

Lipid Management: Medicines Optimisation Pathways

Developed by SEL Cardiovascular Medicines Working Group on behalf of the SEL Integrated Medicines Optimisation Committee (IMOC) and following guidance from the National Institute for Health and Care Excellence (NICE), NHS England/Accelerated Access Collaborative (AAC) and UCL Partners

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South East London Integrated Medicines Optimisation Committee (SEL IMOC). A partnership between NHS organisations in South East London Integrated Care System: NHS South East London (covering the boroughs of Bexley/Bromley/Greenwich/ Lambeth/Lewisham and Southwark) and GSTFT/KCH /SLaM/ Oxleas NHS Foundation Trusts and Lewisham & Greenwich NHS Trust

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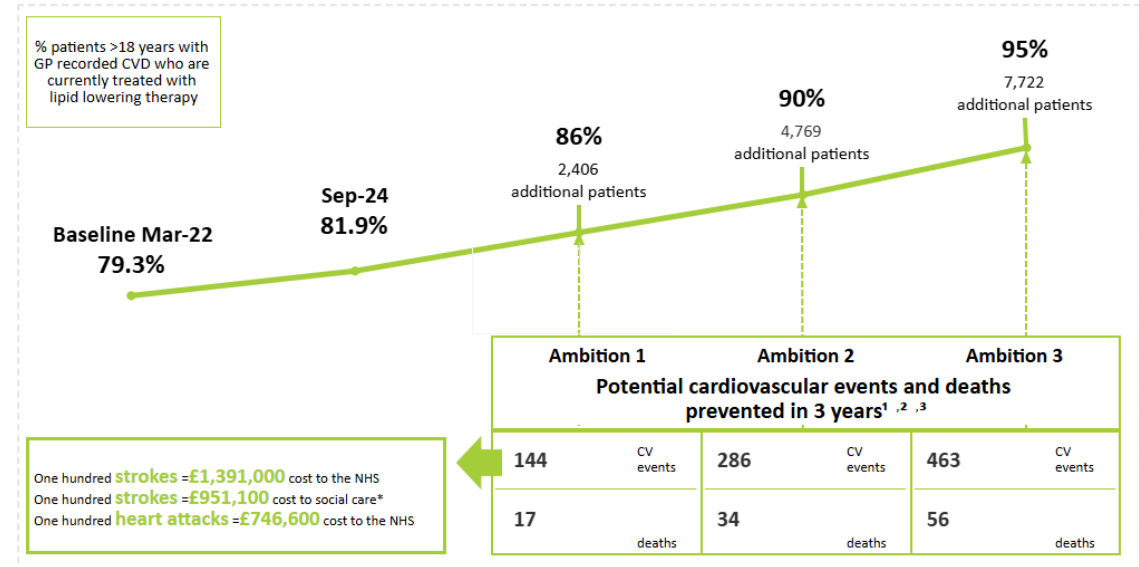
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Why is Lipid Management Important?



Size of the Prize- South East London ICB
Cholesterol Optimisation to Prevent Heart Attacks and Strokes at Scale



For CVDPO03CHOL: Patients with no GP recorded CVD and a GP recorded QRISK score of 20% or more, who are currently treated with lipid lowering therapy:

- NHS South East London Integrated Care Board achievement (June 2024) = 61% (national ambition 65%*).
- At least 2,547 people at high risk of a cardiovascular event would need to be treated with lipid lowering therapy to meet the national ambition

For CVDPO12CHOL: Patients with GP recorded CVD (narrow definition), whose most recent blood cholesterol level is LDL-cholesterol less than or equal to 2.0 mmol/l or non-HDL cholesterol less than or equal to 2.6 mmol/l, in the preceding 12 months:

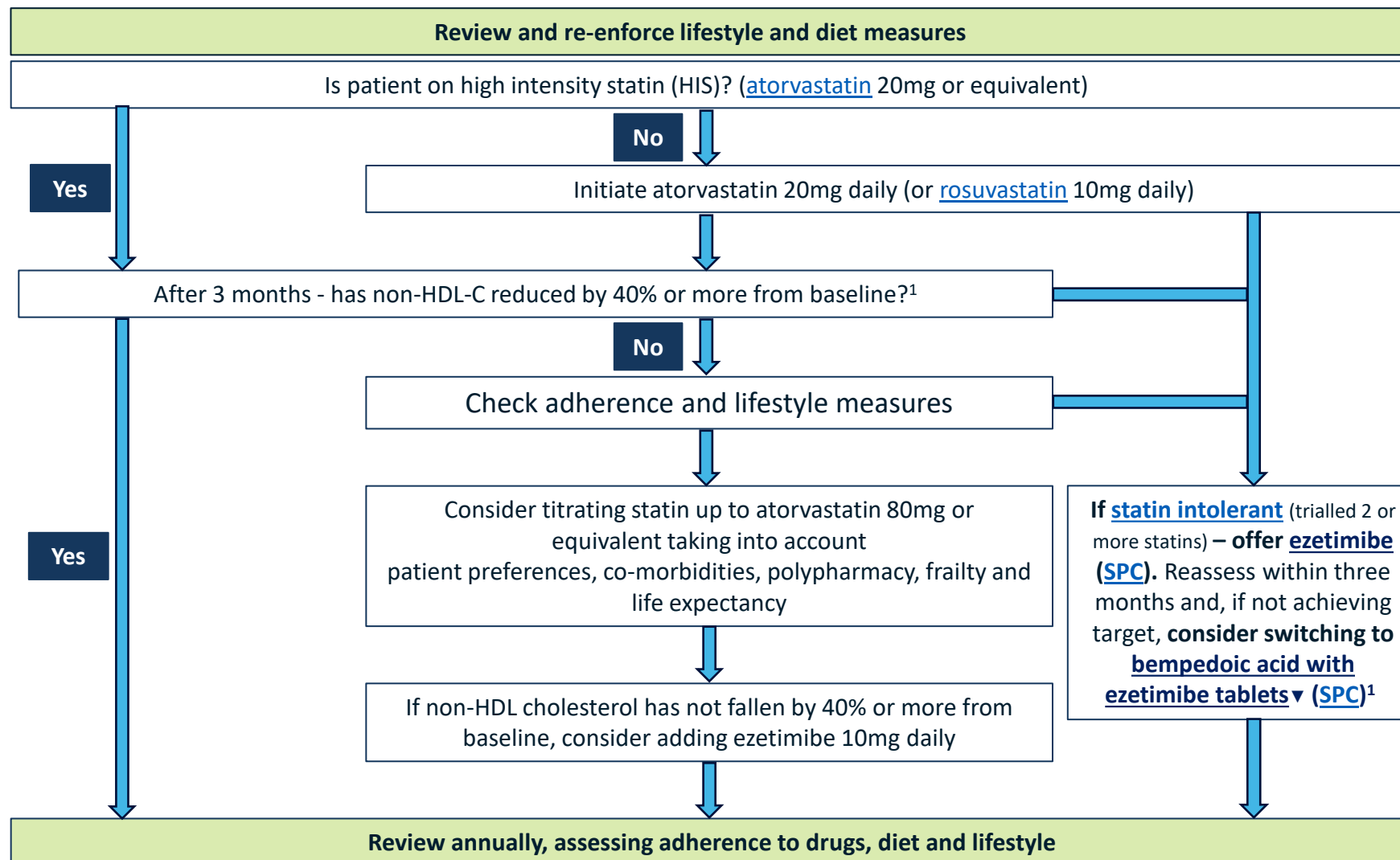
- NHS South East London Integrated Care Board achievement (June 2024) = 38%
- At least 36,215 people with known CVD have not achieved recommended lipid-lowering levels

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Lipid Optimisation Pathway for Patients with High Cardiovascular Risk – Primary Prevention



Lipid lowering therapy should be offered to all patients with a QRISK $\geq 10\%$ after addressing lifestyle modification.⁴

Patients with the following conditions are high CVD risk and **require consideration** for a high intensity statin (HIS) regardless of QRISK: **familial hypercholesterolaemia (FH)**, **type 1 diabetes mellitus (T1DM)**, **chronic kidney disease (CKD)** and/or albuminuria.

Offer HIS to patients with T1DM and age > 40 years or patients with T1DM >10 years or nephropathy or with other CVD risk factors
[NICENG238](#)

Offer HIS to patients with Type 2 DM with CV risk $\geq 10\%$ and to **all patients with CKD**

Consider additional CVD risk factors, if present, together with QRISK score

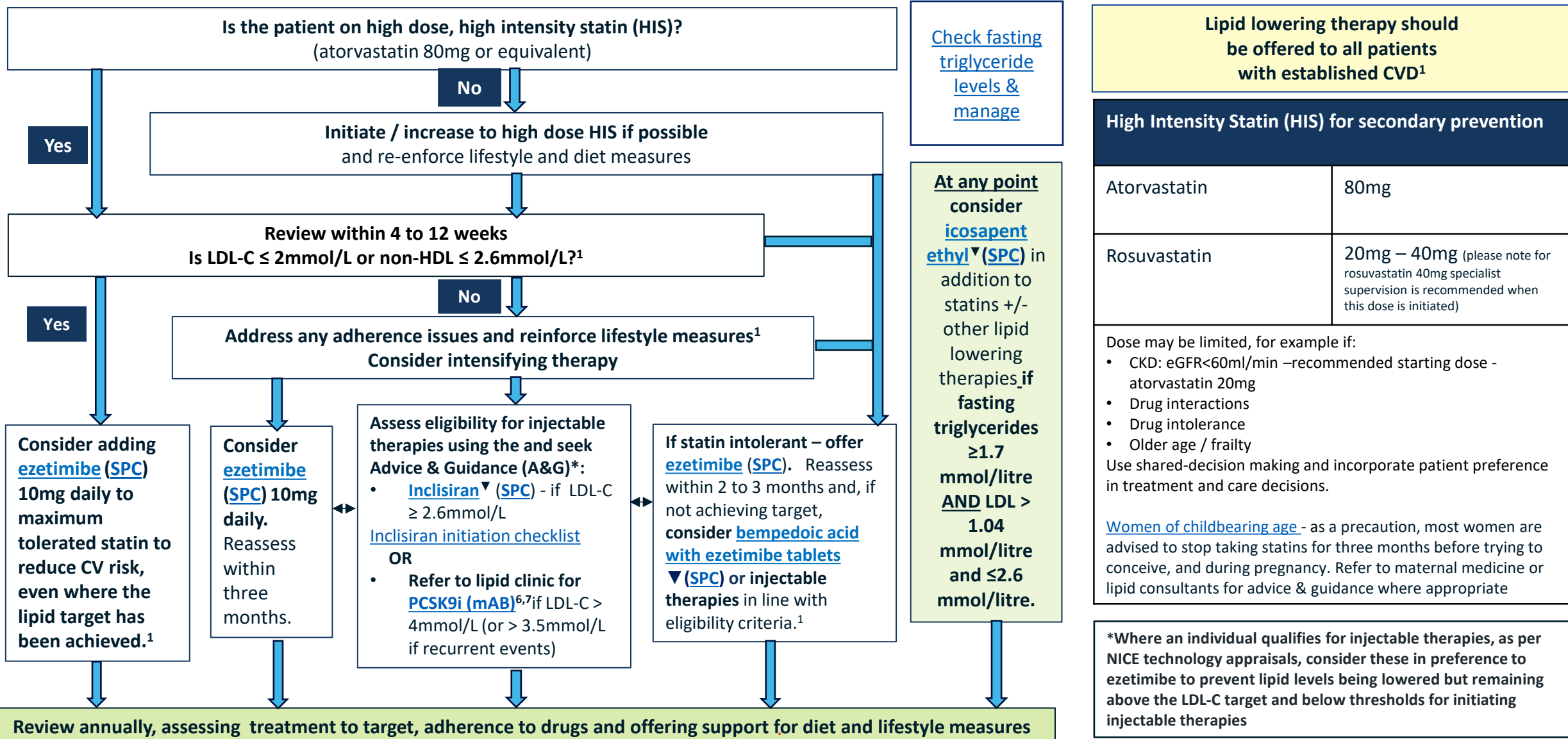
People living with HIV (PLWH)

All people living with HIV aged 40 years or older should be offered a statin for primary prevention of CVD irrespective of lipid profile or estimated CVD risk⁵.

Flowchart & dosage guidance of lipid - lowering management and HIV specialist contact details can be found [here](#)

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Lipid Optimisation Pathway for Patients with Established Cardiovascular Disease - Secondary Prevention



Statin Intolerance Pathway

Statin intolerance is defined as the presence of clinically significant adverse effects that represent an unacceptable risk to the patient or that may reduce adherence to therapy (see [AAC pathway](#))

Discuss with the patient if signs and symptoms are statin intolerance or due to a statin reluctance/non-adherence. **Consider that a statin at any dose reduces CV risk** - if a patient cannot tolerate a high intensity statin (HIS), aim to treat with a maximum tolerated dose of a statin, but if symptoms persist consider alternative options/lipid clinic referral.



For Statin Related Muscle (SRM) symptoms: symmetrical pain/weakness in large proximal muscle groups, worsened by exercise. Measure creatine kinase (CK). See [here](#) for muscle symptoms pathway.



If CK normalises and symptoms have resolved for at least 2 weeks, then rechallenge: Offer a low/moderate dose of HIS e.g. atorvastatin 10 - 20mg daily or rosuvastatin 5 - 10mg daily. Please note: Non-standard dosing may be recommended by specialist clinics e.g. rosuvastatin 5mg weekly or three times a week (off label use but accepted practice).



If tolerating [ezetimibe](#) (SPC) but not achieving lipid lowering targets: consider [inclisiran](#) (SPC) following specialist advice if for secondary prevention or consider initiating [bempedoic acid](#) 180mg daily (SPC).

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Shared Decision-Making Resources

Benefits per 10,000 people taking statin for 5 years	Events avoided
Secondary Prevention: Major CV events* avoided in patients with pre-existing CVD & a 2mmol/L reduction in LDL	1,000
Primary Prevention: Major CV events* avoided in patients with no pre-existing CVD & a 2mmol/L reduction in LDL	500

*Major CV events = CV death, non-fatal myocardial infarction and non-fatal stroke

Shared decision-making resources:

- [BHF information on statins](#)
- [Heart UK: Information on statins](#)
- [NICE shared decision-making guide](#)
- [Statins - side effects](#)

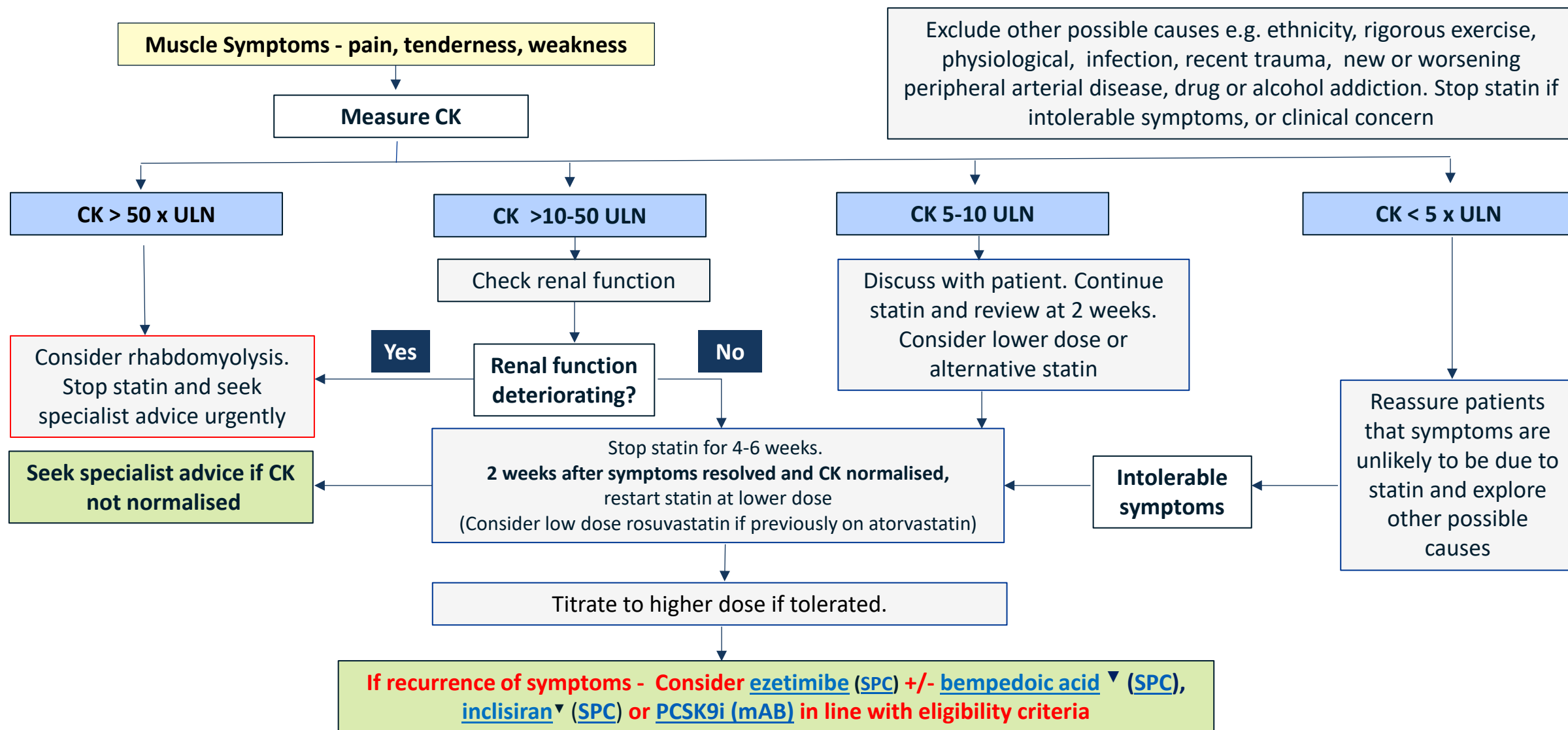
Adverse events per 10,000 people taking statin for 5 years	Adverse events
Myopathy	5
Haemorrhagic Strokes (NICE CKS) The recommendation to avoid use of statins for secondary prevention in people with a history of intracerebral haemorrhage has been removed and information added to the basis to explain this change, based on a large trial which demonstrated no difference in adverse impact. The topic was also aligned with the recommendations contained in the updated NICE guideline (NG236)	5-10
Diabetes Cases	50-100

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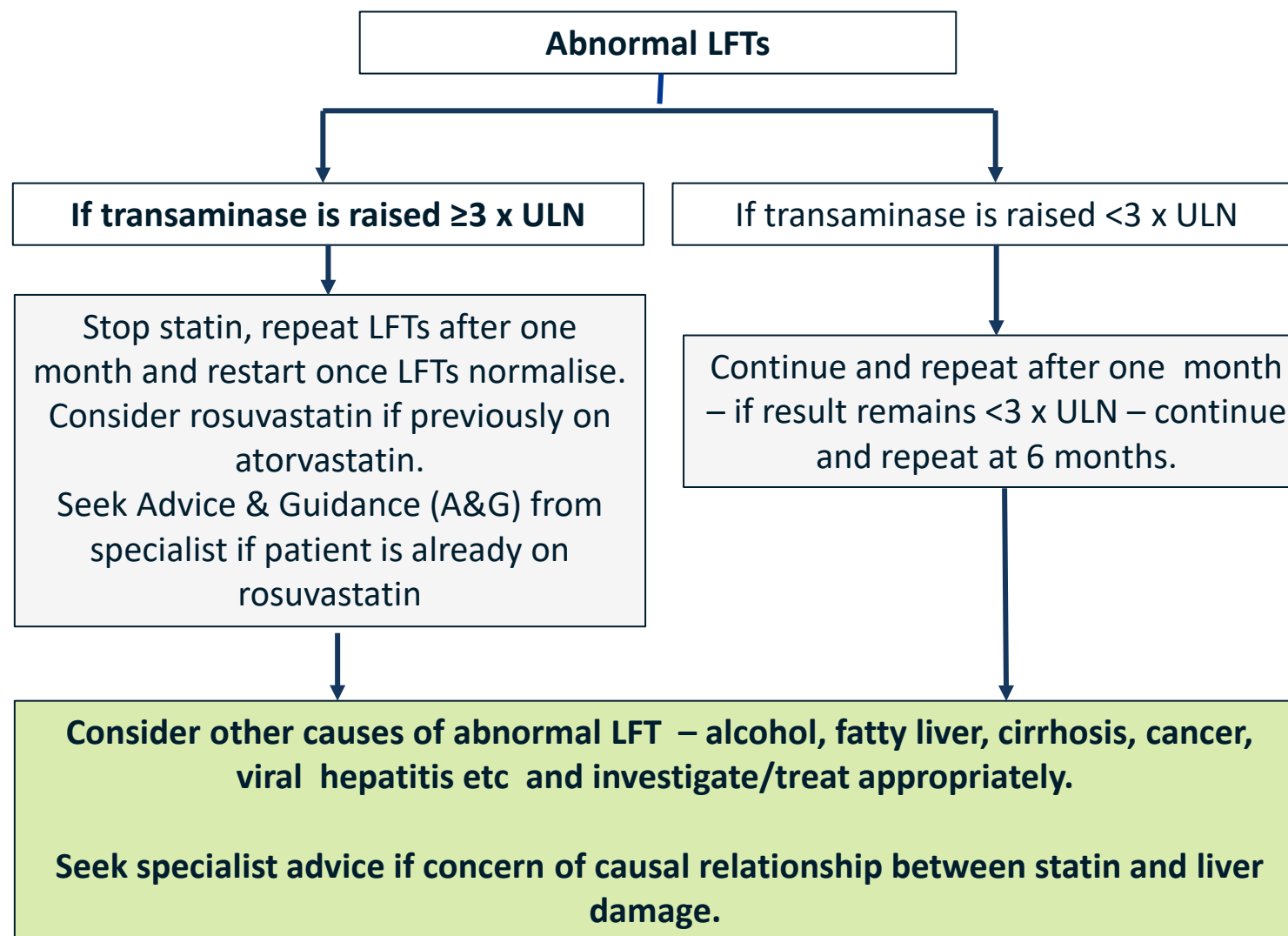
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Muscle Symptoms Pathway



Abnormal Liver Function Test (LFT) Pathway



Check liver function (ALT/AST) at baseline, within 3 months and at 12 months after initiation of statin therapy.

Do not routinely exclude from statin therapy people who have liver transaminase levels that are raised but < 3 x ULN

Most adults with fatty livers are likely to benefit from statins and this is not a contraindication.

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Lipid Management Options and LDL-C Reduction:

Approximate reduction in LDL-C						High intensity statins (HIS) reduce LDL-C >40% (highlighted green) and are more effective at preventing cardiovascular events than low / medium intensity statins. NICE/AAC recommends atorvastatin and rosuvastatin as HIS. *Simvastatin 80mg is not recommended due to muscle toxicity risk.
Drug / daily dose	5mg	10mg	20mg	40mg	80mg	
Pravastatin (SPC) (3rd line statin if atorvastatin and rosuvastatin are inappropriate)		20%	24%	29%		
Simvastatin (SPC) (3rd line statin if atorvastatin and rosuvastatin are inappropriate)		27%	32%	37%	42%*	
Atorvastatin (SPC)		37%	43%	49%	55%	
Rosuvastatin (SPC)	38%	43%	48%	53% specialist initiation		
Atorvastatin with Ezetimibe (SPC) 10mg		52%	54%	57%	61%	
Ezetimibe 10mg with Bempedoic acid 180mg (SPC)	Approx. 38%*					*17-18% LDL-C lowering for bempedoic acid, ezetimibe 21% approximations vary in current study data.

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Recommended Criteria For Referral to Lipid Clinic (SEL Hospital and Community Settings)



Hospital lipid clinic	Referral Criteria	Community lipid service	Referral criteria (Lambeth, Southwark and Bexley boroughs)
Severe hypercholesterolaemia	Cholesterol >9.0 mmol/L (or non-HDL-C > 7.5 mmol/L) regardless of existing heart disease / family history	Statin intolerance	Intolerance of 3 or more statins OR Severe adverse reaction to one statin AND not meeting target reductions in LDL-C/ non-HDL-C on ezetimibe 10mg daily
Suspected familial hypercholesterolaemia (FH)	Cholesterol >7.5 mmol/L and LDL-C >5.0 mmol/L AND - Premature CVD (age <60yrs) in the patient OR - Family history: 1st degree relative MI < 60 years old , 2nd degree relative MI <50 years old OR - Presence of tendon xanthomata	Secondary prevention of CVD	Unable to meet target reductions in LDL-C or non-HDL-C despite maximal doses of statins + ezetimibe
Family screening	Cascade screening from identified patient with familial hypercholesterolaemia with a genetic diagnosis of FH	Medicines adherence support	Persistent non-adherence to drug therapies despite best efforts of the GP practice
Severe Hypertriglyceridemia	- Triglyceride > 20 mmol/L OR - Triglyceride 10 - 20 mmol/L which persists on a fasting lipid profile (2 samples 1 week apart) OR - Triglyceride 4.5 - 9.9 mmol/L WITH non-HDL cholesterol > 7.5 mmol/L	Please note the community clinic will also undertake follow up of specific patients reviewed in secondary care specialist lipids services and discharged with a management plan suitable for primary care. Currently community clinics run by GSTT are available in Lambeth, Southwark and Bexley boroughs. See here for lipid clinic contact details	
Statin intolerance	Intolerance of 3 or more statins OR Severe adverse reaction to one statin AND not meeting target LDL-C/ non-HDL-C on ezetimibe 10mg daily. For primary prevention statin intolerance please refer to community lipid clinic (where available) in the first instance.		
Secondary prevention of CVD	Unable to meet target reductions in LDL-C or non-HDL-C despite maximal doses of statins + ezetimibe		

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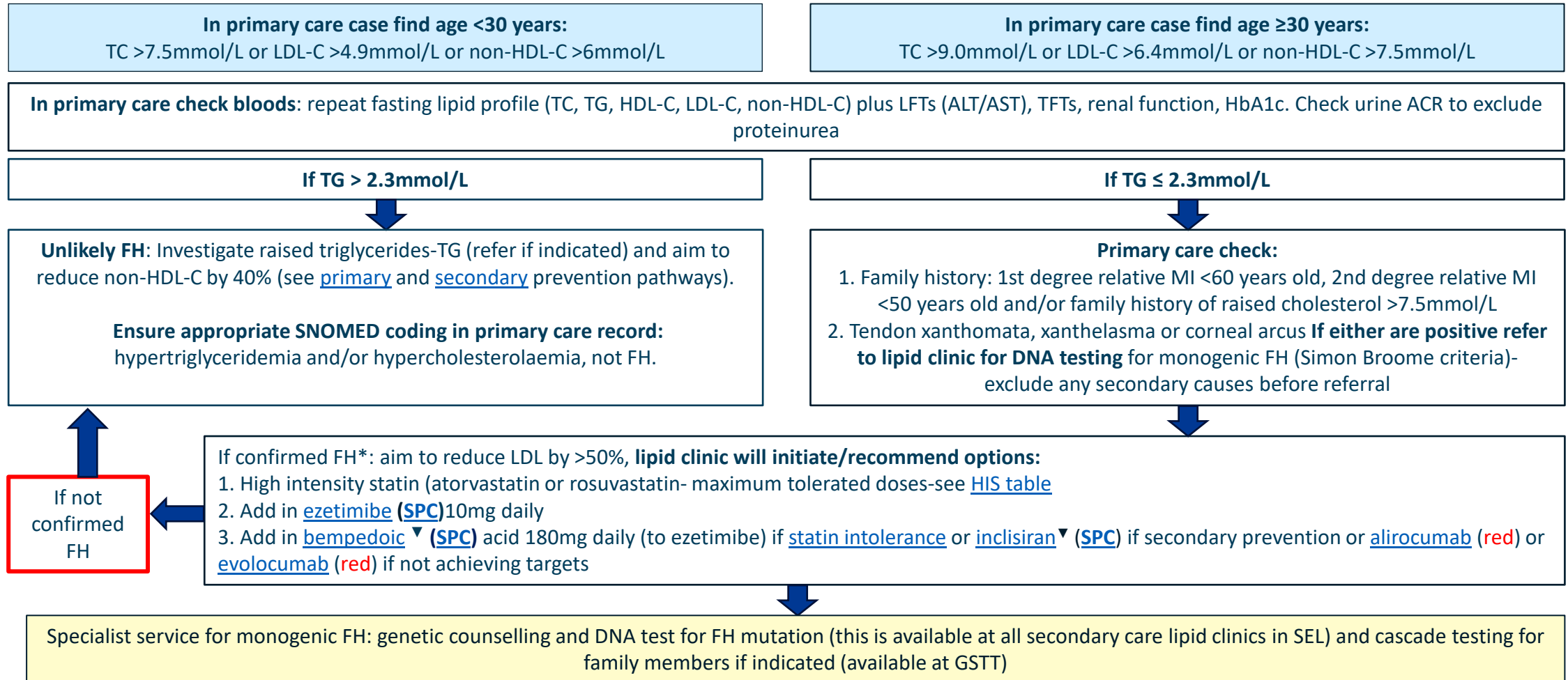
Summary of Lipid Lowering Therapy

(*CV events defined as death, non-fatal MI and non-fatal stroke)

Lipid lowering therapy	NICE approved indication	Administration	LDL – lowering effect	CV outcome data	LT safety data
High intensity statin Atorvastatin (or Rosuvastatin) (Green)	Primary prevention, Secondary prevention, Familial hypercholesterolaemia (FH)	Oral tablet given once daily	High intensity statins can lower LDL-C by 40% -55% (depending on agent and dose) ⁸	Multiple outcome studies confirming CV outcomes benefit across a wide range of patient cohorts. For every 10,000 people treated for 5 years: - In secondary prevention (established CVD): 1,000 heart attacks, strokes or deaths avoided. NNT over 5 years = 10 - In primary prevention: 500 heart attacks, strokes or deaths avoided⁷. NNT over 5 years = 20	Long term safety data has been well established over 30 years. For every 10,000 people treated for 5 years: 5 cases of myopathy 5-10 haemorrhagic strokes 50-100 new cases of diabetes ⁹
Ezetimibe (Green)	With statin to reduce CV risk: primary and secondary prevention, or if statin intolerance, FH	Oral tablet given once daily	An additional LDL-C reduction of 24% in combination with statins ¹⁰	Two CV outcomes studies in secondary prevention on top of statins ^{11,12} For every 10,000 people with CVD treated for 7 years: Approximately 200 major CV events* avoided. NNT 50 for preventing major cardiovascular event over 7 years. ¹³	Long term safety data has been well-established over 20 years. Side effects are usually mild and transient ¹⁴ .
Bempedoic acid ▼ (Amber1) Bempedoic acid with ezetimibe ▼ (Green)	With ezetimibe in statin intolerance if ezetimibe alone does not control LDL-C well enough	Oral tablet given once daily	An additional LDL-C reduction of approximately 28% (range 22-33%) when combined with ezetimibe ¹⁵	One CV outcome study . For every 10,000 patients treated for 3 years. Approximately 130 major CV events* avoided. ¹⁶ NNT = 77	Safety data from trials of up to 3 years. Increased risk of hyperuricemia (NNH = 19) , gout (NNH = 100) and cholelithiasis (NNH = 100) reported. ¹⁶
Inclisiran (PCSK9i) ▼ (Amber1)	Secondary prevention in patients who meet eligibility criteria	S/C injection administered every six months, once stabilised	An additional LDL-C reduction of approximately 50% (range 48-52%) alone or in combination with statins or ezetimibe ¹⁷	No CV outcomes data. On-going studies due to report in 2026.	Short term safety data from trials of up to 2 years. Injection site reactions reported (NNH = 12).
Icosapent ethyl ▼ (Amber 2)	Secondary prevention in patients on statins who meet eligibility criteria	Two capsules taken orally twice daily with food	An 18% reduction in triglyceride levels when added to statin therapy	One CV outcomes study in secondary prevention. Given in addition to statin therapy. For every 10,000 people treated for 4.9 years approximately 370 major CV events would be avoided. NNT over 4.9 years =28 ¹⁸	Safety data established in a trial over 5 years. Small increase in hospitalisation with atrial fibrillation / flutter (NNH = -100) and increased bleeding (NNH = 167) ¹⁸
PCSK9i (Alirocumab / Evolocumab) (Red)	Secondary prevention and FH in patients who meet eligibility criteria	SC injection every 2 weeks (can be self-administered)	An additional LDL-C reduction of approximately 50% (range 25-70%) alone or in combination with statins or ezetimibe. ^{6,7}	Two CV outcomes studies in secondary prevention on top of statins ^{19,20} For every 10,000 people treated for 2.5 years: Approximately 150 major CV events* avoided. NNT over 2.5 years = 65 ²¹	Safety data has been established over 7 years . Injection site reaction reported (NNH - 167 ¹⁹ and 58 ²⁰).

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Familial Hypercholesterolaemia (FH) Pathway

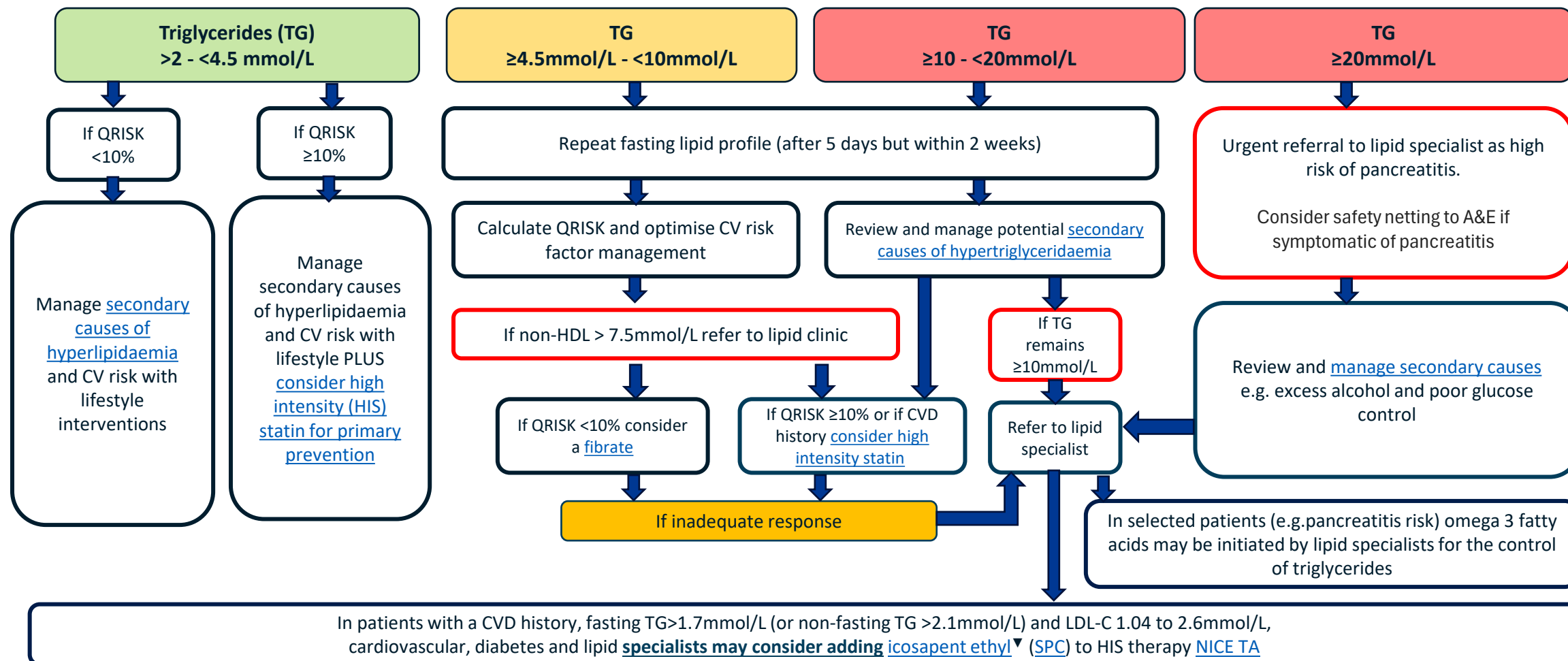


*Ensure correct coding in primary care record for confirmed FH. SNOMED: familial hypercholesterolaemia: 398036000, homozygous FH 238078005, heterozygous FH 23807900, hypertriglyceridemia 302870006

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Guidance for the Management of Hypertriglyceridaemia

In all cases address any [secondary causes](#) and give appropriate lifestyle advice



Management of Triglycerides

Address possible secondary causes and appropriate lifestyle interventions **before referral to lipid clinic:**

Excessive alcohol intake (e.g. >40 units/week) , poorly controlled/new diabetes (e.g. HbA1c >53mM/M), TG – raising medication (e.g. steroids), hypothyroidism (e.g. TSH >15), Metabolic Dysfunction-Associated Steatotic Liver Disease (see [guidance](#)) - assess risk of advanced liver fibrosis: Fibrosis (FIB) 4 [score](#) (refer to hepatology), acute/chronic liver disease (e.g. ALT >55), renal disease (e.g. CKD 3), obesity, smoking

Fibrate therapy:

Such as fenofibrate 160mg daily [SPC](#) (if contra-indicated or not tolerated seek specialist advice)

- **Discontinue:** if Cr increase >50% (adjust dose as per SPC) and if ALT/AST >3xULN
- **Check** CK if muscular symptoms: The combination of fibrate with statin increases risk of myopathy

Icosapent ethyl therapy[†](SPC):

Recommended by [NICE](#) for patients with CVD (secondary prevention) in combination with statin therapy where fasting TG >1.7mmol/L and LDL-C > 1.0mmol/L and ≤ 2.6mmol/L. In SEL this is **amber 2** - initiation by and first prescription from a cardiovascular, diabetes or lipid specialist followed by primary care prescribing.

- **Cautions** [\(SPC\)](#): avoid in patients prescribed dual antiplatelets or an antiplatelet with an anticoagulant- refer to [CRUSADE](#) score for post-MI bleeding risk or [ORBIT](#) bleeding risk score for AF to assess individual risk: benefits. [MHRA alert](#)
- **Adherence:** In order for this medication to be effective it must be taken as prescribed and so adherence and tolerability should be monitored at each review. If patients cannot take 2 capsules twice a day, then STOP therapy. Pulse checks are also recommended at each review to identify potential AF, refer for ECG if indicated and manage associated stroke risk if AF is diagnosed.

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Resources/supporting materials

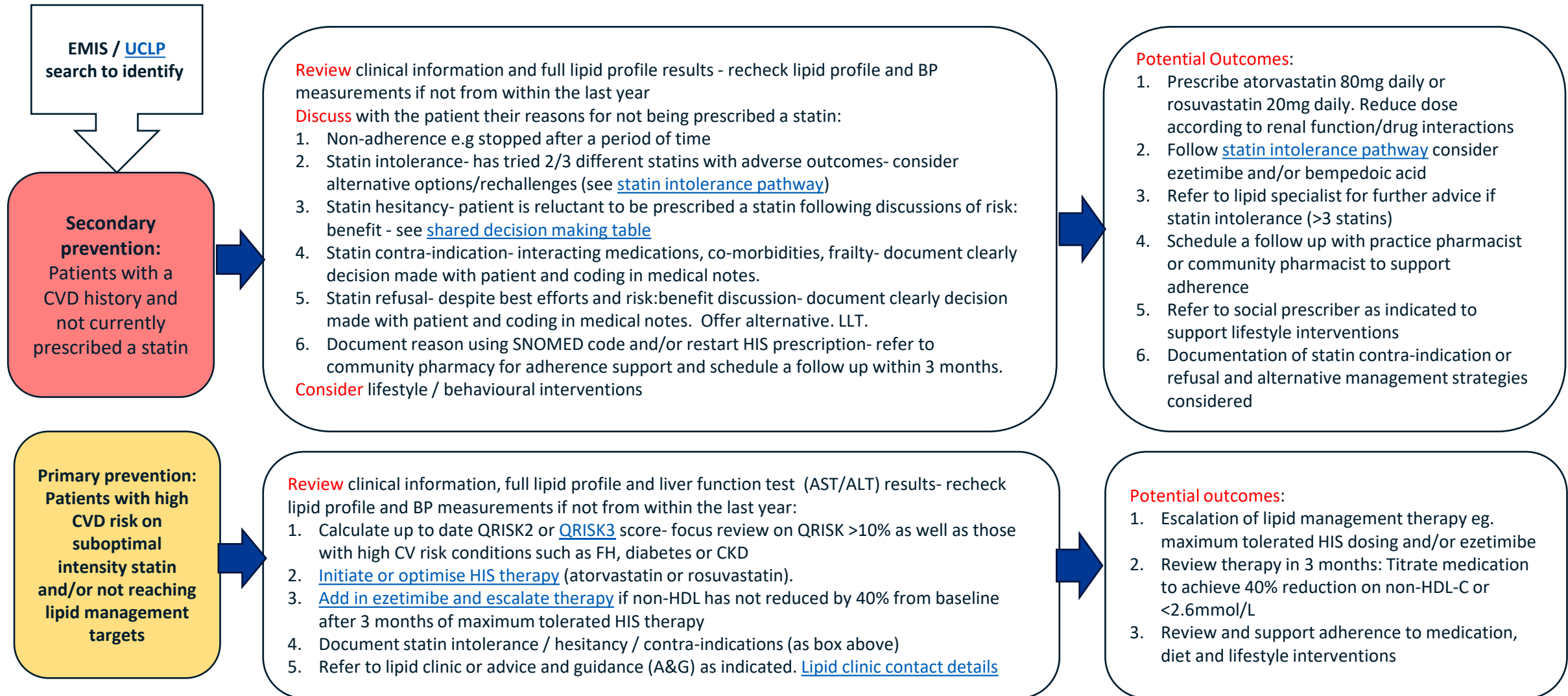
- The UCLPartners search and stratification tools, part of the UCLPartners [Proactive Care Frameworks](#), stratify patients with high impact conditions so that care may be optimised according to clinical priority and capacity, see below for some useful links:
- UCLPartners Proactive Care Search and Stratification tools- Register [here](#)
- [Cholesterol search tool](#)
- [Familial hypercholesterolaemia](#)
- [Size of the Prize for cholesterol](#)
- **PrescQIPP and SEL supporting materials:**
- [Deprescribing statin algorithm](#) (registration required)
- [SEL lipid management webinars](#)
- [PrescQIPP lipid modification e-learning](#) (registration required)
- [Bempedoic FAQ](#)
- [Inclisiran FAQ](#)

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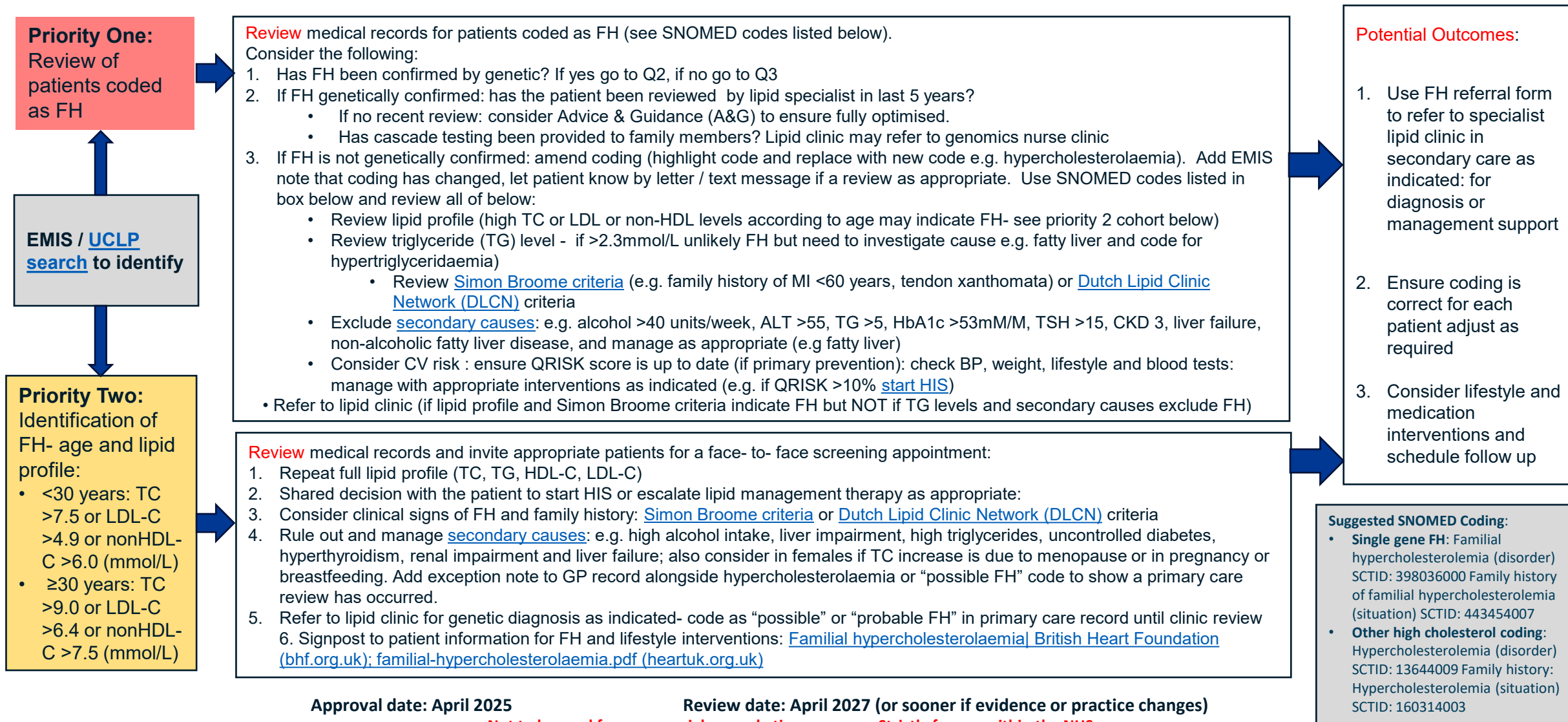
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Optimising lipid management for patients in primary care: Supporting a review of priority cohorts in secondary and primary prevention of CVD



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Familial Hypercholesterolaemia (FH) review in primary care: Supporting identification, diagnosis, management and coding



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SEL Lipid Specialist Services and Contact Details

Before referral to lipid clinic: Identify and address potential secondary causes of hyperlipidaemia, such as uncontrolled diabetes mellitus, obesity, excess alcohol consumption, untreated hypothyroidism, proteinuria and some medications, for example, thiazide diuretics, ciclosporin, steroids and antipsychotics:

SEL Lipid Clinic	Lipidologist for referrals	Contact Details
GSTT	Prof AS Wierzbicki/Prof MA Crook	Via eRS or gst-tr.diabetesandendocrine@nhs.net
KCH	Dr Nandini Rao	Via eRS or to book an appointment/query re appointment/blood test request forms Tel: 02032994181 or email: Laura.Gonzalez@nhs.net
PRUH	Dr Nandini Rao	Via eRS or kch-tr.br-referrals@nhs.net
LGT	Prof MA Crook	Via eRS or tlh-tr.LewishamReferrals@nhs.net or endocrinology at QEH: lipidology clinics at the Bromley diabetes centre, Outpatients QEH: Tel 02088364969
Community	Lambeth, Southwark and Bexley boroughs	Via eRS and/or email: gst-tr.KHPCommunityCVD@nhs.net

The aim of hospital and community clinics is to focus on patients with primary hyperlipidaemia, **before referral please exclude:**

- For hypercholesterolaemia **exclude** hypothyroidism (check TSH), chronic renal disease or nephrotic syndrome, variant diets (zero carbohydrate; protein supplements)
- For **hypertriglyceridaemia** **exclude** new/uncontrolled diabetes (check HbA1c), excess alcohol intake and fatty liver (may require referral to gastro if FIB-4 score indicates)
- For suspected familial hypercholesterolaemia **exclude** secondary causes and refer to the hospital based lipid clinic not the community clinic.

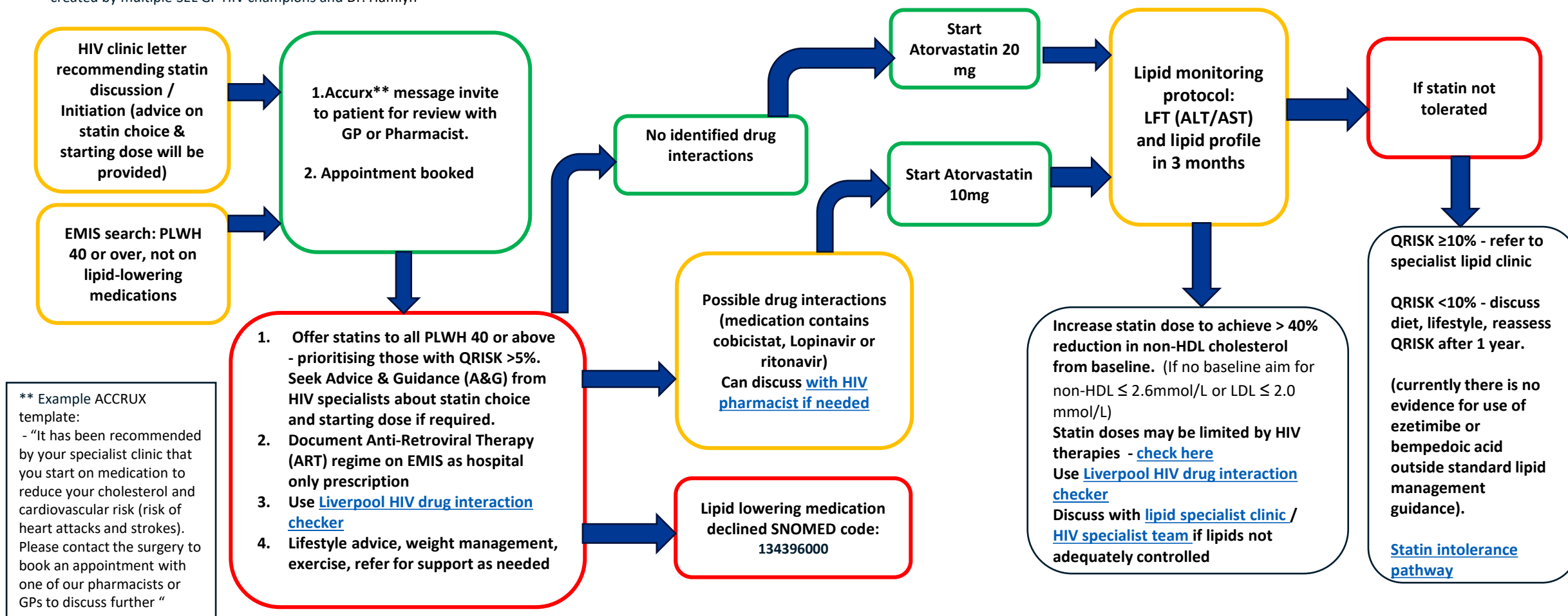
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Statin Initiation for Primary Prevention for People Living with HIV (PLWH) 40 years and above*

*adapted from Statin Initiation for Primary Prevention for PLW HIV over 40 years
created by multiple SEL GP HIV champions and Dr. Hamlyn



** Example ACCRUX template:
- "It has been recommended by your specialist clinic that you start on medication to reduce your cholesterol and cardiovascular risk (risk of heart attacks and strokes). Please contact the surgery to book an appointment with one of our pharmacists or GPs to discuss further"

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Common Statin/ARV Interactions and Recommended Doses for PLWH



For further information and advice about interactions please see: <https://www.hiv-druginteractions.org/checker> or seek Advice & Guidance from [HIV Specialist team](#)

ARV Regimen	Effect on Statins	Recommended atorvastatin starting dose	Maximum atorvastatin dose	Recommended rosuvastatin starting dose	Maximum rosuvastatin dose
Ritonavir- or cobicistat-boosted darunavir	Increased atorvastatin and rosuvastatin concentrations.	10mg	40mg	5mg	20mg
Ritonavir- or cobicistat-boosted elvitegravir	Increased atorvastatin and rosuvastatin concentrations.	10mg	40mg	5mg	20mg
Ritonavir- or cobicistat-boosted atazanavir	Significantly higher atorvastatin and rosuvastatin levels.	10mg	10mg	5mg	10mg
Lopinavir/ritonavir	Significantly higher atorvastatin and rosuvastatin levels.	10mg	20mg	5mg	10mg
Efavirenz	Variable reductions in atorvastatin. Rosuvastatin preferred first line.	20mg	80mg	10mg	40mg
Other ARV regimens	See https://www.hiv-druginteractions.org/checker or seek Advice & Guidance from HIV Specialist team				

Please note some antiretrovirals, such as boosted protease inhibitors (e.g. darunavir/ritonavir/cobicistat/atazanavir) and efavirenz can increase lipids, while others are more lipid-friendly. Consider referring patients with persistently elevated lipids to their HIV clinic for optimisation of their antiretroviral regimen.

Standard dosing of Ezetimibe is advised for all ARV regimes.

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Contact Details for HIV Pharmacy Teams

Trust	HIV Pharmacy Team
KCH PRUH	0203 299 3851 kch-tr.sexualhealth.pharmacists@nhs.net
GSTT	020 7188 2618 (option 2) gst-tr.hw.pharmacy@nhs.net
Lewisham Greenwich Bexley	02083333000, Extn 48603 02031926752 Lh.alexiscclinic@nhs.net 02088366206 Lg.trafalgarpatientqeh@nhs.net

For further guidance:

[Home - REPRIEVE Trial](#)

[BHIVA-rapid-guidance-on-the-use-of-statins.pdf](#)

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Glossary

Abbreviations used for lipid profiles:

- TC: total cholesterol
- TG: triglycerides
- HDL-C: high density lipoprotein-cholesterol
- LDL-C: low density lipoprotein cholesterol
- Non-HDL-C: non-high density lipoprotein cholesterol

Calculating non-HDL-C
 $\text{non-HDL-C} = \text{total cholesterol} - \text{HDL cholesterol}$

- mAB: monoclonal antibody
- FH: familial hypercholesterolaemia
- ICS: integrated care system
- CV: cardiovascular
- CVD: cardiovascular disease
- LFTs: liver function tests
- DM: diabetes mellitus
- CKD: chronic kidney disease
- BP: blood pressure
- HIS: high intensity statin
- AST/ALT: aspartate aminotransferase/alanine transaminase
- ULN: upper limit of normal
- TSH: thyroid stimulating hormone
- Cr: creatinine
- CK: creatine kinase
- ECG: electrocardiogram
- AF: atrial fibrillation
- PCSK9i: proprotein convertase subtilisin/kexin type 9 inhibitors
- CrCl: creatinine clearance
- NNH: number needed to harm
- NNT: number needed to treat

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