

To: *Renal Services Clinical Reference  
Groups (Adults and Paediatrics)  
Rheumatology Clinical Reference  
Groups (Adults and Paediatrics)  
Renal Clinical Networks*

NHS England  
Wellington House  
133-155 Waterloo Road  
London  
SE1 8UG

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Dear colleagues

**Re: Avacopan for ANCA-associated vasculitis – interim position**

On 26 June 2026, the European Medicines Agency (EMA) recommended revoking the European Union marketing authorisation for Tavneos® (avacopan). We are aware this has generated questions from clinicians and patients.

This letter sets out a single, agreed interim position from the NHS England Renal and Rheumatology adult and paediatric Clinical Reference Groups (CRGs), to support consistent practice across England, while the UK regulator (the MHRA) completes its own review.

**Background**

Avacopan, in combination with either rituximab or cyclophosphamide, is licensed for the treatment of adults with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA), in line with [NICE Technology Appraisal TA825](#). It has been commissioned for routine use in adults in England since December 2022. Use in post-pubescent children is also supported, in accordance with the NHS England policy '*Commissioning medicines for children in specialised services*' ([NHS England » Commissioning medicines for children in specialised services](#)).

The EMA recommendation follows a review prompted by concerns about the integrity and reliability of the data from the pivotal clinical trial that supported the licence; it does not arise from a new safety signal.

The US Food and Drug Administration has separately raised concerns about the same trial data, including in relation to the risk of liver injury, and has proposed withdrawing the medicine in the United States. Regulatory decisions made by the EMA and FDA do not apply in the UK.

**The UK regulatory position**

The Medicines and Healthcare products Regulatory Agency (MHRA) is conducting its own review of the benefits and risks of avacopan under Section 68 of the Human Medicines Regulations 2012. The MHRA has confirmed that, while its review is ongoing, Avacopan retains its UK marketing authorisation and remains available as before, and that the existing risk-minimisation advice in the product information continues to apply – including monitoring of liver function and white blood cell count, and assessment for serious infection.



Patients should be advised not to stop treatment without first discussing it with their specialist team. The MHRA statement is available here:

<https://www.gov.uk/government/news/mhra-review-of-the-benefits-and-risks-of-avacopan>.

### **Interim guidance pending the MHRA review**

We ask services and clinicians to adopt the following position while the MHRA review is completed:

1. The MHRA advises that these issues remain under review. Until this concludes, avacopan remains licensed and available in the UK, with existing risk-minimisation measures unchanged.
2. Treatment decisions should continue to be made by expert vasculitis clinicians within specialist MDTs, based on individual patient benefit–risk assessment. For post-pubescent children, use of the drug should continue to be discussed in line with the criteria outlined in the *'Commissioning medicines for children in specialised services'* policy. The current regulatory position should be discussed with both existing and prospective patients as part of shared decision-making.
3. Patients on avacopan should continue liver function monitoring, along with white blood cell monitoring and assessment for serious infection, in line with product information.
4. To ensure consistency, services should follow this national position and manage any treatment changes through the standard specialist MDT process.
5. Suspected adverse reactions should be reported via the MHRA Yellow Card scheme.

### **Next steps**

The MHRA has indicated that it will communicate the outcome of its review, including any revised advice for clinicians and patients, once it is complete. We will update this guidance at that point.

Please share this letter with relevant colleagues.

Yours sincerely



**Prof. Smeeta Sinha**  
National Clinical Director  
Renal Services



**Dr Shouvik Dass**  
National Specialty Advisor Specialised  
Rheumatology



**Dr Daljit Hothi**  
National Specialty Advisor for  
Specialised Paediatric Renal Services



**Dr Kate Armon**  
National Clinical Lead  
Specialised Paediatric Rheumatology

