NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Appraisal consultation document

Mogamulizumab for previously treated mycosis fungoides and Sézary syndrome

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

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

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

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

Issue date: July 2020

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

After consultation:

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

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

The key dates for this appraisal are:

Closing date for comments: 19 August 2020

Second appraisal committee meeting: To be confirmed

Details of membership of the appraisal committee are given in section 5.

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1 Recommendations

1.1 Mogamulizumab is not recommended, within its marketing authorisation, for treating mycosis fungoides or Sézary syndrome in adults who have had at least 1 previous systemic treatment.

1.2 This recommendation is not intended to affect treatment with mogamulizumab 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

Standard care for mycosis fungoides or Sézary syndrome in people who have had at least 1 previous systemic treatment includes methotrexate, bexarotene, interferon and chemotherapy.

The clinical trial evidence is very uncertain because mogamulizumab is compared with vorinostat, a treatment that is not used or licensed in the UK. Also, many people switch treatments and there are a lot of differences among the trial population. This means it is unclear how well mogamulizumab works.

Mogamulizumab does not meet NICE's criteria to be considered a life-extending treatment at the end of life. The most likely cost-effectiveness estimate is much higher than what NICE normally considers an acceptable use of NHS resources. So mogamulizumab cannot be recommended for routine use in the NHS.

Collecting further data is unlikely to address the clinical uncertainty because of the limitations in the trial design. So mogamulizumab cannot be recommended for use within the Cancer Drugs Fund.

2 Information about mogamulizumab

Marketing authorisation indication

2.1 Mogamulizumab (Poteligeo, Kyowa Kirin) is indicated for 'the treatment of adult patients with mycosis fungoides or Sézary syndrome who have received at least one prior systemic therapy'.

Dosage in the marketing authorisation

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

Price

2.3 The list price of mogamulizumab is £1,329 per vial containing 4 mg of mogamulizumab per ml (excluding VAT; BNF online, accessed July 2020). The company has a commercial arrangement, which would have applied if the technology had been recommended.

3 Committee discussion

The appraisal committee (section **Error! Reference source not found.**) considered evidence submitted by Kyowa Kirin, a review of this submission by the evidence review group (ERG), the 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 ERG's corrections, using a 45-year time horizon and lognormal extrapolation of next treatment-free survival and disease-free survival, were acceptable and had a small effect on the cost-effectiveness results (see technical report table 10)
- it is acceptable to remove allogenic stem cell transplant after current treatment from the company's economic model because this was not allowed in the trial and reduces the risk of bias (issue 4, see technical report page 24)

- it is acceptable to use an average 'on treatment' health state specific utility value in the economic model rather than cycle-specific values for the first 12 weeks (issue 6, see technical report page 28).

It recognised that there were remaining areas of uncertainty associated with the analyses presented (see technical report, table 9, page 31), and took these into account in its decision making. It discussed the following issues (issues 1, 2, 3, 5 and 6), which were outstanding after the technical engagement stage.

Treatment pathway

People with mycosis fungoides or Sézary syndrome would welcome a new treatment option

3.1 Cutaneous T-cell lymphoma is a rare type of non-Hodgkin lymphoma that affects the skin. It includes mycosis fungoides, the most common type, and Sézary syndrome which is closely related. The clinical experts explained that Sézary syndrome is an aggressive disease and prognosis tends to be poor. Both patient experts described how living with a scaly itching rash all the time significantly affects their health-related quality of life. Sleep is affected. Cracks and open wounds are common, particularly on the hands and feet, which limits the ability to walk and carry out daily activities. The clinical experts explained that the disease particularly affects people's appearance and people sometimes rely on carers to help with daily activities. They confirmed that the treatments recommended in the British Association of Dermatologists and UK Cutaneous Lymphoma Group guidelines after at least 1 systemic treatment were used in clinical practice. These included methotrexate, bexarotene, interferon and chemotherapy. The patient experts indicated that they had had little benefit with treatments such as chemotherapy but had a dramatic improvement after mogamulizumab. This improved their itching and skin condition, so that they could carry out daily activities more easily, and considerably improved their quality of life. Neither of the patient experts reported side effects from mogamulizumab. The committee concluded

that people with mycosis fungoides or Sézary syndrome who have had at least 1 systemic treatment before would welcome an additional treatment option.

The company propose mogamulizumab for a subgroup of the population covered by the marketing authorisation

3.2 Mogamulizumab is for treating mycosis fungoides or Sézary syndrome after at least 1 previous systemic treatment (see section 2.1). But the company proposed mogamulizumab as an option for a subgroup of the population covered by the marketing authorisation; that is, after at least 1 systemic treatment for people with severe disease that has progressed with brentuximab vedotin or if it is not appropriate. Severe disease was defined as stage 2B and above for mycosis fungoides and all stages of Sézary syndrome. Brentuximab vedotin is recommended as an option for severe CD30-positive disease after at least 1 treatment (see NICE's technology appraisal guidance on brentuximab vedotin for treating CD30-positive cutaneous T-cell lymphoma). The committee understood that mogamulizumab would most likely be used as an option after 1 systemic treatment for CD30-negative disease and after 2 systemic treatments for CD30-positive disease. But it noted that brentuximab could also be used later in the treatment pathway. The clinical experts explained that around 15 to 20% of people have CD30-positive disease. They also confirmed that the company's proposed subgroup with severe disease was clinically relevant. The committee concluded that the company positioned mogamulizumab for a subgroup of the population covered by the marketing authorisation and it would account for this in its recommendations.

Standard care is the most appropriate comparator

3.3 The company submitted cost-effectiveness analyses which used clinical effectiveness data comparing mogamulizumab with vorinostat, a treatment that is not licensed or used in the UK (see section 3.4). In its revised base case, the company included the costs of having bexarotene

alone for all patients in the standard care arm because it considered it to be the most used NHS treatment for mycosis fungoides and Sézary syndrome. A clinical expert explained that triple therapy with bexarotene, extracorporeal photopheresis and interferon is used in clinical practice. But bexarotene alone would not generally be used, particularly for Sézary syndrome, because it was not effective. Another clinical expert suggested that chemotherapy may also be an option for people who were eligible for mogamulizumab. The committee considered that the company's approach may oversimplify a complex treatment pathway. It concluded that standard care was the most appropriate comparator, which includes treatments such as methotrexate, bexarotene, interferon and chemotherapy.

Clinical evidence

There is no evidence comparing mogamulizumab with standard care so the relative treatment effect is unknown

3.4 The clinical evidence for mogamulizumab came from MAVORIC, a phase 3, open-label randomised controlled trial. MAVORIC compared mogamulizumab with vorinostat in 372 adults with stage 1B to 4B relapsed or refractory mycosis fungoides or Sézary syndrome. There was no evidence directly comparing mogamulizumab with treatments currently used as NHS standard care (see section **Error! Reference source not found.** and section 3.3). The ALCANZA trial was used in NICE's technology appraisal guidance on brentuximab vedotin for treating CD30-positive cutaneous T-cell lymphoma. It compared brentuximab with the physician's choice of treatment (methotrexate or bexarotene). The committee understood that:

- an indirect treatment comparison using ALCANZA was not possible because there was no common treatment to connect the 2 trials
- the population in ALCANZA was different to MAVORIC because patients with Sézary syndrome were excluded, all patients had CD30-

positive disease, and some had primary cutaneous anaplastic large cell lymphoma (a subtype of cutaneous T-cell lymphoma)

- there was a high level of crossover in ALCANZA and the company did not have access to individual patient level data to calculate crossover-adjusted survival estimates for the comparator arm.

The company assumed that vorinostat was a suitable proxy for standard care in the NHS because it showed similar progression-free survival to the physician's choice arm in ALCANZA. The ERG explained that if vorinostat and the physician's choice were similar, patients in the physician's choice arm in ALCANZA would have longer progression-free survival and overall survival because patients had less severe disease. However, overall survival for the physician's choice arm was shorter than with vorinostat. The clinical experts could not comment on vorinostat's clinical effectiveness because it is not available in the UK. However, they emphasised that mogamulizumab had been shown to be effective in delaying disease progression and improving quality of life both in the trial and in their clinical experience. The committee noted that mogamulizumab improved progression-free survival in MAVORIC compared with vorinostat (hazard ratio 0.43, 95% confidence interval 0.31 to 0.58). But it was concerned about using these clinical effectiveness data because vorinostat was not licensed for use in the UK and did not represent NHS standard care. It considered that the evidence for mogamulizumab was severely limited and concluded that its relative treatment effect compared with NHS standard care was unknown.

The MAVORIC subgroup with severe disease is clinically relevant but analyses are unreliable

3.5 The company used clinical effectiveness data from a post hoc subgroup of 287 patients with severe disease in MAVORIC to reflect its proposed positioning (see section 3.2). The committee recalled that severe disease was considered a clinically relevant subgroup. But it noted that in this subgroup it could not easily determine the proportion of patients who had

disease progression after brentuximab (CD30-positive disease) and those not eligible for brentuximab (CD30-negative disease). It was also concerned that the clinical effectiveness data included people at different stages in the treatment pathway and did not differentiate between mycosis fungoides and Sézary syndrome. It considered that this was not appropriate given the differences in expected survival between the conditions. The committee would have liked to have seen separate analyses by disease type and line of treatment. It recalled that all analyses used vorinostat as a comparator, which did not represent NHS standard care (see section 3.4). Based on the evidence presented, the committee concluded that the MAVORIC subgroup with severe disease was clinically relevant. But the company's analysis was unreliable because it included a mixed population which grouped several lines of treatment together, did not differentiate between disease type and did not compare mogamulizumab with a relevant comparator.

Economic model

The company's model structure is acceptable, but the treatment costs do not reflect clinical practice

3.6 In the company's partitioned survival model 3 different treatment pathways were modelled:

- patients who did not have an allogenic stem cell transplant
- patients who had an allogenic stem cell transplant after current treatment (that is, mogamulizumab or standard care)
- patients who had an allogenic stem cell transplant after subsequent treatment.

The company used clinical expert advice to estimate the proportion of patients having an allogenic stem cell transplant after current treatment because this was not allowed in MAVORIC. The committee was aware that the estimated treatment effect in MAVORIC may have differed if allogenic stem cell transplant had been allowed. The ERG also explained

that using fixed time points and trial data may not reflect clinical practice. The committee preferred to remove allogenic stem cell transplant after current treatment, to reduce potential bias. It understood that this had a small effect on the cost-effectiveness estimates. The company modelled standard care using MAVORIC clinical effectiveness data because it considered that vorinostat could be used as a proxy for standard care (see section 3.4). In its revised base case, the company preferred to use the costs of bexarotene alone and a treatment duration of 48 weeks to represent the likely costs for people who have NHS standard care. The committee reiterated its concerns with using vorinostat as a comparator but recalled that there was no evidence comparing mogamulizumab with standard care (see section 3.4). It concluded that the company's economic model structure was acceptable, but the model did not include treatment costs that reflected clinical practice.

Overall survival

The results from the crossover adjustment methods represent the upper and lower range of plausible overall survival in the standard care arm

3.7 In MAVORIC, 72% of patients in the severe disease subgroup crossed over from vorinostat to mogamulizumab after disease progression. Therefore, overall survival in the vorinostat arm was heavily confounded and both the company and ERG agreed that an adjustment was needed to estimate what would have happened in the comparator arm if there was no crossover. Both the company and ERG also agreed that the rank preserving structural failure time model suggested that survival with vorinostat was longer than with mogamulizumab and this was not clinically plausible. The company preferred the inverse probability of censoring weights (IPCW) method to adjust for crossover because it produced estimates in line with the company's clinical expert advice and accounted for a potential post-progression benefit of mogamulizumab. The ERG preferred the 2-stage estimation method to adjust for crossover. The ERG explained that there was bias and substantial uncertainty associated with

both approaches and that the estimates of treatment effect varied widely (exact data are confidential and cannot be reported here). For the IPCW-adjusted Kaplan–Meier data, the company clarified that a sharp drop in survival at around 6 months was an artefact of the trial protocol because this was when the first crossover happened. The ERG's clinical expert suggested that this did not look plausible. But the clinical experts at the appraisal committee meeting suggested that this pattern may be seen for patients who had many lines of pre-treatment. The committee was not convinced that the IPCW-adjusted curve was clinically plausible for the average patient in the modelled population with severe disease. It understood that the 2-stage estimation adjusted curve showed better survival in the comparator arm, which led to higher cost-effectiveness estimates. The company suggested that the long-term predictions using the 2-stage estimation adjusted curve did not account for the potential disease-modifying effect of mogamulizumab. This was because the modelled survival benefit was longer in the comparator arm than in the mogamulizumab arm for patients with disease progression after current treatment was stopped, which it considered to be implausible. The ERG questioned whether the main survival benefit of mogamulizumab would be gained when patients were on subsequent treatment and emphasised the lack of evidence to support the disease-modifying effect of mogamulizumab. One patient expert described how their symptoms slowly returned after mogamulizumab was temporarily stopped for around 12 weeks. The committee was not convinced that mogamulizumab provided a prolonged benefit after disease progression and could be considered disease-modifying. It recognised that the choice of crossover adjustment had a large impact on the cost-effectiveness results. The committee concluded that the results from the 2-stage estimation and IPCW methods represented the upper and lower range of plausible overall survival in the standard care arm.

All extrapolations are uncertain but the ERG's preferred exponential curve for both treatment arms is acceptable for decision making

3.8 Alongside the company's preferred IPCW crossover adjustment, it chose a lognormal curve to extrapolate overall survival in the mogamulizumab arm and applied an exponential curve to the standard care arm. The ERG explained that using the company's preferred IPCW crossover adjustment, the exponential curve provided the best statistical fit for the mogamulizumab arm. The committee agreed that the company would need to make a strong case to justify using different parametric curves in each treatment arm. The company explained that based on visual inspection, a lognormal curve provided a better fit to the first half of the curve where more data were available. The company clarified that it also used observational data to validate the survival predictions from its preferred model. The company suggested that data from the Hospital Episode Statistics (HES) database were closest to the data from the subgroup with severe disease in its proposed positioning. But it noted that the HES data only included people who had 1 treatment, and only a small number of them had Sézary syndrome. The ERG preferred to use the 2-stage estimation crossover adjustment and applied an exponential extrapolation for both treatment arms because this gave the best statistical fit. The committee understood that MAVORIC was not powered to estimate overall survival, the data were immature and there was a high level of crossover. Therefore all extrapolations were uncertain. The committee was not convinced that mogamulizumab provided an overall survival benefit compared with standard care. It would have liked to have seen scenario analyses using HES data to model overall survival in the standard care arm. It concluded that the ERG's preferred exponential curve for both treatment arms was acceptable for decision making.

A 2-year stopping rule is not appropriate

3.9 The company included a 2-year stopping rule for mogamulizumab in its revised base case. There was no evidence to support a stopping rule because it was not included in either the summary of product

characteristics or the MAVORIC trial. The committee understood that the estimated treatment effect could have differed if a stopping rule had been used. The company suggested that the treatment effect was unlikely to differ substantially because in MAVORIC only a small proportion of people were having mogamulizumab after 2 years (exact data are confidential and cannot be reported here). The committee recalled that it was not convinced that mogamulizumab was disease-modifying (see section 3.7) and there would be a prolonged treatment benefit after stopping treatment. Before technical engagement 1 clinical expert suggested that a 2-year stopping rule would not be appropriate if patients were still benefitting from treatment. At the appraisal committee meeting the clinical experts explained that treatment would not normally be stopped if it was tolerated and there was an ongoing clinical benefit. The patient experts expressed how they would feel distressed if mogamulizumab was stopped at 2 years, leaving them without any effective treatment options. The committee concluded that a 2-year stopping rule was not appropriate.

Utility values

The company's approach to modelling carer utility values is not appropriate

3.10 The company included carer utility values based on a vignette study. It suggested that this was a conservative approach because a utility gain was only applied in the disease control health state. The committee questioned if it was appropriate to include carer utility values for disease control (0.56) and subsequent treatment (0.37) that were lower than for patients having mogamulizumab (exact data are confidential and cannot be reported here). The committee recalled that this condition has an impact on the quality of life of carers (see section **Error! Reference source not found.**). However, the patient experts indicated that they mostly self-managed the condition. The committee noted that some people would have help from district nurses, for example with wound dressing. The committee considered that the company's approach to modelling carer utilities was not robust because the utility gain was

implausibly large compared with the expected utility gain for patients. It recognised that there was a lack of detailed methodology on how to model carer utility values but noted that the company used vignettes in the general population, which was not in the current NICE guide to the methods of technology appraisal. The committee would have liked to have seen:

- more details of the difference in health-related quality life of patients in the disease control health state and the subsequent treatment health state
- if more plausible carer utility values were available from the literature
- if it was possible to map utility for patients from more sensitive instruments to EQ-5D.

Overall, the committee was not convinced that the company's approach to modelling carer utility values was appropriate. So it preferred to remove them but recognised the burden placed on some carers (see section 3.16).

End of life

Mogamulizumab is not considered to be 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's revised base case using the IPCW crossover adjustment predicted a median survival of 21 months and a mean survival of 37 months in the standard care arm. The committee's preferred assumptions (see section 3.13) predicted a mean survival of between 33 months and 59 months in the standard care arm depending on if an IPCW or 2-stage estimation crossover adjustment was used. The committee noted that median overall survival was around 1.3 years using the HES data for people who have had 1 treatment, but only a small number had Sézary syndrome (see section 3.8). It recalled that

mogamulizumab could also be used after 2 previous treatments, but the HES database did not include these. The committee noted that all modelled survival relied on the MAVORIC trial and recalled its earlier concerns that vorinostat was not an appropriate comparator. The committee was not convinced that the short life expectancy criterion had been met for the company's proposed population. But it recognised that it may be met for people with Sézary syndrome, which has a poorer prognosis. However, it noted that it had not seen clear evidence from the company to support this. The committee recalled substantial uncertainty in the clinical data (see section 3.4 and section 3.5) and concluded that it had not seen enough evidence to conclude that the short life expectancy criterion had been met. It concluded that mogamulizumab could not be considered a life-extending treatment at the end of life.

Cost-effectiveness estimate

Because of the uncertainty an acceptable ICER is towards the lower end of the range normally considered cost effective

3.12 NICE's guide to the methods of technology appraisal notes that above a most plausible incremental cost-effectiveness ratio (ICER) of £20,000 per quality-adjusted life year (QALY) gained, judgements 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 presented. The committee noted the high level of uncertainty, specifically:

- The relative treatment effect of mogamulizumab compared with NHS standard care was unknown because MAVORIC did not include the most appropriate comparator (see section 3.4).
- The company's preferred subgroup was limited because it included a mixed population in a single analysis and was from a post hoc analysis (see section 3.5).

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- There was a high level of crossover, adjustments were potentially biased and the methods produced a wide range of estimates of treatment effect (see section **Error! Reference source not found.**).

- The overall survival data are immature. Also, overall survival was not a primary endpoint in MAVORIC so the trial was not powered to estimate this (see section 3.8).

Therefore, it agreed that an acceptable ICER would be towards the lower end of the range normally considered a cost-effective use of NHS resources (£20,000 to £30,000 per QALY gained).

All cost-effectiveness estimates are uncertain but the most plausible ICER is much higher than £20,000 per QALY gained

3.13 The company's revised base-case ICER for mogamulizumab compared with standard care was £25,724 per QALY gained, including the commercial arrangement for mogamulizumab. However, this did not include all of the committee's preferred assumptions, which were:

- Applying the ERG's corrections (using a 45-year time horizon, removing allogenic stem cell transplant after current treatment and using a lognormal extrapolation for next treatment-free survival and disease-free survival). This had a small impact on the ICER and was resolved at technical engagement.

- Using standard care as a comparator, which included various treatments (see section 3.3).

- That the results from the 2-stage estimation and IPCW methods represent the upper and lower range of plausible overall survival in the standard care arm (see section **Error! Reference source not found.**).

- Using an exponential curve to extrapolate overall survival in both treatment arms (see section 3.8).
- Removing the 2-year stopping rule (see section 3.9).
- Excluding carer utility values that the company included in the model (see section 3.10).

The committee understood that after taking into account all of its preferred assumptions, the most plausible ICER ranged between £48,533 and £94,250 per QALY gained. It understood that there was a small impact on the ICER when including the commercial arrangement for bexarotene (exact data are confidential so cannot be reported here). It noted the substantial uncertainty in all cost-effectiveness estimates. But it recognised that the lower ICERs reflected the IPCW adjustment method, which it considered to be clinically implausible and produced optimistic cost-effectiveness results, and the higher ICERs reflected the 2-stage estimation method, which it considered to perhaps be overly pessimistic.

All cost-effectiveness estimates are uncertain but the most plausible ICER is much higher than £20,000 per QALY gained

3.14 The committee concluded that based on its preferred assumptions, all ICERs within the plausible range were substantially higher than £20,000 per QALY gained. Therefore, mogamulizumab could not be recommended for routine use in the NHS.

Cancer Drugs Fund

No Mogamulizumab does not meet the criteria to be considered for inclusion in the Cancer Drugs Fund

3.15 Having concluded that mogamulizumab could not be recommended for routine use, the committee then considered if it could be recommended for treating mycosis fungoides and Sézary syndrome 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). The committee noted that:

- The company had not expressed an interest in the treatment being available through the Cancer Drugs Fund.
- The most plausible ICER range, including all the committee's preferred assumptions, was between £48,533 and £94,250 per QALY gained. The committee considered that this was substantially higher than £20,000 per QALY gained, so there was no plausible potential to satisfy the criteria for routine use.
- The key uncertainty relates to the crossover adjustment and extrapolation of overall survival in the standard care arm. Data to resolve this uncertainty could not be collected as part of the Cancer Drugs Fund.

The committee concluded that mogamulizumab did not meet the criteria to be considered for inclusion in the Cancer Drugs Fund.

Innovation

Mogamulizumab is not innovative and all benefits are captured in the model

3.16 The company considered mogamulizumab to be innovative because there are limited effective treatment options for people with severe disease who have had at least 1 systemic treatment. The company emphasised the importance of improved health-related quality of life for this disease, which causes lesions that affect people's appearance. The committee recalled this, the reported benefits in improving symptoms and the burden on carers (see section **Error! Reference source not found.** and section 3.10). It recognised that using its preferred assumptions, carer utility values had not been included in the model. But it noted that all cost-effectiveness estimates, even those including a carer utility gain in the

model, were substantially higher than £20,000 per QALY gained. The committee concluded that the relevant benefits associated with mogamulizumab could be adequately captured in the model.

Equalities considerations

There are no equalities issues relevant to the recommendation

3.17 No equalities issues were raised during scoping and technical engagement. No potential equality issues were identified in the company submission. The committee concluded that there were no equalities issues relevant to the recommendation.

4 Proposed date for review of guidance

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

Stephen O'Brien
Chair, appraisal committee
July 2020

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 D.

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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.

Abitha Senthinathan
Technical lead

Alex Filby
Technical adviser

Louise Jafferally
Project manager

ISBN: [to be added at publication]