NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final appraisal document

Niraparib for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy

1 Recommendations

1.1 Niraparib is recommended for use within the Cancer Drugs Fund as an option for maintenance treatment for advanced (FIGO stages 3 and 4) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer after response to first-line platinum-based chemotherapy in adults. It is recommended only if the conditions in the managed access agreement for niraparib are followed.

1.2 This recommendation is not intended to affect treatment with niraparib 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 no maintenance treatments routinely available for advanced ovarian, fallopian tube or peritoneal cancer that has responded to first-line platinum-based chemotherapy. For some people, maintenance treatment is available through the Cancer Drugs Fund.

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Clinical evidence comes from PRIMA, an ongoing clinical trial, which shows that niraparib delays disease progression. But it has not shown whether people having niraparib live longer, because they have not been followed up for long enough.

Because of the clinical uncertainty, the cost-effectiveness estimates are very uncertain. They may be higher than what NICE normally considers an acceptable use of NHS resources. So, niraparib cannot be recommended for routine use in the NHS.

Longer follow-up data from PRIMA could help address the uncertainty about the clinical effectiveness of niraparib in this population. Niraparib has the potential to be a cost-effective use of NHS resources. So, it is recommended for use in the Cancer Drugs Fund while more data from the trial are collected.

2 Information about niraparib

Marketing authorisation indication

2.1 Niraparib (Zejula, GlaxoSmithKline) has a marketing authorisation in the UK 'as monotherapy for the maintenance treatment of adult patients with advanced epithelial (FIGO Stages 3 and 4) high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy'.

Dosage in the marketing authorisation

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

Price

2.3 The list price is £4,500 for 56 × 100-mg capsules (excluding VAT; BNF online accessed November 2020). The company has a commercial arrangement (a simple discount patient access scheme and a managed access agreement including a commercial access agreement). This makes niraparib 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 appraisal committee considered evidence submitted by GlaxoSmithKline, a review of this submission by the evidence review group (ERG), NICE's technical report, and responses from 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:

- the first-line treatment response rates from the PRIMA trial were generalisable to rates seen in UK practice (issue 1, see technical report page 2)
- the dose of niraparib included in the model for continued treatment after 3 years is appropriate (issue 1, see technical report page 2)
- not including the long-term remission assumption in the model is appropriate (issue 7, see technical report page 11).

At technical engagement, the company accepted the ERG's revised costs for heart rate and blood pressure monitoring and the alternative resource-use estimates for progression-free survival in the routine surveillance arm.

The committee recognised that there were remaining areas of uncertainty associated with the analyses presented and took these into account in its decision making. It discussed the following issues (issues 1 to 6 and 8 to 12), which were outstanding after the technical engagement stage.

The condition

People with ovarian cancer would welcome a new effective maintenance therapy

3.1 The patient expert explained that advanced platinum-sensitive ovarian, fallopian tube or primary peritoneal cancer is a devastating condition.

Knowing that the disease can relapse is a major psychological burden for people with the disease and their families. For most people without a BRCA1 or BRCA2 gene mutation there are no first-line maintenance treatments available for disease that has responded to platinum-based chemotherapy, although bevacizumab is available for some people through the Cancer Drugs Fund. People who are not eligible for first-line maintenance treatment have routine surveillance until the disease relapses. The patient expert explained that taking a maintenance treatment has a psychological benefit and improves quality of life compared with being on routine surveillance, which can feel like waiting for the cancer to come back. The clinical experts agreed with the patient expert. The committee recognised the need for effective maintenance treatment options after first treatment for advanced disease. It concluded that people would welcome new maintenance treatment options.

Treatment pathway

There is an unmet need for maintenance treatments after first-line platinum-based chemotherapy

3.2 First-line treatment for advanced ovarian, fallopian tube, or primary peritoneal cancer is surgery and platinum-based chemotherapy. Options for surgery are primary debulking surgery before first-line chemotherapy treatment, or interval debulking surgery between cycles of first-line chemotherapy. First-line maintenance treatment with a poly-ADP-ribose polymerase (PARP) inhibitor is available through the Cancer Drugs Fund for people with a BRCA1 or BRCA2 gene mutation. For people without a BRCA1 or BRCA2 gene mutation, there are no first-line PARP inhibitor maintenance treatments. Routine surveillance is the only option for people who are not eligible for maintenance treatment. The clinical experts explained that there is a high unmet need for more maintenance treatment options after first-line treatment for advanced disease. They noted that there is a clear population that would benefit from niraparib maintenance

therapy at this point in the treatment pathway. The committee concluded that there is an unmet need for new effective maintenance treatment options after first-line platinum-based chemotherapy.

Clinical evidence

The population covered by niraparib's marketing authorisation indication is broader than the population included in PRIMA

3.3 PRIMA is a double-blind, randomised controlled trial comparing niraparib with placebo as maintenance treatment of advanced ovarian cancer. It included people with or without a BRCA gene mutation, who had advanced (International Federation of Gynecology and Obstetrics [FIGO] stages 3 and 4) high-grade ovarian, fallopian tube or primary peritoneal cancer that was in response (complete or partial) to first-line platinum-based chemotherapy. The primary end point was progression-free survival based on blinded independent central review. PRIMA excluded people with stage 3 cancer who had no visible residual disease after primary debulking surgery. The rationale for excluding this group was that their prognosis was considered to be better than other groups with advanced ovarian cancer. However, niraparib's marketing authorisation includes all people with stage 3 or 4 high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response to first-line platinum-based chemotherapy. The committee concluded that the population covered by the marketing authorisation indication is broader than the population included in PRIMA.

Prognosis of stage 3 cancer is likely to be better when there is no visible residual disease after primary debulking surgery, compared with after interval debulking surgery

3.4 The ERG commented on the prognosis of stage 3 cancer after surgery. It suggested that the prognosis for no visible residual disease might be similar when achieved by primary debulking surgery and interval

debulking surgery. But the clinical experts explained that the prognosis for no visible residual disease after primary debulking surgery might be better than after interval debulking surgery. This is based on evidence from the EORTC-NCIC trial, which compared the outcomes of people with ovarian cancer with no visible residual disease after either type of surgery. The group with the best prognosis in the EORTC-NCIC trial was people with no visible residual disease after primary debulking surgery. However, the clinical experts explained that there is still uncertainty around which type of surgery leads to the best outcomes, and that the biggest prognostic factor is having no visible residual disease. The committee concluded it is likely that the prognosis of stage 3 cancer is better when there is no visible residual disease after primary debulking surgery, compared with after interval debulking surgery.

The treatment effect of niraparib is likely to be similar irrespective of surgery type

3.5 The clinical experts explained that although prognosis is likely to be different after primary debulking surgery compared with interval debulking surgery, they would not expect there to be a difference in the treatment effect of niraparib after either type of surgery. They highlighted that niraparib has been shown to be effective as a first-line maintenance treatment (see section 3.10) and for maintenance treatment for relapsed disease. There is no reason to expect that the outcomes after niraparib treatment would differ because of the type of surgery that had been done, if there is no visible residual disease. The committee concluded that the treatment effect of niraparib is likely to be similar for stage 3 cancer that has no visible residual disease after either primary debulking surgery or interval debulking surgery.

The proportion of people with stage 3 cancer and no visible residual disease after surgery is highly uncertain

3.6 The clinical experts explained that there is variation in the rate of achieving no visible residual disease after surgery in clinical practice in England. They also explained that the rates of primary debulking surgery and interval debulking surgery vary, because neither is widely accepted as the standard of care. They estimated that about 25% to 50% of people with advanced ovarian cancer may have stage 3 cancer and no visible residual disease after primary debulking surgery. However, this estimate is not reliable because there is no evidence available to support it. The committee concluded that the proportion of people with stage 3 cancer and no visible residual disease after surgery is highly uncertain, and there is no robust estimate of the size of this population in clinical practice.

The PRIMA intention-to-treat analysis is appropriate for decision-making

3.7 PRIMA did not include people with stage 3 cancer and no visible residual disease after primary debulking surgery. However, this population is included within the marketing authorisation indication (see section 3.3). Although the prognosis is likely to be different for no visible residual disease after primary debulking surgery compared with interval debulking surgery (see section 3.4), niraparib's treatment effect is unlikely to be different (see section 3.5). The company presented an analysis to adjust for the difference in prognosis between these groups. This used data from a clinical trial (PAOLA-1) of olaparib (a different PARP inhibitor) to show the treatment effect for a simulated 'PRIMA intention-to-treat population', which excluded people with stage 3 cancer and no visible residual disease after primary debulking surgery, compared with a population that included only these people. The ERG explained that although there is a difference in prognosis between these groups, the effect of this cannot be reliably estimated. And the PAOLA-1 data are not generalisable to PRIMA because of differences in the treatments taken. It explained that even if the treatment effect could be reliably estimated, the proportion of people

with stage 3 cancer and no visible residual disease after primary debulking surgery could not be reliably estimated (see section 3.6). The clinical experts agreed that there are no robust estimates of the proportion of people with stage 3 cancer and no visible residual disease irrespective of the type of surgery they had, so it is not possible to reliably adjust the PRIMA intention-to-treat data. The ERG explained that adjusting the PRIMA intention-to-treat data by reweighting the population with stage 3 cancer and no visible residual disease after interval debulking surgery would rely on having an estimate of the proportion of people with stage 3 cancer and no visible residual disease after primary debulking surgery. The committee acknowledged that PRIMA did not include people with stage 3 cancer and no visible residual disease after primary debulking surgery, and there was no reliable method to adjust the PRIMA data to account for this. It concluded that the population in PRIMA does not fully reflect the population who would likely be offered niraparib in clinical practice, but the PRIMA intention-to-treat analysis is appropriate for decision making.

PRIMA is generalisable to the dosage used in clinical practice

3.8 Because of a protocol change during the study, about two-thirds of people in PRIMA took a fixed dose of 300 mg of niraparib and around one-third took an individualised dose of niraparib based on weight and platelet count. The clinical experts explained that individualised dosing would be used in practice because of toxicity concerns, which is reflected in the summary of product characteristics. The company did subgroup analyses of fixed and individualised dosing in PRIMA. These suggested that niraparib increased progression-free survival compared with placebo, irrespective of the type of dosing. The ERG suggested that these analyses should be considered exploratory because they were done post hoc and were non-stratified. The committee agreed that the analyses were uncertain because the individualised dosing group had fewer participants and shorter follow up than the fixed-dose group. Also, PRIMA

was not powered to show a difference between the dosing groups. The committee acknowledged that the progression-free survival benefit is more uncertain for the individualised dosing group, as shown by wider confidence intervals. It noted that the summary of product characteristics states that exploratory subgroup analyses of fixed and individualised dosing show comparable efficacy for them both. The clinical experts explained that based on the dose taken by participants in PRIMA, it was likely to be generalisable to clinical practice. They also noted that niraparib's efficacy using individualised dosing is supported by evidence from NOVA (a study of niraparib in relapsed disease). This suggested that a dose of less than 300 mg does not reduce efficacy. The committee concluded that the evidence in PRIMA is generalisable to the dose which will be used in clinical practice.

Subsequent treatments used in PRIMA are not fully representative of clinical practice, but data are generalisable to clinical practice

3.9 Of the participants who had progressed disease in PRIMA, 85% of people on niraparib and 81% on routine surveillance had chemotherapy after progression. The clinical experts explained that this reflects clinical practice, because PRIMA excluded people with stage 3 cancer and no visible residual disease after primary debulking surgery. So, people in PRIMA had a poorer prognosis than the population who would be eligible for niraparib in the NHS. A small percentage of participants in PRIMA had a PARP inhibitor or immunotherapy after first-line niraparib maintenance treatment. The clinical experts explained that this is not representative of clinical practice in England. The committee acknowledged that PRIMA included a small proportion of people having subsequent treatments that are not available in the NHS but concluded that the PRIMA data are generalisable clinical practice.

Clinical effectiveness

Niraparib improves progression-free survival compared with placebo

3.10 Median progression-free survival in PRIMA was 13.8 months with niraparib and 8.2 months with placebo. The difference in median progression-free survival was 5.6 months (hazard ratio 0.62, 95% confidence interval 0.50 to 0.76; p<0.001). Subgroup analyses indicated that niraparib increases median progression-free survival compared with placebo for people with or without a BRCA gene mutation. The committee concluded that niraparib improves progression-free survival for people with ovarian cancer that has completely or partially responded to first-line platinum-based chemotherapy.

PRIMA data on overall survival and time to second progression are immature

3.11 Overall survival was a secondary end point in PRIMA. Less than 11% of participants in PRIMA had died at the latest analysis (9.9% in the niraparib arm and 12.6% in the placebo arm). The difference in overall survival was not statistically significant (hazard ratio for death 0.70, 95% confidence interval 0.44 to 1.11) and it is not yet clear whether niraparib will improve overall survival. The clinical experts acknowledged the uncertainty in the results but suggested that niraparib might improve overall survival and may lead to cure in some people. Time from randomisation to disease progression on the next anti-cancer therapy (PFS2) was also a secondary end point in PRIMA. The PFS2 event rate (20%) was low and there was no statistically significant difference between niraparib and placebo (hazard ratio 0.81, 95% confidence interval 0.58 to 1.14). The committee concluded that the data for overall survival and PFS2 for niraparib after first-line treatment are immature and the survival benefit is uncertain.

The company's economic model

The company's model structure is appropriate for decision making

3.12 The company presented a 3-state partitioned survival model to estimate the cost effectiveness of niraparib compared with routine surveillance. The 3 health states were progression-free, progressed disease and death. The committee noted that PFS2 data are available in PRIMA. These could have been used to inform a 4-state model to capture the effect of second progression on quality of life and related costs. The company suggested that using a 4-state model would add additional uncertainty because the PFS2 data are immature (see section 3.11). The committee concluded that although there are uncertainties with the company's 3-state model, it is robust enough for decision making.

The overall-survival estimates in the company's model are highly uncertain

3.13 A key driver of the results in the model is the way in which overall survival estimates for niraparib are derived. The company estimated overall survival for the routine surveillance arm by fitting a log-logistic accelerated failure time model to the observed overall-survival data from PRIMA. The estimates were validated against overall-survival data for people on routine surveillance over 15 years from the University of Edinburgh Ovarian Cancer Database. The company estimated overall survival in the niraparib arm using a hazard ratio derived from assuming a 1:2 ratio for progression-free survival gain to overall-survival gain, and applied this to the log-logistic routine surveillance overall-survival curve. This ratio is based on an assumption that a 1-month gain in progression-free survival leads to a 2-month gain in overall survival. The ratio was chosen based on the relationship between progression-free survival and overall survival in a study of olaparib compared with routine surveillance as second-line maintenance treatment (Study 19), which has long-term follow-up data. The ERG considered that there was not sufficient evidence to support the

use of a progression-free survival to overall-survival ratio or to determine what ratio would be most appropriate. It explained that the hazard ratio derived from the 1:2 ratio used in the company's model did not reflect the hazard ratio observed for overall survival in PRIMA (see section 3.11). The ERG also explained that it is methodologically inappropriate to apply a hazard ratio to a log-logistic accelerated failure time model, which does not assume proportional hazards. Also, using a hazard ratio assumes a constant treatment effect over time and there is no evidence to support this assumption. The company highlighted that in other studies of olaparib maintenance such as Study 19, overall survival improved for olaparib compared with routine surveillance as more data accumulated during follow up. The committee acknowledged that the PRIMA overall-survival data are very immature. So, it is not known if the long-term results will show improvement in overall survival of a similar magnitude for niraparib as that seen with olaparib in Study 19. The clinical experts considered that the company's assumption that overall-survival benefit is twice the progression-free survival benefit is plausible. But they stated that the overall-survival data from PRIMA are too immature to reliably quantify the overall-survival benefit. Overall survival data for niraparib are available in PRIMA. The company could have extrapolated long-term overall survival for niraparib, as it did for the routine surveillance arm. The committee was disappointed that these data had not been included in the company's model. The company did not consider it appropriate to extrapolate the overall-survival data from PRIMA, because there were no real-world data that could be used to validate the curve for the treatment arm. The ERG highlighted that any estimation of overall survival should be validated, as should the use of a ratio for progression-free survival gain to overall survival gain. The committee acknowledged that extrapolated overall-survival from PRIMA data would be uncertain, but the ratio of progression-free survival to overall survival is also uncertain. It concluded that overall-survival gain may be at least equivalent to progression-free survival gain. But it is highly uncertain whether the overall survival gain will exceed the

progression-free survival gain, or by how much. It concluded that further overall-survival data will reduce the uncertainty.

Assumptions in the economic model

Time to treatment discontinuation is modelled appropriately by the company

3.14 The summary of product characteristics for niraparib recommends that treatment should be continued until disease progression or toxicity. It does not include a time-limited stopping rule. The company included a stopping rule in its model, which assumed that 15% of people who had not stopped treatment at 3 years would continue to have niraparib. A 3-year stopping rule was included in PRIMA, but some people took niraparib for longer than 3 years. The ERG noted that the proportion of people who continued taking niraparib after 3 years is unknown, so the ERG's base case did not include treatment discontinuation at 3 years. The clinical experts explained that most people would stop treatment with niraparib at 3 years unless there was evidence of stable, persistent disease. They considered that the proportion of people assumed to stop niraparib at 3 years in the company's model is appropriate. The committee concluded that the company's approach, which assumed a proportion of people stopping treatment at 3 years, is appropriate.

Age-related utility decrements should be included in the model

3.15 The company did not include age-related utility decrements in its base-case analysis. It suggested that this is appropriate because the quality of life measured in PRIMA was consistent across age groups and did not change considerably over a 56-week period. The ERG explained that the company's approach overestimates both the utility of people as they age and the cost effectiveness of niraparib. The ERG included age-related utility decrements in its analyses. The committee agreed it is reasonable to assume that people's quality of life decreases as they age, which should be reflected in the model. The committee did not consider the

company's justification for not including age-related utility decrements to be valid. It concluded that age-related utility decrements should be included in the model.

Subsequent treatments are modelled appropriately, but data are immature

3.16 The ERG noted that the PRIMA data are not mature enough to understand which second-line, third-line and maintenance treatments will be offered to people whose disease relapses. It highlighted the importance of interpreting overall-survival data alongside data on subsequent treatments after disease progression. This may be possible when more mature data becomes available from PRIMA. Because the subsequent treatments in the immature PRIMA data were not wholly representative of the treatment options in clinical practice (see section 3.9), the company obtained the costs for subsequent treatments from key opinion leaders and used these in its model. The committee concluded that the data on subsequent treatments in PRIMA are immature, but the company appropriately included subsequent treatments that are reflective of clinical practice in its model.

Cost-effectiveness results

None of the analyses reflect the committee's preferred assumptions

3.17 Because of confidential commercial arrangements for subsequent treatments in relapsed disease, none of the cost-effectiveness results are reported here. But none of the company's or ERG's analyses reflected the committee's preferences, which are as follows:

- use the PRIMA intention-to-treat population (see section 3.7)
- use a progression-free survival gain to overall survival gain ratio of 1:1 (see section 3.13)

- do not include a long-term remission assumption or costs in the progression-free survival health state after 10 years, which was agreed at technical engagement
- include the stopping rule with 15% of people still on niraparib at 3 years continuing treatment (see section 3.14)
- include age-related utility decrements (see section 3.15)
- include the revised costs of monitoring heart rate and blood pressure, which was accepted by the company at technical engagement
- include the alternative resource-use estimates for routine surveillance during progression-free survival, which was accepted by the company at technical engagement.

Niraparib is not recommended for routine use in the NHS

3.18 The committee acknowledged that the company's incremental cost-effectiveness ratios (ICERs) were within the range usually considered a cost-effective use of NHS resources. But the committee's preferred ICER was not within the range usually considered a cost-effective use of NHS resources. It noted that the biggest driver of cost effectiveness was the niraparib overall-survival estimate and that this was highly uncertain. Therefore, the committee concluded that the ICER for niraparib compared with routine surveillance was very uncertain, and that it could not recommend niraparib maintenance treatment for routine NHS use in adults with advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy.

Cancer Drugs Fund

Niraparib meets the Cancer Drugs Fund criteria

3.19 Having concluded that niraparib could not be recommended for routine use, the committee then considered if it could be recommended as maintenance treatment for advanced ovarian cancer after response to first-line platinum-based chemotherapy within the Cancer Drugs Fund. 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 noted that:

- The company expressed an interest in niraparib being considered for the Cancer Drugs Fund.
- Data from PRIMA are immature and median overall survival was not reached in the placebo arm.
- PRIMA is still ongoing and further data could help reduce uncertainties about long-term progression-free survival, overall survival and time to second progression.
- Overall survival was a key driver of the cost-effectiveness results.
- The Systemic Anti-Cancer Therapy dataset could provide data on stage 3 cancer with no visible residual disease after primary debulking surgery, the proportion of people having subsequent treatment and the treatments used.
- The company's price for niraparib, including a commercial arrangement, means that it has plausible potential to be cost effective.

The committee concluded that niraparib met the criteria to be considered for inclusion in the Cancer Drugs Fund. It recommended niraparib for use within the Cancer Drugs Fund as an option for people with advanced (FIGO stages 3 and 4) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer after response to first-line platinum-based chemotherapy if the conditions in the managed access agreement are followed. When the guidance is next reviewed the company should use the committee's preferred assumptions as set out in section 3.17, unless new evidence indicates otherwise.

Innovation

The model is adequate to capture the benefits of niraparib

3.20 The company considered niraparib to be innovative. It explained that there are no PARP inhibitors available as first-line maintenance treatment for

people who do not have a BRCA1 or BRCA2 gene mutation. It noted that niraparib will be the first treatment to offer the benefit of maintenance therapy to people with advanced ovarian cancer, irrespective of BRCA mutation status. The clinical experts agreed that niraparib would be a step-change in the first-line treatment of advanced ovarian cancer for people without a BRCA1 or BRCA2 gene mutation. The committee considered that the model included all health-related quality-of-life benefits. It concluded that it had not been presented with evidence of any additional benefits from maintenance treatment with niraparib that had not already been included.

Other factors

3.21 No equality or social value judgements issues were identified.

3.22 NICE's advice about life-extending treatments for people with a short life expectancy did not apply.

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 advanced high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer after response to first-line platinum-based chemotherapy and the doctor responsible for their care thinks that niraparib 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 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 use in the Cancer Drugs Fund, 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. Drugs that are recommended for use in the Cancer Drugs Fund will be funded in line with the terms of their managed access agreement, after the period of interim funding. The NHS England and NHS Improvement 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 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 Review of guidance

5.1 The data collection period is expected to end as outlined in the data collection arrangement, when the final analysis of the PRIMA study is available. Once enough evidence is available, the process for exiting the Cancer Drugs Fund will begin at this point and the review of the NICE guidance will start.

5.2 As part of the managed access agreement, the technology will continue to be available through the Cancer Drugs Fund after the data collection period has ended and while the guidance is being reviewed. This assumes that the data collection period ends as planned and the review of

guidance follows the standard timelines described in NICE's guide to the processes of technology appraisal.

Brian Shine
Vice-chair, appraisal committee A
January 2021

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.

Albany Meikle
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