

Medicine: cemiplimab (brand name: Libtayo®)

Sanofi

The Scottish Medicines Consortium (SMC) has assessed cemiplimab for the treatment of cutaneous squamous cell carcinoma (CSCC). It was assessed for use in adult patients who have metastatic or locally advanced disease, who cannot have surgery or radiation treatment to cure their disease. This document summarises the SMC decision and what it means for patients.

What has SMC said?

After careful consideration, SMC has accepted cemiplimab on an interim basis (interim acceptance) for the treatment of CSCC 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 cemiplimab 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 cemiplimab. In addition, SMC was able to apply a more [flexible approach*](#) in the assessment, as it is for a rare condition where patients are likely to have a life expectancy of less than three years with currently available treatments.

What does SMC's decision mean for patients?

The decision to accept cemiplimab 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 cemiplimab used for?

Cemiplimab is used to treat patients with cutaneous squamous cell carcinoma (CSCC), which is a type of skin cancer. Advanced CSCC can cause unsightly sores that can be smelly, weep and cause pain. This is extremely difficult to live with and can lead to social isolation. Cemiplimab is used to treat CSCC which is metastatic (spread to other parts of the body) or locally advanced (spread from where

*<https://www.scottishmedicines.org.uk/media/4731/pace-overview-document.pdf>

it started to nearby tissue or lymph nodes). It is used for adult patients who cannot have surgery or radiotherapy treatment to cure their cancer.

How does cemiplimab work?

Cemiplimab is an immunotherapy. This is a type of cancer treatment that stimulates the immune system (the body's natural defence system) to fight the cancer. Some cancer cells produce proteins that switch off certain immune cells (called T-cells). Cemiplimab attaches to these T cells, which stops the cancer switching them off, and helps the immune system fight the cancer.

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

You can find more detailed information about the SMC assessment of cemiplimab by looking at the SMC Detailed Advice Document (SMC2216).

More information

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

MASScot



<http://www.masscot.org.uk/>



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You can find out more about cemiplimab 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>