



Medicine: berotralstat (brand name: Orladyeo®)

BioCryst Pharmaceuticals

The Scottish Medicines Consortium (SMC) has assessed berotralstat for preventing attacks of hereditary angioedema (HAE) in patients 12 years and older. This document summarises the SMC decision and what it means for patients.

What has SMC said?

After careful consideration, SMC has accepted berotralstat for preventing attacks of HAE as described above, for restricted use. The restriction means that berotralstat may be used in patients who experience two or more clinically significant attacks per month.

This SMC advice takes into account a confidential discount offered by the pharmaceutical company that improves the cost-effectiveness of berotralstat. In addition, SMC was able to apply a more [flexible approach](#)* in the assessment, as it is for a rare condition.

What does SMC's decision mean for patients?

If your healthcare professional thinks that berotralstat for use as described above is the right medicine for you, you should be able to have the treatment on the NHS in Scotland.



What is berotralstat used for?

Berotralstat is used to prevent attacks of HAE in patients who are 12 years or older. HAE is a rare inherited condition, which causes swelling that can affect any part of the body including the hands, feet, arms, legs, intestines, face and throat. Attacks are unpredictable and can be life threatening in cases where the swelling around the throat presses against the airway.

How does berotralstat work?

People with HAE have high levels of a substance called bradykinin in their bloodstream. The activation of an enzyme called kallikrein raises the levels of bradykinin in the blood. Berotralstat blocks the activity of kallikrein. This may help to reduce the amount of bradykinin in the bloodstream and prevent symptoms of HAE.

*<https://www.scottishmedicines.org.uk/how-we-decide/pace/>

How does SMC make its decision?

SMC carefully considers every new medicine to make sure it benefits patients and is considered to be an acceptable use of the limited resources in NHSScotland.

To do this SMC considers the following:

- Evidence from the company about how well the medicine works compared with current treatments available in Scotland, in relation to how much they will cost to buy and administer.
- Information from patient groups about the potential impact of the medicine on patients and carers.
- Advice from healthcare professionals about any benefits of the new medicine compared to current treatment, along with how the new medicine is likely to be used.

When SMC assesses a medicine it takes account of the needs of all patients in NHSScotland, not only those who may be treated with the medicine under consideration.

You can find more detailed information about the SMC assessment of berotralstat by looking at the SMC Detailed Advice Document (SMC2405).

More information

The organisation below can provide more information and support for people with HAE and their families. SMC is not responsible for the content of any information provided by external organisations.

HAE UK



<https://www.haeuk.org>



07975 611787

You can find out more about berotralstat (Orladeyo®) in the Patient Leaflet by searching for the medicine name on the electronic medicines compendium (EMC) website.



<https://www.medicines.org.uk/emc/>