

East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG, Surrey Heath CCG, Crawley CCG, Horsham & Mid-Sussex CCG

Briefing Paper for Prescribing Clinical Network on NICE Clinical Guideline 71 - Familial hypercholesterolaemia: identification and management

Published: 27 August 2008; updated July 2016 and how the traffic Light Status of Fibrates, Nicotinic Acid, Bile Sequestrants and Omega-3 fatty acids correspond with CG71 and CG 181 Cardiovascular disease: risk assessment and reduction, including lipid modification Clinical guideline CG181 Published date: July 2014 last updated: September 2016

NICE CG Guidance	NICE Clinical Guideline 71 - Familial hypercholesterolaemia: identification and management
Date of issue	Published: 27 August 2008; updated July 2016
Available at	https://www.nice.org.uk/guidance/cg71/chapter/1-Guidance

Background

A review of the traffic light status and restrictions for:

- Fibrates
- Nicotinic acid
- Bile sequestrants
- Omega-3 fatty acids

in familial hypercholesterolaemia (FH) post the update of NICE CG71 Familial hypercholesterolaemia: identification and management and with the NICE CG181

Current PCN decisions on third line lipid modifying drugs reflect CG181 Cardiovascular disease: risk assessment and reduction, including lipid modification (published date: July 2014 and last updated: September 2016), but do not reflect indications of the same drugs recommended for FH in the updated CG 71. The purpose of this briefing is to ensure the policy statements and traffic light status reflects both CG 71 and CG181 Cardiovascular disease: risk assessment and reduction, including lipid modification.

Guidance

CG 71- Familial hypercholesterolaemia: identification and management	CG 181 - Cardiovascular disease: risk assessment and reduction, including lipid modification
<p>1.3.1.15 Adults with FH with intolerance or contraindications to statins or ezetimibe should be offered a referral to a specialist with expertise in FH for consideration for treatment with either a bile acid sequestrant (resin), nicotinic acid, or a fibrate to reduce their LDL-C concentration.</p> <p>1.3.1.16 The decision to offer treatment with a bile acid sequestrant (resin), nicotinic acid or a fibrate in addition to initial statin therapy should be taken by a specialist with expertise in FH.</p> <p>1.3.1.17 Healthcare professionals should exercise caution when adding a fibrate or nicotinic acid to a statin because of the risk of muscle-related side effects (including rhabdomyolysis). Gemfibrozil and statins should not be used together.</p> <p>1.3.2.7 People with FH should not routinely be recommended to take omega-3 fatty acid supplements. For people with FH who have already had a myocardial infarction (MI), refer to 'MI: secondary prevention' (NICE guideline CG48) - <i>this has now been updated as CG172 which states that people should not be offered or advised to use omega-3 fatty acid capsules or omega-3 fatty acid supplemented foods.</i></p>	<p>Do not routinely offer fibrates, bile sequestrants, omega-3 fatty acid compounds or nicotinic acid for the prevention of CVD to any of the following:</p> <ul style="list-style-type: none"> • people who are being treated for primary prevention • people who are being treated for secondary prevention • people with CKD • people with type 1 diabetes • people with type 2 diabetes <p>1.3.48 Do not offer omega-3 fatty acid compounds for the prevention of CVD to any of the following:</p> <ul style="list-style-type: none"> • people who are being treated for primary prevention • people who are being treated for secondary prevention • people with CKD • people with type 1 diabetes • people with type 2 diabetes. <p>1.3.49 Tell people that there is no evidence that omega-3 fatty acid compounds help to prevent CVD.</p> <p>Combination therapy for preventing CVD</p> <p>1.3.50 Do not offer the combination of a bile acid sequestrant (anion exchange resin), fibrate, nicotinic acid or omega-3 fatty acid compound with a statin for the primary or secondary prevention of CVD.</p>

Fibrates

Current PCN statement for Prevention of CVD: BLACK

As per NICE CG 181 the PCN concluded that fibrates should not routinely be offered for the prevention of CVD. The limited evidence from fibrate trials does not support their widespread use, however they may be useful in the treatment of specific groups of patients particularly those with severe hypertriglyceridaemia. Fibrates should be considered as GREEN on the traffic light system for these groups of patients.

Current PCN Statement for hypertriglyceridaemia: GREEN

Fibrates should ONLY be considered as GREEN on the traffic light system for specific groups of patients particularly those with severe hypertriglyceridaemia. Fibrates should NOT routinely be offered for lipid modification / prevention of CVD. The limited evidence from fibrate trials does not support their widespread use.

Proposed PCN statement:

As per NICE CG 181 the PCN recommends that fibrates should not be routinely offered for the prevention of CVD and should therefore be considered BLACK on the traffic light for this indication.

As per NICE CG71 for patients with FH with intolerance or contraindications to statins or ezetimibe they should be offered a referral to a specialist with expertise in FH for consideration for treatment with either a bile acid sequestrant (resin), nicotinic acid, or a fibrate to reduce their LDL-C concentration. For these patients, fibrates should be considered BLUE on the traffic light with an accompanying information sheet to highlight monitoring requirements.

Nicotinic Acid

Current PCN statement for Prevention of CVD: BLACK

NICE do not recommend the use of nicotinic acid (Niacin) for the prevention of cardiovascular disease for:

- people who are being treated for primary prevention
- people who are being treated for secondary prevention
- people with CKD
- people with type 1 diabetes
- people with type 2 diabetes

The PCN concur with this.

Current PCN statement for dyslipidaemia: BLACK

Product discontinued.

Proposed PCN statement:

As per NICE CG 181 the PCN recommends that nicotinic acid should not be routinely offered for the prevention of CVD and should therefore be considered BLACK on the traffic light for this indication.

As per NICE CG71 for patients with FH with intolerance or contraindications to statins or ezetimibe they should be offered a referral to a specialist with expertise in FH for consideration for treatment with either a bile acid sequestrant (resin), nicotinic acid, or a fibrate to reduce their LDL-C concentration.

Nicotinic acid is currently not available in the UK and should be considered BLACK.

Bile Sequestrants

Current PCN statement for Prevention of CVD: BLACK

NICE do not recommend the use of bile acid sequestrants for the prevention of cardiovascular disease for:

- people who are being treated for primary prevention
- people who are being treated for secondary prevention
- people with CKD
- people with type 1 diabetes
- people with type 2 diabetes

The PCN concur with this.

Current PCN statement for dyslipidaemia / hypertriglyceridaemia:

There is no statement on the PAD

Proposed PCN statement:

As per NICE CG 181 the PCN recommends that bile sequestrants should not be routinely offered for the prevention of CVD and should therefore be considered BLACK on the traffic light for this indication.

As per NICE CG71 for patients with FH with intolerance or contraindications to statins or ezetimibe they should be offered a referral to a specialist with expertise in FH for consideration for treatment with either a bile acid sequestrant (resin), nicotinic acid, or a fibrate to reduce their LDL-C concentration.

For those patients, bile sequestrants should be considered BLUE on the traffic light without an information sheet.

Omega-3 fatty acids

Current PCN statement for Prevention of CVD: BLACK

NICE do not recommend the use of Omega-3 fatty acid compounds for the prevention of cardiovascular disease for:

- people who are being treated for primary prevention
- people who are being treated for secondary prevention
- people with CKD
- people with type 1 diabetes
- people with type 2 diabetes

The PCN concurred with this.

Current PCN statement for raised triglycerides: GREEN

The Surrey Prescribing Clinical Network recommends the use of Omega 3 fatty acids as an adjunct in the reduction of plasma triglycerides when: A patient has a triglyceride concentration exceeding 10mmol/litre as this is associated with acute pancreatitis OR As a possible treatment option in patients with a triglyceride concentration of 4.5-10mmol/litre when other treatment options have failed or are contraindicated and the individual has other risk factors (e.g. diabetes).

Proposed PCN statement:

As per NICE CG 181, the PCN recommends that omega-3 should not be routinely offered for the prevention of CVD and should therefore be considered BLACK on the traffic light for this indication. CG 172 was published after CG 71 and recommendations about statins and other lipid lowering agents were removed from the update of this guideline.

Recommendation:

To adopt the proposed PCN statements to reflect CG71 and CG181 for the following:

- Fibrates
- Nicotinic acid
- Bile sequestrants
- Omega-3 fatty acids