

Decision Explained

Medicine: cannabidiol (brand name: Epidyolex®)

GW Pharma Ltd

The Scottish Medicines Consortium (SMC) has assessed cannabidiol for the treatment of patients aged 2 years and over, with seizures (fits) caused by a rare condition called tuberous sclerosis complex (TSC). It is used together with one or more anti-epileptic medicines. This document summarises the SMC decision and what it means for patients.

What has SMC said?

After careful consideration, SMC has accepted cannabidiol for treating patients with seizures caused by TSC as described above.

This SMC advice takes into account a confidential discount offered by the pharmaceutical company that improves the cost-effectiveness of cannabidiol. In addition, SMC was able to apply a more <u>flexible approach*</u> in the assessment, as it is for a rare condition.

What does SMC's decision mean for patients?

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



What is cannabidiol used for?

Cannabidiol was considered for use to treat seizures in patients aged 2 years and over with TSC, which is a rare genetic condition caused by mutations in the TSC1 or TSC2 genes. This causes growths (tubers) to develop in different organs of the body, most commonly in the brain, eyes, heart, kidney, skin and lungs. This leads to the main symptoms of the condition which include: epilepsy (seizures); autism and cognitive impairment; and heart problems. Seizures, one of the most common symptoms, usually develop in childhood and can be difficult to treat. Cannabidiol is used together with other anti-epileptic medicines to help control the seizures.

How does cannabidiol work?

It is not fully understood how cannabidiol works. It is thought to act on a number of different proteins that control the excitability of nerve cells. These actions may reduce the frequency of seizures by cutting down the chances of excessive electrical activity developing in the brain.

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 cannabidiol by looking at the SMC Detailed Advice Document (SMC2402).

More information

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

Tuberous Sclerosis Association



https://tuberous-sclerosis.org



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



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

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