HEREFORDSHIRE AND WORCESTERSHIRE PATHWAY
for use of PCSK9 Inhibitors in the management of PRIMARY HYPERCHOLESTEROLAEMIA or MIXED DYSLIPIDAEMIA in Adults
April 2020

'Definite' or 'Possible' Primary Heterozygous-Familial Hypercholesterolaemia
(see overleaf for definition)

- **Without CVD** — **LDL-C > 5.0 mmol/l**
- **With CVD** (see overleaf for definition) — **LDL-C > 3.5 mmol/l**

Primary Non-Familial Hypercholesterolaemia
OR
Mixed Dyslipidaemia

- **High Risk CVD** (see overleaf for definition) — **LDL-C > 4.0 mmol/l**
- **Very High Risk CVD** (see overleaf for definition) — **LDL-C > 3.5 mmol/l**

LDL-C Concentration persistently* above specified thresholds
despite **adherence to maximal tolerated lipid-lowering therapy** (defined overleaf)
*at least 2 consecutive values

ALIROCUMAB (NICE TA 393) **75mg – 150mg SC every 2 weeks**

OR

Blueteq initiation form required

EVOLOCUMAB (NICE TA 394) **140mg SC every 2 weeks****

(either agent administered in combination with maximal tolerated oral lipid lowering therapy where possible)
** 420mg monthly dosing schedule NOT approved for use by NICE

Assess LDL-C response over baseline# @ 4 weeks:
Require > 25% decrease LDL-C
lowest LDL-C while receiving maximum tolerated lipid lowering therapy

NO → **DISCONTINUE TREATMENT**
Continue management with oral lipid lowering agents

Intolerant/adverse event within 3 months - consider alternative agent

YES → **Continue and review 6 monthly Blueteq continuation form every 6 months**

Note: The needle cover of the evolocumab glass pre-filled syringe is made from dry natural rubber (a derivative of latex); alirocumab may be considered in patients with known latex allergy.

CVD: Cardiovascular Disease
LDL-C: Low Density Lipoprotein Cholesterol

Prepared and agreed by Chemical Pathology and Cardiology across Herefordshire and Worcestershire
Approved by Medicines and Prescribing Committee 5th August 2020

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Primary Heterozygous-Familial Hypercholesterolemia *(Reference: NICE CG71, updated 2019)*

Patients should be diagnosed in accordance with the recommendations within NICE Clinical Guideline CG71 ensuring:

- Exclusion of secondary causes of hypercholesterolemia AND
- Diagnosis of "definite" or "possible" FH using Simon Broome or Dutch Lipid Clinic Network criteria

Cardiovascular Disease (CVD) Definitions as per NICE Guidance *(Reference: NICE TA 393 Alirocumab and TA 394 Evolocumab)*

High risk of CVD: Acute Coronary Syndrome (ACS) (such as myocardial infarction or unstable angina requiring hospitalisation), coronary or other arterial revascularisation procedures, chronic heart disease, ischaemic stroke, peripheral arterial disease

Very high risk of CVD: Recurrent cardiovascular events or cardiovascular events in more than 1 vascular bed (polyvascular disease)

'Adherence to maximal tolerated lipid-lowering therapy' *(Reference: consensus opinion across Herefordshire and Worcestershire)*

Defined as: Failure of at least two statins, including rosuvastatin, AND the addition of ezetimibe in combination with each statin (or as ezetimibe monotherapy)

Maximum doses reached or treatment or further titration limited by contraindication or intolerance (for example, evidence of new-onset muscle pain, significant gastrointestinal disturbance and/or alterations of liver function tests) respectively.

Each agent to be trialled at maximum tolerated dose for a period of at least 4 months with assurance of adherence before assessing effect.

Commissioning Arrangements

1. **Both alirocumab and evolocumab should be initiated and maintained by specialists with appropriate clinical experience; there should be no maintenance prescribing in primary care.**
2. **Use of any agents outside of the commissioning pathway will not be reimbursed by commissioners under the excluded PbR arrangements; this includes switching between agents (other than intolerance or adverse event within 3 months) and re-introduction of agents after prior failure.**
3. **Any proposed changes to the pathway require an application to and consideration by the Herefordshire and Worcestershire Medicines and Prescribing Committee.**
4. **For patients who fall outside of this pathway but where there is demonstrable evidence that the patient has exceptional clinical circumstances, an Individual Funding Request may be submitted for consideration.**
5. **Homozygous Familial Hypercholestrolaemia is NHS England commissioning responsibility and is not covered by this pathway.**

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