

A Comprehensive Guide to Implementation of Inclisiran in Primary Care: The DHG Protocol

Cardiovascular disease is the leading cause of death globally⁽¹⁾, causing approximately 25% of all deaths in the UK⁽²⁾ and costing the NHS about £7.4 billion/year⁽³⁾. LDL-C has been identified as the main risk factor for CVD⁽⁴⁾ with 1 in 4 deaths from CVD associated with raised LDL-C⁽²⁾. Because of this **LDL-C management for secondary prevention is now recognised as clinical priority for patients and the NHS, through incentives in the [2023/2024 QOF](#) amounting to 30 points and ~£36 million in funds⁽⁵⁾.**

The NHS Long Term Plan acknowledges cardiovascular disease as a clinical priority and the **single biggest area where the NHS can save lives over the next 10 years⁽⁸⁾** with recent national CVDPREVENT data showing over 76% of patients with cardiovascular disease have LDL-C levels above 1.8 mmol/L⁽⁷⁾.

In a European study also over **80% of very high-risk patients were UNABLE TO REACH 2019 ESC/EAS LDL-C GOALS on statins alone⁽⁶⁾.**

Inclisiran is an additional therapy that has been identified by [NHS England and Improvement](#) as a medicine that it wishes to adopt systematically and at scale⁽⁹⁾ that could bridge the gap in the lipid management pathway and help secondary prevention patients achieve the 1.8mmol/L.

This implementation guide has been formulated to help you deliver this in Primary care and hit the Cholesterol QOF targets for 23/24.

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Finding the patients

Step 1 - Search tools

Recommended tools to combine (NICE specific Inclisiran Eligible cohorts):

- 1) ARDENS REPORT** – if your practice uses Ardens, the report can be found in **Clinical Reporting - > Ardens Ltd folder -> Conditions | Cardiovascular -> Alerts -> CVD - ?Inclisiran indicated as CVD + LDL>2.5 or non-HDL >3.4 + not on maximum tolerated lipid lowering therapy.**
- 2) MANCHESTER INNOVATIONS** – These reports need to be imported onto S1, the [searches](#) and [guidance on cohorts requiring action](#) can be found here -> [CVD Prevention: Lipid Pathway - Resources for Health and Care - Health Innovation Manchester](#). The report for Inclisiran is called **'n | COHORT 4a - Eligible for Injectables'**.

Additional tools:

- 3) CDRC** - [Lipids, Familial Hypercholesterolaemia \(FH\), PCSK9i & Inclisiran Search Guide](#) to access the tool you need to [join the SystemOne group](#). Cohorts 'Lipids 5.5-5.7' specifically identify NICE eligible Inclisiran patients.
- 4) UCLP** - These reports need to be imported onto S1, the searches and guidance can be found [Search and risk stratification tools - UCLPartners](#) 'Priority Group 3 (on high intensity Statin suboptimal non-HDL)' highlights patients for optimisation but not specifically NICE eligible Inclisiran patients.
- 5) Eclipse Live** – [CVD risk stratification tool](#)

The Inclisiran NICE TAG eligibility requires LDL-C, the practice can use the [Friedewald equation](#) to calculate this prior to initiation for patients with Non-HDL >3.4 (estimated equivalent to 2.6 LDL as per [2021 ESC guidance](#)).

Step 2 - Combining reports

Once the reports are imported, these can be collated into one list to maximise identification of eligible patients.

On System 1 Clinical Reporting click click **'New'** and then select the option under **'Report Joining'** for **'Join to more than two reports'**

1) Name the report and select a location – for example **'Lipid Management - ?Eligible for Inclisiran (any report)'**

2) Click **'Select Report(s)'** and then search for the above reports (and any others) to add them into the join. Select the Join Type as **'Report on patients found in any of the selected reports'**

3) Click **'Ok'** and then run the report to find the patients that appear on any of the included reports.

The screenshot shows the 'Amend Report' dialog box. The 'Name' field is 'Lipid Management - ?Eligible for Inclisiran (any report)'. The 'Category' is 'CVD Prevention'. The 'Sub category' is empty. There are checkboxes for 'Add report to favourites' and 'Restrict access to system administrators and selected users'. A 'Join to more than two reports' section is visible, showing a list of reports to be joined. The 'Join type' is set to 'Report on patients found in any of the selected reports'. The 'Percentage calculation' section has radio buttons for different calculation methods, with 'Use organisation capitation to calculate this report's percentage' selected.

Name	Category
## Priority Group 3 (on high intensity Statin suboptimal non-HDL)	CVD Prevention / UCLP Sec...
15. LMCX019 - Inclisiran candidate cohort	Lipid Management / Cohorts
CVD - ?Inclisiran indicated as CVD + LDL>2.5 or non-HDL >3.4 + not on maximum tolerated lipid lowering therapy	Conditions Cardiovascular (...)
n COHORT 4a - Eligible for injectables #FOR ACTION#	CVD Prevention / Lipid Searc...

System1 Resources to support implementation

Patient Status Alert (PSA)

This can be linked to your combined report, right click on the report and select **'create PSA'**. This helps clinicians identify patients who may be eligible for Inclisiran. Example of set up and appearance on patient front screen are below and to the right:

Click action, type in **'Drug Injections'** select specific page **'PCSK9 Inhibitor'**. Clinicians can then click **'action'** on the PSA on patients front screen which will take them to the **'Ardens 'Drug Injection' Template'** for administration and prescribing.

Amend Patient Status Alert

Details

Name: Consider Inclisiran Therapy

Category: DHG PCN

Icon:

Description: Patient possibly eligible for Inclisiran based on NICE Tag* - if suitable offer Inclisiran therapy or code as declined/not tolerated/not indicated *Secondary prevention (exc TIA), LDL 2.6 and above, max tolerated lipid lowering therapy.

Trigger type: Clinical Report

Trigger report: Lipid Management - ?Eligible for Inclisiran (any report, exc TIA)

Output

When triggered

- Show icon, name and message on Patient Home
- Show icon below top-right Patient Demographics box
- Show on Medication Chart (secondary care prescribing)

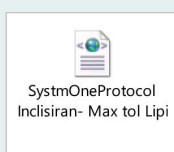
Message: Please check eligibility for Inclisiran based on NICE Tag* - if suitable offer Inclisiran therapy, or code as Inclisiran declined/not tolerated/not indicated. *Secondary prevention (exc TIA) + LDL 2.6 and above + max tolerated lipid lowering therapy.

Linked action: Drug Injections (page 20)

Ok Cancel

Consider Inclisiran Therapy: Please check eligibility for Inclisiran based on NICE Tag* - if suitable offer Inclisiran therapy, or code as Inclisiran declined/not tolerated/not indicated. *Secondary prevention (exc TIA) + LDL 2.6 and above + max tolerated lipid lowering therapy. [Action](#) [More](#)

As part of the NICE TAG, eligible patients should be coded as **'Patient on maximal tolerated lipid lowering therapy'**. DHG SystemOne protocol (document embedded) can be imported onto S1, this automatically adds the code when **'1st dose administration of Inclisiran'** is selected under the **'Injection given'** box when completing the Ardens drug injection template.



DHG implementation protocol Steps 1-5

Step 1: Qualifying eligibility

Patients from the searches above should be eligible within the NICE TAG however you can use the below as checklist for this.

HISTORY of CVD

- Acute coronary syndrome (MI, unstable angina requiring hospitalisation)
- Coronary or other arterial revascularisation procedures
- Coronary Heart Disease, Peripheral Arterial Disease or Ischaemic Heart Disease

1

MAX TOLERATED LIPID LOWERING THERAPY

- Maximum tolerated statins - with or without lipid-lowering therapies
- Statin declined/ not tolerated/indicated - with or without other lipid-lowering therapies

2

LDL 2.6 OR ABOVE (mmol/L)

- LDL-C \geq 2.6 despite max tolerated lipid lowering therapy

3

HCP administered, Subcutaneous Injection, No dose adjustments [Dosing & administration guide](#) for special populations, dosing & administration. [Prescribing information](#)

Step 2: Consulting & Inviting in eligible patients

CONSULT PATIENTS IN ROUTINE CLINIC

- **Verbally communicate eligibility and clinical benefit to patient during Annual Health review appointments.**
- **Opportunistically find eligible patients during routine appointments**
- **Physical copies of Patient Info Leaflet can be ordered via Novartis**

INVITE IDENTIFIED PATIENTS IN

- **LETTER:** Adapt DHG patient letter / create your own – ensure [patient information leaflet](#) is included
- **ACCURX:** Attach patient letter to the template, optional: 'allow patients to respond'
- **PHONE/TEXT/EMAIL:** Can also be used

Dear Mr Mouse-TestPatient

At Framfield Surgery, we continually strive to deliver the best care and improve on patient care reducing the risk of disease.

You may have been aware of a medication, Inclisiran, mentioned in the national media, that has recently been assessed by NICE (National Institute of Health and Care Excellence) and accepted to assist in the treatment of people who have vascular disease, or had cardiovascular events (Stroke/ Heart attacks/ Coronary heart Disease).

Our records show that you may benefit from this medication.

Inclisiran works alongside statins or other medications that patients are taking to reduce their cholesterol – but in a slightly different way. It essentially increases the amount of receptors the liver makes which mean it captures more LDL cholesterol and thus reduces the risk that the cholesterol can cause any harm.

Here is a link for further information regarding Inclisiran;
<https://www.health.novartis.co.uk/sites/health.novartis.co.uk/files/inclisiran-patient-leaflet-april-2022.pdf>

The treatment is given as an injection subcutaneously at an interval of first dose, second dose in 3 months' time – and then after that every 6 months which would be administered by a practice nurse at the surgery.

If you are interested in starting this medication or wish to discuss this further with the clinical team; please call Framfield Surgery to book with one of the nursing team.

Mode of Action:

Inclisiran is a siRNA inhibitor, it works differently to existing lipid lowering medications. Statins work to reduce cholesterol production in the liver whereas Inclisiran increases hepatic LDL-C uptake which reduces LDL-C levels in the bloodstream.

[Patient Information Leaflet](#) | [Inclisiran HEART UK](#)

Step 3: Prescribing & administration

PRESCRIBING CLINICIANS: ISSUING THE PRESCRIPTION

- 1) Click 'Action' on the PSA to launch the Ardens Injection Template, then complete as follows:
- 2) 'Prescribe' Click to prescribe **Leqvio**. Here mark as PA item, and untick 'patient can initiate request' on repeat box.
- 3) 'Authorise' Complete PSD (patient specific directive) for loading doses (1st & 2nd Injections). (A maintenance PSD is required once loading doses completed).

NON-PRESCRIBING CLINICIANS: ADMINISTRATION

- Either click 'Action' using the PSA from above taking you to the Ardens Injection Template **OR** Launch: - **Ardens Auto-Consultation/ Imms and Injections/ Drug Injection Template'**, Click on **PCSK9 INHIBITOR Tab**.

DOSE SPECIFIC PROCEDURES: DOCUMENTING/RECALLS

- **1st dose:** Ensure patient coded 'maximal tolerated lipid lowering therapy'. Under 'injection given' box – click '1st dose Inclisiran'. Set up 3 month+ scheduled task / recall for 2nd dose – (2nd dose must not be given before 3 months). Discuss & document consent re. no long-term CV outcomes data/ inform re. new side effects.
- **2nd dose:** Set up Inclisiran 6 month recall for 3rd dose (maintenance). Task prescriber to change electronic PSD to Maintenance regime.

Without Ardens/PSA

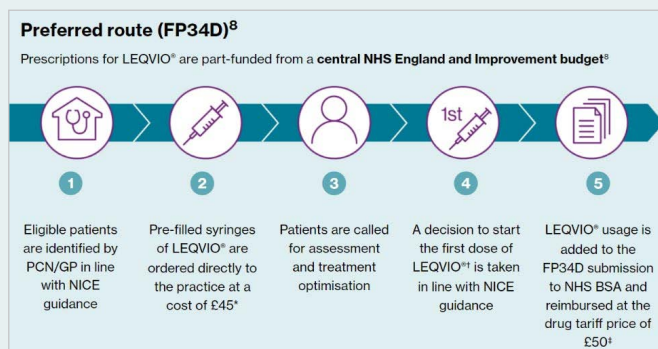
Issue FP10, PSD & record administration of injection following your normal procedure.

Resources

- [Dosing & administration guide](#)
- [Ardens injection template](#)
- [HCP Administration video](#)
- [Inclisiran guide Health Innovation Manchester](#)

Step 4: Ordering & reimbursement

Stock can be ordered directly from the wholesaler (AAH), using the codes below and is expected to be delivered the next day.



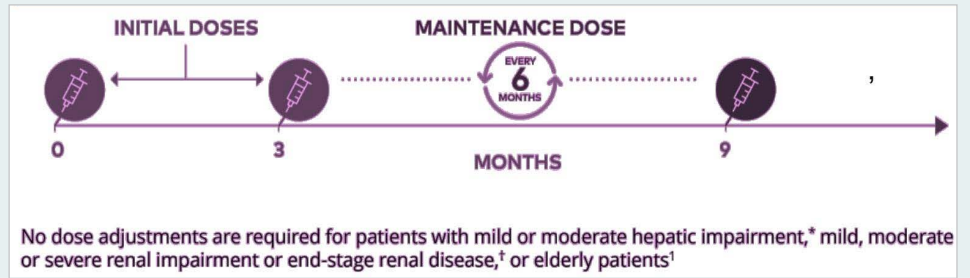
Product Name	EAN Code	PIP Code
Inclisiran (LEQVIO) [®]	7613421044237	4174751

Resources

- [Ardens FP34D searches](#)
- [Local pathway](#)
- [NHS Funding & Supply further information](#)

Step 5: Monitoring & doses

- Lipid Profile bloods: Set up recall for 3 months onwards for QOF purposes or as requested by the patient
- No specific monitoring or refrigeration required
- No clinically significant interactions with other medicinal products expected
- Side effects: Injection site only – none severe/persistent. Please advise patient to report any side effects & complete a [MHRA yellow card](#)



MAXIMISING QOF INCOME: ARDENS QOF CHOLESTEROL TEMPLATE:

- ASCVD patients need to be coded effectively for search tools to identify Inclisiran eligible patients & to maximise QOF income
- The Ardens Cholesterol template is an easy tool to add the relevant codes
- This will show up on the patient screen as an alert or can be found under **autoconsultations>ardensCONTRACTS**

Patients can be reviewed/contacted to offer statin optimisation, if the patient has declined/ineligible do so - the following codes can be added:

Not on a statin: Statins contraindicated (**XaG2V/315363002**)

Statin declined (**XaIII/134396000**)

Statin not tolerated (**XaJ5i/ 413174003**) – found under the ‘**statin**’ drop down box in the template.

On suboptimal statin or suboptimal dose: maximal tolerated lipid lowering therapy (**XaJYw/407568002**) – found in the ‘**exception**’ drop down box.

Increasing QOF point value using case finding tools:

Ardens - [QOF Case Finder](#)

CDRC - [Lipid Qof Support](#)

QOF 2023/24 - Cholesterol

ardens help & feedback

✓ QOF Ruleset ❤️ CVD Preve...

★ CHOL_REG: Patients on CHD, PAD, Stroke/TIA or CKD register

CHD	QOF	X		
PAD	QOF	X		
Stroke or TIA	QOF	X		
CKD	QOF	X		

★ CHOL001: CHD, PAD, Stroke/TIA or CKD + prescribed a statin or other LLT where statin declined/unsuitable

Exception for each LLT needed if appropriate

Statin					
Bempedoic Acid					
Ezetimibe					
Icosapent Ethyl					
Inclisiran					
PCSK9					
Exception					

★ CHOL002: CHD, PAD or Stroke/TIA + non-HDL cholesterol <2.5mmol/L or LDL cholesterol <1.8mmol/L in last 12m

Non-HDL cholesterol ...		m...	LDL cholesterol level		m...
Serum Non-HDL chol...		m...	Serum LDL cholester...		m...
Exception			Plasma LDL choleste...		m...

QOF Indicators 2023/2024

CHOL001:

Percentage of patients on the QOF Coronary Heart Disease, Peripheral Arterial Disease, Stroke/TIA or Chronic Kidney Disease Register who are **currently prescribed a statin, or where a statin is declined or clinically unsuitable, another lipid-lowering therapy**

CHOL002:

Percentage of patients on the QOF Coronary Heart Disease, Peripheral Arterial Disease, or Stroke/TIA Register, who have a recording of non-HDL-C in the preceding 12 months that is lower than 2.5 mmol/L, or where non-HDL-C is not recorded a **recording of LDL-C in the preceding 12 months that is lower than 1.8 mmol/L**

Additional Resources

Pathways & guidance

- [NHS England Commercial partnerships - Introducing Inclisiran](#)
- [Quality and Outcomes Framework guidance for 2023/24](#)
- [2021 ESC Guidelines on cardiovascular disease prevention in clinical practice](#)
- [National Lipid Management Pathway NHS](#)
- [Primary Care Lipid Optimisation Clinical Pathway for Secondary Prevention AHSN](#)

HCP resources

- [CVD Prevention: Lipid Pathway, HCP Resources, Search Tools & Webinars- HIM](#)
- [Lipids, PCSK9i & Inclisiran Search Guide for SystmOne - CDRC](#)
- [Friedwald Calculator for LDL calculations - MDCALC](#)
- [Tackling Cholesterol Together \(HEART UK\) Comprehensive HCP Education Programme - Webinars, CPD E-learning etc.](#)
- [Inclisiran Prescribing Information](#)
- [Inclisiran \$\nabla\$ \(LEQVIO \$^{\circledR}\$ \) HCP PDF & Video Resources | Novartis UK HCP Portal](#)
- [Lipid management and Familial Hypercholesterolemia - The AHSN Network](#)

Patient resources

- [Inclisiran \$\nabla\$ \(LEQVIO \$^{\circledR}\$ \) Patient Information Leaflets PDF | Novartis UK HCP Portal](#)
- [Literature and Booklets for Health Professionals PDF or Hard Copies - HEART UK](#)
- [Inclisiran - HEART UK](#)

References

- (1) [Causes of death - Our World in Data](#)
- (2) BHF. <https://www.bhf.org.uk/-/media/files/for-professionals/research/heart-statistics/bhf-cvd-statistics-uk-factsheet.pdf?rev=e771367bf0654a4dae85cbc9dbefae17&hash=76C0182379BB6EE118EC6F76FA35A158>
- (3) Gov.uk. <https://publichealthmatters.blog.gov.uk/2019/02/14/health-matters-preventing-cardiovascular-disease/>
- (4) Int J Environ Res Public Health. 2022 Jul; [Serum Cholesterol Levels and Risk of Cardiovascular Death: A Systematic Review and a Dose-Response Meta-Analysis of Prospective Cohort Studies - PMC \(nih.gov\)](#)
- (5) [CVD Prevention: Lipid Pathway - Resources for Health and Care - Health Innovation Manchester](#)
- (6) Ray KK et al. Eur J Prev Cardiol 2021;28(11):1279-1289
- (7) HQIP. <https://www.hqip.org.uk/wp-content/uploads/2023/03/Ref-376-CVDPREVENT-Third-Annual-Audit-Report.pdf>
- (8) [NHS Long Term Plan » Cardiovascular disease](#)
- (9) [B0948-Medicines-Optimisation-Pack Inclisiran-FINAL.pdf \(yhahsn.org.uk\)](#)

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