DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Derbyshire commissioning guidance for the use of PCSK9 inhibitors for the management of primary hypercholesterolaemia and mixed dyslipidaemia

Primary homozygous familial hypercholesterolaemia is NHSE commissioned

Does the patients have primary non-familial hypercholesterolemia or mixed dyslipidaemia?

Yes

With CVD and at high risk
LDL-C >4.0 mmol/L (See table 1)

Yes

With CVD and at very high risk
LDL-C >3.5 mmol/L (See table 1)

The CCG's will only commission 2 treatment options (1 switch) per patient - this includes either 1 treatment failure or 1 intolerance.

NICE approved treatment

Local expert advice

These drugs should only be managed by lipid specialists.
If more than 1 treatment is suitable, the least expensive should be chosen.
Choices are listed in most cost effective order:

Evolocumab (TA394)

Or

Alirocumab (TA393)

(Continue with existing oral lipid lowering therapy)

Monitor efficacy, adherence to treatment and adverse effect

Has the biologic drug been withdrawn because of an adverse event (treatment failure or intolerance)?

Yes – consider alternative biologic agent

No

Has the patient had an adequate response to treatment? (Locally decided by clinician)

Yes – maintain same treatment and monitor patient every 12 months

No

Check adherence and injection technique.
If inadequate response (locally decided by clinician) persists
Stop treatment

Dosing schedule

Table 1

Biologic		NICE TA	Loading dose	Maintenance dose	Response measured
Alirocumab	Monoclonal antibody that targets proprotein convertase subtilisin/kextin type 9 (PCSK9)	TA393	N/A	75mg or 150mg every 2 weeks	18 months
Evolocumab	Monoclonal antibody that inhibits proprotein convertase subtilisin/kexin type 9 (PCSK9)	TA394	N/A	140mg every 2 weeks (most cost effective) **or** 420mg monthly	18 months

	Without CVD	With CVD	
		High risk of CVD[1]	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

[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 needing hospitalisation); coronary or other arterial revascularisation procedures; coronary heart disease; ischaemic stroke; peripheral arterial disease.

[2] Very high risk of CVD is defined as recurrent cardiovascular events or cardiovascular events in more than 1 vascular bed (that is, polyvascular disease).