

Subject: Specialised Services Circular (SSC 2364)
Sent on behalf of: Chair of the SW Specialised Service Circular Group

Dear Colleagues,

Please find attached the following Specialised Services Circular(s):

SSC Number	SSC Title	Trusts approved to prescribe in accordance with the SSC, providing appropriate internal governance arrangements are in place
2364	Early Access to Medicines Scheme – Risankizumab for the treatment of adolescent patients aged 16 to 17 years with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant or contraindicated to TNFα antagonist therapies.	<ul style="list-style-type: none">• University Hospitals Bristol and Weston NHS Foundation Trust

Is an implementation plan required from all SW trusts (regardless of commissioned status) for this SSC? No

For all other South West region trusts this is for information only.

Trusts should ensure that use is registered on the Blueteq system (if appropriate).

Treatment will only be funded where the drugs minimum dataset is fully and accurately populated.

Please direct any queries to: england.speccomm-southwest@nhs.net



England

Specialised Commissioning South West
NHS England
South Plaza
Marlborough Street
Bristol
BS1 3NX

Email: england.speccomm-southwest@nhs.net
12/05/2022

All Chief Executives

All Medical Directors

All Chief Pharmacists

Dear Colleague,

Re: Early Access to Medicines Scheme – Risankizumab for the treatment of adolescent patients aged 16 to 17 years with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant or contraindicated to TNF α antagonist therapies.

I am writing to advise you regarding NHS England's position on the recent positive Scientific Opinion for risankizumab published by the Medicines and Healthcare Regulatory products Agency (MHRA). It advises on where the technology will be commissioned by NHS England and under what circumstances.

Following the publication of the positive Scientific Opinion on 13th April 2022, Trusts who provide specialised children services for the treatment of Crohn's disease should use the EAMS application process to apply for access to risankizumab for eligible patients. A list of eligible sites is provided in appendix 1.

The Medicines and Healthcare Regulatory products Agency MHRA launched the Early Access to Medicines Scheme (EAMS) in April 2014. More information about the scheme can be found here: <https://www.gov.uk/apply-for-the-early-access-to-medicines-scheme-eams>

Further to the designation of Promising Innovative Medicine (PIM) status for risankizumab in November 2021 (EAMS Step 1), MHRA issued a positive Scientific Opinion on 13th April 2022 which supports risankizumab for:



the treatment of adolescent patients aged 16 to 17 years with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant or contraindicated to tumour necrosis factor-alpha (TNF α) antagonist therapies

A summary of the MHRA EAMS Public Assessment Report (PAR) is available here:

<https://www.gov.uk/government/collections/early-access-to-medicines-scheme-eams-scientific-opinions>

Following the publication of the positive Scientific Opinion on 13th April 2022, Trusts should use the EAMS application process to apply for access to risankizumab for eligible patients from this date. For patients wishing to access risankizumab, Trusts must complete a Blueteq form to register each patient with NHS England once the application form has been submitted to AbbVie and the patient has been considered eligible for this EAMS.

Further information regarding this can be requested from the dedicated EAMS email address: england.eams@nhs.net.

Patients must be informed that risankizumab is being made available ahead of a marketing authorisation decision through EAMS and that if risankizumab does not receive a marketing authorisation, or if NICE publishes negative guidance, or guidance that restricts the licensed population, then this will affect their continued treatment. They should also be made aware that if future recommendations are made restricting the length of the course of treatment then treatment provided during EAMS will count toward the recommended course length.

AbbVie has appointed Clinigen to act on its behalf to manage the administration of the risankizumab EAMS program via its dedicated access portal.

To register a patient with the EAMS, the physician will need to register with Clinigen via Clinigen Systems at <https://onlineservices.clinigengroup.com/>.

To contact the AbbVie medical team directly, email ukmedinfo@abbvie.com.

Risankizumab is made available free of charge for EAMS patients during the EAMS period. Following marketing authorisation of risankizumab (anticipated in Q3 2022),

centres that register patients for this EAMS prior to marketing authorisation will be able to continue to receive free of charge supply for new patients registered with AbbVie between marketing authorisation and a funding recommendation from NICE.

NICE are appraising the product as a priority. Should NICE issue positive Technology Appraisal guidance, this guidance will usually be implemented 30 days after final guidance is published.

Providers of specialised children services for the treatment of Crohn's disease should engage with their local specialised commissioning team to consider the implications of implementing this scheme.

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.

Cc Provider Chief Executive
Provider Chief Pharmacist

Annex 1 - List of eligible sites

Specialised Children Services for Crohn's Disease

Alder Hey Children's NHS Foundation Trust
Ashford and St Peter's Hospitals NHS Foundation Trust
Barts Health NHS Trust
Bedfordshire Hospitals NHS Foundation Trust
Birmingham Children's Hospital NHS Foundation Trust
Bradford Teaching Hospitals NHS Foundation Trust
Brighton and Sussex University Hospitals NHS Trust
Cambridge University Hospitals NHS Foundation Trust
Central Manchester University Hospitals NHS Foundation Trust
Chelsea and Westminster Hospital NHS Foundation Trust

Great Ormond Street Hospital for Children NHS Foundation Trust

Guy's and St Thomas' NHS Foundation Trust

King's College Hospital NHS Foundation Trust

Leeds Teaching Hospitals NHS Trust

London North West Healthcare NHS Trust

Maidstone and Tunbridge Wells NHS Trust

Norfolk and Norwich University Hospitals NHS Foundation Trust

North Tees and Hartlepool NHS Foundation Trust

Northampton General Hospital NHS Trust

Nottingham University Hospitals NHS Trust

Oxford University Hospitals NHS Foundation Trust

Royal Free London NHS Foundation Trust

Sheffield Children's NHS Foundation Trust

Sheffield Teaching Hospitals NHS Foundation Trust

Shrewsbury and Telford Hospital NHS Trust

South Tees Hospitals NHS Foundation Trust

St George's University Hospitals NHS Foundation Trust
Taunton and Somerset NHS Foundation Trust

The Newcastle Upon Tyne Hospitals NHS Foundation Trust

The Royal Wolverhampton NHS Trust

University College London Hospitals NHS Foundation Trust

University Hospital Southampton NHS Foundation Trust

University Hospitals Bristol NHS Foundation Trust

University Hospitals of Leicester NHS Trust

University Hospitals of North Midlands NHS Trust

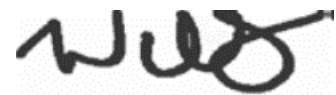
Worcestershire Acute Hospitals NHS Trust

York and Scarborough teaching Hospitals NHS Foundation Trust

With best wishes,



Dr Peter Wilson
Medical Director (Commissioning)



Tracey Williams
Principal Pharmacist