Innovative Medicines Optimisation Clinic (PCSK9i & Statin Intolerance)

Team Structure

The Overall Multidisciplinary Steering Committee for the Service
Cardiology + Endocrinology + Pharmacy
(Cardiologist, Lipidologists, Consultant Pharmacist, Advanced Pharmacist, Cardiology Nurse, FH Nurse)

The Team Delivering the Clinics & Service on Weekly Basis
Independent Pharmacist Prescribers (Consultant Pharmacist + Advanced Pharmacist)
Cardiology Nurse

The Team Supporting Supply & Monitoring
Advanced Pharmacist + LTHT Boots Pharmacy
Cardiology Nurse + Pharma sponsored Home Care Service + Cardiology Admin

Other Team Members
IT support to maintain a registry of all patients started on PCSK9i
Various research HCP to support data entry and analysis

© The Leeds Teaching Hospitals NHS Trust Cardiology Innovative Medicines Clinic Pathway. For more details contact: consultant cardiology pharmacist Dr Rani Khatib on r.khatib@leeds.ac.uk, Abi Barrowcliff (Advanced Pharmacists), or Eunice Ikongo (Cardiology Nurse).
Referral to the Innovative Medicines Clinic - PCSK9i

- For patients to be considered for initiation on a PCSK9 inhibitor they need to be referred to the Multidisciplinary PCSK9 Inhibitors Clinic (also known as the Cardiology Innovative Medicines Clinic).

- A letter or email referral should be sent to:

  **Professor Alistair Hall, Consultant Cardiologist**
  Or
  **Dr Rani Khatib, Consultant Cardiology Pharmacist**

  At the Cardiology Department, Leeds Teaching Hospitals NHS Trust.

- The letter should include background history of the patient and the reasons why they should be considered for PCSK9 Inhibitors. The following essential information should be included:
  
  - Full cardiovascular history (if present).
  - If patient has a diagnosis of Familial Hypercholesterolaemia.
  - Full lipid profile including LDL-C.
  - Lipid lowering medicines prescribed and any intolerances.
  - If statin intolerance, please list which statins were tried and the type of intolerance. Was CK levels measured?
  - List of all medicines patient is currently on.
  - Any other co-morbidities including status of renal function and liver function

- Once the referral is received, it will be acknowledged by letter or email.

- The patient will be discussed in an MDT meeting including members of the teams running the clinic and steering committee where needed.

- If the patient potentially meets the NICE criteria they will be invited to attend clinic. They will be contacted by a member of the MDT team by phone and after that by letter.

- In clinic patients will be assessed using a person-centred approach to explore current and potential lipid medicines optimisation needs. An example of one of the pathways described on the next page.
Primary non-familial hypercholesterolaemia or mixed dyslipidaemia

Patient diagnosed with Primary non-familial hypercholesterolaemia or mixed dyslipidaemia

Without CVD

Primary Prevention

Assess 10yrs CV risk and initiate statins as per NICE lipid guidelines.

Without CVD

Primary Prevention

With CVD (high or very high risk)

Secondary Prevention

Intolerance to statins (see definition below)

OR

LDL-C remains persistently above the LDL-C threshold (see NICE table)

With CVD

High risk

With CVD

Very high risk

LDL-C > 4mmol/L

LDL-C > 3.5mmol/L

PCSK9 Inhibitors Indicated

Statins intolerance is defined as:

- Contraindication for using statins (e.g. allergy, active liver disease or unexplained persistent elevations of serum transaminases, long term interactions).
- Development of serious or intolerable side effects despite testing 3 different statins. (please see statin intolerance guidance)

© The Leeds Teaching Hospitals NHS Trust Cardiology Innovative Medicines Clinic Pathway. For more details contact: consultant cardiology pharmacist Dr Rani Khatib on r.khatib@leeds.ac.uk, Abi Barrowcliff (Advanced Pharmacists), or Eunice Ikongo (Cardiology Nurse).
The PCSK9i Pathway

Patient identified with high LDL levels (>3.5) and referred to PCSK9 clinic for consideration

Visit 1 - Assessment for suitability for PCSK9 inhibitors & alternative options (initiation if suitable) + Education + Administration. Pharmacist Prescriber (Consultant / Advanced Pharmacist) + Cardiology Nurse support.

Phone call follow up with Cardiology nurse (1-2 calls)

Visit 2 (3 months) - Assess response, adherence and additional / alternative therapies / address side effects. Pharmacist Prescriber

Visit 3 (6 months) - Assess response, adherence and stability - start home care process. Paper work. additional / alternative therapies / address side effects. Pharmacist Prescriber + Cardiology Nurse Support

Phone call follow up with Cardiology Nurse (1-2 calls)

Visit 4 (9 months) - Optional - Adherence and additional / alternative therapies / address side effects. Pharmacist Prescriber

Continue with prescription writing + Home care + annual bloods / review (by phone) (Pharmacist & Nurse)

Supply from Boots

1st inj in clinic & 2nd to use in 2 weeks, further supplies from Boots

Supply from Boots

Supply from Boots

Supply from Boots Until home care starts

Supply from Home Care Company

© The Leeds Teaching Hospitals NHS Trust Cardiology Innovative Medicines Clinic Pathway. For more details contact: consultant cardiology pharmacist Dr Rani Khatib on r.khatib@leeds.ac.uk, Abi Barrowcliff (Advanced Pharmacists), or Eunice Ikongo (Cardiology Nurse).
PCS\ks{9} clinic patient experience questionnaire

Patient experience

Feedback forms were provided to patients who attended the clinic. 26 patients completed the survey. Findings were as follows:

- 14 were males. The average age for all respondents was 63 (±7.8) yrs.
- 17 of those patients were prescribed a PCS\ks{9}.
- 23 classed themselves as statin intolerant before attending clinic.
- Patients prescribed PCS\ks{9} were asked about the use of PCS\ks{9} (where prescribed). The responses were as follows:
  - 16 of the 17 (94\%) either agreed or strongly agreed that the medicine easy to administer. One patient stated that the medicine was hard to administer due to arthritis.
  - All patients were happy with the PCS\ks{9} and felt that it fulfilled its purpose.
  - All patients were satisfied with the information on storage, administration, disposal, and possible side effects of the injection.
- With regards to the evaluation of the clinic by all patients regardless of PCS\ks{9} prescribing, the responses were as follows:
  - 23 of the 26 patients (89\%) either agreed or strongly agreed that all questions and concerns about their medicines were answered. The rest did not answer.
  - All patients either agreed or strongly agreed that they were provided with clear plans and goals about their cholesterol lowering medicines, any tests that they needed and their health as a whole.
  - All patients also at least agreed that after attending the clinic they fully understood their cholesterol lowering medicines and why they were prescribed.
  - When asked to rate their experience about the overall service they received from the clinic, 3 (12\%) were satisfied and 23 (88\%) were very satisfied.
  - All patients stated that they were satisfied that their cholesterol was better controlled than before attending the clinic.

All patients at least agreed that they were supported and listened to, found the clinic to be valuable and would recommend for patients with high cholesterol

Quotes from patients who took part in the patient survey about the clinic

- ‘I was really pleased with all the aspects of the clinic and medicine, as I believe this has changed my life and anxiety over heart disease’
- ‘Great staff and the injection has greatly lowered my cholesterol so I am really grateful’.
- ‘It works! I am both very lucky and grateful to have been given the opportunity to attend this clinic. Who knows, it might have bought me more time with my family than if I had not had this opportunity. Excellent and extremely competent and caring staff in a well-run clinic. Thank you very much’. 
• ‘I am very satisfied with all aspects. Everyone at the clinic is very supportive and helpful. I am happy to keep using the medicine’

• ‘And most importantly the new medication regime has lowered my LDL from 4.7 - 1.4 a stunning outcome. A really, really good service overall. Thanks to all the clinic staff...’

• ‘Very good for me. My cholesterol has come way down’.

• ‘I cannot think of a what this excellent clinic could be improved. The staff are great, any queries I have are answered thoroughly and the medication I have been prescribed are working well to keep my cholesterol levels very low, well done to all concerned’

• ‘Good advice given about my medicine. Management of the appointment moving from consultant pharmacist to research nurse to future appointment works extremely well. There is plenty of time to discuss any issues/concerns with experienced and knowledgeable people.’