

BNSSG Primary care guidance for the prescribing and supply of Inclisiran

Healthier Together

Improving health and care in Bristol,
North Somerset and South Gloucestershire

Setting: Primary Care

For staff: General Practitioners, Independent Prescribers

Inclisiran (Leqvio®)

Inclisiran (Leqvio®) is the first of a new type of cholesterol-lowering treatment to boost the liver's ability to remove LDL-cholesterol from the blood. It is given by subcutaneous injection, either on its own or alongside statins or other cholesterol-lowering drugs.

[NICE TA733](#) (6th October 2021, FAST-TRACK TA⁵) recommends 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 ischaemic stroke, coronary heart disease 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 and
- the company provides Inclisiran according to the commercial arrangement (see next page).

Inclisiran has been added to the [BNSSG Joint Formulary](#) as TLS BLUE (for prescribing in specific circumstances) as per the recommendation in NICE TA733 (section 3.3) and NHSE/I ([letter](#) dated 22/9/21).

Treatment Pathway

The [BNSSG Inclisiran treatment guidelines](#) for familial/non-familial hyperlipidaemia in secondary prevention of CVD provide detail on the decision algorithm to aid clinicians in identifying appropriate patients in which to commence Inclisiran in primary and secondary care.

BNSSG has adopted the [ACC National Guidance for Lipid Management for Primary and Secondary Prevention of CVD](#) to include Inclisiran alongside other approved treatments:

- high intensity statins (HISTs)
- ezetimibe for use as an adjunct when statin monotherapy is ineffective, or as monotherapy for those patients that are intolerant to statins (NICE TA385)
- PCSK9 inhibitors (alirocumab, evolocumab) for use either alone or in combination with statins or ezetimibe (NICE TA393, 394)
- Bempedoic acid with ezetimibe for treating primary hypercholesterolaemia or mixed dyslipidaemia as an adjunct to diet in adults (NICE TA694)

Inclisiran is administered as a subcutaneous injection into the abdomen, upper arm, or thigh. The recommended dose is 284 mg Inclisiran loading dose at 0 months and 3 months, then long-term maintenance every 6 months. It is intended for administration by a Healthcare Professional, not the patient. No additional monitoring is required. For further information please refer to the [SPC for Inclisiran](#).

Pricing structure and mechanism of supply for Inclisiran

NHSE/I have set up a novel funding mechanism for the prescribing of Inclisiran in primary care. Support for primary care will be provided by the West of England Academic Health and Science Network (AHSN) who have a number of useful resources and also details training opportunities that can be found following this link [Familial Hypercholesterolaemia \(FH\) and Lipid Optimisation - West of England Academic Health Science Network \(weahsn.net\)](https://weahsn.net).

AAH Pharmaceuticals UK will supply Inclisiran to primary care in England from September 2021. It does not need to be kept in a fridge.

For further information about the new part VIIC category in the drug tariff for Inclisiran and pricing, see: <https://psnc.org.uk/our-news/Inclisiran-leqvio-added-to-a-new-section-in-the-drug-tariff-part-viic/> There is the expectation centrally that in-patients with CVD may receive an initial dose.

- Inclisiran should be prescribed in primary care as a **personally administered item**. Practices to purchase stock from wholesaler (AAH) by calling the AAH customer care team on 0344 561 8899 and claim via the monthly submitted FP34D. Alternatively it may be prescribed on FP10.
- **Practices can buy Inclisiran for £45 but the reimbursement price to primary care will be £50 if prescribed via the FP34D route. This reimbursement is not available if prescribed on FP10.**

Inclisiran initiated in or recommended by secondary care

There are 2 cohorts of patients within secondary care that have been identified, these are:

1. High risk Acute Coronary Syndrome (ACS) patients who are already established on High Intensity Statin Treatment (HIST) with an LDL>2.6mmol/L
 - a. These patients may receive their first dose whilst as an inpatient. The date of the first dose will be documented on the patient's discharge summary and this will be clearly communicated as "subcutaneous stat for 1 dose. GP to continue administration, next dose due in 3 months"
2. Patients seen in an outpatient setting by the lipid clinic who have been assessed as being eligible for Inclisiran treatment. In this instance a recommendation will be made to the GP to initiate Inclisiran through the usual outpatient clinic letter.

Inclisiran initiation in primary care

Inclisiran is **TLS BLUE (for prescribing in specific circumstances)** in the [BNSSG Joint Formulary](#) and treatment can be initiated within primary care. Please refer to [local](#) and national guidance as detailed above in Treatment Pathway.

BNSSG Specialist Contact Information:

Please refer to the Advice and Guidance pages on Remedy: BNSSG referral pathways:

For the Lipid Clinic:

<https://remedy.bnssgccg.nhs.uk/adults/biochemistry/lipid-advice-guidance-service/>

For Cardiology:

<https://remedy.bnssgccg.nhs.uk/adults/cardiology/advice-guidance-service/>