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GDL16
Royal Wolverhampton NHS Trust Lipid Management for Primary and Secondary Prevention of CVD

Contents

Attachment (s):

Attachment 1: Lipid Guideline

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1.0 Procedure Statement (Purpose / Objectives of the Procedure)

Purpose

The purpose of this guideline is to provide a comprehensive framework for lipid optimisation, to improve the detection, management, and treatment of lipid disorders, particularly in patients at high risk of cardiovascular disease (CVD). The guideline aims to standardise care, enhance patient outcomes, and support the NHS Long Term Plan priorities for CVD prevention.

Rationale for Development:

- Address the increasing burden of CVD as a leading cause of morbidity and mortality and disproportionately affects the local population.
- To ensure consistent implementation of latest evidence-based practices for lipid management across the Trust.
- Support clinicians in achieving lipid targets through structured pathways and tools.

Aims / Objectives

Improve Patient Outcomes:

- Enhance early identification and risk stratification of patients with lipid disorders.
- Reduce the incidence of CVD events through effective lipid management.

Standardise Clinical Practice:

- Provide clear, evidence-based guidance for lipid optimisation in primary and secondary prevention.
- Ensure adherence to the evidence base and local governance requirements.

Support Clinicians:

- Develop tools, training, and resources to improve clinician confidence and capability in lipid management.
- Facilitate multidisciplinary collaboration to deliver integrated care.

Promote Sustainability:

- Embed lipid optimisation into routine clinical workflows to ensure long-term impact.
- Monitor and evaluate outcomes to drive continuous improvement.

Expected Outcomes

Clinical Outcomes:

- Achieve measurable reductions in LDL-C and non-HDL-C levels in high-risk patients.
- Decrease the incidence of CVD events, including myocardial infarction and stroke.

Operational Outcomes:

- Increase the proportion of patients receiving appropriate lipid-lowering therapies.
- Improve clinician adherence to lipid management pathways.

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Patient-Centered Outcomes:

- Enhance patient understanding and engagement in their care.
- Improve access to lipid management services, particularly for underserved populations.

Organisational Outcomes:

- Demonstrate alignment with NHS Long Term Plan priorities and national lipid management targets.
- Provide a scalable model for lipid optimisation that can be adapted regionally or nationally.

In adhering to this Policy, all applicable aspects of the Conflicts of Interest Policy must be considered and addressed. In the case of any inconsistency, the Conflicts of Interest Policy is to be considered the primary and overriding Policy.

2.0 Accountabilities

Primary responsibility for the implementation and adherence to this lipid optimisation guideline lies with individual clinicians and staff involved in the delivery of lipid management services.

Departments such as Cardiology, Stroke and pharmacy services are tasked with embedding the guideline into routine clinical workflows and ensuring alignment with evidence-based practices.

The Medicines Management Group holds oversight responsibility for reviewing and approving the application of this guideline across the Trust.

All teams are collectively accountable for ensuring compliance with the guideline, maintaining patient safety, and driving measurable improvements in lipid management outcomes.

3.0 Procedure/Guidelines Detail / Actions

Lipid Guideline (Attachment 1) – provided as a supporting attachment

4.0 Equipment Required

The successful implementation of this guideline requires access to prescribing systems and standard office equipment. Additionally, access to cholesterol monitoring tools and laboratory services for lipid profiling is required, and these must be available within the Trust's diagnostic and care facilities to support accurate assessments and follow-ups.

5.0 Training

Training on the lipid optimisation guideline will be delivered through targeted sessions such as workshops, webinars, and team briefings, alongside Trust-wide communication methods including email updates, intranet postings, and staff newsletters to ensure all relevant staff are informed of key deliverables.

Specific training materials, such as user guides and quick reference tools, will be made available on the Trust intranet for easy access. Staff can access training through the Trust’s established learning platforms and booking systems, with additional support

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provided for those requiring competency assessments or refresher sessions.

6.0 Financial Risk Assessment

1	Does the implementation of this document require any additional Capital resources	Yes – No
2	Does the implementation of this document require additional revenue resources	Yes – No
3	Does the implementation of this document require additional manpower	Yes – No
4	Does the implementation of this document release any manpower costs through a change in practice	Yes – No
5	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff.	Yes – No
	Other comments	

7.0 Equality Impact Assessment

An equality analysis has been carried out and it indicates that:

Tick	Options
	A. There is no impact in relation to Personal Protected Characteristics as defined by the Equality Act 2010.
	B. There is some likely impact as identified in the equality analysis. Examples of issues identified, and the proposed actions include:

An equality analysis has been completed for this guideline and indicates that Option A: There is no impact in relation to Personal Protected Characteristics as defined by the Equality Act 2010. The assessment concluded that the guideline supports equitable access to lipid management services and does not disproportionately disadvantage any individual or group. Any future updates to the guideline will include a reassessment to ensure ongoing compliance with equality and diversity standards.

8.0 Maintenance

The responsibility for ensuring this guideline remains current lies with the Pharmacy directorate, which will oversee periodic reviews and updates in line with the latest evidence and national recommendations. Any proposed changes or amendments will be reviewed and recommended by the Cardiology and/or CVD pharmacist in collaboration with multidisciplinary stakeholders, ensuring the document continues to reflect best practices and aligns with Trust priorities.

9.0 Communication and Training

Key actions and responsibilities within this guideline will be communicated through targeted methods such as team briefings, email updates, and intranet announcements, alongside general communications like newsletters to ensure Trust-wide awareness.

Initial training sessions will be provided to all relevant staff to support implementation. Refresher training will be scheduled annually or as needed to address updates or reinforce best practices.

All training resources will be accessible via existing Trust-wide platforms.

10.0 Audit Process

The audit process for this guideline will involve routine monitoring of compliance with the lipid optimisation pathway. Key performance indicators (KPIs) such as guideline directed drug and dose choice and the percentage of patients meeting lipid targets will be tracked.

The Pharmacy directorate will oversee audits, producing reports at least annually. The monitoring method of choice will be random sampling of patient records to assess adherence to the guideline. Audit outcomes will be presented at governance meetings (such as Cardiology and Stroke), where feedback will be collected, and necessary actions will be agreed upon to ensure continuous improvement and alignment with the document's objectives.

Criterion	Lead	Monitoring method	Frequency	Evaluation
Percentage of eligible patients initiated on: High intensity statin High intensity statin + Ezetimibe eGFR <30 and Atorvastatin 20mg + Ezetimibe	Pharmacy Directorate Cardiology/ CVD Pharmacist	Random patient sampling	Annually	Cardiology and Stroke Services – at governance meetings

11.0 References - Legal, professional or national guidelines

- Buckley, John. (2014). Joint British Society Guidelines (JBS3). Heart. 100. ii1-ii67. 10.1136/heartjnl-2014-305693.
- Kirsten *et al*. 2005. Hospital Pharmacy 40(8):687-692
- Navarese *et al*. 2015. Annals of internal medicine 163(1):40-51
- Soon Jun Hong *et al*. 2018. Clinical therapeutics 40(2): 226-241.e4
- NICE 2016. TA385 www.nice.org.uk/guidance/ta385
- NICE 2016. TA393 www.nice.org.uk/guidance/TA393
- NICE 2016. TA394 www.nice.org.uk/guidance/TA394
- NICE 2008. CG71 www.nice.org.uk/guidance/cg71
- NICE 2021. TA694 www.nice.org.uk/guidance/TA694
- NICE 2021. TA733 www.nice.org.uk/guidance/TA733
- NICE 2022. TA805 www.nice.org.uk/guidance/ta805
- NICE 2023. NG238 www.nice.org.uk/guidance/ng238
- NICE 2023. CG189 www.nice.org.uk/guidance/cg189
- Schubert J et al. Intensive early and sustained lowering of non-high-density

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lipoprotein cholesterol after myocardial infarction and prognosis: the SWEDEHEART registry. Eur Heart J. 2024 Oct 14;45(39):4204-4215

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Part A - Document Control

<table>
<tr><td>Procedure/ Guidelines number and version

GDL16

V1.0</td><td>Title of Procedure/Guidelines

Royal Wolverhampton NHS Trust Lipid Management for Primary and Secondary Prevention of CVD</td><td colspan="2">Status:

Final</td><td>Author:
Cardiovascular Pharmacist

Chief Officer Sponsor:
Chief Medical Officer</td></tr>
<tr><td rowspan="2">Version / Amendment History</td><td>Version</td><td>Date</td><td>Author</td><td>Reason</td></tr>
<tr><td>V1.0</td><td>April 2025</td><td>Cardiovascular Pharmacist</td><td>Implementation of Guideline</td></tr>
<tr><td colspan="5">Intended Recipients: This guideline is intended for all healthcare professionals involved in lipid management, including all prescribing clinicians and pharmacy teams. The guideline aims to provide clear and practical guidance tailored to these roles, fostering consistency in practice and high-quality patient care across the Trust.</td></tr>
<tr><td colspan="5">Consultation Group / Role Titles and Date:

• 10/10/24: Dr. S Ahmad – Consultant Cardiologist
• 15/10/24: Professor Gama – Lead Chemical Pathologist
• 4/2/25: Dr. S McBride, Dr. N Ahmad, Dr. S Das and Sr R Jones (Stroke Consultants and Senior Stroke Nurse)
• 20/3/25 – Dr. Anna Stone, ICB Prescribing Lead and RWT deputy clinical director</td></tr>
<tr><td colspan="2">Name and date of group where reviewed</td><td colspan="3">28/1/25 – Cardiology governance – approved</td></tr>
<tr><td colspan="2">Name and date of final approval committee (if trust-wide document)</td><td colspan="3">• 1/4/25 – Medicines Management Group
• Trust Policy Group – June 2025</td></tr>
<tr><td colspan="2">Date of Procedure/Guidelines issue</td><td colspan="3">June 2025</td></tr>
<tr><td colspan="2">Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)</td><td colspan="3">June 2028 - Every 3 years</td></tr>
</table>

Training and Dissemination: The lipid optimisation guideline will be communicated through a combination of targeted and Trust-wide methods to ensure thorough dissemination and engagement. Targeted communication will include email updates to relevant teams, briefings at multidisciplinary meetings, and direct communication with clinical leads. Trust-wide communication methods, such as postings on the intranet, newsletters, and dedicated workshops, will ensure broader awareness across staff groups. Training will include initial workshops and live webinars to support understanding and implementation. Refresher sessions will be provided annually or as needed, and tailored training resources will be made available on the Trust's intranet. Clear instructions on how to access these training sessions will be communicated via email and the Trust's learning management platform.	
To be read in conjunction with: n/a	
Initial Equality Impact Assessment: Completed Yes / No Full Equality Impact assessment (as required): Completed Yes / No / NA If you require this document in an alternative format e.g., larger print please contact Policy Management Officer 85887 for Trust- wide documents or your line manager or Divisional Management office for Local documents.	
Contact for Review	Cardiovascular Pharmacist
Monitoring arrangements	Monitoring audit to be completed and presented to Cardiology governance.
Document summary/key issues covered. This lipid optimisation guideline provides a structured approach to improving the detection, management, and treatment of lipid disorders, with a focus on reducing cardiovascular disease (CVD) risk. It aligns with latest evidence-based recommendations and outlines practical steps for clinicans, including patient identification, lipid profiling, and tailored interventions. The guideline aims to standardise care across the Trust, support clinicians with tools and training, and embed sustainable practices to enhance patient outcomes. It also includes clear processes for monitoring progress, ensuring compliance, and fostering continuous improvement in lipid management.	
Key words for intranet searching purposes	Lipids, Cholesterol, CVD, Statin, ezetimibe.

GDL16/V1.0/June 2025 – Attachment 1

Royal Wolverhampton NHS Trust Lipid Management for Primary and Secondary Prevention of CVD

INITIAL CONSIDERATIONS:

- Measure ***lipid profile*** (total cholesterol, HDL-C, non-HDL-C, triglycerides, LDL-C) and HbA1c as part of an initial baseline assessment. ● Exclude secondary causes of hyperlipidaemia and manage as needed.
- Ensure appropriate baseline and follow up tests as detailed on page 2. Measure BMI. ● Identify and exclude people with contraindications/drug interactions ● If non-fasting triglyceride above 4.5mmol/L see page 2.

PRIMARY PREVENTION

Offer lifestyle changes and consider statin therapy for adults who do not have established CVD but fall into the categories below. Use QRISK risk assessment tool where appropriate (see page 2, '*Primary Prevention Risk Assessment*')

- Age ≤84 & QRISK ≥10% over next 10 years (including Type 2 diabetes)
- Type 1 diabetes, if they have one or more of:
  - Aged over 40 years
  - Diabetes for >10 years
  - Established nephropathy
  - Other CVD risk factors
- CKD eGFR < 60 mL/min/1.73m² and/or albuminuria
- Age ≥85 years if appropriate consider co-morbidities, frailty & life expectancy

Discuss the benefits of lifestyle changes and identify and address all modifiable risk factors - smoking, diet, obesity, alcohol intake, physical activity, blood pressure and HbA1c.

Offer people the opportunity to have their risk of CVD assessed again after they have tried to change their lifestyle (where applicable)

Consider additional risk factors, if present, together with QRISK score (treated for HIV, severe mental illness, taking medicines that cause dyslipidaemia, systemic inflammatory disorder (e.g. SLE), impaired fasting glycaemia, recent change in risk factors)

PRIMARY PREVENTION

If lifestyle modification is ineffective or inappropriate, discuss the risks and benefits of statins, and offer treatment based on an informed shared-decision.

Atorvastatin 20mg daily

- Measure full lipid profile again after 2-3 months (non-fasting).
- High intensity statin treatment should achieve reduction of non-HDL-C > 40% from baseline. If not achieved after 2-3 months;
  - Discuss treatment adherence, timing of dose, diet and lifestyle
  - If at higher risk (based on comorbidities, risk score or clinical judgement – see page 2 *'Additional Risk Factors'*) consider increasing the dose every 2-3 months up to a maximum dose of atorvastatin 80mg daily.
  - For how to increase in people with CKD see *'Special Patient Populations'* (page 2).

- If patients on a high-intensity statin have side effects, offer a lower dose or an alternative statin (see page 2 *'Extent of lipid lowering with available therapies'*)
- If maximum tolerated dose of statin does not achieve non-HDL-C reduction > 40% of baseline value after 2-3 months consider adding Ezetimibe 10mg daily (NICE TA385)
- If statin treatment is contraindicated or not tolerated;
  - See AAC Statin Intolerance Algorithm for advice regarding adverse effects (click here)
  - Ezetimibe 10mg monotherapy may be considered. Assess response after 2-3 months.
  - Ezetimibe 10mg/bempedoic acid 180 mg combination may be considered when ezetimibe alone does not control non-HDL-C/LDL-C (NICE TA694).

If non-HDL-C reduction remains < 40% of baseline despite maximal tolerated lipid lowering therapy (including people with intolerances and contraindications) consider referral to specialist lipid management clinic according to local arrangements

SEVERE HYPERLIPIDAEMIA. DIAGNOSIS AND REFERRAL

If TC>7.5mmol/L and/or

LDL-C

>4.9mmol/L, Triglycerides <5mmol/L,

A personal and/or family

history of confirmed CHD (<60 years)

and no secondary causes:

suspect familial hypercholesterolaemia

Do not use QRISK risk assessment tool

Refer to Lipid Clinic for further assessment

Also refer to Lipid Clinic:

if TC>9.0mmol/L and/or

LDL-C >6.5mmol/L and/or

non-HDL-C >7.5mmol/L

or

Triglycerides >10mmol/L

(regardless of family history) (page 2)

SECONDARY PREVENTION

Offer statin therapy to adults with CVD, this includes CHD, angina, Acute Coronary Syndrome (MI or unstable angina), revascularisation,stroke or TIA, or peripheral arterial disease. Do not delay statin treatment if a person has acute coronary syndrome. Take a lipid sample on admission (within 24 hours).

Identify and address all modifiable risk factors - smoking, diet, obesity, alcohol intake, physical activity, blood pressure and HbA1c.

SECONDARY PREVENTION

Do not delay statin treatment in secondary prevention while managing modifiable risk factors. Prescribe a high intensity statin:

Atorvastatin 80mg daily +/- Ezetimibe*

Use a lower dose of atorvastatin if there is a potential drug interaction, high risk of or experiencing adverse effects, or patient preference.

Offer atorvastatin 20mg + Ezetimibe 10mg if CKD (people with GFR< 60 mL/min/1.73m²).

*Consider initiation of ezetimibe in addition to statin therapy where; there is a history of recurrent CVD event(s) or, presence of diabetes mellitus or, it is unlikely that target non-HDL cholesterol levels will be achieved with statin monotherapy (in light of baseline lipid profile) or, statin dose is restricted (e.g. due to intolerance, renal function, frailty)

- Measure full lipid profile again after 2-3 months (non-fasting).
- Aim for a non-HDL-C of < 2.5 mmol/L or LDL-C of < 1.8 mmol/L (JBS3)
- LDL and non-HDL-C levels should be reduced as much as possible. Personalise targets based on clinical judgement and an informed discussion with patient. ***See Titration Thresholds / Targets* (page 2)**

- If high intensity statin treatment does not achieve expected reduction (see table on page 2) after 2 to 3 months
  - Discuss treatment adherence, timing of dose, diet and lifestyle measures
  - If started on less than atorvastatin 80mg and the person is judged to be at higher risk (based on co-morbidities or clinical judgment), consider increasing to 80mg atorvastatin or maximally tolerated dose. For how to increase in people with CKD see *'Special Patient Populations'* (page 2).
- If patients on a high-intensity statin have side effects, offer a lower dose or an alternative statin (see page 2 *'Extent of lipid lowering with available therapies'*)

Escalating lipid lowering treatment

If maximum tolerated dose of statin does not control non-HDL-C/LDL-C to target after 2-3 months - confirm statin adherence, then consider the following escalation of treatment options based on shared decision making with the patient.

- Ensure an informed discussion between the clinician and the person about the risks and benefits of additional lipid-lowering treatments.
- Take into account the person's preferences, the presence of comorbidities, whether they are on multiple medications, whether they have frailty and their life expectancy.
- Do not routinely de-escalate lipid lowering therapies when levels are lower than NICE target, except if clinically indicated or based on the person's needs or preferences

If statin treatment is contraindicated or not tolerated - follow AAC Statin Intolerance Algorithm for advice regarding adverse effects (click here).

If statin intolerance is confirmed, consider:

- **Ezetimibe 10mg** monotherapy. Assess response after 3 months (TA385)
- **Ezetimibe 10mg/bempedoic acid 180 mg** combination when ezetimibe alone does not control non-HDL-C to target. (NICE TA694)

If LDL-C remains ≥2.6mmol/L (on repeat lipid test) despite maximally tolerated lipidlowering therapies, consider Injectable therapies - assess eligibility criteria (TA393/394, TA733)

Ezetimibe 10mg daily (NICE TA385). Reassess after three months. If LDL-C remains ≥2.6mmol/L; consider **injectable therapies** - assess eligibility (TA393/394, TA733)

** Inclisiran and PCSK9i should not be prescribed concurrently

Injectable therapies**

- **Inclisiran** - if fasting LDL-C ≥ 2.6mmol/L despite maximum tolerated lipid lowering therapy (TA733)

OR

- **PCSK9i** - see overleaf for LDL-C thresholds. (TA393/4)

If eligibility criteria not met, consider **ezetimibe 10mg daily** (if not previously considered)

Additional CV risk reduction considerations - check fasting triglycerides levels and consider icosapent ethyl. See triglycerides section overleaf.

Consider ezetimibe in addition to the maximum tolerated intensity and dose of statin to reduce CVD risk further, even if the lipid target for secondary prevention of CVD is met. (NG238)

MANAGEMENT

This guidance applies to new patients with CVD and may also be taken into consideration for those on statins at their annual review. If 40% reduction of non-HDL-C, or target levels are not achieved, offer high intensity statins. Discuss with people who are stable on a low- or medium-intensity statin the likely benefits and potential risk of side effects if changed to a high-intensity statin when they have a medication review and agree with the person whether a change is needed.

Ezetimibe, alirocumab, evolocumab or inclisiran can be added when patients' LDL-C levels are not at target with the maximally tolerated dose of statins. If statins are contraindicated or not tolerated and ezetimibe alone does not control LDL-C to target, bempedoic acid with ezetimibe is an option. Do not offer a fibrate, nicotinic acid, bile acid binder or omega-3 fatty acids alone or in combination with statin, for the prevention of CVD (check NICE NG238 and TA805 for exceptions).

PRIMARY PREVENTION RISK ASSESSMENT

Use QRISK3 version of the calculator (or QRISK2 if not available).

- Do not use this risk assessment tool for people with established CVD or those who are already at high risk of developing CVD because of FH or other inherited disorders of lipid metabolism.
- Do not use a risk assessment tool to assess CVD risk in people with type 1 diabetes, or eGFR < 60 mL/min/1.73 m² and/or albuminuria (as already at high risk of developing CVD).
- Consider people aged ≥ 85 at increased risk of CVD because of age alone particularly people who smoke or have hypertension.
- If QRISK <10% over next 10 years, do not rule out treatment if there is an informed preference for taking a statin or a concern that risk may be underestimated.
- Consider a lifetime risk tool (e.g. QRISK3-lifetime) to inform discussions on CVD risk and to motivate lifestyle changes, particularly for people with a 10-year score < 10%, and people < 40 who have CVD risk factors.

Additional Risk Factors

Note, standard CVD risk scores including QRISK may underestimate risk in people who have additional risk because of underlying medical conditions or treatments. These include, but not limited to the following group of people;

- obesity increases CVD risk (NICE CG189)
- treated for HIV
- severe mental illness
- taking medicines that can cause dyslipidaemia such as antipsychotic medication, corticosteroids or immunosuppressant drugs
- already taking medicines to treat CVD risk factors
- autoimmune disorders such as SLE, and other systemic inflammatory disorders
- non-diabetic hyperglycaemia
- significant hypertriglyceridaemia (fasting triglycerides 4.5-9.9mmol/L)
- recent risk factor changes e.g. quit smoking, BP or lipid treatment

Consider socio-economic status as an additional factor contributing to CVD risk (if not already in the risk calculator).

SPECIAL PATIENT POPULATIONS

Type 1 Diabetes

While NICE recommends offering statins to patients with Type 1 diabetes as detailed in the algorithm, it also states to consider statins in those aged 18 to 40 with type 1 diabetes, including those who have had diabetes for ≤ 10 years

Chronic Kidney Disease

Offer atorvastatin 20mg for the primary or secondary prevention of CVD to people with CKD (eGFR less than 60 mL/min/1.73m² and/or albuminuria)

Increase the dose if target is not achieved and eGFR is 30 mL/min/1.73m² or more.

Agree the use of higher doses with a renal specialist if eGFR is less than 30 mL/min/1.73m²

Statins in Pregnancy and Lactation

Statins should be stopped 3 months before attempting to conceive and not be restarted until breastfeeding is finished. Stop statins if pregnancy is a possibility.

ABBREVIATIONS

ALT: alanine aminotransferase
AST: aspartate aminotransferase
CHD: coronary heart disease
CKD: chronic kidney disease
FH: familial hypercholesterolaemia
JBS: Joint British Societies
LDL-C: low density lipoprotein cholesterol
non-HDL-C: non-high density lipoprotein cholesterol
PCSK9i: proprotein convertase subtilisin kexin 9 monoclonal antibody inhibitor
SLE: systemic lupus erythematosus
SPC: summary of product characteristics
TC: total cholesterol

EXTENT OF LIPID LOWERING WITH AVAILABLE THERAPIES

Approximate reduction in LDL-C					
Statin dose mg/day	5	10	20	**40**	**80**
Fluvastatin			21%	27%	33%
Pravastatin		20%	24%	29%	
Simvastatin		27%	32%	37%	42%
Atorvastatin		37%	43%	49%	55%
Rosuvastatin	38%	43%	48%	53%	
Atorvastatin + Ezetimibe 10mg		52%	54%	57%	61%

Low intensity statins will produce an LDL-C reduction of 20-30%

Medium intensity statins will produce an LDL-C reduction of 31-40%

High intensity statins will produce an LDL-C reduction above 40%

Simvastatin 80mg is not recommended due to risk of muscle toxicity

- **Rosuvastatin** may be used as an alternative to atorvastatin if compatible with other drug therapy. Some people may need a lower starting dose (see BNF).
- Low/medium intensity statins should only be used if intolerance or drug interactions.
- **Ezetimibe** when combined with any statin is likely to give greater reduction in non-HDL-C or LDL-C than doubling the dose of the statin.
- **PCSK9i** (NICE TA393, TA394) alone or in combination with statins or ezetimibe produce an additional LDL-C reduction of approximately 50% (range 25-70%).
- **Bempedoic acid** when combined with ezetimibe (TA694) produces an additional LDL-C reduction of approximately 28% (range 22-33%).
- **Inclisiran** (TA733) alone or in combination with statins or ezetimibe produces an additional LDL-C reduction of approximately 50% (range 48-52%) but no clinical outcome evidence is currently available.

MONITORING

Baseline Measurements

In addition to full lipid profile, measure renal, thyroid and liver profiles (including albumin) and HbA1c to exclude secondary causes and co-morbidities.
Measure baseline liver transaminase (ALT or AST) before starting a statin.
Measure CK if unexplained muscle pain before starting a statin.
CK should not be measured routinely especially if a patient is asymptomatic.

	Primary Prevention		Secondary prevention	
	Lipid Profile	ALT or AST	Lipid Profile	ALT or AST
Baseline	✓	✓	✓	✓
2-3 months	✓	✓	✓	✓
6-9months	If targets are not met, and up-titration is agreed, repeat full lipid profile and ALT or AST within 2-3 months of each up-titration of statin dose or addition of ezetimibe as required			
12 months	✓	✓	✓	✓
Yearly	✓*		✓*	

Provide annual medication reviews for people taking statins to discuss effectiveness of therapy, medicines adherence, lifestyle modification and address CVD risk factors.

**Offer in secondary prevention, and consider in primary prevention an annual lipid profile to inform the discussion around effectiveness of lipid lowering therapy and any medicines non- adherence.*

Monitoring

Repeat lipid profile.
Do not stop statins because of an increase in blood glucose or HbA1c

Advise that the risk of muscle pain, tenderness or weakness associated with statins is small and the rate of severe muscle adverse effects (rhabdomyolysis) is extremely low.

Liver Transaminases

Measure liver transaminase within 3 months of starting treatment and then within 2-3 months of every additional up titration and then again at 12 months, but not again unless clinically indicated.

If ALT or AST are greater than 3 times the upper limit of normal then do not initiate a statin or discontinue statin therapy already prescribed and repeat the LFTs in a month.

If ALT or AST are elevated but are less than 3 times the upper limit of normal then:

- Do not routinely exclude from statin treatment
- Continue the statin and repeat in a month.
- If they remain elevated but are less than 3 times the upper limit of normal then continue statin and repeat again in 6 months.

TITRATION THRESHOLD / TARGETS

	NICE titration threshold	JBS3**
Primary prevention	Escalate lipid lowering therapy if non-HDL-C reduction from baseline ≤ 40%	non-HDL-C <2.5mmol/L (LDL-C <1.8mmol/L)
Secondary Prevention	Aim for an LDL-C of ≤ 2.0 mmol/L, or non-HDL-C of ≤ 2.6 mmol/L*	
FH	Optimise lipid lowering therapy to achieve at least 50% reduction in LDL-C (or non-HDL-C.)	

*Consider ezetimibe to reduce CVD risk further, even if the NICE lipid target for secondary prevention of CVD is met.
**LDL-C and non-HDL-C levels should be reduced as much as possible in people with CVD. Consider a personalised target, as clinically indicated, e.g. JBS3 consensus recommendation

SPECIALIST SERVICES

Scope of specialist service available locally may include; lipid clinic, PCSK9i clinic (offering initiation and subsequent follow up), FH genetic diagnosis and cascade testing. NICE eligibility criteria for PCSK9i and LDL-C thresholds are summarised below.

NICE TA393 Alirocumab NICE TA394 Evolocumab	Without CVD	With CVD	
		High risk [1]	Very high risk [2]
Primary non-FH or mixed dyslipidaemia	Not recommended	LDL C > 4.0 mmoL/L	LDL C > 3.5 mmoL/L
Primary heterozygous-FH	LDL C > 5.0 mmoL/L	LDL C > 3.5 mmoL/L	

[1] History of any of the following: ACS; coronary or other arterial revascularisation procedures; CHD, ischaemic stroke; PAD. [2] Recurrent CV events or CV events in more than 1 vascular bed (that is, polyvascular disease).

Bempedoic acid/ezetimibe and inclisiran are available in primary care and do not require initiation by specialist services.' PCSK9i may be available for prescribing in primary care: see local initiation pathways.

TRIGLYCERIDES

Triglyceride concentration	Action
Greater than 20mmol/L	**Refer to lipid clinic for urgent specialist review** if not a result of excess alcohol or poor glycaemic control. At risk of acute pancreatitis.
10 - 20mmol/L	Repeat the TG measurement with a fasting test (after an interval of 5 days, but within 2 weeks); review and address potential secondary causes of hyperlipidaemia. Seek specialist advice if the TG concentration remains > 10mmol/L. At risk of acute pancreatitis
4.5 - 9.9mmol/L	If non-fasting triglycerides are greater than 4.5mmol/L, repeat with a fasting TG measurement Be aware that the CVD risk may be underestimated by risk assessment tools, optimise the management of other CVD risk factors present and seek specialist advice if non-HDL-C concentration is > 7.5 mmol/L.

Icosapent ethyl (TA805)

- Check fasting triglycerides levels.
- Manage secondary causes of hypertriglyceridaemia.
- Consider icosapent ethyl (TA805) if patient has established cardiovascular disease (secondary prevention) **and**
  - on statins and fasting TG ≥ 1.7mmol/L and LDL-C between 1.04 and ≤2.6mmol/L
- See table above and refer as appropriate.

STATIN INTOLERANCE

Statin intolerance is defined as clinically significant adverse effects from statin therapy that are considered an unacceptable risk to the patient or that may result in adherence to therapy being compromised.

For people who are intolerant of the recommended statin treatment see the NHSE AAC statin intolerance algorithm, available on the NHSE AAC page (Click here)

Adapted from NHSE/AAC Summary of national guidance for lipid management (updated March 2024)

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"This summary accurately reflects NICE guidance and JBS3 recommendations", NICE March 2024