This policy statement is approved by Halton, Knowsley, Liverpool, South Sefton, Southport and Formby, St Helens, Warrington, West Lancashire, and Wirral CCGs

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PAN MERSEY APC

PAN MERSEY AREA PRESCRIBING COMMITTEE
PRESCRIBING POLICY STATEMENT
REF: PS156 FINAL
APC BOARD DATE: 27 JUL 2016

NHS Pan Mersey Area Prescribing Committee

ALIROCUMAB (Praluent®▼) subcutaneous injection

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The Pan Mersey Area Prescribing Committee recommends the prescribing of ALIROCUMAB (Praluent®▼) by specialists only, for treating primary hypercholesterolaemia and mixed dyslipidaemia in accordance with NICE TA393.

NICE technology appraisal (TA) 393 (June 2016) recommends alirocumab (Praluent®▼) as an option for treating primary hypercholesterolaemia or mixed dyslipidaemia, only if:

- Low-density lipoprotein concentrations are persistently above the thresholds specified in the table below despite maximal tolerated lipid-lowering therapy. That is, either the maximum dose has been reached or further titration is limited by intolerance (as defined in NICE's guideline (CG71) on familial hypercholesterolaemia (FH): identification and management)
- The company provides alirocumab with the discount agreed in the patient-access scheme.

	Without CVD	With CVD	
		At high risk of CVD[1]	At very high risk of CVD[2]
Primary non-familial hypercholesterolaemia or mixed dyslipidaemia	Not recommended at any LDL-C concentration	Recommended only if LDL-C concentration is persistently above 4.0 mmol/litre	Recommended only if LDL-C concentration is persistently above 3.5 mmol/litre
Primary heterozygous-familial hypercholesterolaemia	Recommended only if LDL-C concentration is persistently above 5.0 mmol/litre	Recommended only if LDL-C concentration is persistently above 3.5 mmol/litre	

[1] High risk of CVD is defined as a history of any of the following: acute coronary syndrome (such as myocardial infarction or unstable angina requiring hospitalisation), coronary or other arterial revascularisation procedures, chronic heart disease, ischaemic stroke, peripheral artery disease.
[2] Very high risk of CVD is defined as recurrent cardiovascular events or cardiovascular events in more than one vascular bed (that is, polyvascular disease).
Abbreviations: CVD, cardiovascular disease; LDL-C, low-density lipoprotein cholesterol.

Alirocumab should only be prescribed by specialists in the management of lipid disorders (e.g. cardiologists, clinical biochemists). Alirocumab will be supplied via a homecare scheme and therefore prescribing will be retained in secondary care. Other treatments (e.g. statins, fibrates, ezetimibe) should be continued unless a specialist advises otherwise.

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

ALIROCUMAB (Praluent®▼) and EVOLOCUMAB (Repatha®▼) for treating primary hypercholesterolaemia and mixed dyslipidaemia in accordance with NICE TA393 and TA394

Costing report

Alirocumab and evolocumab are recommended as options for treating primary hypercholesterolaemia and mixed dyslipidaemia in adults, subject to certain criteria, detailed in the prescribing policy statement above.

The NICE costing report states that estimating the eligible population is challenging. Clinical experts believe that alirocumab and evolocumab will mostly be given as add-on therapies to existing treatment, when low-density lipoprotein cholesterol (LDL-C) levels are not being adequately controlled.

The NICE resource impact tool only includes estimates for patients with primary hypercholesterolaemia. Estimates for mixed dyslipidaemia were excluded based on the potential for double counting (because with both primary hypercholesterolaemia and mixed dyslipidaemia people have raised cholesterol levels) and clinical opinion that most people with mixed dyslipidaemia will not frequently have the drugs.

Using the NICE cost impact template, it is estimated that the cost of implementing these technology appraisals is £113,071 per 100,000 population. This does not take into account the patient access scheme, so actual cost will be lower.

Assumptions

Total population	**100,000**
People aged 18 and over	78,619
Non-familial hypercholesterolaemia (FH)	
People with non-FH with LDL-C ≥ 4 mmol/L and high risk of CVD	150
People with non-FH with LDL-C ≥ 3.5 mmol/L and very high risk of CVD	130
Total at high risk of CVD and with LDL-C concentrations above 4.0 mmol/litre or very high risk of CVD with LDL-C concentrations above 3.5 mmol/litre	280
People requiring treatment with alirocumab or evolocumab	22
Familial hypercholesterolaemia	
People with FH with LDL-C ≥ 5 mmol/L and no history of CVD	4
People with FH with LDL-C ≥ 3.5 mmol/L and history of CVD	19
Total with no history of CVD and LDL-C concentrations ≥ 5.0 mmol/L or a history of CVD with LDL-C concentrations ≥ 3.5 mmol/L	23
People requiring treatment with alirocumab or evolocumab	3
Current practice	
Number prescribed alirocumab or evolocumab	0
Future practice	
Number prescribed alirocumab for non-FH indication	11
Number prescribed evolocumab for non-FH indication	11
Number prescribed alirocumab for FH indication	2
Number prescribed evolocumab for FH indication	2
Costs	
Annual cost of alirocumab per patient (not including PAS)	£4,383.00
Annual cost of evolocumab per patient (not including PAS)	£4,422.60

Assumes 50:50 split between alirocumab and evolocumab use.