SHARED CARE AGREEMENT

Name of medicine	**Alirocumab (Praluent)**
Indication	Hypercholesterolaemia and elevated (atherosclerotic) cardiovascular risk

Version: 1.0 Approval date: September 2022 Review date: September 2025

The Shared Care Agreement (SCA) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface. It does not contain all of the relevant product information, which should be sought using the current British National Formulary and manufacturer's Summary of Product Characteristics. The SCA must be used in conjunction with the NHS Lothian Procedure for the Shared Care of Medicines, available here.

Roles and responsibilities

Listed below are specific responsibilities that are additional to those included in the NHS Lothian Policy and Procedures for Shared Care. Please refer to the policy for core roles and responsibilities that apply to all Shared Care Agreements.

Consultant – Lipid Clinic (RIE)

Assessment and initiation – up to 8 weeks

- Assessment of eligibility for therapy, patient counselling
- Initial patient training, including self-administration of s/c injection
- Short-term prescription (4 doses, over 8 weeks) to establish tolerability and lipid-lowering efficacy
- Patient will be advised to contact lipid clinic to report adverse effects, or for advice regarding administration, storage, auto-injector pen disposal etc
- Repeat and review lipid profile (6 to 8 weeks). Assess indication for long-term therapy. Consider further short-term prescription if required.
- Where long-term therapy is indicated (from 8 weeks), write to GP to request long-term prescription. The latter should include reference to this shared-care agreement.

Longer-term shared care – beyond 8 weeks

- Minimum further follow-up at Lipid Clinic: 6 months, 12 months
- Discharge from lipid clinic if Alirocumab is well-tolerated and effective (consistent non-HDL cholesterol reduction). Provide GP with clear advice on long-term follow-up.
  {*Note that patients with genetically-confirmed Familial Hypercholesterolaemia will in most cases remain under lipid clinic follow-up*.}
- Provide email or telephone advice, or accept re-referral for discharged patients who develop adverse effects, or where there is concern over lipid-lowering efficacy

General Practitioners and primary care non-medical prescribers

- Consider Lipid Clinic recommendation for long-term Alirocumab prescribing from primary care
- Review annual (non-fasting) lipid profile (only applicable where patients no longer under Lipid Clinic follow-up)
- Consider seeking email or telephone advice (or re-refer to lipid clinic) where patients develop adverse effects, or there is concern over lipid-lowering efficacy

Patient, relatives, carers

- Contact lipid clinic directly regarding suspected adverse effects, or other matters related to Alirocumab
- *Otherwise, responsibilities as per: NHS Lothian Policy and Procedures for the Shared Care of Medicines*

Support and Advice for the GP and primary care non-medical prescribers

- RIE.BioLipidsAdvice@nhslothian.scot.nhs.uk
- Lipid Clinic, RIE: 0131 242 6870, 0131 242 6853
- Advice can also be sought through SCI-gateway referral to Lipid Clinic, RIE

Key Information on the Medicine

Refer to current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background to disease and use of drug for the given indication

Alirocumab is a monoclonal PCSK9 inhibitor. PCSK9 inhibitors lower non-HDL cholesterol by increasing the number of LDL-receptors available to remove non-HDL cholesterol from the circulation. (Note: Alirocumab is NOT an immunosuppressive drug.) Non-HDL cholesterol lowering provides significant atherosclerotic cardiovascular risk (CV) reduction in those at high CV risk, and with elevated non-HDL cholesterol.

Indication

Alirocumab is licensed for adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, and those with established atherosclerotic disease. It is also indicated for those >12 years-old with homozygous familial hypercholesterolaemia.

The East Region Formulary lists Alirocumab for restricted use in adults only, as recommended by the SMC. The SMC advice is intended to reserve therapy for those at high risk of (atherosclerotic) cardiovascular disease, AND with a significantly raised LDL-C despite maximally tolerated statin and/or ezetimibe treatment:

1. Familial Hypercholesterolaemia
    a. LDL-C ≥5.0 mmol/L – primary prevention
    b. LDL-C ≥3.5 mmol/L – secondary prevention
2. Secondary prevention
    a. LDL-C ≥4.0 mmol/L – single cardiovascular event
    b. LDL-C ≥3.5 mmol/L – multiple, or polyvascular cardiovascular events

Dosage and administration

- 75 mg (or 150 mg) every 2 weeks
  [increasing dose from 75 to 150 mg – consider seeking lipid clinic advice]
- Both dosage levels are self-administered by a single subcutaneous injection
- No dose adjustment required for age, body weight, race or gender

Note: full details are available within the SPC and BNF. Key information is included here for speed of access.

Monitoring

Test	Frequency	Abnormal Result	Action if Abnormal Result
Full lipid profile [Lipid Clinic to review]	Once (at 6 to 8 weeks)	Non-HDL cholesterol reduction <20%	Lipid clinic to review patient
Full lipid profile [GP to review, where patient no longer under lipid clinic follow-up]	Annual	LDL-C >2.5 mmol/L for secondary prevention	Review adherence, consider increasing dose to 150 mg, consider re-referral to lipid clinic

Cautions, contraindications - Refer to current Summary of Product Characteristics: www.medicines.org.uk
Contraindications

- Hypersensitivity to the active substances, or to any of the excipients

Cautions

- Not licensed for use in: pregnancy, breast-feeding. Patients will be counselled by the lipid clinic at initiation regarding the risk of treatment during pregnancy or breastfeeding. Seek lipid clinic advice if inadvertently prescribed during pregnancy or breast-feeding.
- SPC states no dose-adjustment required for eGFR <30. However local (lipid clinic) recommendation is to prescribe with caution in this group of patients. Lipid clinic will be responsible for risk assessment.
- Limited data in patients with severe hepatic impairment (Child-Pugh class C)

Note: full details are available within the SPC and BNF. Key information is included here for speed of access.

Adverse effects - Refer to current Summary of Product Characteristics: www.medicines.org.uk for full detail.

- **Common (≥1/100 to <1/10):** local injection site reactions (including erythema, itching, swelling, pain), itching beyond the injection site, upper respiratory tract symptoms (oropharyngeal pain, rhinorrhoea, sneezing)
- **Rare (≥1/10,000 to <1/1,000):** urticaria, eczema nummular, hypersensitivity, hypersensitivity vasculitis
- A history consistent with a genuine adverse effect typically involves significant symptoms in the 48-72 hr following a dose, which then diminish until the next 2-weekly dose is administered. Monitoring symptoms while omitting 1 to 2 doses may also help to determine whether they represent an Alirocumab-mediated adverse effect.
- Contact Lipid Clinic, RIE (contact details above) for further information/advice

Note: full details are available within the SPC and BNF. Key information is included here for speed of access.

Drug interactions - Refer to current Summary of Product Characteristics: www.medicines.org.uk for full detail.

- Statins and other lipid-modifying therapy are known to increase production of PCSK9, the protein targeted by alirocumab. This leads to the increased target-mediated clearance and reduced systemic exposure of alirocumab. Compared to alirocumab monotherapy, the exposure to alirocumab is about 40%, 15%, and 35% lower when used concomitantly with statins, ezetimibe, and fenofibrate, respectively. However, reduction of LDL-C is maintained during the dosing interval when alirocumab is administered every two weeks and therefore no adjustment in dose should be required.
- There are no known interactions with other medications.

Note: full details are available within the SPC and BNF. Key information is included here for speed of access.

The presence of this SCA does not compel a primary care prescriber to prescribe if they feel that it is out with the scope of their competencies (as per GMC guidance on safe prescribing) or resources, as ultimate responsibility lies with the prescribing, not the recommending, clinician.

Approved by the General Practice Prescribing Committee (GPPC) on 13.09.2022