

Specialised Commissioning South West
NHS England
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18 January 2024

All Chief Executives

All Medical Directors

All Chief Pharmacists

Dear Colleagues,

Re: NICE Technology Appraisal Guidance: Crizanlizumab for preventing sickle cell crises in sickle cell disease [TA743]: Withdrawal of guidance

I am writing to advise you regarding the withdrawal of <u>NICE TA743 guidance for</u> crizanlizumab in preventing sickle cell crises in sickle cell disease.

The MHRA has revoked the Conditional Marketing Authorisation for crizanlizumab, and as such, the Managed Access Agreement, which forms the basis of the NICE Technology Appraisal, has now been withdrawn by NICE.

Though no new safety concerns were identified, the benefit-risk balance of crizanlizumab is no longer considered favourable by the MHRA, resulting in the revocation.

NICE in their TA update on 10 January 2024 has stated that:

NICE has withdrawn this guidance. Novartis will stop marketing crizanlizumab (Adakveo) because its marketing authorisation has been withdrawn by the Medicines and Healthcare products Regulatory Agency (MHRA). Novartis has issued a direct letter to healthcare professionals specialising in haematology. No new people will start taking crizanlizumab in the UK. Healthcare professionals should discuss alternative treatment options with people currently having crizanlizumab.

As a result of the revocation of the Conditional Marketing Authorisation and withdrawal of NICE TA743, with effect from 10 January 2024, NHS England will no longer commission crizanlizumab.

Novartis UK is planning a product recall of any remaining stock held by providers. The full recall plan is being agreed with the MHRA; once agreed, the company will coordinate the recall directly with NHS Trusts and credit all received and validated stock. Any enquiries related to the recall should be directed to Novartis UK.

High quality care for all, now and for future generations



Clinicians are advised not to start any new patients on crizanlizumab treatment. In the absence of a MHRA licence and considering the recall of stock, prescribers will be required to discuss alternative management options with existing patients.

A 'Dear Healthcare Professional' letter has been shared with Trusts via email and post. The letter is also available at:

https://www.medicines.org.uk/emc/product/12943/dhpcs#about-medicine

I would be grateful if you could cascade this information to relevant clinical teams within your organisation to support the consistent adoption of the policy nationally.

Yours sincerely,

Luke Culverwell

Deputy Director of Sr

Hulveys

Deputy Director of Specialised Commissioning

Tracey Williams
Principal Pharmacist