormone sensitive; see [NICE's technology appraisal guidance on docetaxel for the treatment of hormone-refractory metastatic prostate cancer](#))
- abiraterone (see [NICE's technology appraisal guidance on abiraterone for castration-resistant metastatic prostate cancer previously treated with a docetaxel-containing regimen](#)) or enzalutamide (see [NICE's technology appraisal guidance on enzalutamide for metastatic hormone-relapsed prostate cancer previously treated with a docetaxel-containing regimen](#)), if neither has been used before and docetaxel has already been given
- cabazitaxel (see [NICE's technology appraisal guidance on cabazitaxel for hormone-relapsed metastatic prostate cancer treated with docetaxel](#)) for people who have already had docetaxel
- radium-223 dichloride (see [NICE's technology appraisal guidance on radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases](#)) for people with symptomatic bone metastases and no metastases in the soft internal organs of the body (visceral metastases), who have already had docetaxel or cannot have it
- olaparib monotherapy (see [NICE's technology appraisal guidance on olaparib for previously treated BRCA mutation-positive hormone-relapsed metastatic prostate cancer](#)) for people whose disease has progressed after a novel hormonal agent.

## Comparators

3.3 The company proposed olaparib with abiraterone as a treatment for adults with untreated hormone-relapsed metastatic prostate cancer in whom chemotherapy is not clinically indicated. In NICE's final scope for this appraisal, the relevant comparators listed were abiraterone and enzalutamide. The company proposed enzalutamide as the main comparator and abiraterone as a secondary comparator because enzalutamide is more commonly used in clinical practice. The EAG

considered enzalutamide and abiraterone to be equally relevant comparators because both treatments are used in clinical practice. The clinical experts agreed with the EAG. They said that the only consideration that would make a difference clinically is that people with diabetes would likely be offered enzalutamide (because the steroids administered with abiraterone can increase blood sugar levels). The committee concluded that abiraterone and enzalutamide are both relevant comparators. It further noted that olaparib is combined with abiraterone, which emphasises the importance of abiraterone as a comparator.

### **Marketing authorisation population**

3.4 The marketing authorisation is for ‘the treatment of adult patients with hormone-relapsed metastatic prostate cancer in whom chemotherapy is not clinically indicated’ (see [section 2.1](#)). The relevant comparators enzalutamide and abiraterone (see [section 3.3](#)) have marketing authorisations for adults with hormone-relapsed metastatic prostate cancer who are asymptomatic or mildly symptomatic after failure of ADT and in whom chemotherapy is not yet clinically indicated. The EAG highlighted that the marketing authorisation differs between olaparib with abiraterone (for whom chemotherapy is not clinically indicated) and enzalutamide and abiraterone (for whom chemotherapy is not yet clinically indicated). The company explained that, at the time of the enzalutamide and abiraterone appraisals for hormone-relapsed metastatic prostate cancer, docetaxel was not available in the metastatic hormone-sensitive setting. So, most people in the trials had not had prior chemotherapy and could go on to have docetaxel in the hormone-relapsed metastatic setting. Since then, NICE has recommended docetaxel with ADT, and enzalutamide, for treating hormone-sensitive metastatic prostate cancer. The company explained that omitting ‘yet’ in the marketing authorisation reflected that the olaparib with abiraterone clinical trial included people who had and had not previously had docetaxel before progressing to hormone-relapsed metastatic prostate cancer. The clinical experts

supported this positioning and confirmed that the trial was generalisable to how olaparib with abiraterone would be used in UK clinical practice, if recommended. The NHS commissions only 1 novel hormonal agent per person at any stage of the treatment of prostate cancer. This is because the survival benefits of having a novel hormonal agent at the earliest opportunity (such as in the metastatic hormone-sensitive setting) are greater than if it were saved for a later line of therapy. The NHS England Cancer Drugs Fund clinical lead (from here, the Cancer Drugs Fund lead) highlighted that of people who have novel hormonal agents, 60% have them in the metastatic hormone-sensitive setting, rather than docetaxel. The clinical experts explained that novel hormonal agents are more efficacious, tolerable and less toxic than docetaxel. So, in clinical practice, even if a person is fit enough for chemotherapy, most clinicians would offer people a novel hormonal agent. Only 40% of people who have a novel hormonal agent have it at the hormone-relapsed metastatic prostate cancer stage. The 40% comprises 30% who have a first-line novel hormonal agent when chemotherapy is not yet clinically indicated and 10% who have 1 after chemotherapy. People who have 1 when chemotherapy is not clinically indicated would be eligible for olaparib with abiraterone. The committee considered the clinical input. It concluded that the interpretation of marketing authorisation, and positioning of olaparib with abiraterone, was understood by clinicians. It also concluded that the trial was generalisable to the target population.

## **Clinical effectiveness**

### **Clinical trial**

- 3.5 The clinical evidence for olaparib with abiraterone came from a double-blind phase 3 randomised controlled trial, PROpel (n=796). The trial evaluated olaparib (300 mg) with abiraterone (1,000 mg; and prednisone or prednisolone [5 mg]) compared with placebo with abiraterone (1,000 mg; and prednisone or prednisolone [5 mg]) in adults who had not had treatment for hormone-relapsed metastatic prostate cancer. The

primary outcome was radiographic progression-free survival (PFS) by investigator assessment. Secondary outcomes included overall survival (OS), adverse events, health-related quality of life, time to stopping treatment and time to symptomatic skeletal-related events.

### Clinical trial results

3.6 The company presented results from the intention-to-treat (ITT) population, and subgroups of HRR mutation, non-HRR mutation, BRCA mutation and non-BRCA mutation. The OS benefit was larger in the BRCA subgroup (hazard ratio [HR] 0.29, 95% confidence interval [CI] 0.14 to 0.56) than in the ITT population (HR 0.81, 95% CI 0.67 to 1.00), the non-BRCA subgroup (HR 0.91, 95% CI 0.73 to 1.13), the HRR subgroup (HR 0.66, 95% CI 0.45 to 0.95) and the non-HRR subgroup (HR 0.89, 95% CI 0.70 to 1.14). The PFS benefit was also larger in the BRCA subgroup than the ITT, non-BRCA, HRR and non-HRR subgroups (the results are academic in confidence and cannot be reported here). The committee concluded that olaparib with abiraterone improves OS and PFS compared with abiraterone.

### BRCA subgroup effectiveness

3.7 PROpel prespecified subgroup analyses by HRR mutation. At clarification, the EAG asked the company for posthoc subgroup results from people with and without the BRCA mutation. This is because it thought the improvements in PFS and OS seen in PROpel appeared to be largely attributable to the subgroup of people with BRCA mutations. [NICE has recently recommended olaparib for previously treated BRCA mutation-positive hormone-relapsed metastatic prostate cancer](#) in line with its marketing authorisation. The company explained that PROpel was powered to show efficacy and safety in the ITT population. This was regardless of a person's biomarker status, and highlighted that posthoc subgroup analyses should be interpreted with caution. The EAG acknowledged this but noted that there was a large difference in relative



efficacy between people with and without BRCA mutations. The company stated that only 11% of the ITT population had BRCA mutations, so the benefit seen in the ITT population was unlikely to be driven by this small subgroup. It also explained that the combination of olaparib with abiraterone leads to an improved antitumour effect that shows some benefit in people with non-HRR mutations. The clinical experts and EAG agreed that olaparib's mechanism of action is different when combined with a novel hormonal agent compared with when used alone. This is because the combination causes an interaction between the androgen receptor pathway and DNA repair pathway. This means that novel hormonal agents may enhance the effect of olaparib in tumours without the BRCA mutations and olaparib may augment the effectiveness of novel hormonal agents. Prostate Cancer UK and the clinical experts agreed that people without the BRCA mutation, including those with non-BRCA HRR mutations, also get important benefits from treatment with olaparib and abiraterone. The clinical experts explained that cancers with a non-BRCA HRR mutation are less aggressive than those with BRCA mutations. So, people tend to live longer and more time is needed until the survival gains for people in the treatment arm become apparent. The committee noted that, although the OS gain was modest (about 2 months) in the subgroup without BRCA mutations, the PFS benefit was about 8 months. It recognised that this additional time before the cancer progresses could have a large positive impact on a person's quality of life. The committee acknowledged the potential challenges associated with BRCA testing in clinical practice (see [section 3.10](#)). It recognised that there were larger survival benefits for people with BRCA and other HRR mutations having olaparib with abiraterone. The committee noted the challenges associated with subgroup analyses and the potential for OS and PFS benefits in non-mutation groups. But it concluded that the ITT population was the most appropriate to consider in its decision making.

## **Subsequent olaparib monotherapy**

3.8 NICE has recommended [olaparib for previously treated BRCA mutation-positive hormone-relapsed metastatic prostate cancer](#) for people whose condition has progressed after treatment with a novel hormonal agent. In PROpel, 11% of people in the comparator arm had a BRCA mutation and so were eligible for olaparib. But the proportion that had subsequent olaparib was much smaller (the results are academic in confidence and cannot be reported here). The EAG was concerned that the difference in subsequent olaparib use between the trial and the proportion eligible for olaparib may underestimate the survival of people in the placebo with abiraterone arm, compared with what would be expected in the NHS. Consequently, this may overestimate the cost effectiveness of olaparib with abiraterone. The company stated that about 50% of people with hormone-relapsed metastatic prostate cancer will only have 1 line of therapy and not progress to have a subsequent treatment. It also said that olaparib monotherapy is being under-used in the NHS so the number of people having olaparib in clinical practice would be smaller than the proportion eligible for it. The Cancer Drugs Fund lead said that about 12 people per month are having olaparib, which is lower than expected. The clinical experts agreed that only about 2.5% of people in the real world would have olaparib, which is similar to the proportion in the trial. They explained that BRCA testing is not universally available, and where it is, only 60% of people have a useable tissue sample. This is because the amount of tissue available is often small, and it can often be old if the prostate biopsy was taken some time before or at diagnosis. Many people with metastatic prostate cancer do not have a tissue diagnosis because many are diagnosed at an older age based on their high prostate-specific antigen (PSA) level. Because olaparib was only recently approved, there is limited capacity for testing in genomic laboratories. The Cancer Drugs Fund lead agreed that this contributes to the low uptake of olaparib monotherapy, but expected that this will improve. The committee considered the uncertainty in the subsequent use of olaparib monotherapy and concluded that the company's evidence was acceptable.

## Economic model

### Company's modelling approach

3.9 The company presented a 3-state partitioned survival model to estimate the cost effectiveness of olaparib with abiraterone compared with enzalutamide and abiraterone. The 3 health states were progression free, after progression and death. The model was based on PFS and OS outcomes from the olaparib with abiraterone and abiraterone alone arms of PROpel. The company's economic analysis assumed equivalence between abiraterone and enzalutamide (see [section 3.10](#)), so PFS and OS outcomes for enzalutamide were informed by the abiraterone arm of PROpel (see [section 3.5](#)). The committee concluded that the model was suitable for decision making.

### Enzalutamide and abiraterone clinical equivalence

3.10 PROpel compared olaparib with abiraterone against placebo with abiraterone (see [section 3.5](#)). There was no direct evidence comparing olaparib with abiraterone against enzalutamide. The company assumed that abiraterone and enzalutamide were clinically equivalent in its economic model (HR 1.00) based on an exploratory network meta-analysis (NMA) for OS and clinical expert opinion. The comparator treatments (prednisone or placebo) in the relevant trials for olaparib with abiraterone, enzalutamide and abiraterone were not considered clinically equivalent for PFS, so a PFS NMA was not done. The company's NMA found that there was no meaningful OS difference between enzalutamide and abiraterone (the results are academic in confidence and cannot be reported here). The clinical experts supported this. They highlighted that the relative efficacy of abiraterone and enzalutamide has been discussed for many years, and that these drugs are considered equivalent in terms of efficacy. The EAG considered the NMA to be inappropriate for deriving effect estimates because of substantial heterogeneity between the included trials. Instead, the EAG ran an updated, broader literature search to include non-randomised studies. It identified 9 relevant studies and

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included them in a meta-analysis. The results showed an OS benefit in favour of enzalutamide (HR 0.84, 95% CI 0.77 to 0.91). The company highlighted a number of limitations with the EAG's meta-analysis, including that non-randomised evidence is more prone to bias and is of a lower evidence standard than randomised evidence. The committee acknowledged the issues associated with the company's NMA and the EAG's meta-analysis. It considered the clinical input and concluded that the assumption of clinical equivalence between enzalutamide and abiraterone was reasonable to inform the economic modelling for this appraisal.

### **Overall survival extrapolation curve**

3.11 In the company's economic model, independent parametric curves were fitted to the available OS data. The company's base case used a generalised gamma curve to extrapolate the olaparib with abiraterone, enzalutamide and abiraterone treatment arms. It was based on diagnostic and hazard function assessment, visual and statistical fit, and clinical expert validation. The EAG noted that the log-logistic distribution had a similar statistical fit to the trial data as the generalised gamma. Also, it produced clinically plausible long-term OS estimates across all treatment arms. The company explained that the generalised gamma OS estimates were marginally more aligned with the PROpel median OS and latest 4-year landmark data across both treatment arms (the results are academic in confidence and cannot be reported here). But it ran a scenario analysis using the log-logistic curve to explore the uncertainty around the long-term OS extrapolation. The EAG highlighted that each curve predicted a different 10-year current treatment OS estimate. The generalised gamma distribution estimated that 2.6% of people having abiraterone would be alive after 10 years, whereas the log-logistic predicted 8.4% would be alive. The EAG's clinical adviser suggested that estimates of 8% to 10% of people alive at 10 years are likely for the current care options. The company said that almost all of their clinical

advisers agreed that the generalised gamma curve was the most clinically plausible based on current care options. The clinical experts in the committee meeting supported this. They explained that, although some people stay on treatment for a long time, OS trends towards 0% and does not level out at around 10% as the log-logistic suggests. They stated that they did not consider 8.4% survival at 10 years to be plausible. The committee considered the available data and views, and concluded that the generalised gamma was the most appropriate parametric curve for extrapolating OS.

## **Cost-effectiveness estimates**

### **Company and EAG cost-effectiveness estimates**

3.12 The company's and EAG's base cases differed by 1 assumption: the appropriate hazard ratio to apply for the relative efficacy of abiraterone and enzalutamide (see [section 3.10](#)). The company assumed that both treatments were clinically equivalent (HR 1). The EAG considered enzalutamide to be more effective (HR 0.84). The company and EAG also explored scenarios using alternative populations (ITT, BRCA-mutation or HRR-mutation subgroup, see [section 3.7](#)) and OS extrapolation curves (generalised gamma or log-logistic, see [section 3.11](#)). The company's base case used a series of pairwise comparisons between olaparib with abiraterone, abiraterone and enzalutamide. The EAG's base case used a fully incremental analysis. The committee considered the cost-effectiveness estimates presented in a fully incremental format in its decision making. The company's and EAG's base-case incremental cost-effectiveness ratios (ICERs) were both less than £30,000 per quality-adjusted life year (QALY) gained.

### **Acceptable ICER**

3.13 The committee noted that olaparib with abiraterone is the first combination therapy to be licensed for first-line use in hormone-relapsed metastatic prostate cancer. It also considered that there are limited treatments

available for people with metastatic prostate cancer (see [section 3.1](#)). The committee acknowledged that there was some remaining uncertainty about the subsequent use of olaparib monotherapy (see [section 3.8](#)). It agreed that an acceptable ICER would be towards the higher end of the range normally considered a cost-effective use of NHS resources (£20,000 to £30,000 per QALY gained).

### **The committee's preferred cost-effectiveness estimate**

3.14 The committee's preferred assumptions aligned with the company's base case. These were to use:

- the ITT trial population
- a hazard ratio of 1 for abiraterone compared with enzalutamide
- the generalised gamma curve for OS extrapolation.

After accounting for the committee's preferred assumptions, the cost-effectiveness estimates were within a range that was considered to be an acceptable use of NHS resources.

### **Equality**

3.15 The committee understood that hormone-relapsed metastatic prostate cancer is more common in people who are older, or of a Black African ethnicity. People of Ashkenazi Jewish ethnicity have a greater risk of having a BRCA mutation, and so have a higher risk of developing prostate cancer. Some people with hormone-relapsed metastatic prostate cancer are trans. Age, race and gender reassignment are protected under the Equality Act 2010. Differences in incidence and prevalence cannot be addressed in a technology appraisal, but because the recommendation applies to all people, the committee noted that access to treatment would not be restricted for some people over others.

### **Other factors**

3.16 NICE's advice about the severity of the condition did not apply.

## Conclusion

### Recommendation

3.17 The committee agreed that its preferred cost-effectiveness estimates were within the range considered an acceptable use of NHS resources. So, it concluded that olaparib with abiraterone and prednisone or prednisolone is recommended for untreated hormone-relapsed metastatic prostate cancer in adults for whom chemotherapy is not clinically indicated.

## 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 [Chapter 2 of Appraisal and funding of cancer drugs from July 2016 \(including the new Cancer Drugs Fund\) – A new deal for patients, taxpayers and industry](#) states that for those drugs with a draft recommendation for routine commissioning, interim funding will be available (from the overall Cancer Drugs Fund budget) from the point of marketing authorisation, or from release of positive draft guidance, whichever is later. Interim funding will end 90 days after positive final guidance is published (or 30 days in the case of drugs with an Early Access to Medicines Scheme designation or cost comparison evaluation), at which point funding will switch to routine commissioning budgets. The [NHS England Cancer Drugs Fund list](#) provides up-to-date information on all cancer treatments recommended by NICE since 2016. This includes whether they have received a marketing authorisation and been launched in the UK.

- 4.3 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 funding and resources for it within 2 months of the first publication of the final draft guidance.
- 4.4 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 person has untreated hormone-relapsed metastatic prostate cancer and chemotherapy is not clinically indicated, and the doctor responsible for their care thinks that olaparib with abiraterone and prednisone or prednisolone 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

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## **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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Technical lead

### **Eleanor Donegan**

Technical adviser

### **Jeremy Powell**

Project manager

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