



Resource impact summary report

Resource impact

Published: 6 October 2021

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NICE has recommended inclisiran as an option for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults. It is recommended only if:

- There is a history of any of the following cardiovascular events:
 - acute coronary syndrome (such as myocardial infarction or unstable angina needing hospitalisation)
 - coronary or other arterial revascularisation procedures
 - coronary heart disease
 - ischaemic stroke or
 - peripheral arterial disease, and
- low-density lipoprotein cholesterol (LDL-C) concentrations are persistently 2.6 mmol/l or more, despite maximum tolerated lipid-lowering therapy, that is:
 - maximum tolerated statins with or without other lipid-lowering therapies or,
 - other lipid-lowering therapies when statins are not tolerated or are contraindicated, and
- the company provides inclisiran according to the commercial arrangement.

For further information please see the technology appraisal guidance.

Clinical trial evidence shows that inclisiran can lower LDL-C levels when statins or other lipid-lowering therapies have not reduced them enough. Early results from the trials suggest that inclisiran could help prevent heart attacks and strokes. However, the effect on cardiovascular event risk is uncertain as there is a lack of long-term evidence.

The company, clinical and patient experts highlighted that treatment with inclisiran has the potential to increase treatment adherence because it only requires 2 injections a year after the first year. If inclisiran is administered in primary care this will result in an increase in appointments and patient contacts. The Accelerated Access Collaborative and NHS England and NHS Improvement plan to support the implementation of inclisiran.

NHS England and NHS Improvement will make interim funding for inclisiran available from release of positive draft guidance or from launch in the UK, whichever is later. Further information about funding arrangements will be provided by NHS England and NHS Improvement. Please send any enquiries to: england.lipidsphm@nhs.net.

Due to uncertainty around the impact on NHS services, the resource impact will need to be determined at a local level. Any interim national funding should be excluded from the resource impact at a local level.

A <u>resource impact template</u> is available to support NHS organisations with assessing the resource and capacity impact for their locality. Users can input the discounted price of inclisiran and other local prices and values specific to their organisation.

The company has a commercial arrangement (commercial access agreement). This makes inclisiran available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

The technology is commissioned by integrated care systems or clinical commissioning groups. Providers are primary care services.