NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Draft guidance consultation

Voclosporin with immunosuppressants for treating lupus nephritis

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

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

The evaluation 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 age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation?

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- After considering these comments, the committee will prepare the final draft guidance.
- Subject to any appeal by stakeholders, the final draft guidance may be used as the basis for NICE's guidance on using voclosporin in the NHS in England.

For further details, see <u>NICE's manual on health technology evaluation</u>.

The key dates for this evaluation are:

- Closing date for comments: 20 December 2022
- Second evaluation committee meeting: 16 February 2023
- Details of membership of the evaluation committee are given in section 4.

1 Recommendations

- 1.1 Voclosporin plus mycophenolate mofetil is not recommended, within its anticipated marketing authorisation, for treating active class 3 to 5 (including mixed class 3 and 5, and 4 and 5) lupus nephritis in adults.
- 1.2 This recommendation is not intended to affect treatment with voclosporin 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

Treatment options for lupus nephritis include immunosuppressants such as mycophenolate mofetil taken with hydroxychloroquine and corticosteroids. There are several immunosuppressant options depending on factors such as condition severity, previous treatments and other conditions such as organ damage.

Clinical trial evidence suggests voclosporin plus mycophenolate mofetil is more effective at stopping lupus nephritis from getting worse than mycophenolate mofetil alone. But these results are uncertain because it is not clear by how much a person's condition will improve in clinical practice. Indirect comparisons of voclosporin with other treatment options are also uncertain because the included trials look at different outcomes.

The company's cost-effectiveness estimates are uncertain because their accuracy is unclear. They also do not consider different treatments for lupus nephritis over time depending on whether the condition is responding to treatment.

Because of the uncertainty, the most plausible cost-effectiveness estimates are likely above the range NICE normally considers a cost-effective use of NHS resources. So, voclosporin is not recommended.

2 Information about voclosporin

Anticipated marketing authorisation indication

2.1 Voclosporin (Lupkynis, Otsuka) is anticipated to be indicated 'in combination with mycophenolate mofetil for the treatment of adult patients with active class 3, 4 or 5 (including mixed class 3/5 and 4/5) lupus nephritis'.

Dosage in the marketing authorisation

2.2 The dosage schedule will be available in the summary of product characteristics for voclosporin.

Price

- 2.3 The proposed list price for voclosporin is commercial in confidence. The list price of mycophenolate mofetil (MMF) is £6.83 per 50-pack of 500-mg tablets (excluding VAT; drugs and pharmaceutical electronic market information tool, accessed October 2022).
- 2.4 The company has a commercial arrangement, which would have applied if voclosporin had been recommended.

3 Committee discussion

The <u>evaluation committee</u> considered evidence submitted by Otsuka, a review of this submission by the external assessment group (EAG), and responses from stakeholders. See the <u>committee papers</u> for full details of the evidence.

Clinical need

Nature of the condition

3.1 Lupus nephritis is a complication of systemic lupus erythematosus, a chronic condition that causes inflammation in connective tissues. It occurs in around 40% to 60% of people with systemic lupus erythematosus and affects the kidneys, specifically glomeruli cells. Clinical experts highlighted the high unmet need for people with lupus nephritis because the condition

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is not curable. The disease follows a cycle of relapsing and remitting. Some people develop end-stage renal disease if their condition does not respond to treatment and need dialysis or kidney transplants to survive. Lupus nephritis is a debilitating disease which significantly impacts people with the condition and those who care for them. Patient experts highlighted the most challenging aspects for people with lupus nephritis are the symptoms, reduced ability to work and impact on mental wellbeing. Patient experts explained that in a 2020 survey of 67 people with lupus nephritis, 81% reported fatigue as the most difficult symptom, followed by joint pain and swelling (60%). People with the condition explained how every day is a challenge with such lack of energy. The committee also heard that in the same survey 57% of people with lupus nephritis felt isolated once a week and that 58% need help with household care, while 33% need help with personal care. Carers of people with lupus nephritis are significantly impacted because of helping with daily tasks and having less time to work and socialise. There is also constant anxiety about the health of people with lupus nephritis because of the lack of a cure and regular tests to monitor the condition. The committee also heard how carers feel helpless, especially when lupus nephritis symptoms are worse. Patient and clinical experts also explained how current treatments have significant adverse effects. These side effects can cause other conditions that need separate treatment. They also severely impact quality of life and in some cases may affect adherence to dosing regimens. The committee concluded that lupus nephritis is a debilitating condition and there is high unmet need for effective treatments with manageable side effects.

Clinical management

Treatment options

3.2 Clinical and patient experts highlighted that lupus nephritis is a highly heterogeneous condition. This may result in significant differences in treatment options because of varying needs and personal circumstances.

Clinical experts explained that lupus nephritis rarely happens in isolation Draft guidance consultation – voclosporin with immunosuppressants for treating lupus nephritis [ID3962] Issue date: November 2022 Page 5 of 18 © NICE 2022. All rights reserved. Subject to Notice of rights. and that treatment choices depend on lots of other factors, including disease severity, previous treatments and comorbidities such as organ damage. They explained that lupus nephritis follows a cycle of relapsing and remitting, meaning treatments are used to either induce or maintain remission. They added that treatments varied only by the immunosuppressives taken with hydroxychloroquine and tapered doses of corticosteroids. The immunosuppressives used to induce remission include methylprednisolone with mycophenolate mofetil, low- and high-dose cyclophosphamide, rituximab with mycophenolate mofetil, and tacrolimus with or without mycophenolate mofetil. Maintenance treatments include mycophenolate mofetil, azathioprine and tacrolimus monotherapy. The committee concluded that the treatment options for lupus nephritis were highly heterogenous and were expected to frequently change based on disease response.

Treatment positioning of voclosporin

3.3 Clinical experts explained that voclosporin, a calcineurin inhibitor, would be an add-on treatment to mycophenolate mofetil and corticosteroids for treating lupus nephritis. The company highlighted that clinical evidence for voclosporin includes people who had voclosporin at different points in the treatment pathway. It also highlighted the marketing authorisation for voclosporin does not specify a treatment line. Clinical experts expressed uncertainty on how voclosporin would be used in clinical practice. Some experts agreed it would be used as a first-line induction treatment or a later add-on treatment for people whose condition doesn't respond to mycophenolate mofetil alone, like the AURORA trials (see <u>section 3.4</u>). Other experts suggested that voclosporin may be used hesitantly in the first line because of the lack of long-term evidence and that use after other treatments is more likely. The EAG explained that calcineurin inhibitors were usually used as later-line treatments. So, clinician hesitation would be expected for using voclosporin as a first-line induction treatment. But it said that mycophenolate mofetil alone was the most suitable comparator if voclosporin was to be used as a first-line treatment. It added that

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tacrolimus plus mycophenolate mofetil would be the most suitable comparator for later-line treatments. Clinical experts and the Innovative Medicines Fund clinical lead explained that voclosporin would be used to induce remission and not as a maintenance treatment. Clinical experts added this is a more appropriate consideration of treatment positioning rather than first line and later lines of therapy. Lupus nephritis follows cycles of relapse and remission so a treatment previously used to induce remission could be considered a treatment option in the future. The committee considered that it was very uncertain how voclosporin would be used. It noted the AURORA trials only showed an ability to induce remission, but voclosporin's mechanism of action suggests maintenance use may also be possible. It recalled the opinion of clinical experts that voclosporin would not be used for more than 9 to 12 months, but it may be used again if it was effective at inducing remission at first use. So, the committee concluded that voclosporin would be used to induce remission but not necessarily as a long-term maintenance treatment. It identified first-line induction treatments taken with mycophenolate mofetil (methylprednisolone, rituximab and tacrolimus) and mycophenolate mofetil alone as the most likely appropriate comparators (see section 3.2).

Clinical evidence

Pivotal clinical trials and outcome measures

3.4 The clinical evidence for voclosporin is from the phase 3 AURORA 1 and AURORA 2 trials. These were multicentre, double-blind, placebocontrolled randomised trials. AURORA 2 was a 24-month long-term continuation study for people who had completed the 12-month AURORA 1 study. People had voclosporin or placebo, plus mycophenolate mofetil and low-dose corticosteroids. The primary endpoint of AURORA 1 was complete renal response at 12 months, which was 40.8% for voclosporin and 22.5% for placebo. AURORA 1 recruited 357 people from 27 countries, 216 of whom also enrolled in AURORA 2. Clinical experts noted that complete renal response in the AURORA trials

 was a composite endpoint, comprising several measures. This included

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changes to the urine protein to creatinine ratio and estimated glomerular filtration rate, as well as the use of rescue medication and prednisone. Partial renal response depended only on changes to the urine protein to creatinine ratio. Clinical experts explained that changes in the urine protein to creatinine ratio do not always necessarily lead to meaningful changes in the disease in the long term. They suggested using kidney biopsy results as an alternative measure of response but noted the practical challenges of doing kidney biopsies. Although the AURORA trials had some limitations, the committee concluded that they show clear clinical advantages of voclosporin over mycophenolate mofetil in inducing renal response when measured by protein in the urine.

Generalisability of clinical trials

3.5 The EAG noted that the AURORA trials (see section 3.4) included no people from the UK. This meant that the generalisability of AURORA data to the UK population may have been limited. Clinical experts considered that the population included in the AURORA trials is reflective of the populations seen in the NHS. However, clinical experts did question the generalisability of the AURORA trials because of the corticosteroid doses used. An expert highlighted that the doses were lower than recommended by guidelines and used in NHS clinical practice. The EAG explained it had clinical advice that agreed the steroid use was lower than in practice, but that the dose would still be effective and in line with clinical guidelines. It also noted that both treatment arms of the AURORA trials had lower-dose steroids. Patient and clinical experts emphasised that a key benefit of voclosporin is the potential ability to have lower-dose steroids. The reduced use of steroids is desirable because of reduced side effects, especially damage to the immune system. However, clinical experts raised concerns that some clinicians would not use lower steroid doses with voclosporin, like the AURORA trials, and would use standard higher doses based on previous experience. The committee recalled that both arms of the AURORA trials used lower doses of steroid than standard practice and that there was no direct evidence comparing use of

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voclosporin with higher and lower doses of steroids. The committee concluded that the population in the AURORA trials are generalisable to the UK population but that the steroid doses used are not reflective of established NHS clinical practice.

Attrition bias

3.6 It was noted that 39.5% of people discontinued AURORA 1 and did not enrol into AURORA 2. The committee was concerned with the possibility of attrition bias (that is, that discontinuation may not be random and there may be systematic differences between the population that discontinued AURORA 1 and the population that continued enrolment to AURORA 2). The EAG explained that the rate of and reasons for discontinuation were comparable across the trial arms, reducing the risk of bias. But the break in randomisation caused a high risk of bias in AURORA 2. It also noted that response outcomes significantly increased at 12 months and 18 months, caused by the switch from AURORA 1 to AURORA 2 data. The committee concluded that the company had not fully explored correcting for attrition bias in the AURORA 2 data. It would have liked to see extrapolations made from 12 months onwards based on AURORA 1 data, as well as extrapolations based on AURORA 2 data adjusted to account for attrition bias in trial participants. To achieve this, it suggested multiple imputation, or sensitivity analyses that assume different responses for people who did not enrol in AURORA 2. For example, assuming people who had voclosporin and were lost to follow-up were non-responders, while assuming people who had placebo were responders, as well as different variations of this.

Network meta-analysis

3.7 Because of the lack of direct comparative evidence for voclosporin and other relevant comparators besides mycophenolate mofetil, the company developed a network meta-analysis. The analysis included complete and partial renal response data for the treatment options outlined in <u>section 3.2</u>. Data was identified by a systematic literature review. The

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company's base case included a fixed effects network meta-analysis. The company justified this approach because random effects network metaanalysis estimates were not converging. The EAG suggested a random effects network meta-analysis using informative priors. This is because considerable variation across the trials included could lead to heterogeneity. The company provided a random effects analysis during technical engagement but did not include it in its updated base case. It explained that this was because the fixed and random effect analyses produced similar results. The EAG agreed with the limited change between the network meta-analysis results. But, it added that wider confidence intervals with the random effects network meta-analysis may impact estimated results for other comparators (the results of which were not presented by the company). The committee considered that the fixed effects network meta-analysis was subject to uncertainty arising from the considerable heterogeneity across the trials included. It noted this heterogeneity led to uncertainty in the cost-effectiveness results. The committee concluded that it would have preferred the company to have used the random effects network meta-analysis in its base case. In addition, it noted that heterogeneity across the populations and trial outcomes included in the network meta-analysis increased uncertainty of results.

Economic model

Company's model structure

3.8 The company developed a cohort-level state-transition Markov model to estimate the cost effectiveness of voclosporin plus mycophenolate mofetil compared with relevant comparators. People were modelled to transition between 3 lupus nephritis-related chronic kidney disease (CKD) states (stages 1 to 3a, stages 3b to 4, stage 5) and death. People with stages 1 to 3a CKD could move between active disease, partial response and complete response substates. People with stages 3b to 4 CKD were only modelled in an active disease substate. People with stage 5 CKD could

move between dialysis and kidney transplantation. During technical Draft guidance consultation – voclosporin with immunosuppressants for treating lupus nephritis [ID3962] Issue date: November 2022 Page 10 of 18

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engagement, the company updated the model to allow disease progression from stages 1 to 3a to stages 3b to 4 CKD, apply consistent death costs, apply correct relative dosing intensity, and reassure the EAG of accurate model inputs and formulas. These changes were to align with some aspects of the EAG's preferred base case, but some issues remained. For instance, in the updated company base case, people with stages 3b to 4 CKD could not have response in the model. The company suggested that a minority of people (about 2.5%) with stages 3b to 4 CKD would have a response. Clinical experts agreed that only a small number of people with stages 3b to 4 CKD would have response, but the number was not zero. The EAG suggested this should be reflected in the model structure. The EAG also identified that transition probabilities were uncertain for voclosporin and mycophenolate mofetil. This is because transitions for AURORA 1 and 2 participants were derived by the 'count method', which is associated with limitations because of small sample sizes. The company explained that it attempted to use alternative statistical methods to estimate transition probabilities, but the approaches provided unrealistic outcomes that did not match the trial data. The EAG agreed that the company's additional scenarios should be interpreted with caution. This is because imputations were based on explicit assumptions of what the data was likely to be if they were not missing. Several additional modelling issues were also raised by the EAG, including:

- The estimated proportion of people with stage 5 CKD who had kidney transplant was too high. Clinical advice to the EAG suggested that the company's assumed kidney transplant rate of 90% over 2 years was high. The EAG adopted a rate of 65% in its base case based on clinical advice.
- Model transparency was raised as a key issue because the EAG found errors (for example, with adverse event disutility calculations in the model) and multiple instances of insufficient descriptions of calculations and sources of information. In addition, the EAG noted that the model

lacked the flexibility to refer to previous treatment settings which limited the ability for the model to be cross checked by the EAG.

The committee concluded that because of the uncertainties with the model structure and model transparency, it had reservations about the robustness of the model's outputs. The committee concluded it would have more confidence in a model that addressed the EAG's concerns, for example, if the model had the flexibility to refer to previous treatment settings and if sources of data were clearly referenced and described. It also noted that uncertainty could be further reduced if the restriction in the model structure which stops people with CKD stages 3b to 4 from moving to response was amended, because this would better reflect clinical practice.

Modelling of costs

3.9 Modelled monitoring costs were raised as an issue by the EAG because the company excluded additional monitoring costs for voclosporin. This was inconsistent with the modelled costs for tacrolimus, the other calcineurin inhibitor in the model. The company suggested this is because voclosporin has superior efficacy and safety to tacrolimus. The committee noted that the summary of medical product characteristics for voclosporin recommends careful monitoring of renal function. Clinical experts and the Innovative Medicines Fund clinical lead explained that this would be included within routine monitoring for lupus nephritis. They explained that tacrolimus needs therapeutic drug monitoring to confirm optimal dosing and renal toxicity. However, voclosporin does not need this extra monitoring. The EAG further raised modelled costs as a key issue because the company assumed no treatment discontinuation for non-trial comparators. The company explained this was because of a lack of evidence to the contrary. Based on clinical input, the EAG considered this was a clinically implausible assumption. The committee concluded that extra monitoring costs for voclosporin were not appropriate because of the different monitoring requirements for tacrolimus and voclosporin. But, it

did conclude that assuming no treatment discontinuation for non-trial comparators was inappropriate.

Long-term treatment effects

- 3.10 AURORA 1 and 2 data for voclosporin used in the company's model covered 3 years. So, the company used assumptions to extrapolate data for approximately 69 further years. To do this, the company assumed:
 - long-term transition probabilities for treatments equalled the average transition probabilities for month 30 and month 36, combined with a treatment waning effect
 - for active disease and partial response states, voclosporin plus mycophenolate mofetil transition probabilities equalled those of mycophenolate mofetil alone
 - for complete response states, voclosporin plus mycophenolate mofetil transition probabilities equalled the average of voclosporin plus mycophenolate mofetil and mycophenolate mofetil alone
 - transition probabilities for other comparators were assumed to be the same as the active disease state.

The EAG adopted a different approach, assuming voclosporin plus mycophenolate mofetil and mycophenolate mofetil alone were equal for all health states. Despite these changes to the company base case, the EAG still expressed considerable uncertainty in using on-treatment short-term data to predict off-treatment long-term outcomes. Submissions from stakeholders highlighted that a long-term treatment effect is an unproven assumption, but that short-term benefits can be predictive of improved longer-term outcomes. The EAG explained the uncertainty was likely to only be reduced with additional long-term data or clinical expert input. The committee also determined that the long-term extrapolations could better reflect the relapsing and remitting nature of the disease. It would have preferred to see a repeating cycle of induction and maintenance reflected, instead of induction followed by maintenance treatment with other therapies for over 69 years. However, it acknowledged that modelling such extrapolations would be difficult to

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construct. The committee concluded that longer-term efficacy is difficult to establish and extrapolate from short-term data such as that used in the network meta-analyses, particularly when these are associated with heterogeneity (see <u>section 3.6</u>). Because of this, there is high uncertainty with both the company's and EAG's approaches to the long-term treatment effect extrapolations.

Duration of treatment

3.11 The company's model assumed treatment stops at 36 months, in line with the availability of AURORA trial data. The company explained that clinical experts supported this modelling assumption. The marketing authorisation for voclosporin does not specify a stopping rule but recommends a riskbenefit analysis at 24 weeks. Clinical advice to the EAG also supported stopping treatment at 36 months in the model. The clinical experts explained that induction treatment with voclosporin is unlikely to be for 36 months. This is because of the relapsing and remitting nature of the condition meaning treatment would be expected for approximately 9 to 12 months. But re-treatment with voclosporin to induce response would be expected and desirable in the future. The committee noted that retreatment was not included in the company's model. It concluded that assuming treatment stops at 36 months was arbitrary because of uncertainty in treatment duration depending on whether voclosporin was used to induce or maintain remission. Therefore, the committee considered that treatment duration in the model was longer than expected in clinical practice when used to induce remission. It noted that although the modelled treatment duration was 36 months, almost half of people who started voclosporin in AURORA 1 had stopped treatment by this point. Based on this and the input from the clinical experts, the committee considered that it would be beneficial to see an analysis using a treatment duration that better reflected expected practice. It also noted it would be beneficial to see additional scenario analyses exploring a range of treatment durations.

Cost-effectiveness estimates

Company and EAG cost-effectiveness estimates

3.12 The deterministic cost-effectiveness results include confidential prices for voclosporin and other treatments. Therefore, the exact results cannot be reported here. The company's deterministic base-case incremental costeffectiveness ratio (ICER) for voclosporin against mycophenolate mofetil was significantly higher than the lower end of the range normally considered cost effective. In addition, the EAG's corresponding base-case ICER was higher than the typical cost-effectiveness threshold. ICERs varied for other comparator treatments. The committee recalled that the main difference between the EAG and company base cases was the approach to extrapolating long-term treatment effects (see section 3.10). It considered that without long-term data, both approaches were associated with high uncertainty. In addition, it noted that it would have more confidence in a model that addressed the EAG's concerns about structural transparency and input accuracy. It also noted that uncertainty could be further reduced if the response restriction for people with stages 3b to 4 CKD was amended to better reflect clinical practice (see section 3.7). The committee determined that resolving such uncertainties could potentially increase the estimated ICERs. The committee concluded it could not recommend voclosporin for routine use. This is because the most plausible ICER was likely above the range normally considered cost effective and because of the issues with the company's model and uncertainty in all the cost-effectiveness estimates.

Managed access

Managed access through the Innovative Medicines Fund

3.13 Having concluded that voclosporin could not be recommended for routine use, the committee then considered if it could be recommended with managed access via the Innovative Medicines Fund for treating lupus nephritis. The committee heard from representatives from the Innovative Medicines Fund that access for voclosporin via the fund would not lead to

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additional data being gathered that could resolve the uncertainties presented in the maximum time available in managed access. Furthermore, there is no mechanism to collect this data. The committee concluded that it would not be appropriate to recommend voclosporin with managed access via the Innovative Medicines Fund for treating lupus nephritis.

Other factors

Innovation

3.14 Clinical experts suggested that there may be a potential for uncaptured benefits within the company's model. They highlighted the significant impact of lupus nephritis and treatments on people's immune systems and fertility. In addition, they noted the potential use of voclosporin with lower doses of steroids (see section 3.5) would enable a reduction in the significant harmful effects associated with higher doses of steroids. Experts suggested that such benefits were not captured in the model because the comparator arm also used a lower dose of steroids. The committee noted that that there was no evidence comparing the use of voclosporin with higher and lower doses of steroids. The committee also considered whether voclosporin was innovative. It heard from clinical experts that voclosporin is not considered a step change in treatment for lupus nephritis. This is because other calcineurin inhibitors such as tacrolimus are already used in practice. So, the committee concluded that voclosporin was not innovative for treating lupus nephritis. It also recalled that there were concerns with the company's model that made estimated outcomes and ICERs uncertain.

Equality issues

3.15 Patient and clinical experts identified that people with Indian-Asian, African-Caribbean and Chinese family backgrounds are more likely to have poorer outcomes with lupus nephritis. However, clinical experts also noted that there was no evidence to suggest voclosporin showed different effectiveness for different subgroups of people. The committee heard that

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women are disproportionately affected by lupus nephritis. It also heard from patient experts how current treatments such as cyclophosphamide can cause infertility or increase the risk of birth defects in a developing fetus. The committee were grateful for these issues being raised but noted that voclosporin is taken with mycophenolate mofetil and steroids. It recalled that mycophenolate mofetil cannot be used during pregnancy and so this would also apply to voclosporin. However, it did note that voclosporin was unlikely to be associated with a risk of permanent infertility. So, it would provide an alternative option to treatments such as cyclophosphamide. The committee also noted that the differences in prevalence cannot usually be resolved in a technology appraisal, although the committee can consider whether a specific equality issue has a significant impact on access to treatment. Overall, the committee agreed that its recommendation would not have a different effect on people protected by the equality legislation than on the wider population. The committee concluded that there were no relevant equality issues.

Conclusion

Recommendation

3.16 The committee recalled the high uncertainty associated with the company's model and long-term treatment effect estimations. Because of this, the committee considered that it would have more confidence in the company's model if further changes were made. This included addressing uncertainties with the model structure capturing response for all people and model transparency. It recalled that both the EAG and company base case were associated with high uncertainty and that the most plausible cost-effectiveness estimates are likely above the range normally considered a cost-effective use of NHS resources. This means voclosporin cannot be recommended with mycophenolate mofetil for treating lupus nephritis.

4 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 <u>committee D</u>.

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

Chair

Dr Megan John

Chair, technology appraisal committee D

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.

Owen Swales Technical lead

Fatima Chunara Technical adviser

Kate Moore Project manager

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