NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Appraisal consultation document

Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer

The Department of Health has asked the National Institute for Health and Care Excellence (NICE) to produce guidance on using niraparib in the NHS in England. The appraisal committee has considered the evidence submitted by the company and the views of non-company consultees and commentators, clinical experts and patient experts.

This document has been prepared for consultation with the consultees. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the consultees and commentators for this appraisal and the public. This document should be read along with the evidence (see the committee papers).

The appraisal committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, gender, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?

Note that this document is not NICE's final guidance on this technology. The recommendations in section 1 may change after consultation.

After consultation:

- The appraisal committee will meet again to consider the evidence, this appraisal consultation document and comments from the consultees.
- At that meeting, the committee will also consider comments made by people who are not consultees.
- After considering these comments, the committee will prepare the final appraisal determination.
- Subject to any appeal by consultees, the final appraisal determination may be used as the basis for NICE's guidance on using niraparib in the NHS in England.

For further details, see NICE's guide to the processes of technology appraisal.

The key dates for this appraisal are:

Closing date for comments: 1 March 2018

Second appraisal committee meeting: 14 March 2018

Details of membership of the appraisal committee are given in section 6.

1 Recommendations

1.1 The committee recognised the promising nature of niraparib, but was not persuaded that there is sufficient evidence of clinical and cost effectiveness for it to be recommended for routine commissioning for the maintenance treatment of relapsed, platinum-sensitive high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer that is in response (complete or partial) to platinum-based chemotherapy in adults.

1.2 The committee saw the potential of niraparib as a suitable candidate for use in the Cancer Drugs Fund. Therefore the company is invited to submit a proposal for including niraparib in the Cancer Drugs Fund for treating relapsed, platinum-sensitive high-grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer that has responded to the most recent course of platinum-based chemotherapy in adults, only if:

- they have a germline BRCA mutation and have had 2 courses of platinum-based chemotherapy or
- they do not have a germline BRCA mutation and have had 2 or more courses of platinum-based chemotherapy.

1.3 The Cancer Drugs Fund proposal should:

- detail any commercial access arrangements
- show plausible potential for cost effectiveness
- explain how data collection will address the main clinical uncertainties described in section 3
- state the likelihood that additional research will reduce uncertainty enough to support positive guidance in the future
- state how data will be collected and what data are currently available
- state when the results will be available
- if appropriate data are already being collected, summarise the study protocol.

Why the committee made these recommendations

People with relapsed, platinum-sensitive high-grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer have a high unmet clinical need because the disease has a poor prognosis and chemotherapy is the only available treatment for many people. Niraparib appears to be a promising treatment for this disease. Olaparib may be another treatment option, but it is only recommended for people with a BRCA mutation who have had 3 or more courses of platinum-based chemotherapy.

A clinical trial shows that niraparib extends progression-free survival, but the final results on overall survival are not available yet. Therefore, it's not clear whether niraparib will increase the length of time people live. Because of the uncertainty in the clinical evidence, the estimates of cost effectiveness are very uncertain. Therefore niraparib cannot be recommended for routine use in the NHS.

If niraparib increases the length of time people live, it may have the potential to be cost effective in people with a germline BRCA mutation who have had 2 courses of platinum-based chemotherapy, or people who do not have a germline BRCA mutation and have had 2 or more courses of platinum-based chemotherapy. More evidence is needed to address the uncertainties in the clinical and cost effectiveness for these groups of patients. The company is therefore invited to submit a proposal for including niraparib in the Cancer Drugs Fund.

2 Information about niraparib

Marketing authorisation indication	Niraparib (Zejula, Tesaro) has a marketing authorisation in the UK for 'the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy'.
Dosage in the marketing authorisation	300 mg, taken orally, once daily until disease progression.
Price	£4,500 for a 58-capsule pack of 100-mg capsules; £6,750 for an 84-capsule pack of 100-mg capsules (excluding VAT; British national formulary [BNF] online [accessed January 2018]). The pricing arrangement considered during guidance development was that the company had agreed a patient access scheme with the Department of Health. This scheme would provide a simple discount to the list price of niraparib with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence. The Department of Health considered that this patient access scheme would not constitute an excessive administrative burden on the NHS.

3 Committee discussion

The appraisal committee (section 6) considered evidence submitted by Tesaro and a review of this submission by the evidence review group (ERG). See the committee papers for full details of the evidence.

Clinical need and current management

People with ovarian cancer have a high unmet clinical need

3.1 The patient expert explained that relapsed ovarian, fallopian tube, or peritoneal cancer is a devastating condition with a poor prognosis. It is of great importance to patients and their families that new and innovative treatments that extend and improve quality of life are available. The patient expert emphasised that any extension to life is incredibly precious. The clinical and patient experts also explained that UK survival rates for ovarian cancer are among the worst in Western Europe. Possible reasons for this include late diagnosis of ovarian cancer in the UK and a tendency

for more radical surgical techniques and greater access to other drug treatments in other countries. The committee concluded that patients with ovarian cancer have a high unmet clinical need.

People with ovarian cancer will welcome a new treatment option that extends periods of remission and improves quality of life

3.2 The committee noted that olaparib is another maintenance treatment for relapsed platinum-sensitive ovarian cancer, but that NICE found this to be cost effective only for people with BRCA 1 or BRCA 2 mutations who have had 3 or more courses of platinum-based chemotherapy. For people who have had fewer than 3 courses of platinum-based chemotherapy, or who have had 3 or more courses but do not have BRCA1 or BRCA 2 mutations, chemotherapy is the only available active treatment. The clinical and patient experts explained that the chemotherapy regimens that are used have multiple and debilitating side effects that are a huge burden to patients and diminish their quality of life. Also, with each course of chemotherapy, there is an increased risk of resistance. Patients and clinicians therefore welcome any treatment that extends the period between courses of chemotherapy, because this means longer periods in which people can lead a normal life. The clinical experts explained that poly-ADP-ribose polymerase (PARP) inhibitors such as niraparib are considered to be extremely promising and innovative new treatments. The patient expert emphasised that it would be most beneficial to patients to have niraparib as a treatment option after 2 courses of chemotherapy when they still feel relatively well, rather than after 3 courses of chemotherapy as is the case with olaparib. The committee concluded that a new treatment that extends periods of remission and improves quality of life for patients with ovarian cancer would be greatly valued by patients and their families.

The evidence on clinical effectiveness is relevant to clinical practice in England

3.3 The clinical evidence came from NOVA, which was a double-blind, randomised, placebo-controlled trial. NOVA assessed the clinical effectiveness of niraparib in people who have relapsed, platinum-sensitive ovarian cancer, with and without a germline BRCA mutation. Patients had previously had 2 or more platinum-based chemotherapy regimens and had responded to the last regimen. The committee considered that NOVA was well conducted, and the baseline characteristics of people in the trial were well balanced between treatment groups and represent patients who would be eligible for niraparib therapy in clinical practice in England.

Niraparib improves progression-free survival compared with placebo in people with or without a germline BRCA mutation, but the benefit appears to be greatest in people with a germline BRCA mutation

3.4 Progression-free survival was the primary endpoint in NOVA. The median progression-free survival for niraparib and for placebo in people without a germline BRCA mutation (that is, the germline mutation-negative group) was 9.9 and 3.9 months respectively. The difference in median progression-free survival between niraparib and placebo was 5.4 months (Hazard Ratio [HR] 0.45; 95% confidence interval [CI] 0.34 to 0.61; $p<0.001$). For patients with a germline BRCA mutation (that is, the germline mutation-positive group), median progression free survival for niraparib and placebo was 21 and 5.5 months respectively. The difference in median progression-free survival was 15.5 months (HR 0.27, 95% CI 0.17 to 0.41; $p<0.001$). The committee noted that niraparib increased progression-free survival compared with placebo in both groups, but the greatest apparent benefit was in the germline mutation-positive group. The clinical experts advised that having a BRCA mutation is a good predictor of response to a PARP inhibitor. The committee concluded that niraparib improves progression-free survival in people with or without a germline BRCA mutation, but the benefit appears to be greatest in people with a germline BRCA mutation.

Progression-free survival was higher in patients with homologous recombination deficiency (HRD) positive tumours than in the overall germline mutation-negative group, but the HRD test is not considered reliable enough for predicting treatment benefit

3.5 The company presented data for a germline mutation-negative subgroup of patients who had HRD-positive tumours. The difference in median progression-free survival between niraparib and placebo in the HRD-positive subgroup was 9.1 months (HR 0.38, 95% CI 0.24 to 0.59; p<0.001). The committee noted that this was higher than for the overall germline mutation-negative group (see section 3.4). The clinical experts explained that the results for the HRD-positive subgroup are unreliable because the 2 available tests for HRD do not reliably identify patients who would and would not benefit from therapy. HRD testing is therefore considered to be experimental and, as a result, is not routinely available within the NHS. The committee concluded that HRD testing is not reliable as a means of identifying patients who would and would not benefit from niraparib treatment, and therefore it decided against making a specific recommendation for this group.

Overall survival data from NOVA are immature

3.6 Fewer than 20% of patients in the intention-to-treat population of NOVA had died at the latest analysis, and median overall survival had not been reached. The committee considered whether treatment with niraparib is likely to lead to an increase in overall survival and the size of any benefit. The clinical experts advised that the progression-free survival benefit shown for niraparib would be expected to translate into an overall survival benefit, but the magnitude of this is difficult to establish. They referred to analyses from NOVA showing the time between progression after niraparib or placebo maintenance therapy, and progression after the next subsequent anti-cancer therapy. The time between the 2 points was not significantly different between niraparib and placebo, indicating that the next line of treatment worked equally well regardless of whether patients had had niraparib or placebo. The clinical experts explained that there are

multiple factors that could confound the overall survival results, including the use of subsequent therapies and crossover in the trial. They also highlighted that there is a small subgroup of exceptional survivors (about 15% of patients) who are still in remission and disease-free for over 5 years with a PARP inhibitor. However, there are no methods currently available to identify these people in advance. The committee concluded that there is no reason to suppose that the overall survival benefit will be less than the progression-free survival benefit, but it is uncertain whether the overall survival benefit will be equal to or exceed the progression-free survival benefit.

Niraparib extends the chemotherapy-free interval, but it is not known whether this influences response to subsequent platinum-based chemotherapy

3.7 In both the germline mutation-positive and germline mutation-negative groups, there was a statistically significant increase in the chemotherapy-free interval for niraparib compared with placebo. The committee recalled that this is an important outcome for patients because of the debilitating effects of chemotherapy (see section 3.1). For the germline mutation-positive group, the median chemotherapy-free interval for niraparib was 22.8 months compared with 9.4 months for placebo (HR 0.26, 95% CI 0.17 to 0.41; p<0.001). For the germline mutation-negative group, the median chemotherapy-free interval for niraparib was 12.7 months compared with 8.6 months for placebo (HR 0.50, 95% CI 0.37 to 0.67; p<0.001). The committee considered whether prolonging the chemotherapy-free interval through maintenance treatment with niraparib could affect response to the subsequent course of platinum-based chemotherapy. The clinical experts explained that this is currently unknown and is difficult to predict with the available data. The committee concluded that niraparib extends the chemotherapy-free interval, compared with placebo, but that it is not known whether this influences response to subsequent platinum-based therapy.

Indirect treatment comparison of niraparib and olaparib

Niraparib has not been shown to be more effective than olaparib in patients with a germline BRCA mutation who have had 3 or more courses of chemotherapy

3.8 There is no direct trial evidence comparing niraparib and olaparib. The company therefore carried out an indirect comparison of niraparib and olaparib to estimate their relative efficacy in people with BRCA mutation-positive ovarian cancer who have had 3 or more courses of chemotherapy (for whom olaparib is recommended by NICE). The results showed no statistically significant differences in progression-free survival between the 2 treatments, although the point estimates favoured olaparib. The committee noted that the ERG had made some adjustments to the analysis but this also showed no statistically significant differences. The committee concluded that niraparib has not been shown to be more effective than olaparib in people with BRCA mutation-positive ovarian cancer who have had 3 or more courses of chemotherapy.

Adverse events

Niraparib has a manageable adverse-event profile

3.9 The most common adverse events with niraparib in NOVA were nausea, loss of appetite, fatigue, headache, constipation, thrombocytopenia, anaemia and neutropenia. In the niraparib and placebo arms, 74.1% and 22.9% of patients had a grade 3 or higher adverse event respectively. In the niraparib arm 14.7% of patients stopped treatment because of adverse events (2.2% in the placebo arm). The clinical and patient experts explained that niraparib is extremely well tolerated and adverse events tend to be manageable and short lived. Most of the haematological adverse events were identified through routine blood tests, and the patients were unaware of them. The committee concluded that niraparib has a manageable adverse-event profile.

The company's economic model

The choice of model structure was not critical to the decision making

3.10 The company presented a 3-state decision analytic model to estimate the cost effectiveness of niraparib in 3 groups of patients:

- people without a germline BRCA mutation who have had 2 or more courses of platinum-based chemotherapy (that is, the germline mutation-negative-2L+ group), compared with routine surveillance
- people with a germline BRCA mutation who have had 2 courses of platinum-based chemotherapy (that is, the germline mutation-positive-2L group), compared with routine surveillance
- people with a germline BRCA mutation who have had 3 or more courses of platinum-based chemotherapy (that is, the germline mutation-positive-3L+ group), compared with olaparib.

The model used mean progression-free survival and overall survival for each treatment, rather than modelling transitions between health states. The costs and quality-adjusted life years (QALYs) for each treatment were accumulated based on the mean time spent in the progression-free and progressed-disease health states. The ERG considered that the company's model structure was inappropriate and preferred a partitioned survival model approach. The committee heard that the company had explored other model structures including a partitioned survival model, and found that the cost effectiveness results differed by no more than £1,000 per QALY gained, as long as the same assumptions for survival were used, which is a key driver of the results. The committee accepted that the model was adequate for decision making and that the choice of model structure was not critical.

The modelling of progression-free survival is very uncertain

3.11 The choice of survival curves to model progression-free survival had a major impact on the cost effectiveness results for the germline mutation-negative-2L+ and the germline mutation-positive-2L groups. The company

and the ERG disagreed about the selection of curves and used different curves to inform their respective base-case analyses. The ERG considered that the company relied too heavily on the statistical fit of the curves over clinical validity, which caused the company to apply a 20-year cap to the curves to overcome the implausibly long tails produced by the selected distributions. The ERG preferred curve choices based on a distribution that predicted no patients remained alive and progression-free by 10 years for niraparib, and by 5 years for routine surveillance, combined with visual fit to the observed Kaplan–Meier data. However, the committee heard from the clinical experts that it is biologically plausible that patients on niraparib could survive longer than 10 years, and therefore the ERG's assumption of a cut-off at 10 years was potentially pessimistic. The committee also heard from the company that in their opinion, the ERG's distributions showed a worse statistical fit. The committee concluded that there is a progression-free survival benefit with niraparib but the best way to model it is very uncertain.

The overall survival estimates in the model are highly uncertain

3.12 The company estimated overall survival in the model by assuming a 2:1 ratio for overall survival and progression-free survival gain. The company explained that this was based on the relationship between overall survival and progression-free survival gain in a trial of olaparib (study 19), using mature data from a subgroup of people with a BRCA mutation. The ERG considered that the 2:1 ratio was unreliable and needed further validation. It preferred to assume that all patients regardless of treatment have the same post-progression risk of death, leading to much higher incremental cost-effectiveness ratios (ICERs) for niraparib. The clinical experts considered that the company's assumption that overall survival benefit is twice the progression-free survival benefit was likely to be optimistic, but that the size of any survival benefit was not yet known. The committee accepted that study 19, which was carried out in patients with ovarian cancer treated with a PARP inhibitor, was the best currently available evidence on overall survival benefit. However this does not mean that the

NOVA trial will ultimately yield the same result for niraparib, particularly as the subgroup from study 19 was people with a BRCA mutation, so the results may not apply to people without a BRCA mutation. The committee concluded that it is not possible to resolve the uncertainty about the overall survival benefit with niraparib until mature data from NOVA become available.

Time to treatment discontinuation, as measured in the NOVA trial, is a better indicator of length of treatment in clinical practice than progression-free survival

3.13 The company and the ERG had different approaches to modelling time to treatment discontinuation. The assumptions used had a major impact on the cost effectiveness results (see section 3.14) for the germline mutation-negative-2L+ group and to a lesser extent the germline mutation-positive-2L group. The company applied log-logistic and lognormal distributions for the germline mutation-negative-2L+ and the germline mutation-positive-2L groups respectively. The ERG explained that progression-free survival in the model was based on independent review committee evaluation but time to treatment discontinuation was based on investigator assessment. Time to treatment discontinuation in the model is shorter than progression-free survival because patients could be clinically assessed to have progressed before the independent review committee reviewed the evidence. The ERG preferred to assume that time to treatment discontinuation is equal to progression-free survival, because niraparib is only stopped on disease progression or because of unacceptable toxicity. The clinical experts explained that time to treatment discontinuation in the trial would more closely reflect treatment discontinuation in clinical practice than independent retrospective assessment of progression-free survival. The committee concluded that the company's estimation of time to treatment discontinuation was more reflective of real life clinical practice and therefore the most appropriate.

Niraparib has not been shown to be cost effective compared with routine surveillance in people with a germline BRCA mutation who have had 2 previous courses of chemotherapy, or in people without a germline BRCA mutation who have had 2 or more previous courses of chemotherapy

3.14 The ICERs estimated by the company and ERG for the germline mutation-negative-2L+ group ranged from £29,560 to £101,500 per QALY gained, respectively. However, the committee understood that the ERG's estimate of £101,500 per QALY gained was based on the assumption that time on treatment would be equal to investigator assessed progression free survival which it had concluded was less reflective of real life clinical practice than using time to treatment discontinuation in the trial (see section 3.13). For the germline mutation-positive-2L group, the ICERs ranged from £25,835 (company's base case) to £68,429 (ERG's base case) per QALY gained. The committee considered that the results for both groups were associated with considerable uncertainty because of the immaturity of the overall survival data and uncertainty about the best way to model progression-free survival. It also considered that the ERG's estimates were likely to represent worst case scenarios being based on less favourable assumptions for progression-free and overall survival. The committee concluded that these uncertainties could only be resolved with the availability of more mature data from NOVA. Therefore, the committee was not confident that niraparib represented a cost effective use of NHS resources and could not recommend it for routine commissioning. However, if the company's prediction of a 2:1 ratio for overall survival to progression-free benefit is substantiated in the NOVA trial, then this would very favourably affect the ICER.

Niraparib is not cost effective compared with olaparib in patients with a germline BRCA mutation who have had 3 or more previous courses of therapy

3.15 The ICERs for the germline mutation-positive-3L+ population ranged from £14,078 per QALY gained for niraparib (company's base case estimate) to dominated (ERG's estimate). The committee recalled that there was no direct trial evidence comparing niraparib with olaparib but that the results

of the indirect comparisons suggested no statistically significant differences in progression-free survival between the 2 drugs (see section 3.8). Therefore, the committee considered that niraparib could only be considered cost effective at the same or a lower overall cost than olaparib. The committee concluded that it could not recommend niraparib as a cost-effective use of NHS resources for people with a germline BRCA mutation who have had 3 or more previous lines of chemotherapy.

End of life

3.16 The committee considered the advice about life-extending treatments for people with a short life expectancy in NICE's Cancer Drugs Fund technology appraisal process and methods. It noted that the company had made a case for applying the end-of-life criteria to the subgroup of people without a germline BRCA mutation.

End-of-life criteria for people without a germline BRCA mutation are not met

3.17 The committee acknowledged that there are various sources of evidence that provide different estimates for life expectancy without niraparib for people without a germline BRCA mutation, and that the precise figure is uncertain. However, it noted that the estimated life expectancy with routine surveillance from the company's model, which it had accepted as suitable for decision making (see section 3.10), was 2.87 years. The committee was therefore not persuaded that the life expectancy for people without a germline BRCA mutation had been shown to be less than 24 months without niraparib treatment, and it concluded that the end-of-life criteria were not met.

Cancer Drugs Fund

Niraparib meets the criteria to be considered for inclusion in the Cancer Drugs Fund for people with a germline BRCA mutation who have had 2 courses of

platinum-based chemotherapy, or in people without a germline BRCA mutation who have had 2 or more courses of platinum-based chemotherapy

3.18 Having concluded that niraparib could not be recommended for routine use, the committee then considered if it could be recommended for treating relapsed platinum-sensitive ovarian cancer in the germline mutation-negative-2L+ and the germline mutation-positive-2L populations within the Cancer Drugs Fund. The committee discussed the new arrangements for the Cancer Drugs Fund agreed by NICE and NHS England in 2016, noting the addendum to the NICE process and methods guides.

3.19 The committee recognised that niraparib is an innovative treatment for relapsed ovarian cancer and therefore it considered whether clinical uncertainty associated with niraparib could be addressed through collection of additional data and maturing evidence from the NOVA trial. It agreed that:

- mature data on overall survival and progression-free survival would be a valuable addition to the clinical evidence base and likely to resolve the major uncertainties identified
- with further evidence it may be possible to gain a more complete understanding of who would benefit most from treatment using somatic and other testing
- use in the NHS would allow collection of data on the duration of treatment in clinical practice.

3.20 The committee recalled that the ICERs estimated by the company for the germline mutation-positive-2L group and the germline mutation-negative-2L+ group were £25,837 and £29,560 per QALY gained respectively (see section 3.14). It considered that at this level the ICERs had the plausible potential to be cost effective in routine use, pending the results on overall survival from NOVA. The committee concluded that niraparib meets the criteria to be considered for inclusion in the Cancer Drugs Fund for

treating relapsed platinum-sensitive ovarian cancer in the germline mutation-positive-2L and the germline mutation-negative-2L+ populations.

Conclusion

Niraparib has shown promising clinical benefits compared with placebo but it is unclear whether, and by how much, it will extend overall survival

3.21 Evidence from NOVA suggests that niraparib improves progression-free survival and extends the chemotherapy-free interval compared with placebo. However, overall survival data are immature. The committee was therefore unclear whether, and by how much, niraparib will extend overall survival, although it concluded that there is no reason to suppose that the overall survival benefit will be less than the progression-free survival benefit.

The company is invited to submit a proposal for inclusion in the Cancer Drugs Fund for people with a germline BRCA mutation who have had 2 courses of platinum-based chemotherapy, or in people without a germline BRCA mutation who have had 2 or more courses of platinum-based chemotherapy

3.22 The overall survival benefit for niraparib compared with routine surveillance is highly uncertain, and assumptions around the likely benefit have a major effect on the estimates of cost effectiveness. More survival data from NOVA are needed in order to produce robust estimates of cost effectiveness. Therefore, niraparib cannot be recommended for routine commissioning for people with a germline BRCA mutation who have had 2 courses of platinum-based chemotherapy, or in people without a germline BRCA mutation who have had 2 or more courses of platinum-based chemotherapy. However, the committee recognised that niraparib is an innovative treatment that meets the criteria to be considered for inclusion in the Cancer Drugs Fund, and that this would allow uncertainties in the clinical evidence to be addressed through the collection of additional data and maturing evidence from NOVA.

Niraparib is not cost effective compared with olaparib in people with germline BRCA mutation-positive ovarian cancer who have had 3 or more courses of platinum-based chemotherapy

3.23 Niraparib has not been shown to be more effective than olaparib in people with BRCA mutation-positive ovarian cancer who have had 3 or more courses of platinum-based chemotherapy. The committee considered that niraparib can only be considered cost effective at the same or a lower overall cost than olaparib. Therefore, niraparib is not recommended as a treatment option for this group of patients.

4 Recommendations for data collection

4.1 The NOVA trial is ongoing and this will provide mature overall survival data that is needed to provide robust estimates of cost effectiveness.

5 Proposed date for review of guidance

5.1 NICE proposes that the guidance on this technology is considered for review by the guidance executive 3 years after publication of the guidance. NICE welcomes comment on this proposed date. The guidance executive will decide whether the technology should be reviewed based on information gathered by NICE, and in consultation with consultees and commentators.

5.2 If niraparib enters the Cancer Drugs Fund, the process for exiting the Cancer Drugs Fund will begin at the end of the data collection period.

Jane Adam
Chair, appraisal committee
February 2018

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.

Irina Voicechovskaja
Technical Lead

Zoe Charles
Technical Adviser

Thomas Feist
Project Manager

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