

# Olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy

Technology appraisal guidance

Published: TBC

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The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance are at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

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Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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## 1 Recommendations

- 1.1 Olaparib is recommended for use within the Cancer Drugs Fund as an option for the maintenance treatment of BRCA mutation-positive, advanced (FIGO stages 3 and 4), high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer that has responded to first-line platinum-based chemotherapy in adults. It is recommended only if the conditions in the [managed access agreement](#) for olaparib are followed.
- 1.2 This recommendation is not intended to affect treatment with olaparib that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

### Why the committee made these recommendations

There are currently no maintenance treatments for BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after a positive response to first-line platinum-based chemotherapy. Olaparib is currently recommended after 3 or more lines of platinum-based chemotherapy. Using olaparib earlier in the treatment pathway would be an important development because earlier use can achieve the greatest benefit and may have the potential to cure the disease.

An ongoing clinical trial shows that olaparib delays disease progression. But it is not known whether people having olaparib live longer because people in the trial have not been followed up for long enough. The currently available clinical trial evidence does not show a significant difference in overall survival between olaparib and placebo. This makes the estimates of cost effectiveness very uncertain. Therefore, olaparib is not recommended for routine use in the NHS.

If olaparib increases the length of time people live it has the potential to be cost effective, but more evidence from the ongoing trial is needed to address the uncertainties. Therefore, it is recommended for use in the Cancer Drugs Fund, while further data are collected.

## 2 Information about olaparib

<b>Marketing authorisation indication</b>	Olaparib (Lynparza, AstraZeneca) as tablets is indicated as 'monotherapy for the maintenance treatment of adult patients with advanced (FIGO stages 3 and 4) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy'.
<b>Dosage in the marketing authorisation</b>	<p>Olaparib is taken orally. It is currently available both in a tablet and a capsule formulation. However, the capsule formulation is only licensed for people with relapsed BRCA mutation-positive platinum-sensitive ovarian cancer and will be phased out when no longer needed by patients. The marketing authorisation relevant to the current appraisal is for olaparib tablets. Therefore, only olaparib tablets are covered by this appraisal.</p> <p>The dosage of olaparib as tablets is 300 mg (2 × 150 mg tablets) taken twice daily (600 mg per day). A 100-mg tablet is available for dose reductions.</p> <p>For first-line maintenance treatment, it is recommended that olaparib is continued until radiological disease progression, unacceptable toxicity, or for up to 2 years if there is no radiological evidence of disease. Patients with evidence of disease at 2 years, who in the opinion of the treating physician can derive further benefit from continuous treatment, can have treatment beyond 2 years.</p>
<b>Price</b>	The list price for tablets is £2,317.50 per 14-day pack; £4,635.00 per 28-day cycle (excluding VAT; BNF online, accessed May 2019). The company has a <a href="#">commercial arrangement</a> .

### 3 Committee discussion

The appraisal committee ([section 6](#)) considered evidence submitted by AstraZeneca, a review of this submission by the evidence review group (ERG), and the technical report developed through engagement with stakeholders. See the [committee papers](#) for full details of the evidence.

The appraisal committee was aware that several issues were resolved during the technical engagement stage, and agreed that:

- Olaparib has a marketing authorisation for FIGO stage 3 or 4 BRCA mutation-positive advanced ovarian, fallopian tube and primary peritoneal cancer. Therefore FIGO stage 2 disease is not considered in this appraisal.
- Olaparib for maintenance treatment after response to first-line platinum-based chemotherapy does not meet the criteria for using a 1.5% discount rate for costs and benefits. Therefore, the reference case 3.5% discount rate should be applied in the cost-effectiveness analyses.

The price per tablet of olaparib is the same regardless of dose, so the cost of treatment per day for a reduced dose is the same as a full dose. Therefore, the economic modelling should use the cost of whole tablets rather than the average cost per milligram.

The committee recognised that there are remaining areas of uncertainty with the analyses presented (see the technical report) and took these into account in its decision making. It discussed the following issues, which were outstanding after the technical engagement stage.

#### *Clinical need and treatment pathway*

#### **Advanced ovarian, fallopian tube and peritoneal cancer have a high disease burden**

- 3.1 The patient experts explained that advanced ovarian cancer is a devastating condition and people living with this condition have a high unmet clinical need. The disease has a poor prognosis and patients live with the fear of relapse with no prospect of cure. The clinical experts explained that survival rates for ovarian cancer are worse in the UK than in other developed countries. Reasons for this may include more advanced surgical techniques and better access to drug treatments in other countries. The committee concluded that patients with ovarian cancer have a high unmet clinical need.

#### **The availability of olaparib earlier in the treatment pathway is an important**

## development in managing BRCA mutation-positive advanced ovarian cancer

3.2 Currently, there are no first-line maintenance treatment options for newly diagnosed BRCA mutation-positive advanced ovarian cancer. It is usually treated with surgery and platinum-based chemotherapy after which there is no active treatment. Unfortunately, the disease recurs in most people. Olaparib is a poly-ADP-ribose (PARP) inhibitor. Maintenance treatment with PARP inhibitors is available at later lines in the treatment pathway. The availability of olaparib as a first-line maintenance treatment is an important development in the management of BRCA mutation-positive advanced ovarian cancer because it is expected to have the greatest benefit when used early, and is considered to have the potential to cure the disease in some people if given before the first recurrence. The committee heard from a patient expert who started taking olaparib for advanced ovarian cancer after surgery and 4 lines of chemotherapy. She explained that olaparib has been transformative for her, extending her life. It has allowed her to live a normal life with manageable side effects, especially compared with the side effects of chemotherapy. The committee heard that olaparib would be most beneficial after initial chemotherapy, when people still feel relatively well, their body is stronger to cope with any side effects and there is greater potential to cure the disease. The committee concluded that the availability of olaparib after first-line platinum-based chemotherapy represents an important development in the management of BRCA mutation-positive advanced disease and would be highly valued by patients and clinicians.

## The place of PARP inhibitors in the treatment pathway is not yet fully established

3.3 PARP inhibitors are not routinely commissioned as maintenance treatment after second-line platinum-based chemotherapy, although niraparib is currently available through the Cancer Drugs Fund and there is an ongoing NICE appraisal for olaparib as a second-line treatment. Therefore, it is not yet known whether second-line use of PARP inhibitors will become standard care. NICE's technology guidance recommends [olaparib capsules for BRCA mutation-positive advanced ovarian cancer](#) after 3 or more lines of platinum-based chemotherapy. The committee noted that, in SOLO-1, the main clinical trial of olaparib tablets as a maintenance treatment after first-line platinum-based chemotherapy (see [section 3.6](#)), people in the routine surveillance arm could have a PARP inhibitor after disease progression if their disease responded to subsequent platinum-based chemotherapy. The clinical experts explained that the proportion of people who had a subsequent PARP inhibitor in the trial is a

reasonable reflection of current clinical practice. However, it is uncertain how clinical practice will change with further NICE recommendations for second-line use and the potential introduction of olaparib as a first-line treatment. The committee concluded that there is uncertainty around future use of PARP inhibitors because of the evolving pathway of care.

## There is no evidence for retreatment with a PARP inhibitor

- 3.4 The committee considered whether retreatment with a PARP inhibitor would happen in clinical practice, noting that a very small proportion of people in the olaparib arm of SOLO-1 had retreatment later in the pathway. The clinical experts explained that, for relapsed disease, treatment with a PARP inhibitor is normally continued until disease progression or unacceptable toxicity. However, the marketing authorisation stipulates that first-line olaparib treatment should be stopped after 2 years, unless there is evidence of residual disease and the patient is likely to derive further benefit. Therefore, it is possible that tumour sensitivity to PARP inhibitors might be retained after subsequent chemotherapy. The clinical experts explained that there is currently no evidence on retreatment with a PARP inhibitor and there is a need for this to be tested in a clinical trial. The committee concluded that it is unknown whether tumour sensitivity to PARP inhibitors would be retained after subsequent chemotherapy and that there is currently no evidence for retreatment.

## *Stopping treatment after 2 years*

### **Around 15% of patients are likely to continue taking olaparib after 2 years because of residual disease**

- 3.5 In SOLO-1, 82% of patients were in complete response to platinum-based chemotherapy and 18% were in partial response. After 2 years of treatment, 10% of patients continued olaparib because they had residual disease. This is in line with the marketing authorisation (see [section 3.4](#)). The committee considered whether these proportions are generalisable to UK clinical practice. It heard from the clinical experts that despite recent developments in surgical techniques, the outcomes of ovarian cancer in the UK are worse than in other developed countries (see [section 3.1](#)). The clinical experts explained that because BRCA mutation-positive ovarian cancer is very responsive to platinum-based chemotherapy, the proportion of people in the UK eligible for olaparib who would have a partial, rather than complete, response is unlikely to be higher



than 30%, according to the clinical experts. Also, because olaparib reduces tumour burden while maintaining response to platinum-based chemotherapy, the percentage who would have residual disease by the end of the 2-year treatment period is likely to be halved to around 15%. The committee recognised that uncertainty in the percentage of patients with residual disease could have a substantial effect on treatment costs and introduces financial uncertainty for the NHS. The committee concluded that it is reasonable to expect that approximately 15% of patients would continue treatment with olaparib beyond 2 years, however this estimate is uncertain and may be optimistic considering the current outcomes of patients with ovarian cancer in the UK.

## *Clinical trial evidence from the SOLO-1 trial*

### **Olaparib improves progression-free survival**

3.6 SOLO-1 is a double-blind randomised clinical trial of olaparib compared with placebo in people with newly diagnosed FIGO stage 3 or 4, BRCA mutation-positive advanced ovarian cancer after first-line platinum-based chemotherapy. The primary end point of the trial is progression-free survival and a statistically significant improvement was reached at 50.6% data maturity. The median progression-free survival is 13.8 months in the placebo arm and has not been reached in the olaparib arm, but the company estimates it to be at least 3 years longer than placebo (hazard ratio [HR] 0.30, 95% confidence interval [CI] 0.23 to 0.41). The clinical experts explained that these results are extremely promising, and it is exceptional that so many people are disease free after 4 years because this has not been seen previously in ovarian cancer trials. They also explained that maintaining progression-free survival after first-line chemotherapy for a long period is vital and the longer it is maintained the higher the potential for cure from the disease. The committee concluded that olaparib showed an impressive improvement in progression-free survival.

### **Overall survival data are immature but olaparib is expected to extend life**

3.7 Overall survival was a secondary end point in SOLO-1. There was a small non-statistically significant benefit for olaparib compared with placebo, but at 21% maturity the median was not reached in either arm (HR 0.95, 95% CI 0.60 to 1.53). The clinical experts explained that they expect to see similarly positive overall survival benefits as for progression-free survival, but currently the data

are too immature to predict the size of the benefit. The committee noted that the overall survival Kaplan–Meier curves from SOLO-1 converged during the initial follow-up period, which could suggest no further overall survival benefit. However, it heard from the company that study 19, a trial of olaparib for relapsed ovarian cancer, showed a similar pattern of convergence after 37 months of follow up. After 78 months of follow up an overall survival benefit was observed for olaparib compared with placebo. The committee considered that it is unknown to what extent the results of SOLO-1 will mirror those from study 19. The clinical experts explained that the latest data cut from study 19 shows that 10% of patients are disease free after 10 years, indicating cure. These 'super responders' are more likely to be people who had a complete response to platinum-based chemotherapy and, because a complete response is more likely at an earlier stage of the disease, the results from SOLO-1 are expected to be very favourable. The company also presented evidence from other ovarian cancer trials showing that a progression-free survival benefit can translate into an overall survival benefit. A systematic review by Sundar et al. (2012) of 37 trials of advanced primary or recurrent ovarian cancer indicates that the relationship between progression-free survival and overall survival benefit is 1 to 1. The results of 2 trials of first-line treatment of advanced ovarian cancer (GOG-172 and JGOG-3016) suggest that the relationship could be 1 to 2 or more. The committee concluded that the extent to which the progression-free survival benefit will translate into overall survival benefit is uncertain, but it is expected that treatment with olaparib will extend life.

## **The relationship between second progression-free survival and overall survival is not established**

- 3.8 Second progression-free survival (that is, time from randomisation to second progression [PFS-2]) is a secondary outcome in SOLO-1. At the latest data cut, 26.5% of patients in the olaparib arm and 39.7% of patients in the placebo arm had progressed after second-line therapy. The median PFS-2 has not been reached in the olaparib arm and is 41.9 months in the placebo arm (HR 0.50, 95% CI 0.35 to 0.72). The committee heard from the clinical experts and the company that overall survival results may lag behind progression-free survival by several years and that PFS-2 is a reasonable surrogate. However, the committee concluded that while a longer PFS-2 could be considered to be an indicator of continued treatment benefit, in the absence of mature evidence on the effect of olaparib on overall survival, a clear relationship between PFS-2 and

overall survival has not been established.

## *Evidence from the Edinburgh Ovarian Cancer Database*

### **The Edinburgh Ovarian Cancer Database provides real-world survival data**

3.9 The Edinburgh Ovarian Cancer Database collects data on people with ovarian cancer in Scotland since the mid-1980s. The company did an analysis of data from people with BRCA mutation-positive disease diagnosed between 2000 and 2009 (n=129) to indicate long-term survival trends, and to externally validate the survival outputs of its economic model. The committee heard from the clinical experts and the company that the characteristics of people in this analysis are similar to those in SOLO-1 in terms of median age and subsequent PARP inhibitor use, and that most had high-grade serous stage 3 or 4 ovarian cancer. However, there was no information on the number of people with complete or partial response to platinum-based chemotherapy. Therefore, it is not clear how comparable the population of the Edinburgh Ovarian Cancer Database is with the population of SOLO-1. The committee accepted that the Edinburgh Ovarian Cancer Database provides some real-world data on survival outcomes, but it has limitations. In the absence of mature overall survival data from SOLO-1, the data does provide at least an indication of expected survival outcomes in current practice.

## *Model structure*

### **The 4-state health model has limitations but is acceptable for decision making**

3.10 To estimate the cost effectiveness of olaparib compared with routine surveillance the company presented a partitioned survival model with 3 states (progression-free, progressed disease and death). The ERG considered that this model oversimplifies the treatment pathway, because people can have multiple progressions with ovarian cancer. In response to technical engagement, the company submitted an updated partitioned survival model with 4 health states. It includes a PFS-2 health state using data from SOLO-1. Clinical-effectiveness evidence comes from SOLO-1, where subsequent PARP inhibitor use occurred in both arms (see [section 3.3](#) and [section 3.4](#)). The ERG found it problematic that the model does not allow testing for different assumptions about subsequent PARP inhibitor use, and it was concerned that the trial might not reflect UK clinical practice. The committee recalled the clinical experts' view that

subsequent PARP inhibitor use in SOLO-1 is a reasonable reflection of clinical practice but there is uncertainty around use of PARP inhibitors after second-line platinum-based chemotherapy (see [section 3.3](#) and [section 3.4](#)). The ERG suggested that a sequenced model would have been more appropriate for decision making. The committee understood that this type of model needs data from multiple studies to populate the parameters at each available therapy line. It noted that the company had considered this approach but could not develop it because of lack of data to populate each health state. The committee agreed that the model structure proposed by the ERG has some merit, but acknowledged that implementing it would be a complex undertaking. It noted that the main driver of the model is overall survival and, whichever approach is used, the immaturity of the clinical evidence and the complexity of the clinical pathway are limiting factors in the modelling of long-term outcomes. It understood the ERG's concern that the company's model uses extrapolation of PFS-2 to predict survival, not overall survival data from the trial, which is a significant limitation of the company's approach. However, the committee was concerned that a different model structure would not resolve the uncertainties associated with the overall survival modelling. It therefore concluded that the 4-state model is acceptable for decision making.

## *Modelling overall survival*

### **The modelling of overall survival is very uncertain**

3.11 The key driver of the results of the model is the way in which overall survival is modelled. The company did not estimate an overall survival curve for the routine surveillance arm using the immature SOLO-1 overall survival data, because it considered that any extrapolation method using this immature data would result in unrealistic survival estimates in the routine surveillance arm. Instead, it used PFS-2 as a surrogate for overall survival. The committee acknowledged that PFS-2 is generally accepted as an indicator of prolonged benefit in clinical trials of maintenance treatments (see [section 3.8](#)). However, it was concerned that the model outputs do not reflect the SOLO-1 interim results, which show convergence of the curves after about 40 months of follow up (see [section 3.7](#)). By contrast, the model predicts that at 20 years about 20% more people are alive in the olaparib arm compared with the routine surveillance arm (38% compared with 18%). The clinical experts considered that in the absence of more mature clinical data this is a reasonable prediction and in

line with expectations given the overall survival results from study 19. The committee noted that the survival curves in study 19 also converged at early data cuts, but survival gains were observed after several years. It is unknown whether the results of SOLO-1 will mirror this pattern with longer follow up (see [section 3.7](#)). The committee also noted that the modelling results for the routine surveillance arm are broadly consistent with the survival rates from the Edinburgh Ovarian Cancer Database, which it had concluded provides some real-world data on survival outcomes (see [section 3.9](#)). The committee acknowledged this but reiterated that not using the available overall survival data from the trial is a major weakness of the modelling. It considered that the modelling of overall survival is associated with considerable uncertainty and may overestimate the survival gain for olaparib, based on the data available from the trial so far. It concluded that it is not possible to resolve this uncertainty until more mature overall survival data are available from SOLO-1.

## *Cost-effectiveness estimate*

### **Olaparib has not been shown to be cost effective compared with routine surveillance**

3.12 The company's base-case incremental cost-effectiveness ratio (ICER) for olaparib compared with routine surveillance using the 4-state model is £17,480 per quality-adjusted life year (QALY) gained. However, the committee considered that this ICER is highly uncertain for the following reasons:

- The modelling of overall survival is extremely uncertain and may overestimate the survival gain for olaparib based on the data currently available from SOLO-1 (see [section 3.9](#)).
- The percentage of patients eligible for olaparib in the NHS who have a complete response to platinum-based chemotherapy could be less than in the trial. The clinical experts estimate it to be about 70% of all responders, whereas it was 82% in SOLO-1. It is expected that people in complete response are more likely to have long-term benefit than those with residual disease. A lower percentage of people with complete response in the NHS could result in worse outcomes than seen in the trial.
- There is uncertainty about the percentage of people who would have residual disease and be eligible to continue olaparib treatment beyond 2 years, and this could have a large impact on treatment costs. The committee concluded that about 15% of patients in UK clinical practice could be eligible to continue treatment beyond 2 years,

- compared with 10% in the company's model. However, the estimate of 15% may be optimistic because of the worse outcomes of people with ovarian cancer in the UK (see [section 3.5](#)).
- There is uncertainty about use of PARP inhibitors after second-line platinum-based chemotherapy and about retreatment with a PARP inhibitor (see [section 3.3](#) and [section 3.4](#)).
- The price per tablet of olaparib is the same regardless of dose, so the cost of treatment per day for a reduced dose is the same as a full dose. Using the cost of olaparib at full dose increases the ICER, and it was concluded after technical engagement that the modelling should use the cost of whole tablets rather than the average cost per milligram.

Because of these uncertainties the committee considered that the ICER could be substantially higher than the company's estimate, and the committee was not convinced that the ICER had been shown to be within the range normally considered a cost-effective use of NHS resources (that is, between £20,000 and £30,000 per QALY gained). Therefore, it concluded that it could not recommend olaparib for routine use in the NHS as first-line maintenance treatment for BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer.

## *Cancer Drugs Fund*

### **Mature overall survival data would resolve the uncertainties in the clinical and cost-effectiveness evidence**

- 3.13 Having concluded that olaparib could not be recommended for routine use, the committee then considered if it could be recommended within the Cancer Drugs Fund for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy. The committee discussed the arrangements for the Cancer Drugs Fund agreed by NICE and NHS England in 2016, noting NICE's [Cancer Drugs Fund methods guide \(addendum\)](#). It recognised that olaparib is an innovative treatment for advanced disease after first-line platinum-based chemotherapy. It therefore considered whether clinical uncertainty associated with olaparib could be addressed through collection of additional data from SOLO-1. The committee heard from the company that an interim overall survival analysis is expected within the next 2 years. It agreed that more mature

overall survival data would be a valuable addition to the clinical evidence base and are likely to resolve the major uncertainties. The committee concluded that overall survival data from SOLO-1 should be directly used in the company's future modelling of overall survival.

## **Olaparib meets the criteria for inclusion in the Cancer Drugs Fund for treating BRCA mutation-positive advanced ovarian, fallopian tube or primary peritoneal cancer**

3.14 The committee recalled that the company's base-case ICER for olaparib compared with routine surveillance is £17,480 per QALY gained. It is based on the assumptions that 82% of people have complete response to platinum-based chemotherapy before starting olaparib, and no more than 10% of people will continue treatment beyond 2 years. The committee recalled that these assumptions are uncertain and may not reflect clinical practice in the NHS (see [section 3.5](#) and [section 3.12](#)). Importantly, the company's analysis also assumes that about 20% of people will be cured from ovarian cancer. Although the clinical experts had explained that cure is possible and the 20% estimate is plausible, the committee noted that no overall survival benefit has yet been demonstrated in SOLO-1 (see [section 3.7](#)). Therefore, the committee considered that the company's base-case ICER may be an optimistic estimate of the cost effectiveness of olaparib (see [section 3.12](#)) and that it is plausible that the ICER could be much higher, exceeding the range that is usually considered an efficient use of NHS resources. However, while accepting that the upper bound of the range of plausible ICERs is highly uncertain, the committee considered that there is plausible potential for olaparib to be cost effective in routine use, pending the results from SOLO-1. Therefore, olaparib meets the criteria for inclusion in the Cancer Drugs Fund for treating BRCA mutation-positive advanced ovarian, fallopian tube or primary peritoneal cancer after response to first-line platinum-based chemotherapy.

## **Conclusion**

### **Olaparib has the plausible potential to be cost effective and is recommended for use within the Cancer Drugs Fund**

3.15 Results from SOLO-1 show an impressive improvement in progression-free survival for olaparib compared with placebo. However, mature overall survival data are not available yet and the extent to which the progression-free survival benefit will translate into an overall survival benefit is unknown. Because of the



uncertainty about the overall survival benefit, the estimates of cost effectiveness are very uncertain and olaparib cannot be recommended for routine use in the NHS. If olaparib increases overall survival it has the potential to be cost effective. Mature overall survival data from SOLO-1 are needed to address the uncertainties in the clinical and cost effectiveness. Olaparib is therefore recommended for use within the Cancer Drugs Fund as an option for treating BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer while further overall survival data are collected.



## 4 Implementation

- 4.1 When NICE recommends a treatment as an option for use within the Cancer Drugs Fund, NHS England will make it available according to the conditions in the managed access agreement. This means that, if a patient has BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer and the doctor responsible for their care thinks that olaparib is the right treatment, it should be available for use, in line with NICE's recommendations and the Cancer Drugs Fund criteria in the managed access agreement. Further information can be found in NHS England's [Appraisal and funding of cancer drugs from July 2016 \(including the new Cancer Drugs Fund\) – A new deal for patients, taxpayers and industry.](#)
- 4.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance when the drug or treatment, or other technology, is approved for use within the Cancer Drugs Fund. When a NICE technology appraisal recommends the use of a drug or treatment, or other technology, for use within the Cancer Drugs Fund, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final appraisal document or agreement of a managed access agreement by the NHS in Wales, whichever is the later.

## 5 Recommendations for data collection

- 5.1 As a condition of the positive recommendation and the managed access agreement, the company is required to collect efficacy data from the SOLO-1 trial.

## 6 Appraisal committee members and NICE project team

### *Appraisal committee members*

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by [committee A](#).

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

The [minutes](#) of each appraisal committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

### *NICE project team*

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

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ISBN: 978-1-4731-3476-8

## Accreditation

