

Medicine: venetoclax (brand name: Venclyxto®)

AbbVie Ltd

The Scottish Medicines Consortium (SMC) has assessed venetoclax for the treatment of adults with a type of leukaemia called chronic lymphocytic leukaemia (CLL). It is used in combination with another cancer medicine called obinutuzumab to treat patients who have not yet had any other treatment for their CLL. This document summarises the SMC decision and what it means for patients.

What has SMC said?

After careful consideration, SMC has accepted venetoclax in combination with obinutuzumab for use in certain patients (restricted use). The restriction means that venetoclax may be used together with obinutuzumab in two subgroups of patients with CLL who have not yet had any treatment for their CLL:

- patients with del(17p)/TP53 mutation
- patients without del(17p)/TP53 mutation who are not fit enough to receive the chemotherapy FCR (fludarabine, cyclophosphamide and rituximab)

This SMC advice takes into account a confidential discount offered by the pharmaceutical company that improves the cost-effectiveness of venetoclax. 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 venetoclax 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 venetoclax used for?

Venetoclax is used for the treatment of chronic lymphocytic leukaemia (CLL), which is a type of cancer of the white blood cells. Around 5-10% of patients with CLL have a genetic change known as a del(17p)/TP53 mutation in their cancer cells. This genetic change plays a role in the development of the cancer. SMC has accepted venetoclax in combination with obinutuzumab for treating those patients with CLL who have this genetic change. Venetoclax in combination with obinutuzumab was also accepted for patients with CLL who do not have this mutation and are not fit enough to receive treatment with the chemotherapy and immunotherapy medicines fludarabine, cyclophosphamide and rituximab.

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

How does venetoclax work?

Venetoclax works by blocking the actions of a protein called Bcl-2. Bcl-2 is produced in large amounts by cancerous white blood cells and helps them to survive and build up in the body. By blocking Bcl-2, venetoclax helps to reduce the number of cancer cells and slow the progression of 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 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 just those who may be treated with the medicine under consideration.

You can find more detailed information about the SMC assessment of venetoclax by looking at the SMC Detailed Advice Document (SMC2293).

More information

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

Chronic Lymphocytic Leukaemia Support Association (CLLSA)



<https://www.clisupport.org.uk>



0800 977 4396

Leukaemia CARE



<https://www.leukaemiacare.org.uk>



0808 8010 444

Lymphoma Action



<https://lymphoma-action.org.uk>



0808 808 5555

You can find out more about venetoclax (Venclyxto®) 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>