# Devon-wide guidance for the use and prescription of PCSK9 inhibitors

**Applicability:** This guidance outlines the NICE-approved clinical use of PCSK9 inhibitors. It covers the initiation of this treatment and the ongoing responsibility of GP prescription following discharge of patients from the specialist clinic in secondary care.

## What are PCSK9 inhibitors?

PCSK9 inhibitors are a new class of lipid-lowering medications. They are injectable monoclonal antibodies to PCSK9 and are administered as 2 weekly or 4 weekly (alirocumab only) subcutaneous injections. They are potent LDL-C lowering agents and work through a different mechanism to statins.

## Which PCSK9 Inhibitors Are Approved for Use?

Alirocumab and Evolocumab have been approved by NICE (Technology appraisal guidance [TA393 and TA394] June 2016) for use in certain patients with familial hypercholesterolaemia (FH) (with and without CVD) and patients with cardiovascular disease (CVD). Please refer to NICE TAs for specified treatment criteria.

## Will the patient's GP be responsible for ongoing prescription of PCSK9 inhibitor treatment?

**PCSK9 inhibitors should only be initiated by specialists in secondary care**, i.e. lipid specialists or cardiologists depending on local agreement with individual trust. The specialist will be responsible for counselling patients and initiating treatment. Patients will be provided with information on their treatment, plus training on administration and storage of the medication. The patent will remain under the care of the specialist until stabilised on treatment, i.e. when patient demonstrate adequate response with no other concerns related to the medication.

Once stabilised on treatment, the specialist will review and decide the appropriateness for handing over the ongoing prescribing and monitoring responsibility to patient's GP. A standard letter outlining this handover of prescribing responsibility, including exact details of drug and dose, will be sent to the patient's GP prior to the handover. At this point, depending on the clinical context, the patient might also be discharged from the lipid service or specialist clinic with clear criteria of re-referral stated in the letter.

## What monitoring is required for patients receiving PCSK9 inhibitor treatment?

No specific biochemical or haematological monitoring is required for patients receiving this treatment other than an annual blood test for a lipid profile as would be typical for any patient receiving long-term lipid lowering therapy. The annual blood test should preferably be a fasting profile to include total cholesterol, LDL-C, HDL-C and triglyceride.

This guidance has been authored jointly by lipid specialists across Torbay and South Devon NHS Foundation Trust and University Hospitals Plymouth NHS Trust- July 2022.

PCSK9 inhibitors are generally considered to be well tolerated drugs with a side-effect profile similar to placebo in clinical trials. The most common adverse reactions seen in clinical trials were local injection site reactions. There are no contraindications other than known hypersensitivity to the drug or excipients. These drugs are not recommended for use in pregnancy or during breast feeding. The cautions for use are patients with severe renal impairment (defined as eGFR < 30 mL/min/1.73 m2) and in patients with severe hepatic impairment.

**Criteria for re-referral to the specialist include:-**

1) Concern by the patient that they may be suffering from a side-effect of the medication

2) Concern by the clinician that a patient's symptoms may relate to side-effects of the medication.

3) Results of lipid profile showing a significant rise in cholesterol (eg. greater than 1 mmol/L rise in total cholesterol or LDL-C) above the patient's individualised cholesterol target or discharge cholesterol level (whichever is greater). The individualised target and discharge cholesterol levels will be stated in the patient's discharge letter.

4) Concerns about adherence to the medication

5) A change in medical status of the patient that may represent a caution to the use of PCSK9 inhibitors eg. worsening renal or hepatic failure.