Lipid Optimisation in Primary Care – a stratified approach

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Disclosures

Mr Mahmoud Khodadi has received honoraria from:

Novartis

AstraZeneca

EFFECTIVE LDL-C REDUCTION REMAINS A CHALLENGE[1]

In an **European study** of patients prescribed lipid-lowering therapy for primary or secondary prevention:*[1]

Just 33% of patients achieved 2019 ESC/EAS LDL-C goals (95% CI: 32–35)

The likelihood of goal attainment fell with increasing risk (i.e. a lower LDL-C goal)

OVER 80% of very high-risk patients were **UNABLE TO REACH 2019 ESC/EAS LDL-C GOALS** on statins alone†

Greater utilisation of adjunctive therapies is needed to help patients at highest risk reach guideline-recommended LDL-C goals

What about England?

Recent national **CVDPREVENT data** showed that **over 76%** of patients with cardiovascular disease have **LDL-C levels above 1.8 mmol/L‡**
– that's more than 3 in 4 patients[2]

* Data from an 18-country, European-wide, cross-sectional, observational study of patients prescribed lipid-lowering therapy for primary or secondary prevention in primary or secondary care across Europe, including the UK (N=5,888).[1]
† Treatment goals for very high-risk patients: LDL-C <1.4 mmol/L (<55 mg/dL) and ≥50% LDL-C reduction from baseline.[4] As untreated lipid levels were not available, the authors could not quantify to what extent the ≥50% LDL-C reduction from baseline was achieved.[1] All patients with documented ASCVD, either clinical or unequivocal on imaging, are considered very high risk.[3]
‡ Data covering the period up to March 2022. Data was received from 96.6% of GP practices, including approximately 18 million patients.

ASCVD – atherosclerotic cardiovascular disease; CI – confidence interval; ESC/EAS – European Society of Cardiology/European Atherosclerosis Society; LDL-C – low-density lipoprotein cholesterol

References: 1. Ray KK et al. Eur J Prev Cardiol 2021;28(11):1279-1289. **2.** HQIP. https://www.hqip.org.uk/wp-content/uploads/2023/03/Ref-376-CVDPREVENT-Third-Annual-Audit-Report.pdf [Accessed April 2023]. **3**. Mach F et al. Eur Heart J 2020;41(1):111-188.

THE 2023/2024 QOF UPDATES INCLUDE TWO NEW CHOLESTEROL INDICATORS

LDL-C management for secondary prevention of cardiovascular disease has now been **recognised by the 2023/2024 QOF**.[1]

1

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*

2

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***

The 1.8 mmol/L LDL-C target in QOF may not be achievable for some patients with statins alone and **combination therapy may be required.**[1,2]

Choose LEQVIO® for your patients not reaching their LDL-C targets with statins alone[3]

LEQVIO® in combination with a maximally tolerated statin may help your secondary prevention patients achieve the 1.8 mmol/L QOF LDL-C target[1,4,5]

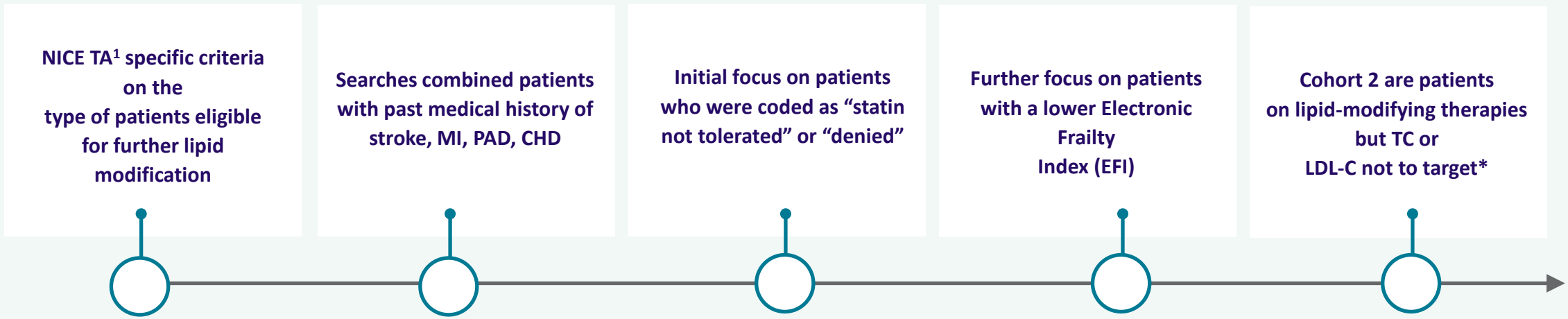
NICE recommends LEQVIO®, within its licensed indication, as an option for treating adult patients who have a history of certain cardiovascular events (acute coronary syndrome such as myocardial infarction or unstable angina needing hospitalisation, coronary or other arterial revascularisation procedures, coronary heart disease, ischaemic stroke or peripheral arterial disease) and persistently elevated LDL-C levels (≥2.6 mmol/L) despite maximum tolerated statins with or without ezetimibe, or other lipid-lowering therapies when statins are not tolerated or are contraindicated.[6]

HDL-C – high-density lipoprotein cholesterol; LDL-C – low-density lipoprotein cholesterol; NICE – National Institute for Health and Care Excellence; QOF – Quality and Outcomes Framework; TIA – transient ischaemic attack

References: 1. NHS. Quality and Outcomes Framework guidance for 2023/24. https://www.england.nhs.uk/wp-content/uploads/2023/03/PRN00289-quality-and-outcomes-framework-guidance-for-2023-24.pdf [Accessed April 2023]. **2.** Ray KK et al. Eur J Prev Cardiol 2021;28(11):1279-1289. **3.** LEQVIO® Summary of Product Characteristics. **4.** Ray KK et al. N Engl J Med 2020;382(16):1507-1519. **5.** Ray KK et al. N Engl J Med 2020;382(16):1507-1519 (supplementary appendix). **6.** NICE. https://www.nice.org.uk/guidance/ta733/resources/inclisiran-for-treating-primary-hypercholesterolaemia-or-mixed-dyslipidaemia-pdf-82611252825541 [Accessed April 2023].

How were patients identified

Simple identification:



* TC >4 mmol/L and LDL-C ≥ 2.6 mmol/L.

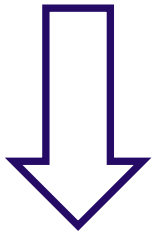
CHD – coronary heart disease; LDL-C – low-density lipoprotein cholesterol; MI – myocardial infarction; NICE – National Institute for Health and Care Excellence; PAD – peripheral artery disease; TA – technology appraisal; TC – total cholesterol

Reference 1..NICE. https://www.nice.org.uk/guidance/ta733/resources/inclisiran-for-treating-primary-hypercholesterolaemia-or-mixed-dyslipidaemia-pdf-82611252825541 [Accessed August 2022].

How were patients brought into the clinic?

Now we had identified the patients, we needed to contact and communicate with them:

1. Patients were sent a letter with information on treatment options



Letters were sent either electronically (via messaging system) or by post

2. Letter encouraged patients to contact us. To ensure high uptake, a dedicated section of long-term conditions admin team proceeded to book these patients in to our lipid clinics

What did the consultations look like?

We set up dedicated lipid clinics:

- 20-minute appointments, led and managed by pharmacists
- Detailed history was evaluated, including past medical history and drug history
- Discussions about the importance of diet and lifestyle, how lipids work and the importance of LDL-C reduction in secondary prevention took place
- The reasons for previous statin reluctance and whether all options had been exhausted were explored
- Finally, the treatment options available were discussed in more detail

Dose, frequency and side effects were of particular importance for patients

LDL-C – low-density lipoprotein cholesterol

How was inclisiran▼ ordered?

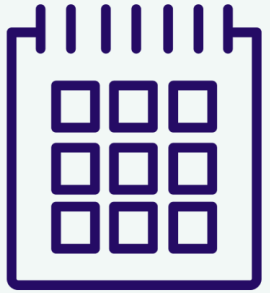
AAH – All About Health; GP – general practice

Reference: 1. AAC. Implementing inclisiran (Leqvio®) into the lipid management pathway. A toolkit for a population health management approach to adopting innovation. September 2021.

How did the patient receive the injection?

After the telephone consultation with the pharmacist, the patient was booked into a **practice nurse clinic** for administering

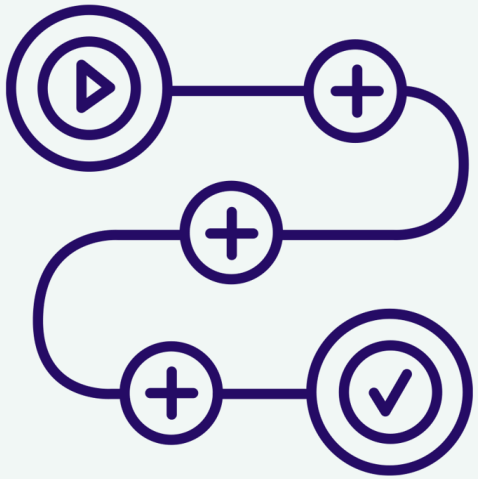
Initial discussions to ensure **nurses were aware of the injection** (subcutaneous administration route) took place



Patient attended the nurse appointment, had their injection and was already booked for their follow-up bloods and future injection in 3 months

What made implementing the pathway into primary care easy??

The pathway and pharmacists



- Relatable and easy-to-follow pathway that is completely understood by the people who are delivering it
- Affinity Care has some very experienced GPwSI in cardiology
- Practice pharmacists are key to the management of our long-term condition patients and in particular those with complex conditions
- **Pharmacists were incorporated in the pathway development from the beginning**
- Blueprint was set by the GPwSI and discussed between them and the pharmacists
- Further teaching to provide confidence on the drugs and the pathway

A thorough understanding of a simple pathway by those who were to deliver it was key to our successful implementation

GPwSI – general practitioners with special interest

Real-life experience

Two patient types:

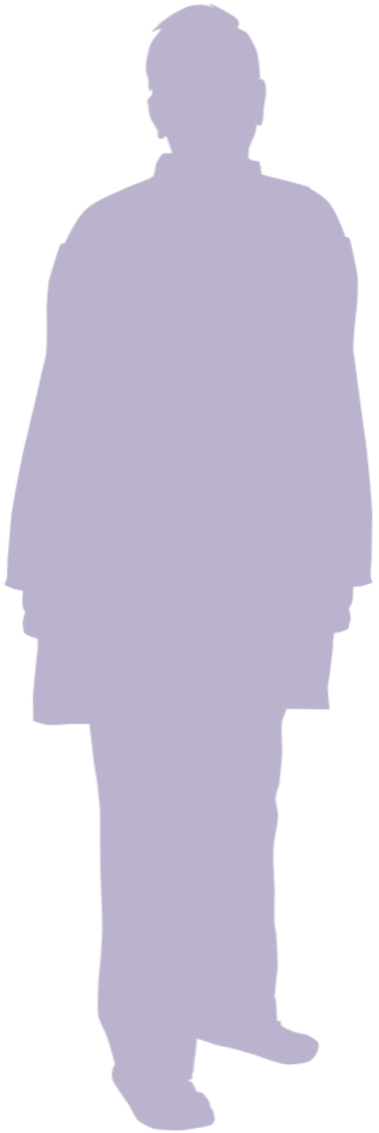
A **Happy to be offered something other than a statin**

B **Reluctant and want a full explanation of everything**

Both are handled the same way:

- Patient happy to start treatment, does not mean we should not be informing them thoroughly and not giving them information that is relevant to them
- Patient who is reluctant should not be given up on, and we should again ensure they are given all the relevant information to make an informed decision

Patient case study



- South Asian Male, 70 years old

Medical history:
- Coronary artery bypass graft surgery (1997)
- STEMI (1997, 2004)

Other health conditions:
- NDH, asthma
- Raised CK and muscle pains caused by intolerance to simvastatin, atorvastatin and rosuvastatin

Current medication:
- Aspirin 75 mg,[1] bisoprolol 2.5 mg,[2] ezetimibe 10 mg,[3] ramipril 2.5 mg,[4] inhalers for asthma

Lab results:
- LDL-C: 4.6 mmol/L
- Total cholesterol: 6.6 mmol/L

Consultation

- ✓ Patient aware of uncontrolled lipids, with diet and lifestyle well looked after
- ✓ Very few reservations: patient had been waiting a long time for another option for lipid management
- ✓ The benefits of lipid management optimisation, and the MOA and side effects of inclisiran ▼ were discussed

Early results:

- Inclisiran▼ injection booked with a nurse a few days later, and follow-up bloods booked 6 weeks later (including full lipid profile and LFTs)

LDL-C: 3.0 mmol/L (35% reduction)
Total cholesterol: 4.9 mmol/L (26% reduction)

- Follow-up consultation: patient did not report any side effects and was happy to continue treatment.
- Ongoing follow up, patient started Bempedoic acid (with Eze), LDL-C now 1.7 mmol/L

Please note that individual results will vary

CK – creatine kinase; LDL-C – low-density lipoprotein cholesterol; LFT – liver function test; MOA – mechanism of action; NDH – non-diabetic hyperglycaemia; STEMI – ST-elevation myocardial infarction

References: 1. Aspirin Summary of Product Characteristics. **2.** Bisoprolol Summary of Product Characteristics. **3.** Ezetimibe Summary of Product Characteristics. **4.** Ramipril Summary of Product Characteristics.

Patient case study

- White male, 65 years old

Medical history:
- NSTEMI (2013)

Other health conditions:
- Raised CK and muscle pains caused by intolerance to simvastatin, atorvastatin and pravastatin
- Compliance big issue

Current medication:
- Aspirin 75 mg,[1] lansoprazole 30 mg,[2] GTN spray prn

Lab results:
- LDL-C: 4.8 mmol/L
- Total cholesterol: 6.8 mmol/L

Consultation

✓ Patient received letter from practice informing about treatment options available for lipid management, which allowed for a more rounded conversation*

✓ Treatment options were discussed and patient showed a preference for an injectable option (compliance issues were mentioned)

Early results:

- Inclisiran ▼ injection booked with a nurse a few days later, and follow-up bloods booked 6 weeks later (including full lipid profile and LFTs)

LDL-C: 1.9 mmol/L (60% reduction)
Total cholesterol: 4.5 mmol/L (34% reduction)

- Follow-up consultation: patient did not report any side effects and was happy to continue treatment. Next injections booked with follow-up bloods due after this

Please note that individual results will vary

* Letter sent out to pre-identified patients from the searches conducted.

CK – creatine kinase; GTN – glyceryl trinitrate; LDL-C – low-density lipoprotein cholesterol; LFT – liver function test; NSTEMI – non-ST-elevation myocardial infarction; prn – *pro re nata* (when necessary)

References: 1. Aspirin Summary of Product Characteristics. **2.** Lansoprazole Summary of Product Characteristics.

Patient case study

- White male, 63 years old

Medical history:
- NSTEMI (2016)
- Coronary artery bypass graft surgery (2016)

Other health conditions:
- Type 2 diabetes mellitus (diet controlled), CKD G3aA1
- Tried simvastatin 40 mg and atorvastatin 80 mg but did not tolerate them

Current medication:
- Aspirin 75 mg,[1] bisoprolol 2.5 mg,[2] lansoprazole 30 mg,[3] GTN spray prn

Lab results:
- LDL-C: 4.6 mmol/L
- Total cholesterol: 7 mmol/L

Consultation

- ✓ Patient was encouraged to retry statins
- ✓ Treatment options were discussed and patient showed willingness to try a different statin or at a different dose
- ✓ Patient wanted to read more about treatment options; at the next appointment (one week after), was keen to start on inclisiran ▼

Early results:

- Inclisiran ▼ inj… …ked with a nurse a few days later, and …r (including …

LDL-C: 1.7 mm…
Total cholest…

- Follow-up … …my side effects and … …Next injections booked with follow-up bloods due after this

It's very important to give patients time to make informed decisions

Please note that individual results will vary

CKD G3aA1 – chronic kidney disease with glomerular filtration rate category G3a and albuminuria category A1; GTN – glyceryl trinitrate; LDL-C – low-density lipoprotein cholesterol; LFT – liver function test; NSTEMI – non-ST-elevation myocardial infarction; prn – *pro re nata* (when necessary)

References: 1. Aspirin Summary of Product Characteristics. **2.** Bisoprolol Summary of Product Characteristics. **3.** Lansoprazole Summary of Product Characteristics.

Patient case study

- White female, 63 years old

Medical history:
- Stroke (2008)
- PAD

Other health conditions:
- COPD, Breast Ca

Current medication:
- Amlodipine 5mg, Anastrazole 1mg, Aspirin 75mg, Atorvastatin 80mg, Lansoprazole 30mg, Inhalers

Lab results:
- LDL-C: 3.2 mmol/L
- Total cholesterol: 4.7 mmol/L

- Patient identified and contacted post pathology filing

Consultation

- ✓ Patient appreciated responsive consultation following pathology filing
- ✓ Focused on target LDL-C < 1.8 mmol/L considering previous CVD history
- ✓ Open discussion around potential % reduction of alternative options
- ✓ Patient's preference was to opt for the medication that would give biggest response, with limited SE risk – started inclisiran ▼

Early results:

LDL-C: 1.5 mmol/L (53% reduction)
Total cholesterol: 3.6 mmol/L (23% reduction)

- Follow-up consultation: patient did no report any side effects and was happy to continue treatment. Next injections booked with follow-up bloods due after this

Please note that individual results will vary

Patient case study

- White female, 70 years old

Medical history:
- Stroke (1993)

Other health conditions:
- Osteoporosis

Current medication:
- Adcal, Atorvastatin 20mg

Lab results:
- LDL-C: 3.4 mmol/L
- Total cholesterol: 5.6 mmol/L

- DLCN: 5

- Patient identified via report, following recent pathology filing (full lipid profiles!)

Please note that individual results will vary

Consultation

- ✓ Young age stroke + pre-treatment LDL-C, DLCN to consider further FH testing
- ✓ Previously tried Simva 20mg, Atorva 40mg – cramps. Her "max tolerated dose"
- ✓ Explored options available: Eze (20% - 2.7), Nustendi (30% - 2.4) (licensed vs NICE)
- ✓ Frank discussion about target below 1.8 mmol/L. How do we get there?
- ✓ Patient informed decision: start Inclisiran

Early results:

LDL-C: 1.7 mmol/L (50% reduction)
Total cholesterol: 3.9 mmol/L (30% reduction)

- Follow-up consultation: patient did no report any side effects and was happy to continue treatment. Next injections booked with follow-up bloods due after this