



Medicine: inclisiran (brand name: Leqvio[®])

Novartis Pharmaceuticals UK Limited

The Scottish Medicines Consortium (SMC) has assessed inclisiran for the treatment of adults with primary hypercholesterolaemia or mixed dyslipidaemia. It is used alongside a cholesterol lowering diet, either alone or together with other cholesterol lowering medication. This document summarises the SMC decision and what it means for patients.

What has SMC said?

After careful consideration, SMC has accepted inclisiran for use in certain patients (restricted use). The restriction means that inclisiran used alongside diet, alone or with other cholesterol lowering medication, may be used by a specialist to lower cholesterol levels in patients who are at high cardiovascular risk. This includes patients:

- with heterozygous familial hypercholesterolaemia (HeFH; an inherited condition which raises the level of LDL-cholesterol in the blood) who have a level of LDL-cholesterol in their blood that is 5.0mmol/L or greater, to help prevent cardiovascular events such as a heart attack or stroke (primary prevention),
- at high risk due to previous cardiovascular events (secondary prevention) with HeFH and an LDL-cholesterol level that is 3.5 mmol/L or greater,
- at high risk due to previous cardiovascular events and who have an LDL-C level of 4.0 mmol/L or greater,
- with cardiovascular disease who have recurrent events or where multiple blood vessels are affected (polyvascular) and where their LDL-C level is 3.5mmol/L or greater.

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

What does SMC's decision mean for patients?

If your healthcare professional thinks that inclisiran 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 inclisiran used for?

Inclisiran is used to lower the level of LDL-cholesterol in the blood. LDL cholesterol is often called “bad” cholesterol because it collects in the walls of blood vessels, raising the chances of health problems like a heart attack or stroke. Inclisiran is used in patients who have primary hypercholesterolaemia or mixed dyslipidaemia. Both of these conditions cause high levels of cholesterol in the blood.

How does inclisiran work?

Inclisiran blocks the production of a protein called PCSK9 that can increase the levels of LDL-cholesterol. By blocking the production of PCSK9, inclisiran decreases the production of cholesterol in the liver and increases the removal of LDL-cholesterol from the blood.

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 inclisiran by looking at the SMC Detailed Advice Document (SMC2358).

More information

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

Heart UK – The Cholesterol Charity



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



ask@heartuk.org.uk

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



<https://www.ema.europa.eu/en>