

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

Dostarlimab with platinum-based chemotherapy for treating advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency

1 Recommendations

- 1.1 Dostarlimab with platinum-based chemotherapy is recommended with [managed access](#) as an option for treating primary advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency in adults who are candidates for systemic therapy. It is only recommended if the conditions in the [managed access agreement](#) for dostarlimab are followed.
- 1.2 This recommendation is not intended to affect treatment with dostarlimab with platinum-based chemotherapy 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

Usual treatment for primary advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency is platinum-based chemotherapy. The prognosis is poor for people with this condition, and there is an unmet need for more effective treatments.

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Clinical trial evidence shows that adding dostarlimab to usual treatment increases how long people have before their condition gets worse. Evidence suggests it also increases how long they live, but the long-term benefits are uncertain because the study only followed people for a short period of time.

Because of the uncertainty about its clinical effectiveness, there are uncertainties in the economic model. Some of the most likely cost-effectiveness estimates are higher than what NICE usually considers an acceptable use of NHS resources. This means dostarlimab with platinum-based chemotherapy cannot be recommended for routine use in the NHS.

Dostarlimab has the potential to be cost effective but more long-term evidence is needed to address the clinical uncertainties. So, dostarlimab is recommended for use with managed access.

2 Information about dostarlimab

Marketing authorisation indication

- 2.1 Dostarlimab (Jemperli, GSK) is indicated 'in combination with platinum containing chemotherapy for the treatment of adult patients with mismatch repair deficient/microsatellite instability-high primary advanced or recurrent endometrial cancer and who are candidates for systemic therapy'.

Dosage in the marketing authorisation

- 2.2 The dosage schedule is available in the [summary of product characteristics for dostarlimab](#).

Price

- 2.3 The list price for dostarlimab is £5,887.33 per 500 mg vial (excluding VAT, BNF online, accessed December 2023).

- 2.4 The company has a commercial arrangement (simple discount patient access scheme). This makes dostarlimab available to the NHS with a

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discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

3 Committee discussion

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

The condition

Clinical need

3.1 Endometrial cancer starts in the lining of the uterus. Symptoms can include vaginal bleeding, pelvic pain, unintended weight loss, nausea and fatigue. Around 23% of people with endometrial cancer have the subtype with high microsatellite instability (MSI-H) or DNA mismatch repair (dMMR) deficiency biomarkers. Endometrial cancer has a significant effect on both life expectancy and quality of life. People with advanced or recurrent endometrial cancer (meaning that the cancer has spread beyond the uterus or come back after previous treatment) have a poor prognosis. Only 15% of women diagnosed at stage 4 live for 5 or more years. The impact is not just limited to physical health, but the mental health and wellbeing of people and their families also. Patient experts emphasised that effective treatment options at this stage are limited, leaving people feeling frustrated, hopeless and abandoned. They highlighted the lack of treatment options in endometrial cancer compared with other cancer types. The committee concluded that advanced or recurrent endometrial cancer has a devastating effect on life expectancy and quality of life and that there is an unmet need for more effective treatments.

Current management

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3.2 Standard care for recurrent or advanced endometrial cancer is platinum-containing chemotherapy, with the most common regimen being carboplatin plus paclitaxel. People whose cancer progresses after chemotherapy may be offered immunotherapy treatment. Pembrolizumab with lenvatinib is available for all people who have previously received treatment for endometrial cancer (see [NICE technology appraisal on pembrolizumab with lenvatinib for previously treated advanced or recurrent endometrial cancer](#)). Dostarlimab is available through the Cancer Drugs Fund for people with MSI-H or dMMR endometrial cancer (see [NICE technology appraisal on dostarlimab for previously treated advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency](#)). This subtype of endometrial cancer is more likely to respond to immunotherapy treatment. The company submission moves dostarlimab to an earlier line of therapy, so instead of being given following disease progression on chemotherapy, dostarlimab could be given in combination with chemotherapy. The company says that bringing an immunotherapy earlier into the treatment pathway will result in more people being offered and benefitting from the treatment. The clinical expert said that once the cancer has progressed after chemotherapy, many people are unable to tolerate further treatment. This means that they are unable to access effective immunotherapy treatments in the second line setting. The patient expert said the current treatment approach is geared towards expecting a recurrence and then adding a more effective second line treatment. They felt the most effective treatments should be offered earlier in the pathway to reduce the risk of recurrence. The committee concluded that earlier access to immunotherapy would be welcomed by patients and clinicians and agreed that the company's positioning was appropriate.

Clinical evidence

Key trial results

3.3 The clinical evidence is based on an interim analysis of RUBY-1, a phase 3, randomised, double-blind, multicentre, placebo-controlled study in people with advanced or recurrent endometrial cancer. It provides direct evidence to compare dostarlimab plus carboplatin with paclitaxel (from now, dostarlimab) with placebo plus carboplatin with paclitaxel (from now, placebo). People in the trial needed to have endometrial cancer with a low potential for cure by radiation therapy, surgery alone, or in combination. In line with the marketing authorisation, the company gave efficacy data for people with dMMR or MSI-H primary advanced or recurrent endometrial cancer (dMMR/MSI-H population). The dMMR/MSI-H population was a pre-specified subgroup of the full RUBY-1 population. There was a statistically significant benefit for dostarlimab compared with placebo for both progression free survival (PFS) and overall survival (OS). At data cut-off (PFS data maturity of 56%), dostarlimab reduced the risk of progression or death by 72% compared to placebo (hazard ratio [HR] 0.28, 95% confidence interval [CI] 0.16 to 0.50). At OS maturity of 26%, dostarlimab reduced the risk of death by 70% compared with placebo (HR 0.30, 95% CI 0.13 to 0.70). The company noted that in addition to the hazard ratios, it was important to consider the percentage of people who were progression free at 24 months, and the longer duration of response with dostarlimab. The estimated probability of being progression free at 24 months was 61.4% (95% CI 46.3 to 73.4) in the dostarlimab arm and 15.7% (95% CI 7.2 to 27.0) in the placebo arm. The probability of the cancer remaining in response to treatment at 12 months was 62.1% (95% CI 44.4 to 75.5) in the dostarlimab arm, and 19.2% (95% CI 8.6 to 33.1) in the placebo arm. The clinical experts confirmed that the benefits seen in RUBY-1 were clinically meaningful. They also said it was similar to trials for other immunotherapy drugs in similar populations. The committee concluded that RUBY-1 is appropriate for decision-making and that dostarlimab shows clinical benefit in the relevant population.

Robustness of clinical trial data

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3.4 As discussed in section 3.3, the clinical evidence for this appraisal is based on RUBY-1. The EAG had concerns about whether RUBY-1 data reflects the true benefit of the treatment. It noted the small sample size of the dMMR/MSI-H population (n=118) and the immaturity of the data. The EAG also had concerns about the randomisation between the 2 arms, as there were more people in the placebo arm than the dostarlimab arm. It said people in the placebo arm were generally older in age and had a higher BMI but better performance status than the dostarlimab group, and that these factors could bias the treatment effect estimate. The company said that further analyses had been done to assess the potential impact of these differences, and the HR remained consistent in these. The clinical experts said that the small sample size was reasonable given the relatively small patient population in the NHS. The committee acknowledged the immaturity of the data, differences in baseline characteristics between the groups and small sample size. It concluded that adding dostarlimab to usual treatment is clinically effective, but the amount of benefit is uncertain.

Economic model

Company's modelling approach

3.5 The company gave a partitioned survival model with 3 health states to estimate the cost effectiveness of adding dostarlimab to platinum-containing chemotherapy (PCC). The 3 health states were PFS, progressed disease and death. Health-state utilities and baseline characteristics were taken from the dMMR/MSI-H population in RUBY-1. The comparator arm of RUBY-1, placebo in combination with carboplatin plus paclitaxel, was used to inform the PCC arm in the model. Diagnostic testing for dMMR/MSI-H is routine in the NHS so the costs for this were not included in the model. In line with the marketing authorisation, a 3-year stopping rule was applied. The EAG preferred to use a higher starting age in the model (67.1 years) to better reflect the NHS population.

The committee concluded that the model structure is appropriate for decision-making and preferred the EAG's starting age of 67.1 years.

Extrapolation of PFS

3.6 Long term PFS was estimated by extrapolating the data from RUBY-1. The company and EAG agreed on the extrapolation approach for the placebo arm but disagreed on the preferred approach for the dostarlimab arm. The company selected a piecewise approach and the EAG selected Weibull. With the EAG's approach, the hazard rates for the dostarlimab arm and PCC arm crossed at around 5 years. From this point, the EAG set both arms to use the PCC arm hazard rate (so there were equal hazard rates between the 2 arms). In the company model, the PFS benefit for dostarlimab was sustained for the duration of the model, but the EAG said that this was implausible. The clinical experts said it was reasonable to assume that dostarlimab had a sustained benefit, based on the durable responses that have been seen with dostarlimab and other immunotherapy treatments. So they didn't expect the hazard rates for dostarlimab to be equal with PCC from 5 years onwards. The clinical experts said that their own estimates for long-term PFS would be closer to the company adviser estimates than the EAG estimates, which they thought were overly pessimistic. Once someone has been progression free for 5 years, their risk of progression is very low, so they felt the drops in PFS probability seen between 5 and 10 years were not realistic. But they noted that it's very difficult to give long-term estimates, because it is not yet known how newer treatments will change the long-term outcomes for people. The NHS Cancer Drugs Fund lead said the pattern from other dMMR/MSI-H tumour types (for example, colorectal cancer) suggests that most relapses occur in 2 years, and from years 2 to 3 there is a clear plateauing in PFS and OS. They said dMMR/MSI-H cancers clearly respond better to immunotherapy treatments than non dMMR/MSI-H cancers, regardless of the tumour location. In dMMR/MSI-H cancer there tends to be a clear plateau at a relatively early stage. The committee

concluded it was reasonable to assume a sustained treatment effect benefit for dostarlimab. So, it preferred the company model, in which the hazard rates did not cross.

Treatment effect waning

3.7 The company base case assumes that the dostarlimab treatment benefit is sustained for the full duration of the model. But the EAG assumes that the treatment effect begins to wane from 80 weeks, over a period of 3 years. The EAG said this was applied to reflect the convergence of the dostarlimab and PCC hazard rates seen in the RUBY-1 follow-up data. It explained that because of limitations in the model structure, it had to converge the dostarlimab hazard rate to the PCC arm, rather than the other way round (which would better reflect the RUBY-1 data). It also allowed the extrapolated OS to sit within the range of survival predictions made by the EAG and company's clinical advisers. The company said that the EAG's approach is clinically implausible and not consistent with the RUBY-1 data, in which the hazard rate for the dostarlimab arm declined over time. The clinical experts said that data from other immunotherapies had shown that this type of treatment has a durable treatment effect in people with dMMR/MSI-H endometrial cancer. They also mentioned emerging data from the relapsed setting, in which the cancer has had durable responses to immunotherapy treatments beyond the 3-year stopping rule. The NHS Cancer Drugs Fund lead noted that the treatment effect waning is typically applied after treatment has stopped, not while treatment is ongoing. They noted that while the data for this indication is immature, immunotherapies have showed sustained benefit in other dMMR/MSI-H tumour types (for example in [nivolumab with ipilimumab for previously treated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency](#)). The committee noted that there wasn't a clear waning effect for dostarlimab seen in the RUBY-1 data. It also noted that immunotherapy treatments are particularly effective in dMMR/MSI-H cancer. The committee acknowledged that the hazard rates

did converge because of the hazard rate in the PCC arm declining over time. But it said that having longer-term data on both the PCC arm and the dostarlimab arm would be a better way to reflect converging hazard rates, rather than the EAG's approach of applying treatment waning to the dostarlimab arm while treatment is ongoing. The committee concluded that there was not enough evidence from RUBY-1 to know if, and when, the dostarlimab treatment effect wanes. It felt that applying a treatment waning effect while treatment with dostarlimab was still ongoing was not justified. Once future data becomes available, the committee would like to see a range of treatment waning assumptions given as scenario analyses.

Extrapolation of OS

3.8 Long term OS was estimated by extrapolating the data from RUBY-1. But the estimates are uncertain because of the immaturity of the data and the small sample size of the dMMR/MSI-H subgroup. There were also large differences between the survival estimates given by the EAG and the company's clinical advisers. These differences resulted in the company and EAG selecting different extrapolation approaches for their base cases. For the PCC arm, the company used the Kaplan–Meier (KM) data from RUBY-1 for the full follow-up period, followed by the log-logistic curve. The EAG used the full log-logistic curve without the KM data. For the dostarlimab arm, the company used the KM data for the full follow-up period, followed by the HR applied to the PCC arm. The EAG preferred to use the exponential curve, with the application of treatment waning from 80 weeks. The company model estimates that 72% of people in the dostarlimab arm will still be alive at 5 years, but the EAG clinical adviser suggested that only 20% will still be alive. The clinical experts said that long-term estimates were extremely difficult to make as there is no long-term experience of people who have benefited from new immunotherapy treatments. But they felt the EAG adviser estimates were pessimistic and didn't reflect the full benefit of immunotherapies. The clinical experts said that people whose cancer responds to immunotherapy treatment have

very durable responses. They said their own estimates for long-term OS would be somewhere in between the company and the EAG's adviser estimates, but closer to the company adviser estimates. The committee recalled the NHS Cancer Drugs Fund lead's comments that dMMR/MSI-H cancers tend to show clear plateauing in PFS and OS at an early stage (see section 3.6). The company noted that there were only 7 OS events in the dostarlimab arm, so it felt that applying a HR to the dostarlimab arm (which was based on more events so was more robust), was the best approach to use given the available data. The committee noted that the short duration of follow-up also gave uncertainties in the PCC arm. It was specifically concerned that the benefit of subsequent immunotherapy treatment had not been reflected in the data because of the short follow-up time. So the long-term OS for the PCC arm may be underestimated, leading to an overestimate of the benefits of dostarlimab. The committee concluded that it was not possible to agree on preferred extrapolation curves because of the immaturity of the data. It preferred the EAG approach of using parametric models for the full duration of the model, rather than using semi-parametric models. This was because the tail of the KM curves was informed by such small numbers. It also recalled that the clinical experts felt the EAG's long-term estimates were too pessimistic. But the committee's view may change once more data becomes available.

Use of subsequent treatments

3.9 People in RUBY-1 were able to have subsequent treatments once they had stopped taking carboplatin plus paclitaxel with or without dostarlimab. The subsequent treatment use seen in RUBY-1 included several treatments not available on the NHS. So, subsequent treatment use in the economic model was informed by clinical expert opinion, as well as RUBY-1 data. The EAG agreed with this approach, but said that expert opinion varies significantly, so the use, costs and effects of subsequent treatment are a source of uncertainty in the model. The clinical expert said

that the treatments they use in the NHS differ from those included in the model (for example, immunotherapy monotherapy). But the company noted that those drugs were either only available in the Cancer Drugs Fund or had only become available in routine commissioning very recently, which is why they were not included in the model. The committee acknowledged the sensitivity analysis which had been done to explore differences in subsequent treatment use in the model. It recalled that the [NICE health technology evaluations manual](#) (see section 2.2.12) specifies that comparators should be established clinical practice in the NHS. It also specifies that technologies which are recommended with managed access are not suitable comparators. The committee concluded that the company's approach was acceptable given the differences between what is routinely available on the NHS, and the data available from RUBY-1. But it will reconsider this once further data has been collected during managed access.

Adverse events

3.10 The company base case included the disutilities and treatment costs for adverse events (AEs) which were grade 3 or above. The EAG said the limited follow-up and small sample size may result in the true impact of AEs being under-reported, and their impact underestimated. In the EAG base case, the EAG preferred to include a broader range of AEs (those affecting at least 2% of people, rather than 5% used in the company base case). It also preferred to increase the costs for ongoing monitoring of immune related AEs in the dostarlimab arm (0.23 visits a week from cycle 19, rather than 0.13). The clinical experts said that most AEs can be managed in an outpatient setting. They noted that AEs can have a delayed onset and can be unpredictable, but clinicians are getting better at spotting and managing them. The patient experts said that based on their research, most people are willing to accept additional AEs if it gives them the chance of living a meaningful life for longer. The patient expert said that compared with chemotherapy, the side effects for dostarlimab

were easy to manage. The committee concluded that, given the small sample size, it was appropriate to include the broader range of AEs (those affecting at least 2% of people). It also agreed that the company's approach for the ongoing monitoring of immune related AEs in the dostarlimab arm was sufficient (0.13 visits a week from cycle 19) and did not need to be increased.

Other issues considered

Apparent lack of efficacy in stage 3 disease

3.11 The committee also discussed the apparent lack of efficacy in people with stage 3 disease. The clinical expert said this was unexpected, and that it may be a statistical quirk caused by the low number of people in this subgroup. The committee concluded that this issue did not need further consideration.

Lack of comparison to pembrolizumab with lenvatinib

3.12 A small number of people may have previously been treated with platinum-based chemotherapy (before or after surgery) by this stage in the treatment pathway. These people would therefore be eligible for pembrolizumab with lenvatinib (see [NICE technology appraisal on pembrolizumab with lenvatinib for previously treated advanced or recurrent endometrial cancer](#)), as an alternative to dostarlimab. The company did not include this comparator in its economic model because of a lack of data. The EAG agreed that there was not enough data to inform this comparison, and the clinical experts said they would be unlikely to use pembrolizumab with lenvatinib in this group. The committee concluded that the patient population for this comparison was very small and that the issue did not need further consideration.

Cost effectiveness estimates

Acceptable incremental cost-effectiveness ratio (ICER)

3.13 [NICE's manual on health technology evaluation](#) notes that above a most plausible ICER of £20,000 per quality-adjusted life year (QALY) gained, decisions about the acceptability of a technology as an effective use of NHS resources will take into account the degree of certainty around the ICER. The committee will be more cautious about recommending a technology if it is less certain about the ICERs given. The committee noted several uncertainties, specifically:

- the robustness of the RUBY-1 results given the small sample size and imbalances in baseline characteristics (see section 3.3)
- if and when the treatment effect starts to wane and over what time period (see 3.7)
- the long-term clinical benefit of dostarlimab because of data immaturity (see 3.6, 3.8).

The committee also considered the large unmet clinical need, the durable benefits that have been seen in dMMR/MSI-H populations, and the data seen in RUBY-1 to date. Given the level of uncertainty, the committee concluded that the maximum acceptable ICER would be £25,000 per QALY gained. It noted that the maximum acceptable ICER may change once more data becomes available.

Company and EAG cost-effectiveness estimates

3.14 The committee considered the ICERs for dostarlimab plus PCC compared with PCC alone. Because of confidential commercial arrangements for dostarlimab and subsequent treatments in the pathway, the ICERs are confidential and cannot be reported here. The committee's preferred cost-effectiveness estimates included the following assumptions:

- AEs which affect at least 2% of people
- piecewise extrapolation (Odds K=1) for PFS
- baseline starting age in the model of 67.1 years
- 0.13 outpatient visits per week from cycle 19 for AE monitoring
- treatment waning should not apply in 3 years of starting treatment.

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The committee was unable to agree on a preferred assumption for the OS extrapolation, based on the immaturity of the data. It also agreed that there was too much uncertainty about the robustness of the ICERs produced by the economic model. Some of the most likely cost-effectiveness estimates are higher than what NICE usually considers an acceptable use of NHS resources. So, the committee concluded it was not possible to recommend dostarlimab with platinum-based chemotherapy for use in routine commissioning.

Cancer Drugs Fund

Cancer Drugs Fund eligibility

3.15 Having concluded that dostarlimab with platinum-based chemotherapy could not be recommended for routine use, the committee then considered if it could be recommended in 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 \(addendum\)](#):

- The company expressed an interest in dostarlimab being considered for funding through the Cancer Drugs Fund.
- The committee noted that RUBY-1 is ongoing. Also, an updated data cut for RUBY-1 became available shortly before the first committee meeting but there was not enough time available for it to be included in the economic model. So, it was not considered by the committee in this appraisal.

The committee considered that further data collection in the Cancer Drugs Fund could address some of the uncertainty in the company's estimates. Using the committee's preferred assumptions for PFS, starting age, treatment waning and AEs, dostarlimab has plausible potential to be cost effective. The committee concluded that dostarlimab met the criteria to be considered for inclusion in the Cancer Drugs Fund. It recommended

dostarlimab with platinum-based chemotherapy use in the Cancer Drugs Fund as an option for people with advanced or recurrent endometrial cancer with MSI-H or dMMR deficiency 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 3.14, unless new evidence shows otherwise.

Other factors

Equality

3.16 The committee noted that black ethnic groups have substantially higher mortality rates for endometrial cancer mortality than other ethnic groups in the UK. The company said that access to innovative treatment on the NHS for late-stage disease can help address severe inequalities in survival outcomes by ethnicity or socio-economic deprivation. The committee considered equality issues and concluded that its recommendations do not affect people protected by the equality legislation differently to the wider population.

4 Implementation

4.1 When NICE recommends a treatment as an option for use with managed access, NHS England will make it available according to the conditions in the managed access agreement. This means that, if a patient has primary advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency and the doctor responsible for their care thinks that dostarlimab with carboplatin and paclitaxel is the right treatment, it should be available for use, in line with NICE's recommendations and the criteria in the managed access agreement.

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 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 with managed access. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, for use with managed access, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final draft guidance or agreement of a managed access agreement by the NHS in Wales, whichever is the later.

5 Evaluation committee members and NICE project team

Evaluation committee members

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

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

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

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Chair

Dr James Fotheringham

Vice Chair, technology appraisal committee A

NICE project team

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

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