Medicines and Healthcare products Regulatory Agency (MHRA): Early Access to Medicines Scheme (EAMS)

Summary of operational arrangements for risankizumab for moderately to severely active Crohn’s Disease in NHS Scotland. EAMS number 41042/0007

The aim of the MHRA Early Access to Medicines Scheme (EAMS) is to provide earlier availability of promising new unlicensed and ‘off label’ medicines to UK patients that have a high unmet clinical need. The medicinal products included in the scheme are those that are intended to treat, diagnose or prevent seriously debilitating or life threatening conditions where there are no adequate treatment options. The MHRA EAMS positive opinion should not be regarded as a medicine licensed by the MHRA or a future commitment by the MHRA to license such a medicine. The opinion and EAMS documentation published by the MHRA are intended only to inform clinicians’ decision making and not to recommend use. Under EAMS the risk and legal responsibility for prescribing an EAMS medicines remains with the prescribing clinician. More information about the scheme can be found here: http://www.mhra.gov.uk/Howweregulate/Innovation/EarlyaccesstomedicinesschemeEAMS/index.htm

Risankizumab is made available free of charge for patients with moderately to severely active Crohn’s disease via EAMS during the EAMS period. This document summarises how the medicine can be used in Scotland.

**Medicine**

Risankizumab 300 mg concentrate for solution for infusion
Risankizumab 90 mg solution for injection in pre-filled syringe

**Indication and patient population**

Risankizumab is indicated for the treatment of adult patients 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 (TNFα) antagonist therapies, vedolizumab and ustekinumab and 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.

**Conditions for entry to EAMS**

The EAMS makes free-of-charge risankizumab for use in the treatment of patients with moderately to severely active Crohn's disease. Risankizumab is available to Health Boards (subject to approval by AbbVie) provided that the following conditions are met:

I. The patient (who is the subject of each order for EAMS risankizumab) is an adult patient with moderately to severely active Crohn's disease who has an inadequate response to, lost response to, or were intolerant or contraindicated to tumour necrosis factor-alpha (TNFα) antagonist therapies, vedolizumab and ustekinumab.
OR 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

II. The Health Board does not have any policies, guidelines or procedures in place which prohibit the acceptance of EAMS medicines

III. While a valid positive EAMS opinion is in place (Marketing Authorisation expected Q3 2022.)

Detailed patient eligibility information is included in the Treatment Protocol – Information for Healthcare Professionals, link appended below.

**Supply arrangements**

1. Clinicians wishing to access treatment for their patients with **risankizumab** need to contact Clinigen and apply online using the link https://onlineservices.clinigengroup.com/ or by contacting Clinigen Customer Services via medicineaccess@clinigengroup.com or 01932 824 100. Clinigen are acting on behalf of AbbVie Ltd for access to treatment and drug supplies. AbbVie Medical Information can be contacted for any other queries at ukmedinfo@abbvie.com or 01628 561092 (option 3).

2. As for all unlicensed medicines and off-label uses of licensed medicines, individual health boards will also have local governance arrangements in place to authorise medicines supplied via EAMS. This review should be expedited as a rigorous risk/benefit assessment has already been conducted by MHRA and can be accessed in the Public Assessment Report (PAR), link appended.

3. Other aspects of the supply arrangements can be accessed via EAMS documentation, links to which are appended at the end of this guidance.

**Practical considerations**

The recommended dose is 600 mg (two 300 mg vials) administered by intravenous infusion at Week 0, Week 4, and Week 8, followed by 360 mg (four 90 mg injections) administered by subcutaneous injection at Week 12, and every 8 weeks thereafter.

The screening and monitoring required for risakizanumab are similar to medicines routinely available to treat this condition.

**Risankizumab 300 mg concentrate for solution for infusion**

Store in a refrigerator (2°C - 8°C). Do not freeze. Keep the vial in the outer carton in order to protect from light. The product requires dilution prior to administration. If not used immediately, the diluted risankizumab solution can be stored (protected from light) for up to 12 hours between 2°C to 8°C. Subsequently, the diluted risankizumab solution can be stored (protected from direct and indirect sunlight) for 4 hours at room temperature after dilution.

**Risankizumab 90 mg solution for injection in pre-filled syringe**

Store in a refrigerator (2°C - 8°C). Do not freeze. Keep the pre-filled syringe in the outer carton in order to protect from light.
Pharmacovigilance and data collection

Clinicians are required to report to AbbVie, using specific documentation and recording mechanisms.

Specific details relating to pharmacovigilance can be found in the Treatment Protocol for Pharmacovigilance, a link to which is appended at the end of this guidance.

EAMS termination arrangements/exit strategy

Following Marketing Authorisation of risankizumab for the treatment of adult patients 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 (TNFα) antagonist therapies, vedolizumab and ustekinumab and 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, the EAMS scheme will close in line with the MHRA regulations and no new patients will be allowed to enrol onto the scheme to access free of charge supply.

Access to treatment for new patients would be via local board processes from the point of licensing until Scottish Medicines Consortium (SMC) accepted advice is issued or, where relevant, until availability via the ultra-orphan pathway is confirmed by Scottish Government.

The provision of risankizumab, free of charge via EAMS for any one patient enrolled in the EAMS shall end, on the earliest of the following to occur:

A. In the event that SMC accepted advice is issued for this medicine and indication, 30 days after the publication of SMC accepted advice on their website (www.scottishmedicines.org.uk).

OR

B. In the event that SMC not recommended advice is issued:
   I. until such time as AbbVie may receive SMC accepted advice for this medicine and indication (e.g. after a resubmission).
   II. until such time that the patient:
      a. Completes the defined course length of treatment
      b. No longer derives clinical benefit (e.g. disease progression or unacceptable toxicity)

OR
C. In the event that Marketing Authorisation is not granted, until such time as the patient no longer derives clinical benefit (disease progression or unacceptable toxicity).

OR

D. In the event of availability through the ultra-orphan pathway, 30 days after Scottish Government confirmation

**Supporting documents**

- Public Assessment Report
- Treatment Protocol – Information for Healthcare Professionals
- Treatment Protocol – Information for Patients
- Treatment Protocol – Information on the Pharmacovigilance System
- Information for NHS Medical Directors