

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Appraisal consultation document

### **Avacopan for treating severe active granulomatosis with polyangiitis or microscopic polyangiitis [ID1581]**

The Department of Health and Social Care has asked the National Institute for Health and Care Excellence (NICE) to produce guidance on using avacopan 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, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?

**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 avacopan 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: 17 June 2022

Second appraisal committee meeting: 7 July 2022

Details of membership of the appraisal committee are given in section 3.

# 1 Recommendations

- 1.1 Avacopan with a cyclophosphamide or rituximab regimen is not recommended, within its marketing authorisation, for treating severe active granulomatosis with polyangiitis or microscopic polyangiitis in adults.
- 1.2 This recommendation is not intended to affect treatment with avacopan 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 granulomatosis with polyangiitis or microscopic polyangiitis usually starts with corticosteroids plus cyclophosphamide or rituximab.

Clinical trial evidence shows that, after a year, avacopan is more effective at stopping the condition getting worse than standard care. It also suggests fewer side effects from corticosteroids, possibly because of less use overall.

There is uncertainty in the cost-effectiveness model, including:

- that maintenance treatment does not reflect NHS clinical practice
- which is the most appropriate estimate for the risk of developing end-stage renal disease.

Taking these uncertainties into account, the most likely cost-effectiveness estimates are above what NICE usually considers an acceptable use of NHS resources. So, avacopan is not recommended.

## 2 Information about avacopan

### Marketing authorisation indication

- 2.1 Avacopan (Tavneos, Vifor Pharma), 'in combination with a rituximab or cyclophosphamide regimen, is indicated for the treatment of adult patients with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)'.

### Dosage in the marketing authorisation

- 2.2 The dosage schedule will be available in the [summary of product characteristics for avacopan](#).

### Price

- 2.3 The company considers the list price of avacopan to be confidential. The company has a commercial arrangement, which would have applied if the technology had been recommended.

## 3 Committee discussion

The [appraisal committee](#) considered evidence submitted by Vifor Pharma, a review of this submission by the evidence review group (ERG), and responses from stakeholders. See the [committee papers](#) for full details of the evidence.

### Population, treatment pathway and positioning

#### People with granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) can have severe symptoms

- 3.1 Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis is a group of rare autoimmune conditions characterised by blood vessel inflammation. The 2 most common types are GPA and MPA. Eosinophilic GPA is the rarest type of ANCA-associated vasculitis and was not a proposed indication. The patient experts explained that people with GPA or MPA can have fatigue, night sweats and rashes. They explained that ANCA-associated vasculitis can affect the sinuses, kidneys, lungs,

abdomen, skin and joints, which can lead to severe pain. They also explained that the condition can have a detrimental effect on everyday life, including work and family life. The clinical experts commented that, when the kidneys are involved, people can develop end-stage renal disease (ESRD). The committee recognised that people with severe active GPA or MPA can have severe symptoms.

### **People with GPA or MPA and clinicians would welcome a new treatment option**

3.2 The clinical experts explained that GPA and MPA are usually treated in 2 phases. The first phase aims to control inflammation and reduce damage associated with the conditions by inducing disease remission (see section 3.4). The second phase of treatment (maintenance treatment) aims to prevent the conditions from relapsing and causing further damage (see section 3.5). The clinical experts agreed that the treatment pathway for people with severe active GPA or MPA is generally well defined. They explained that induction treatment usually includes cyclophosphamide or rituximab with high-dose corticosteroids (usually prednisolone, which is an active metabolite of prednisone). They added that maintenance treatment is usually azathioprine with a lower dose of corticosteroids. The clinical experts also explained that disease relapses are treated by re-inducing remission in a similar way to initial inductions. Both patient and clinical experts commented on the side effects and toxicity of corticosteroids. The patient experts commented that mood swings, weight gain and night sweats are common side effects of prednisolone treatment. They explained that the weight gain can affect self-confidence and means that some people feel like they no longer recognise themselves. One clinical expert commented that infection and cardiovascular disease, which are the most common causes of death in this population, are both associated with corticosteroid use. The clinical experts also commented that the side effects of corticosteroids are generally dose related. They explained that a treatment which could reduce corticosteroid use without reducing treatment efficacy would be

beneficial. The committee concluded that people with GPA or MPA, and clinicians, would welcome a new treatment option that could reduce the need for corticosteroids.

### **The company's positioning of avacopan is appropriate**

3.3 The NICE scope did not specify which types of ANCA-associated vasculitis would be considered in the appraisal. The company explained that only people with GPA or MPA were included in the clinical trial (see section 3.6). It also noted that the marketing authorisation only covered people with severe active GPA or MPA, and specified that avacopan would be used with a cyclophosphamide or rituximab regimen. The committee recognised that NICE only makes recommendations within a technology's marketing authorisation, so agreed that the company's positioning was appropriate.

### **The relevant induction treatment comparators are cyclophosphamide or rituximab with high-dose corticosteroids**

3.4 The clinical experts explained that people with severe disease are usually offered cyclophosphamide or rituximab with high-dose corticosteroids for induction treatment. They added that the decision to use rituximab instead of cyclophosphamide depends on many factors. They commented that people with more severe GPA or MPA may be offered cyclophosphamide because there is less evidence for rituximab for severe disease. The clinical experts also commented that anti-CD20 antibody treatments (such as rituximab) can reduce response to vaccinations by depleting B-cells. So, there is a general desire to avoid using these treatments in the context of the COVID-19 pandemic. The committee concluded that the relevant induction treatment comparators were cyclophosphamide or rituximab with high-dose corticosteroids.

## **The relevant maintenance treatment comparators are azathioprine or rituximab (for people who are eligible) with corticosteroids**

3.5 The committee recalled that, after the initial induction treatment, people will usually have maintenance treatment. The clinical experts explained that, after induction of remission with cyclophosphamide, most people would switch to azathioprine. The clinical experts also noted that, during the maintenance phase of treatment, corticosteroid dose is usually tapered. They explained that people who initially have rituximab induction would only have rituximab maintenance in specific circumstances, in accordance with the [NHS Clinical Commissioning Policy on rituximab for treating ANCA-associated vasculitis in adults](#). This states that rituximab maintenance will only be commissioned if the disease has relapsed and re-induction treatment is needed after rituximab-induced remission or if rituximab is needed to induce remission for cyclophosphamide-refractory disease. The clinical experts commented that, in clinical practice, around 30% to 40% of people who have had rituximab as induction treatment have rituximab maintenance treatment. People who are not eligible for rituximab maintenance treatment would have azathioprine instead. The committee concluded that the relevant maintenance comparators were azathioprine with tapered corticosteroids and rituximab with tapered corticosteroids.

## **Clinical effectiveness**

### **Avacopan is effective in sustaining disease remission and reducing corticosteroid toxicity in the intention-to-treat population**

3.6 The company provided clinical evidence for avacopan from several clinical trials including ADVOCATE, a phase 3 trial. ADVOCATE was a randomised, active-controlled trial comparing oral avacopan 30 mg twice daily with oral prednisone on a tapering schedule. Everyone also had either cyclophosphamide followed by azathioprine, or rituximab followed by nothing. The trial included people with a clinical diagnosis of GPA or

MPA who had at least 1 major item, 3 minor items or 2 renal items of proteinuria and haematuria on the Birmingham Vasculitis Activity Score (BVAS). The primary endpoint was the proportion of people with disease remission at weeks 26 and 52. At week 26, disease remission was defined as a BVAS of 0, and no corticosteroids in the previous 4 weeks. Sustained remission was defined as disease remission at week 26, and a BVAS of 0 at week 52, no corticosteroids in the 4 weeks before week 52 and no disease relapse between weeks 26 and 52. In the intention-to-treat population, at week 26, 72% of people in the avacopan group compared with 70% in the prednisone group had disease remission (estimated common difference 3.4%, 95% confidence interval [CI] -6.0 to 12.8;  $p < 0.001$  for non-inferiority and  $p = 0.240$  for superiority). At week 52, 66% of people in the avacopan group compared with 55% in the prednisone group had sustained disease remission (estimated common difference 12.5%, 95% CI 2.6 to 22.3;  $p < 0.001$  for inferiority and  $p = 0.007$  for superiority). The trial also evaluated corticosteroid toxicity. At week 26, the mean Corticosteroid Toxicity Index Cumulative Worsening Score was 39.7 in the avacopan group compared with 56.6 in the prednisone group (a larger score represents worsening toxicity;  $p = 0.0002$ ). The committee concluded that avacopan was effective at sustaining disease remission and reducing corticosteroid-induced toxicity compared with a prednisone-based regimen in the intention-to-treat population of ADVOCATE.

### **The efficacy of avacopan varies across prespecified clinical subgroups**

3.7 The efficacy of avacopan was explored in several prespecified clinical subgroups in ADVOCATE. The clinical experts explained that some subgroups would be more easily identifiable in clinical practice than others. For example, it may be difficult to differentiate between GPA and MPA. The company noted that, in some of the trial's exploratory subgroups, there were small sample sizes, which increased the likelihood of false positive results. It explained that the trial was not adequately powered in these subgroups. The company highlighted that, at 52 weeks across all subgroups, a larger proportion of people in the avacopan group



had sustained disease remission compared with those who had the prednisone-based regimen. The largest difference was seen in the subgroup with relapsed disease, in which 76.5% of the avacopan group had sustained disease remission compared with 48.0% of the prednisone group. The smallest difference was among people with anti-PR3 antibodies. In this subgroup, 59.7% of the avacopan group had sustained disease remission compared with 57.1% of the prednisone group. This was different from the efficacy results in the anti-MPO positive subgroup, in which 70.2% of the avacopan group had sustained disease remission compared with 53.2% of the prednisone group. The clinical experts explained that antibody tests are routinely done, so it would be straightforward to categorise people into anti-PR3 positive or anti-MPO positive subgroups. However, they also noted that there was still uncertainty about why the efficacy of avacopan would vary so much between antibody subgroups. The committee noted greater efficacy among people who had rituximab induction. At week 52, 71.0% of the avacopan group had sustained disease remission compared with 56.1% of the prednisone group. In the cyclophosphamide subgroup, 55.9% of the avacopan group had sustained disease remission compared with 52.6% of the prednisone group. The committee understood the limitations of the subgroup analyses and concluded that avacopan was efficacious in the overall analysis, although the magnitude varied among the subgroups.

### **In ADVOCATE, non-study supplied corticosteroids in the intervention group reflect expected use in clinical practice**

3.8 In ADVOCATE, people in both the avacopan and prednisone groups could have non-study supplied corticosteroids as needed, for example, to treat disease relapse or hypoadrenalism from previous use of high-dose corticosteroids. The company explained that this use of corticosteroids was in line with the expected use of avacopan in clinical practice. The clinical experts agreed. The mean cumulative corticosteroid dose during the treatment period was 1,349 mg in the avacopan group compared with 3,655 mg in the prednisone group. The ERG noted that although total

corticosteroid use was lower in the avacopan group, non-study supplied corticosteroid use was higher in the avacopan group. The mean non-study supplied corticosteroid use during the treatment period was 1,349 mg in the avacopan group compared with 1,265 mg in the prednisone group. The ERG also noted that a large proportion of people (87.3%) in the avacopan group had non-study supplied corticosteroids during the treatment period. It was concerned that the use of non-study supplied corticosteroids in the avacopan group could have biased the effect estimates from the trial. It was also concerned about the meaningfulness of the apparent comparison of avacopan with lower-dose corticosteroids compared with higher-dose corticosteroids. The company explained that non-study supplied corticosteroid use was reasonably well balanced between the avacopan and prednisone groups, so the benefits seen in ADVOCATE could be attributed to avacopan. The committee understood the ERG's concerns, and queried whether there were differences in the proportions of people who had pulsed high-dose corticosteroids. One clinical expert explained that most non-study supplied intravenous corticosteroids at 4 weeks were for prophylaxis for rituximab treatment rather than for treating relapse. The committee commented that, overall, people in the avacopan group had about one-third less corticosteroids than those in the prednisone group. The committee recalled that a reduction in corticosteroid use would be beneficial for people with GPA or MPA (see section 3.2). It concluded that the non-study supplied corticosteroids in the intervention group reflected expected use in clinical practice.

## **Cost effectiveness**

### **The company's economic model is appropriate for decision making**

3.9 The company provided a Markov model that was similar to the one used in [NICE's technology appraisal guidance on rituximab in combination with glucocorticoids for treating anti-neutrophil cytoplasmic antibody-associated vasculitis](#). The model included 9 health states: active disease,

3 disease-remission states, 3 disease-relapse states, ESRD and death. The cohort's mean starting age (60 years), proportion of people having rituximab induction treatment (65%) and adherence to avacopan (86%) were from ADVOCATE. The clinical efficacy for avacopan was based on the results of ADVOCATE, and included disease remission at 26, 52 and 60 weeks, change in estimated glomerular filtration rate and health-related quality of life. In the company's base case, people were modelled to have standard care or standard care with avacopan. Standard care was defined as high-dose corticosteroids and either cyclophosphamide or rituximab followed by lower-dose corticosteroids with azathioprine. The company explained that modelling azathioprine maintenance treatment after rituximab induction was a deviation from ADVOCATE, but was based on an assumption explored in [NICE's technology appraisal guidance on rituximab](#). The committee was concerned about how maintenance treatment was modelled (see section 3.10). It concluded that the company's overall model structure was appropriate for decision making.

### **The cost-effectiveness analysis should include rituximab maintenance treatment for people who are eligible for it**

3.10 The committee recalled that some people are eligible to have rituximab in the maintenance phase if it was used in the induction phase and other criteria are met (see section 3.5). The company explored the feasibility of comparing maintenance regimens of avacopan plus rituximab with rituximab alone. The company noted that there were no randomised controlled trials assessing maintenance treatment with avacopan plus rituximab. So, the company explained that an indirect treatment comparison was not robust. At clarification, the company provided a model option for rituximab as maintenance treatment. It explained that it had adjusted the baseline hazard ratio for relapse to reflect treatment with rituximab instead of azathioprine. It cautioned that the non-adjusted naive comparison should be treated as exploratory. The ERG commented that the rituximab maintenance scenario was uncertain. It suggested that the company explore additional evidence, for example, observational data.

The company did not provide this. After technical engagement, the ERG provided scenarios that assumed all people who had rituximab induction treatment continued it as maintenance treatment. The ERG explained that, given the model's structure and time constraints, it had been unable to model rituximab for the eligible subset in line with the commissioning policy. The committee noted that the ERG's scenarios overestimated rituximab maintenance treatment compared with clinical practice. The committee concluded that it would have preferred analyses in which 30% to 40% of people who had rituximab as induction treatment continued rituximab as maintenance treatment, with the remaining proportion having azathioprine. This was based on the clinical experts' comments (see section 3.5).

### **Hazard ratios for ESRD from Gercik et al. and Brix et al. are relevant individually and pooled**

- 3.11 In the company's model, people could transition to an ESRD state. The company considered it relevant to include a separate health state because ESRD is a significant complication of ANCA-associated vasculitis. Disease progression to ESRD was modelled by a change in estimated glomerular filtration rate (eGFR). The probability of ESRD in the active and remission health states was adjusted based on the improvement in eGFR in ADVOCATE. In the company's base case, the hazard rate, and probability of ESRD was adjusted based on the hazard ratio for ESRD per ml/min change in eGFR from Gercik et al. (2020; hazard ratio [HR] 0.90, 95% CI 0.86 to 0.95). However, the ERG noted that the company had provided several other options for the hazard ratio in the model. The ERG originally explored a pooled hazard ratio by combining estimates from Gercik et al., Ford et al. (2014) and Brix et al. (2018). The company disagreed with the ERG's pooled approach, explaining that estimates from Cox proportional hazards models were dependent on other covariates in the model. It explained that it would be inconsistent to pool coefficients from models that adjust for different covariates. During technical engagement, the ERG noted the company's

concerns about pooling estimates. It re-evaluated the pooled studies and noted that the estimate from Ford et al. was for ESRD or death. The ERG did not consider it appropriate to include the Ford et al. hazard ratio in the pooled estimate. But the ERG reiterated that both the Gercik et al. and Brix et al. studies were relevant and preferred to pool them (pooled HR 0.95, 95% CI 0.90 to 1.00). The committee understood the company's statistical concerns about pooling estimates. However, it agreed with the ERG that both the Gercik et al. and Brix et al. studies were relevant for consideration. The committee noted that the Gercik et al. study did not provide much detail and was published as a letter. It further noted comments from a clinical expert that the risk of ESRD is dependent on the population being studied. This meant that it may have been appropriate to pool estimates from studies that limited the inclusion criteria. The committee was concerned that the company's approach might have applied a hazard ratio from a single study with a narrower population to the broader, modelled population. The committee would have liked to see additional information from the company about why Brix et al. was not relevant. It concluded that it was relevant to consider scenarios using the Gercik et al. and Brix et al. hazard ratios, both individually and pooled.

### **The 2019/20 reference costs are most appropriate to inform hospitalisation costs**

3.12 The company noted that the average length of hospital stay in ADVOCATE (13.8 days in the avacopan group and 19.6 days in the prednisone group) was longer than the mean length of stay reported in the 2019/20 NHS reference costs. The company explained that hospital costs were adjusted for the longer stays in ADVOCATE using excess bed day costs from 2017/18. It did this because the 2019/20 NHS reference costs no longer separately report excess bed day costs (as previous versions did). At technical engagement, the company updated its base case to use unit and excess bed day costs from 2017/18 inflated to 2020 prices. The ERG noted it was uncertain whether the difference between mean length of stay in ADVOCATE compared with NHS reference costs implied

excess bed days. Additionally, the ERG noted that reference costs appeared to be calculated differently between 2017/18 and 2019/20 because the more recent version does not separately report excess bed day costs. The ERG preferred to use 2019/20 unit costs with no adjustment for excess bed days. NHS England confirmed that the 2019/20 reference costs included all hospitalisation costs, but no longer disaggregated costs into unit and excess bed days. The committee concluded that the ERG's approach to hospitalisation costs was more reflective of costs in the NHS in England.

### **The modelled healthcare costs may not fully represent costs in the NHS**

3.13 The ERG noted the crude modelled annual healthcare costs for the standard care group were substantially lower than the costs in the Clinical Practice Research Datalink (CPRD) study. The CPRD study was a retrospective observational study using real world evidence to evaluate resource use and adverse event rates for people with GPA or MPA in England. The company explained that the CPRD study costs were not appropriate for modelling because there is no information about change in resource use with avacopan. The company also noted that the CPRD included aggregate costs of all hospital episodes, including treatment of unrelated comorbidities, and the model did not account for these costs. The company added that costs for specific episodes were similar between the model and CPRD. It also explained that larger costs from worsening ANCA-associated vasculitis would favour avacopan so the model was likely conservative. The ERG noted it was uncertain why the incremental cost-effectiveness ratio (ICER) increased when adverse event costs from CPRD were used. The committee concluded there was uncertainty around the representativeness of modelled healthcare costs.

## Cost-effectiveness estimate

### Avacopan compared with standard care is not cost effective in the overall population

3.14 The committee was aware that some of the comparator technologies have confidential discounts. Therefore, the committee considered the cost-effectiveness results using those prices, which are confidential and cannot be reported here. Those ICERs did not change the overall recommendation. The ICERs presented in this paragraph are based on publicly available comparator prices. The company's deterministic base-case ICER for avacopan compared with standard care was £19,441 per quality-adjusted life year (QALY) gained. The ERG presented analyses including the committee's preferred approach to hospitalisation costs, which used the 2019/20 reference costs with no adjustment for excess bed days (see section 3.12). The ERG's base case also included a pooled estimate for ESRD (see section 3.11). These 2 changes from the company's base case resulted in an ICER of £40,516 per QALY gained. The committee noted that, in the scenarios with rituximab maintenance treatment, the ICER was £43,554 per QALY gained using the company's other preferred assumptions and £69,364 per QALY gained using the ERG's preferred assumptions. Although the committee had concerns about the rituximab scenarios (see section 3.10), it considered that the most plausible ICER for avacopan compared with standard care would likely be above the ERG's base-case ICER. So, it concluded that avacopan was not cost effective in the overall population.

### Avacopan compared with standard care is not cost effective in the clinical subgroups

3.15 Having concluded that avacopan was not cost effective in the overall population, the committee considered the subgroup analyses. The committee was aware that some of the comparator technologies have confidential discounts and considered cost-effectiveness results using

those prices, which cannot be reported here. Those ICERs did not change the overall recommendation. The ICERs presented in this paragraph are based on publicly available comparator prices. The committee recalled that the antibody subgroups would be relevant for clinical practice. The ICERs for the anti-MPO antibody-positive subgroup were £13,085 per QALY gained using the company's preferred assumptions and £25,455 per QALY gained using the ERG's preferred assumptions. The ICERs for the anti-PR3 antibody-positive subgroup were £76,102 per QALY gained using the company's preferred assumptions and £102,444 per QALY gained using the ERG's preferred assumptions. The committee recalled that the analyses for some subgroups were based on small sample sizes, which increased uncertainty (see section 3.7). It noted that none of the subgroup ICERs included rituximab maintenance treatment. It agreed that the ICERs for the anti-MPO antibody-positive subgroup appeared to be in what NICE considers cost-effective range. But it thought that there was uncertainty about the rituximab modelling which would likely have increased the ICERs. So, it concluded that avacopan was not cost effective in the subgroups.

## **Other factors**

### **There are no equality issues that can be addressed in this technology appraisal**

3.16 The committee understood a potential equality issue about the use of cyclophosphamide had been raised in [NICE's related technology appraisal guidance on rituximab](#). In that appraisal, the committee considered that cyclophosphamide reduces fertility in everyone. But it was aware that the peak age of onset for ANCA-associated vasculitis in England is between 60 and 70 years. The committee agreed that the number of people with ANCA-associated vasculitis who have not completed their family is likely to be very small. The committee recalled that avacopan is proposed as an add-on to standard care. It considered that its recommendation for avacopan would not affect prescription rates



for cyclophosphamide. So, it concluded that its recommendation for avacopan would not have a different effect on people protected by the equality legislation than on the wider population.

### **There may be additional benefits of avacopan that may not be captured in the cost-effectiveness analysis**

3.17 The committee recalled that, during the COVID-19 pandemic, clinicians are being careful about using anti-CD20 antibody treatments (like rituximab, see section 3.4). It also recalled that avacopan was proposed as an add-on to standard care so would not directly replace rituximab. But it also considered that a larger proportion in the avacopan group had sustained remission at week 52 than in the prednisone group. The clinical experts explained that a drug that could maintain disease remission may reduce future need for re-induction treatment with rituximab. The committee concluded that there may be some benefits of avacopan in terms of reducing future need for rituximab that were not captured in the cost-effectiveness analysis. It took this into consideration when making its recommendation.

## **Conclusion**

### **Avacopan is not recommended for treating severe active GPA or MPA**

3.18 The committee recognised that people with severe active GPA or MPA would welcome a treatment option to reduce corticosteroid use. It recognised that avacopan compared with a prednisone-based regimen sustained disease remission for a larger proportion of people, and reduced corticosteroid-induced toxicity. The committee noted that rituximab maintenance treatment was not included in either the company's or the ERG's base case. But, based on comments from the clinical experts, the committee noted that rituximab maintenance treatment should be included in the economic modelling. However, the maintenance treatment scenarios presented by the ERG overestimated use. The committee considered the most plausible ICERs using its preferred

assumptions to be above what NICE normally considers a cost-effective use of NHS resources. So, avacopan is not recommended for treating severe active GPA or MPA.

## 4 Proposed date for review of guidance

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

Megan John

Chair, appraisal committee

May 2022

## 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](#).

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.

### **Catie Parker**

Technical lead

### **Vicky Kelly**

Technical adviser

### **Kate Moore**

Project manager

ISBN: [to be added at publication]