

Brexucabtagene autoleucel for treating relapsed or refractory mantle cell lymphoma

Technology appraisal guidance
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Your responsibility

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

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

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

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1 Recommendations

- 1.1 Treatment with brexucabtagene autoleucel is recommended for use within the Cancer Drugs Fund as an option for relapsed or refractory mantle cell lymphoma in adults who have previously had a Bruton's tyrosine kinase (BTK) inhibitor. It is only recommended if the conditions in the [managed access agreement](#) for brexucabtagene autoleucel treatment are followed.
- 1.2 This recommendation is not intended to affect either treatment in preparation for or treatment with brexucabtagene autoleucel 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 until they and their NHS clinician consider it appropriate to stop.

Why the committee made these recommendations

There is no standard treatment for relapsed or refractory mantle cell lymphoma after a BTK inhibitor. Rituximab, bendamustine and cytarabine (R-BAC) is the most common treatment option. Brexucabtagene autoleucel is a chimeric antigen receptor (CAR) T-cell therapy. The therapy uses the patient's own T cells, which have been modified to attach to and kill cancer cells.

Evidence from a study of brexucabtagene autoleucel, which does not compare the therapy with anything else, suggests that people having it may live for longer and have more time before their disease relapses. However, the evidence is not certain because of the:

- short follow up
- small number of patients
- uncertainty around how long people actually live
- lack of evidence comparing brexucabtagene autoleucel directly with the most common alternative treatment.

There is also not enough evidence to tell if people having treatment with brexucabtagene

autoleucl can be cured.

Brexucabtagene autoleucl meets NICE's criteria to be considered a life-extending treatment at the end of life. This is because people having it are likely to live for less than 24 months, and this treatment could extend their life by at least 3 months. The most likely cost-effectiveness estimates for brexucabtagene autoleucl compared with the most common alternative treatment are not known because the final survival data for brexucabtagene autoleucl are not yet available. However, early estimates suggest it could be cost effective, and collecting further data on progression-free survival, overall survival and age when treatment starts will reduce the uncertainty in the evidence. Therefore, brexucabtagene autoleucl is recommended for use as an option within the Cancer Drugs Fund.

2 Information about brexucabtagene autoleucel

Marketing authorisation indication

- 2.1 Brexucabtagene autoleucel (Tecartus, Kite) is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma after 2 or more lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor.

Dosage in the marketing authorisation

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

Price

- 2.3 The price was submitted as commercial in confidence. The company has a [commercial arrangement](#). This makes treatment with brexucabtagene autoleucel 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 Kite, 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:

- Rituximab, bendamustine and cytarabine (R-BAC) is the most recognised form of standard care in clinical practice in the UK.
- Using data from McCulloch et al. (2020) to inform the progression-free and overall survival of people treated with standard care is more appropriate than using uncertain estimates from an indirect treatment comparison of brexucabtagene autoleucel with standard care.

The committee discussed the following issues (issues 1, 4, 5, 7 and 8), which were outstanding after the technical engagement stage.

The condition

There is an unmet clinical need for more effective treatment options

- 3.1 Mantle cell lymphoma is a subtype of non-Hodgkin lymphoma and can have debilitating symptoms. Rates of relapse after initial treatment are high, and it has a huge effect on quality of life. Mantle cell lymphoma is considered incurable with current treatment. Outcomes for people with refractory or relapsed disease are poor. Treatment options after relapse with a Bruton's tyrosine kinase (BTK) inhibitor are not well established and normally associated with lower responses and rapid disease progression. The patient experts explained that the disease always has the potential to relapse and that the side effects of existing treatments significantly reduce quality of life. A new treatment that offers the possibility of a cure would provide hope and be valued by patients. They

highlighted that, although treatment with brexucabtagene autoleucl can have serious and even life-threatening side effects, people would be happy to accept this risk for a potential cure. Chimeric antigen receptor (CAR) T-cell therapies such as brexucabtagene autoleucl are advanced, personalised cancer immunotherapies that collect and modify patients' own immune cells to treat the cancer. Treatment with CAR T-cell therapies can be intense, requiring several weeks' stay in hospital, but can enable recovery within a few months. The committee concluded that there is an unmet need in this population and that patients and healthcare professionals would welcome potential new treatments. This could include CAR T-cell therapies that improve the chance of survival and offer potential for a cure.

Treatment pathway

Brexucabtagene autoleucl is a new treatment option when there has been no response to, or relapse after, first- and second-line treatments

- 3.2 First-line treatment of mantle cell lymphoma may include rituximab chemotherapy, and stem cell transplant for fitter patients. Ibrutinib (a BTK inhibitor) is the most likely treatment to be used second line. Treatment options for later relapse are not well established. They may include more rituximab chemotherapy such as R-BAC and rituximab plus bendamustine. Treatment with brexucabtagene autoleucl is proposed as a third-line treatment option for people whose disease has relapsed after ibrutinib. The committee concluded that there is no uniformly accepted standard care and limited treatment options for relapsed or refractory mantle cell lymphoma when there is disease progression after first- and second-line treatments including a BTK inhibitor.

Clinical evidence

Brexucabtagene autoleucl is clinically effective but survival data are immature

3.3 The clinical-effectiveness evidence for brexucabtagene autoleucl came from ZUMA-2, an ongoing, phase 3, multicentre, open-label, single-arm study. The company presented results from the study for a modified intention-to-treat group (68 patients who had treatment with brexucabtagene autoleucl), which were used in the economic analysis. The primary outcome measure was overall response rate, defined as complete response or partial response (based on the International Working Group response criteria for malignant lymphoma). Results show a promising overall response rate for patients having treatment with brexucabtagene autoleucl (exact results are confidential and cannot be reported here) and an extension to life for patients who have a complete response to brexucabtagene autoleucl compared with patients who have a partial response. At the latest data cut in December 2019, the median follow up in ZUMA-2 was short and the survival data were immature. The committee noted the apparent plateau in the Kaplan–Meier curves for overall and progression-free survival. But the ERG explained that from month 12 onwards, the Kaplan–Meier plots were heavily influenced by censoring of data (that is, people who did not have an event during follow up whose survival is unknown beyond the point at which they were censored) so very few patients remained at risk of mortality or disease progression. Therefore, the estimates of survival beyond 12 months were highly uncertain. The committee concluded that treatment with brexucabtagene autoleucl is clinically effective, but the benefit cannot be quantified because of the immature survival data and lack of trial data compared with standard care.

Longer-term survival data from the main trial may provide evidence of a cure, but the data are immature

3.4 The company considered that results from ZUMA-2 supported the assumption of long-term survivors based on plateaus in the Kaplan–Meier curves. It also highlighted precedent from previous

appraisals of CAR T-cell therapies in relapsed or refractory B-cell acute lymphoblastic leukaemia and relapsed or refractory diffuse large B-cell lymphoma (DLBCL). The ERG noted that plateaus in the Kaplan–Meier curves are not robust evidence of long-term survival after treatment with brexucabtagene autoleucel because of data censoring and the trial's short follow up. The clinical experts noted that 3 years of follow up is needed to provide reliable evidence of a cure, and clinical consensus is that relapsed or refractory mantle cell lymphoma is generally incurable. They also noted that stem cell transplants are known to cure only a small proportion of patients but estimated that potentially 30% of people with a complete response to treatment with brexucabtagene autoleucel may go on to be cured. However, although there is some evidence of a potential cure with CAR T-cell therapy in relapsed or refractory DLBCL, there is considerable uncertainty over whether this applies also to relapsed or refractory mantle cell lymphoma. This is because of differences in the disease biology, therapy regimens and patterns of relapse. The company reiterated through the technical engagement process that ZUMA-2 remains the only source of direct evidence demonstrating that a proportion of patients will have long-term survival after treatment with brexucabtagene autoleucel. The committee concluded that long-term survival data from ZUMA-2 were consistent with the possibility of a cure, but the data are too immature to establish this.

The results of the main trial are generalisable to the people for whom brexucabtagene autoleucel would be an option in the NHS

3.5 The committee was concerned about how generalisable the results of the ZUMA-2 study were to the NHS, given that it did not include any patients from the UK. It noted that the population in the trial included people who had had a median of 3 prior therapies, all with an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 (which means that their activities are relatively unrestricted by their disease) and a mean age of 63. Forty-three per cent of the trial population had also had a stem cell transplant. The committee noted that trials generally include highly selected populations. The ERG considered that the ZUMA-2 population is likely to be younger and in better health than people with relapsed or refractory mantle cell lymphoma in the NHS who

have had 2 prior lines of therapy including ibrutinib. The clinical experts said that before having treatment with brexucabtagene autoleucel people would need to have a good performance status to tolerate the treatment's toxicity. The clinical experts and NHS England's clinical lead for the Cancer Drugs Fund noted that, although patients in the NHS are likely to be older and less fit than the trial population, people matching the trial population can be selected through careful deliberations by specialist multidisciplinary CAR T-cell treatment centres. The company also said that a mean age of 63 is reasonably reflective of people who would be selected to have treatment with brexucabtagene autoleucel. With ibrutinib established as second-line standard care in the NHS, people in the NHS with relapsed or refractory mantle cell lymphoma will have had fewer treatments before treatment with brexucabtagene autoleucel than people in the trial. The committee concluded that the results from ZUMA-2 were generalisable to patients in the NHS.

Cost effectiveness

The company's model is acceptable for decision-making

3.6 The company presented cost-effectiveness analyses comparing treatment with brexucabtagene autoleucel with standard care, which was assumed to be R-BAC. It used a partitioned survival model with 3 health states (progression-free, progressed disease and death). Progression-free and overall-survival estimates were modelled independently, with the proportion of progressed patients at each cycle calculated as the difference between the values for the overall-survival and progression-free survival curves. The company modelled the cost effectiveness of treatment with brexucabtagene autoleucel using data from ZUMA-2, and the cost effectiveness of R-BAC from a study by McCulloch et al. (2020). The committee concluded that the model was appropriate for decision-making.

The company updated its model and cost-effectiveness analyses after technical engagement

3.7 The committee noted that after technical engagement, the company

updated its economic model to align with all but one of the ERG's suggested amendments. The revised base case incorporated an updated commercial arrangement and used data from McCulloch et al. (2020) to inform the health outcomes and costs of standard care. The only suggested amendment not incorporated into the revised company base case was the increased mortality risk for patients who have long-term survival, which the company disputed. The committee therefore focused on the modelled outcomes for long-term survivors.

People having brexucabtagene autoleucel are likely to be at a higher risk of mortality than the general population

3.8 The company's model assumed that people who have had treatment with brexucabtagene autoleucel and survive beyond the ZUMA-2 trial follow up have a 9% higher probability of death than the general population. This was based on data from a French cohort of people with DLBCL reported in Maurer et al. (2014), which was used in [NICE's technology appraisal guidance on axicabtagene ciloleucel for diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma](#). The ERG considered that the excess mortality risk with DLBCL is not generalisable to people with relapsed or refractory mantle cell lymphoma. It also considered that the excess mortality risk compared with the general population is likely to be higher than predicted by the company. The ERG suggested that it was more appropriate to base the mortality adjustment on data from people with mantle cell lymphoma than with DLBCL. It suggested using data from Eskelund et al. (2016), which reports up to 15 years of follow up (median 11.4 years) of 160 newly diagnosed patients with mantle cell lymphoma after first-line treatment with chemotherapy then autologous stem cell transplant. The ERG said it was possible that excess mortality for people who had treatment with brexucabtagene autoleucel was similar to people with mantle cell lymphoma who had a sustained complete response, regardless of whether this was through a stem cell transplant or CAR T-cell therapy. The ERG derived hazard ratios from the overall-survival curves from Eskelund et al. comparing the age and sex-matched general population with people who have mantle cell lymphoma in complete remission. For at least 1 year the hazard ratio was 4.37 and for at least 5 years it was 2.36. The lower and higher hazard ratios were used as the lower and

upper mortality range of the excess mortality adjustment and used for the incremental cost-effectiveness ratio (ICER) range in the ERG's base-case analysis. The company acknowledged the significant uncertainty associated with the excess mortality adjustment, which was also acknowledged in NICE's technology appraisal guidance on axicabtagene ciloleucl. But it noted that the committee for that appraisal accepted the assumption that long-term survivors are at a 9% greater risk of death than the age and sex-matched general population. The company highlighted that the data from Eskelund et al. are based on people who had an autologous stem cell transplant and so do not necessarily reflect what would happen with treatment with brexucabtagene autoleucl. The company also considered that the ERG's method for deriving estimates for long-term excess mortality had limitations and was associated with significant uncertainty. The clinical experts agreed that the risk of death is expected to be higher in a heavily pre-treated population with relapsed or refractory mantle cell lymphoma than for people with DLBCL treated first-line. However, the clinical experts explained that an autologous stem cell transplant is not considered a curative treatment in mantle cell lymphoma, and patients are expected to relapse, which might not be the case with treatment with brexucabtagene autoleucl if it is proved to be curative. Also, patients in the Eskelund et al. study had not been treated with ibrutinib, which is known to increase survival. They noted that the higher overall mortality compared with the general population reported in Eskelund et al. is in the context of the current consensus that people with relapsed or refractory lymphoma cannot be cured. But the committee accepted that brexucabtagene autoleucl is a novel treatment that represents a step-change in the treatment pathway for the disease. The committee concluded that there is significant uncertainty in the excess mortality risk for long-term survivors, but considered that people having treatment with brexucabtagene autoleucl are likely to have higher mortality risks than the general population, even if they are cured, and this may be higher than estimated for DLBCL.

Patients' age when they start treatment has a significant effect on cost-effectiveness estimates

- 3.9 The ERG highlighted that the cost-effectiveness analysis is very sensitive to the age of the patient population when treatment starts, and depends

on the extent to which the age of patients in the NHS differs from that in the ZUMA-2 trial. This impact is driven mostly by the general population mortality risk used to inform the mortality risk of long-term survivors in the company's base case (see [section 3.7](#)). The ERG also highlighted the considerable difference in age between the ZUMA-2 population (median age 65) and of people with mantle cell lymphoma at diagnosis in the UK (median age 72.9) and noted that the mean age of the ZUMA-2 population (63.2) was used in economic analysis. A clinical expert noted that the ZUMA-2 trial population's mean age of 63 is around 8 to 10 years younger than the NHS population with refractory or relapsed mantle cell lymphoma. The company argued that CAR T-cell therapies are generally only suitable for fitter patients, and that people offered treatment with brexucabtagene autoleucel would undergo the same rigorous selection criteria as currently available CAR T-cell treatments. NHS England's clinical lead for the Cancer Drugs Fund agreed and noted that patient selection by multidisciplinary teams at CAR T-cell therapy centres would be rigorous. The ERG agreed with the company, based on evidence from the Cancer Drug Fund, that the median age of people with relapsed or refractory DLBCL treated with CAR T-cell therapies is 57. But it noted that it was not clear if there would be the same difference in age between real-world and trial data for people with relapsed or refractory mantle cell lymphoma. Illustrative scenario analyses by the ERG showed that even small variations in mean baseline age have a significant impact on the cost-effectiveness estimates. The committee concluded that the age of the patients when treatment starts is a significant area of uncertainty in the cost-effectiveness estimates.

It is not clear if long-term survivors have the same health-related quality of life as people in the general population of the same age and sex

- 3.10 The company's model assumed that people who had treatment with brexucabtagene autoleucel whose disease has not progressed after 5 years of treatment have the same health-related quality of life as the general population. The ERG considered that data from ZUMA-2 is not enough to support this assumption. It noted that, if long-term survivors are more at risk of mortality than the general population, their health-related quality of life would be lower. The ERG incorporated the

company's assumption in its base-case analysis but explored other lower quality-of-life estimates for people who were progression-free for 5 years. It provided illustrative scenario analyses in which the health-related quality of life of long-term survivors was reduced by 10% to 20%. This resulted in higher cost-effectiveness estimates. The clinical experts noted that long-term survivors will have a slightly higher mortality risk and worse health-related quality of life because of the risks associated with CAR T-cell treatments and the effect of prior therapies. The committee concluded that it was not clear if long-term survivors would have the same health-related quality of life as people in the general population of the same age and sex.

End of life

Brexucabtagene autoleucel meets both criteria to be considered a life-extending treatment at the end of life

3.11 The committee considered the advice about life-extending treatments for people with a short life expectancy in [NICE's guide to the methods of technology appraisal](#). The company proposed that brexucabtagene autoleucel met the criteria for life-extending treatments for people with a short life expectancy (normally less than 24 months). The company based expected survival without treatment with brexucabtagene autoleucel on:

- standard care survival estimated from the matching-adjusted indirect comparison done before technical engagement
- reported survival after ibrutinib treatment (mean 3.6 months to 12.5 months)
- standard care survival estimates from economic modelling.

All 3 support the assertion that people with relapsed or refractory disease having third-line treatment have a life expectancy of less than 24 months. Extension to life with treatment with brexucabtagene autoleucel was based on survival estimates from matching-adjusted indirect comparison modelling from the ZUMA-2 trial data (for which median survival was not reached) and from the company economic model (exact results are confidential and cannot be

reported here). The ERG considered that the assumptions also hold for the ERG base case and that the short life-expectancy criterion was met. The committee concluded that treatment with brexucabtagene autoleucel meets both criteria to be considered a life-extending treatment at the end of life.

Cost-effectiveness results

The company proposes brexucabtagene autoleucel for the Cancer Drugs Fund

3.12 The company submitted a proposal for brexucabtagene autoleucel to be considered for the Cancer Drugs Fund rather than routine commissioning, and proposed an accompanying confidential commercial arrangement. The committee considered the ICERs based on this commercial arrangement in its decision-making. The committee understood that it was not considering brexucabtagene autoleucel for routine use, and discussed the arrangements for the Cancer Drugs Fund agreed by NICE and NHS England in 2016, noting [NICE's Cancer Drugs Fund methods guide \(addendum\)](#).

There is a range of possible cost-effectiveness estimates

3.13 In the company's revised base case after technical engagement the deterministic ICER was £46,898 per quality-adjusted life year (QALY) gained for treatment with brexucabtagene autoleucel compared with standard care. This included a mortality adjustment of 1.09 and the confidential commercial arrangement for brexucabtagene autoleucel. The ERG's base-case analysis accounted for the lower and upper mortality range of the excess mortality adjustment (2.36 to 4.37) and produced ICERs ranging from £58,223 to £72,920 per QALY gained. Based on the available evidence, the committee concluded that the ICER (with the discount agreed in the commercial arrangement) ranged between £46,898 and £72,920 per QALY gained, but it favoured the lower ERG adjustment of mortality which gave an ICER of £58,223 per QALY gained. The committee recalled the uncertainty around the age of the patient population when treatment starts (see [section 3.9](#)) and the health-related quality of life of long-term survivors (see [section 3.10](#)) and noted

that the ICER range could be wider.

Cancer Drugs Fund

Further data collection could address uncertainties in the clinical and cost-effectiveness evidence

3.14 The committee recalled that it had concluded that brexucabtagene autoleucel met the criteria to be considered a life-extending treatment at the end of life (see [section 3.11](#)) and that the company had proposed brexucabtagene autoleucel for use in the Cancer Drugs Fund (see [section 3.12](#)). The committee recognised that treatment with brexucabtagene autoleucel is innovative and therefore considered if the clinical uncertainty over its use could be addressed by collecting more data. More data from ZUMA-2 are expected, with additional years of follow up planned. The committee agreed that:

- More data on progression-free, post-progression and overall survival up to 5 years will help clarify if treatment with brexucabtagene autoleucel improves long-term survival.
- Using brexucabtagene autoleucel in the NHS allows data to be collected using the Systemic Anti-Cancer Therapy (SACT) dataset to get more accurate costs and benefits for its use in clinical practice, as well as the median age of the patients who would be offered treatment with brexucabtagene autoleucel.

Brexucabtagene autoleucel meets the criteria to be included in the Cancer Drugs Fund

3.15 Data from ZUMA-2 showed that people having treatment with brexucabtagene autoleucel have good response rates, overall survival and progression-free survival. The committee noted that the company's revised base-case ICER for brexucabtagene autoleucel compared with standard care was below £50,000 per QALY gained. The ERG'S base-case range of ICERs was over £50,000 per QALY gained. The committee acknowledged that the ICERs for brexucabtagene autoleucel compared with standard care were not certain, but concluded that the treatment

had the plausible potential to satisfy the criteria for routine use if this uncertainty could be reduced. The committee recognised that more data on long-term survival and post-progression survival for treatment with brexucabtagene autoleucel would allow for a more robust cost-effectiveness estimate. It agreed that the treatment met the criteria to be considered for inclusion in the Cancer Drugs Fund for treating relapsed or refractory mantle cell lymphoma.

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 relapsed and refractory mantle cell lymphoma and the doctor responsible for their care thinks that treatment with brexucabtagene autoleucel 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 Appraisal committee members and NICE project team

Appraisal committee members

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

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

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

NICE project team

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

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