Healthcare Improvement Scotland | SMC Advice on new medicines

www.scottishmedicines.org.uk

Decision Explained

Medicine: *ex vivo* expanded autologous human corneal epithelial cells containing stem cells (brand name: Holoclar®)

Chiesi Limited

The Scottish Medicines Consortium (SMC) has assessed Holoclar® for treating adult patients with moderate to severe limbal stem cell deficiency caused by physical or chemical burns to the eye. This document summarises the SMC decision and what it means for patients.

What has SMC said?

After careful consideration, SMC has accepted Holoclar® on an interim basis (interim acceptance) for the treatment of eye burns as described above. Interim acceptance is an option available to SMC for medicines which have received a conditional marketing authorisation or licence. This means that Holoclar® is accepted for use subject to ongoing evaluation and reassessment once further evidence is available.

This advice takes into account a confidential discount offered by the pharmaceutical company that improves the cost-effectiveness of Holoclar®.

What does SMC's decision mean for patients?

The decision to accept Holoclar® on an interim basis means that if your healthcare professional thinks that it is the right medicine for you, you should be able to have the treatment on the NHS in Scotland. Once further evidence is available, SMC will reassess the medicine and provide an updated decision on its routine availability in NHSScotland. For further information about the interim acceptance option please see: https://www.scottishmedicines.org.uk/how-we-decide/interim-acceptance-decision-option/

What is Holoclar® used for?

Holoclar® is a stem-cell treatment used to replace damaged cells on the surface of the cornea (the clear layer of cells covering the coloured part of the eye). It is used in adults with moderate to severe limbal stem cell deficiency caused by physical or chemical burns to the eye. These patients do not have enough limbal stem cells in their eye to regenerate the damaged cornea.

How does Holoclar® work?

Holoclar® is an advanced therapeutic medicinal product (ATMP) tissue engineered product. It is made from cells taken from the patient's limbus (area at the edge of the cornea), grown in a laboratory and then used to replace the damaged corneal surface. In many cases, one treatment is sufficient

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 consider 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.
- 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 just those who may be treated with the medicine under consideration.

You can find more detailed information about the SMC assessment of Holoclar® by looking at the SMC Detailed Advice Document (SMC2261).

More information

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

Fight for Sight

https://www.fightsforsight.org.uk 020 7264 3900

RNIB Scotland

https://www.rnib.org.uk 0303 123 9999

You can find out more about Holoclar® in the European public assessment report (EPAR) summary for the public by searching for the medicine name on the European Medicines Agency (EMA) website.

http://www.ema.europa.eu