POSITION STATEMENT

Inclisiran for treating primary hypercholesterolaemia or mixed dyslipidaemia

Recommendation:

Inclisiran is recommended as an option for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia in line with NICE TA733 **AND** the NICE approved 'Summary of National Guidance for Lipid Management for Primary and Secondary Prevention of CVD' – **RAG status:** 'Green (Restricted)' – **see lipid optimisation pathway: secondary prevention in primary care and the community below**

Please note:

Primary care clinicians are reminded that they should continue to treat patients with high cholesterol following lipid guidelines focussing on all available options starting with lifestyle changes and statins, escalating patients to high intensity statins (**see below for clarification**) and ezetimibe where appropriate. If considering injectable therapies clinicians should prioritise these other options first.

The following specific advice have been made available to **primary care prescribers that are considering commencing inclisiran** as recommended by NICE:

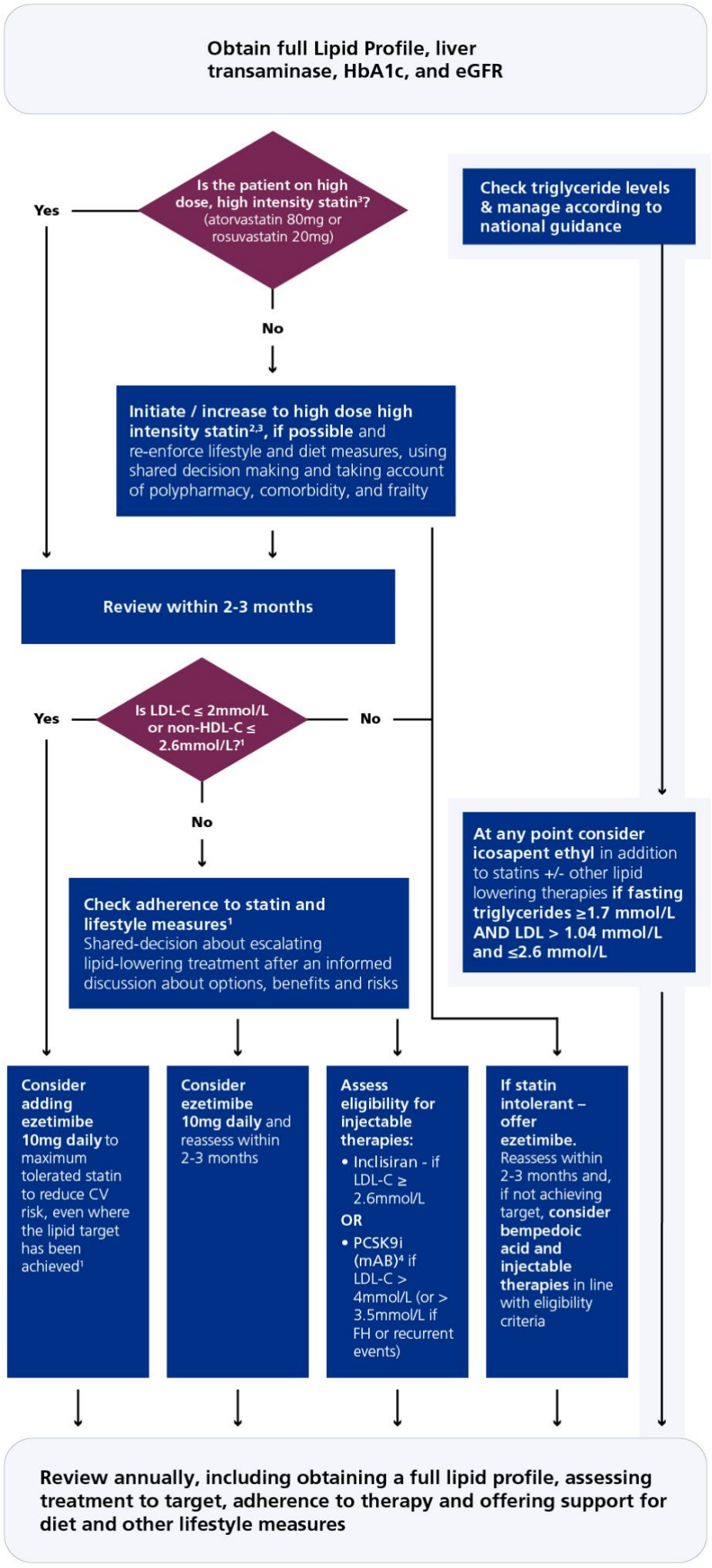
- **Undertake shared decision making with your patients**, ensuring a full and detailed informed consent is taken, documenting the lack of long-term evidence and unknown long term safety profile of this new and novel medication,
- **Encourage your patients to report all side effects to you**, however minor, ensuring you fill in a MHRA "yellow card" when they are reported to you and
- **Report any potential drug interactions or concerns of your own at the earliest opportunity**

Background

NHSE has developed the *'Lipid optimisation pathway: secondary prevention in primary care and the community'* for primary care clinicians to provide clear and simple guidance on how optimal lipid management can be achieved, and to provide an additional resource to support patient management. This pathway was updated in June 2024 to take account of NICE NG238 the Cardiovascular disease: risk assessment and reduction, including lipid modification guidance (published December 2023). **For a full list of high intensity statins see page 3.**

Please note: the pathway below is not a comprehensive clinical guideline setting out all clinical scenarios, nor does it seek to set out the clinical evidence base for interventions which are covered in the relevant NICE technology appraisals.

Pathway 1 Lipid optimisation pathway: secondary prevention in primary care and the community



The full criteria define in NICE TA 733 is:

1. Inclisiran is recommended 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.

2. Inclisiran is recommended only in research for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia in adults who have no history of cardiovascular events. This research is in the form of a clinical trial currently in development.

Please note: 'Maximum tolerated statins' is defined as: either the **maximum dose of a high intensity statin** has been reached, or **further titration is limited by intolerance** (the presence of clinically significant adverse effects that represent an unacceptable risk to the patient or that may reduce compliance with therapy). High intensity statins are defined as (daily dose):

Atorvastatin	20 mg
	40 mg
	80 mg
Rosuvastatin	10 mg
	20 mg
	40 mg

Simvastatin	80 mg

Bibliography

1. National institute for Health and Care Excellence: NICE TA733: Inclisiran for treating primary hypercholesterolaemia or mixed dyslipidaemia. Accessed via: https://www.nice.org.uk/guidance/ta733 [accessed online: 28th August 2025].
2. National institute for Health and Care Excellence: NICE CG71: Familial hypercholesterolaemia: identification and management. Accessed via: https://www.nice.org.uk/guidance/cg71 [accessed online: 28th August 2025].
3. National institute for Health and Care Excellence: British National Formulary: Dyslipidaemias. Accessed via: https://bnf.nice.org.uk/treatment-summary/dyslipidaemias.html [accessed online: 28th August 2025].
4. Royal College of General Practitioners and British Medical Association. RCGP and BMA update: Information on the proposals for the prescription of inclisiran in primary care settings. 3rd December 2021.
5. Khatib et al. Summary of National Guidance for Lipid Management for Primary and Secondary Prevention of CVD. Accelerated Access Collaborative. Approved by NICE. December 2021. Accessed via: https://www.england.nhs.uk/aac/publication/summary-of-national-guidance-for-lipid-management/ (updated 19th September 2024).
6. NHS England. Lipid optimisation pathway: secondary prevention in primary care and the community. Accessed via: https://www.england.nhs.uk/long-read/lipid-optimisation-pathway-secondary-prevention-in-primary-care-and-the-community/. Last updated 8th October 2024 [Accessed online: 23rd September 2025].

Version Control

Version Number	Date	Amendments Made	Author
1.0	January 2022	New document	AG
1.1	August 2025	Document reviewed. No changes.	AG
1.2	September 2025	NHSE Lipid optimisation pathway: secondary prevention in primary care and the community added	AG

Please access this guidance via the LSCMMG website to ensure that the correct version is in use.

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