





**HNY ICB IP Pathfinder Programme Clinical Protocol: Model 3 – Cardiovascular Disease – Primary Prevention Lipids Therapy**

**Background**

The service aims to allow IP community pharmacists to hold consultations with patients review and consider initiation of lipid therapy for primary prevention of cardiovascular disease.

This model will improve access for patients and patient outcomes, assisting them with introducing primary prevention of cardiovascular disease and potentially initiation of lipid therapy.

This model will work in partnership with general practice(s) with the management of identified patients who may benefit from a consultation to discuss primary prevention of cardiovascular disease. Community pharmacies and general practices will work collaboratively together to address any concerns and appropriately manage patients' health and expectations.

<b>Clinical Protocol</b>	
Clinical condition or situation to which this protocol applies	To allow IP community pharmacists to review patients to consider initiation of lipid therapy for primary prevention of cardiovascular disease
Inclusion	The inclusion criteria will be patients identified or referred to the community pharmacy who would benefit from primary prevention of cardiovascular disease
Exclusion	<p>The exclusion criteria will be patients identified with:</p> <ul style="list-style-type: none"> <li>• Impaired renal / hepatic function</li> <li>• Complex health needs</li> <li>• Multiple comorbidities</li> <li>• Those in need of secondary prevention</li> <li>• Familial hypercholesterolaemia</li> <li>• Severe hyperlipidaemia</li> <li>• Under secondary care</li> <li>• Anyone with contraindications or drug interactions to statins</li> <li>• Pregnancy</li> <li>• Statin intolerance / allergies</li> </ul>
Formulary and Guidance to be followed	<p>The IPs will be expected to follow relevant guidance. This includes:</p> <ul style="list-style-type: none"> <li>• local formularies: <ul style="list-style-type: none"> <li>○ <a href="#">Humber</a></li> <li>○ North Yorkshire <ul style="list-style-type: none"> <li>▪ <a href="#">Harrogate</a></li> <li>▪ <a href="#">York and Scarborough</a></li> </ul> </li> </ul> </li> <li>• <a href="#">NICE Guidance</a></li> </ul> <div style="display: flex; justify-content: space-around; align-items: flex-start;"> <div style="text-align: center;">   lipid-management-pathway-version-7-1 </div> <div style="text-align: center;">   statin-intolerance-pathway-v2.pdf </div> </div> <ul style="list-style-type: none"> <li>• Be aware of different BMI guides for different ethnic groups: <a href="#">Ethnic groups need diabetes prevention at lower BMI - NIHR Evidence</a></li> <li>• Patient information leaflet: <a href="#">Atorvastatin: a medicine to treat high blood cholesterol - NHS (www.nhs.uk)</a></li> </ul>



Patient route(s) into the service	<p>Patients will be able enter the IP Pathfinder service via one of the options below:</p> <ol style="list-style-type: none"><li>1. Patient identified by presenting to an IP Pathfinder site who wants to know more about lowering cholesterol / has had a high cholesterol check recently and is not currently on prescribed treatment for hypercholesterolaemia.</li><li>2. Pathfinder site identifying patients who they believe would benefit from being offered a consultation to discuss hypercholesterolaemia.</li><li>3. Patients referred to the pharmacy delivering lipid initiation service by another health organisation.</li></ol>
Patient Pathway –	<ul style="list-style-type: none"><li>• Patients identified from one of the routes above.</li><li>• Patient will be invited to attend an IP Pathfinder site for a consultation regarding their prescribed medicines e.g. via AccuRx message.</li><li>• Pharmacy contacts patient to gain consent for review and books appointment in IP Pathfinder site.</li><li>• Patient attends appointment (remote or face to face) at Pathfinder site. IP conducts holistic consultation including:<ul style="list-style-type: none"><li>○ Review non-fasting full lipid profile (TC, HDL-C, non-HDL-C, triglycerides) and HbA1c</li><li>○ Measure BMI – need to be aware of different BMI guides for different ethnic groups: <a href="#">Ethnic groups need diabetes prevention at lower BMI - NIHR Evidence</a></li><li>○ Complete QRISK3 tool</li><li>○ Offer lifestyle changes / advice (smoking, diet, obesity, alcohol intake, physical activity, blood pressure and HbA1c).</li><li>○ Consider statin therapy for patients who do not have established CVD but fall into following categories:<ul style="list-style-type: none"><li>▪ Age less than 84 &amp; QRISK of 10%+ over next 10 years</li><li>▪ Type 2 diabetes &amp; QRISK of 10%+ over next 10 years</li><li>▪ CKD eGFR &lt; 60ml/min/1.73m<sup>2</sup> and / or albuminuria</li><li>▪ Age 85 or more, if appropriate consider co-morbidities, frailty and life expectancy</li><li>▪ Type 1 Diabetes if they have one or more of the following:<ul style="list-style-type: none"><li>• Over 40 years</li><li>• Had diabetes for 10+ years</li><li>• Established nephropathy</li><li>• Other CVD risk factors</li></ul></li></ul></li></ul></li><li>• If lifestyle modifications are ineffective or inappropriate, discuss the risks and benefits of statins. Offer treatment based on an informed shared-decision, e.g. atorvastatin 20mg tablets</li><li>• Arrange follow up with patient – remember requirement to measure full lipid profile again after 2-3 months (non-fasting).</li></ul>



	<ul style="list-style-type: none"><li>• IP to provide counselling / information regarding the new medication. This leaflet contains everything the patient needs to know and can be provided as a summary either printed or electronically: <a href="http://www.nhs.uk">Atorvastatin: a medicine to treat high blood cholesterol - NHS (www.nhs.uk)</a></li><li>• Community Pharmacist IP to refer to GP practice for peer support / advice if any patient factors / issues arise that fall outside of the current competency or experience of the IP.</li><li>• All prescribing and/or medication changes should be line with NICE Guidance and local formulary guidance (see Formulary &amp; Guidance section above).</li><li>• Medication changes that require monitoring, need to follow NICE Guidance.</li><li>• Patients' care is transferred back to GP at patients' request at any point in the pathway for a routine appointment with the most appropriate healthcare professional.</li><li>• All consultations must be recorded on the clinical consultation record (PharmOutcomes).</li><li>• An automated Post Event Notification (PEN) will be sent via NHS mail as a PDF attachment to a patients' general practice upon completion of the PharmOutcomes platform.</li><li>• Prescribing will be permissible via GP IT systems until Cleo Solo EPS is in place in IP Pathfinder sites.</li><li>• Once Cleo Solo EPS is available at an IP Pathfinder site, Cleo Solo EPS must be used to issue any prescription.</li><li>• Appropriate safety netting must be given to ensure the patient knows where to seek support in case of problems arising.</li></ul>
Consultation requirements	<p>The consultation will consist of:</p> <ul style="list-style-type: none"><li>• Clinical history.</li><li>• Patient assessment including clinical history and where necessary physical examination.</li><li>• Provision of advice, which may include signposting to relevant NHS website information or written information.</li><li>• Clinical management will be in accordance with Clinical Knowledge Summaries <a href="http://cks.nice.org.uk">http://cks.nice.org.uk</a></li><li>• Consideration of drug interactions for any medication including contraindications, sensitives / allergies</li><li>• Safety netting information to the patient</li></ul> <p>Where clinically appropriate the consultation can be provided remotely e.g. by phone or video consultation. The IP must determine if is clinically appropriate / a requirement for the patient to be seen face-to-face or whether the consultation can be safely carried out remotely without impacting on the quality of the service received.</p> <p>Considerations in relation to appropriateness for remote consultation (not exhaustive)</p> <ul style="list-style-type: none"><li>• requirement for a physical examination</li><li>• barriers to communication created by remote consultations that would be addressed by a face-to-face consultation</li></ul>



Session provision	The number of sessions provided and the number of consultations per session (4 hours) will be locally discussed and agreed.
Onward referral of patients	This IP activity is discrete to General Practice. There will be occasions that the IP needs to refer the patient to their GP (or relevant OOH provider) for further assessment or management. These referrals will be made via locally discussed and agreed routes.
Access to blood tests and pathology	Access to pathology is required as part of this model. Until community pharmacies can arrange blood tests themselves e.g., via Community Diagnostic Centre (CDC) discussions need to be held between the patients' general practice and IP Pathfinder site.
Records	Records are to be kept in line with the IP Pathfinder Service Specification.
Notification	Post event notification to be sent to the patients registered GP digitally e.g. by either NHS Mail or another predetermined and agreed digital system. This may include: <ul style="list-style-type: none"><li>• System ID</li><li>• Person full name</li><li>• Date of birth</li><li>• Person address</li><li>• Postcode</li><li>• NHS number</li><li>• GP name</li><li>• GP Practice details</li><li>• GP practice identifier</li><li>• Organisation identifier</li><li>• Organisation name</li><li>• Organisation address</li><li>• Organisation contact details</li><li>• Date</li><li>• Service i.e., lipid initiation</li><li>• Clinician name</li><li>• Medicine(s) prescribed including strength, formulation and dose</li><li>• Quantity of medication prescribed</li><li>• Presenting reason e.g. identified or referred to the community pharmacy</li><li>• Consultation outcome</li><li>• Clinical narrative</li><li>• Referral Date</li><li>• Urgency of referral</li><li>• Referral to (organisation name)</li><li>• Referral to (organisation identifier)</li><li>• Reason for referral.</li></ul>