NHS
North East London

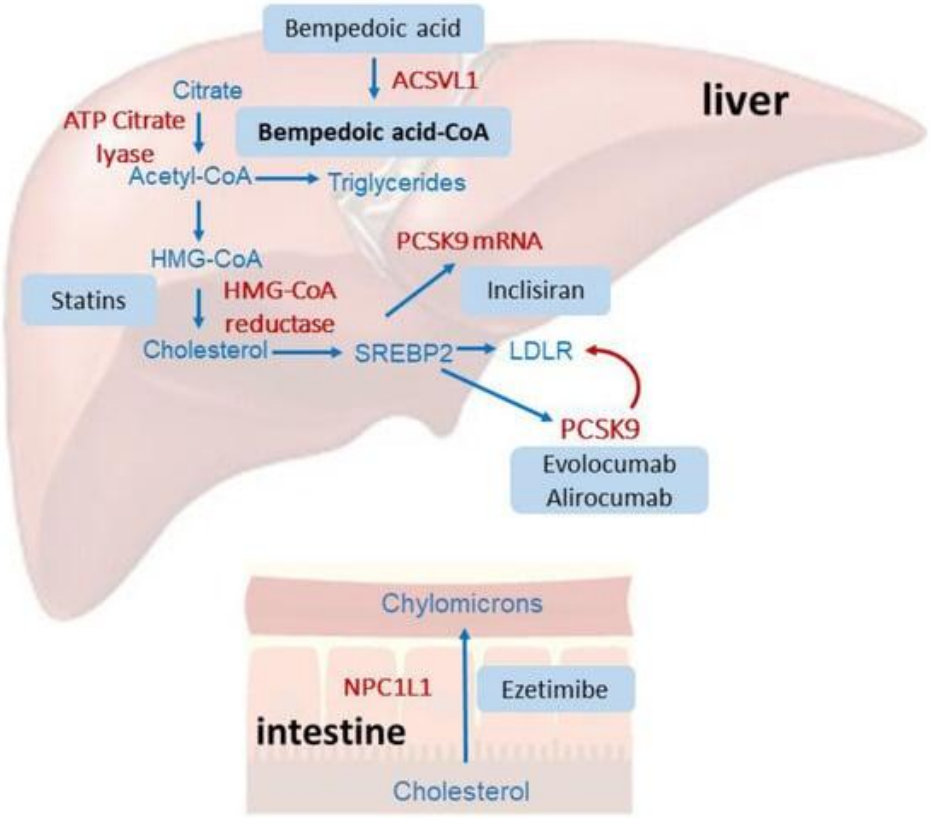
Primary Care Prescribing Support Factsheet

Prescribing and Supply of Bempedoic acid 180mg monotherapy or in combination with ezetimibe 10mg

Document control	
Version	1.0
Produced by	Cardiology Pharmacy Team (Barts Health)
Approved by	NEL Formulary and Pathways Group
Date approved	07/10/2025
Ratified by	North East London System Prescribing and Medicines Optimisation (SyPMO) Board
Date ratified	28/10/2025
Review date	October 2028

1. What is Bempedoic acid 180mg

Bempedoic acid 180mg is used to treat primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia. Bempedoic acid works by inhibiting an enzyme called ATP citrate lyase (ACL) in the liver, which is involved in the production of cholesterol. By reducing cholesterol synthesis upstream of where statins act, it leads to LDL receptor expression in the liver and a lowering of LDL levels in the blood.



2. **Indication:** Primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia.

3. **Formulary and Pathways Group (FPG) approval**

NEL Formulary status	Green
Date approved	28th October 2025

4. **National approval e.g. NICE**

NICE lipid guidance (NG238), national focus on cardiovascular risk reduction (long term plan), supportive resources in identifying and managing individuals with statin intolerance (Accelerated Access Collaborative (AAC) lipid pathways). Noting nationally around 20% of patients with established cardiovascular disease are not on lipid lowering therapies (CVD prevent). Current lipid services and cardiovascular risk reduction clinics are saturated with individuals requiring injectables – bempedoic acid offers opportunity to reduce cardiovascular risk and with ezetimbe combination a 40% reduction in LDL cholesterol that can be effectively manged in primary care. NICE TA 694 further supports bempedoic acid +/- ezetimbe in treating primary hypercholesterolaemia or mixed hyperlipidaemia as an adjunct to diet in adults.

Bempedoic Acid in Pathways

- Bempedoic acid +/- ezetimibe to be considered in patients who:
    1. Are statin-intolerant* or have contraindications to statins; and
    2. Require further LDL-C lowering beyond ezetimibe
- The AAC national guidance places bempedoic acid +/- ezetimibe in the treatment algorithms of primary and secondary prevention based on the criteria above. See below screen shots from the guidance.
- Bempedoic acid's oral administration, liver-specific activation, and low muscle-side effect risk enhance its appeal in statin-intolerant patients.

*defined as person reported intolerance to recommended high intensity statin treatment

The pathway includes bempedoic acid as an alternative offering a cost-effective, oral option for LDL-C lowering in statin-intolerance scenarios in both primary prevention (where high intensity statins are not tolerated or contraindicated) and secondary prevention (to achieve LDL-C reduction when ezetimibe alone is unable to achieve targets).

Primary and Secondary prevention summary from AAC resources (link)

PRIMARY PREVENTION

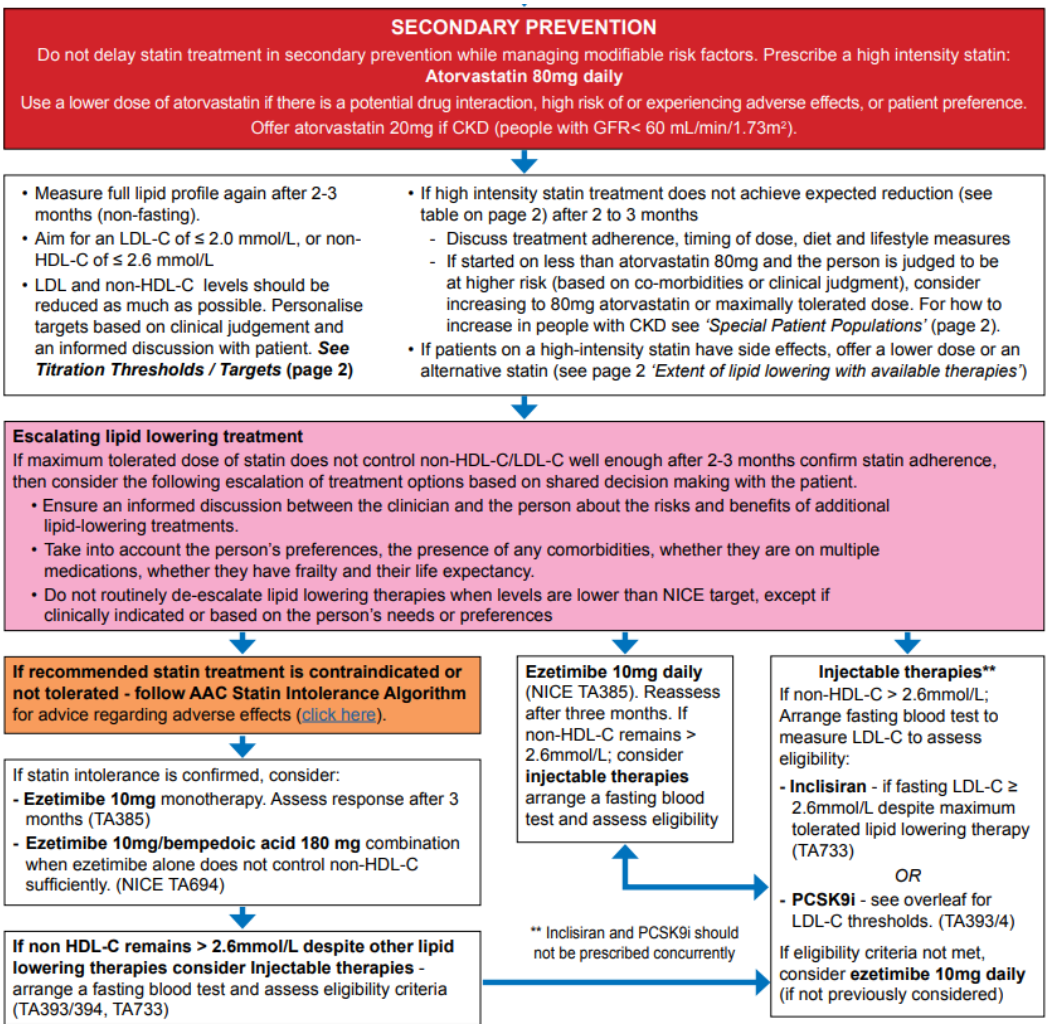
If lifestyle modification is ineffective or inappropriate, discuss the risks and benefits of statins, and offer treatment based on an informed shared-decision.

Atorvastatin 20mg daily

- Measure full lipid profile again after 2-3 months (non-fasting).
- High intensity statin treatment should achieve reduction of non-HDL-C > 40% from baseline. If not achieved after 2-3 months;
  - Discuss treatment adherence, timing of dose, diet and lifestyle
  - If at higher risk (based on comorbidities, risk score or clinical judgement – see page 2 *'Additional Risk Factors'*) consider increasing the dose every 2-3 months up to a maximum dose of atorvastatin 80mg daily.
  - For how to increase in people with CKD see *'Special Patient Populations'* (page 2).

- If patients on a high-intensity statin have side effects, offer a lower dose or an alternative statin (see page 2 *'Extent of lipid lowering with available therapies'*)
- If maximum tolerated dose of statin does not achieve non-HDL-C reduction > 40% of baseline value after 2-3 months consider adding Ezetimibe 10mg daily (NICE TA385)
- If statin treatment is contraindicated or not tolerated;
  - See AAC Statin Intolerance Algorithm for advice regarding adverse effects (click here)
  - Ezetimibe 10mg monotherapy may be considered. Assess response after 2-3 months.
  - Ezetimibe 10mg/bempedoic acid 180 mg combination may be considered when ezetimibe alone does not control non-HDL-C/LDL-C well enough (NICE TA694).

If non-HDL-C reduction remains < 40% of baseline despite maximal tolerated lipid lowering therapy (including people with intolerances and contraindications) consider referral to specialist lipid management clinic according to local arrangements



Primary Prevention

If statin Intolerance*

- Follow AAC statin intolerance pathway and rechallenge with low dose alternative statin
- Start Ezetimibe 10mg daily for 28 days
- Initiate bempedoic acid 180mg daily in combination with ezetimibe (Nustendi®) if confirmed statin intolerance or ezetimibe alone does not achieve LDL-C reduction target

Secondary Prevention

If statin Intolerance*

- Follow AAC statin intolerance pathway and rechallenge with low dose alternative statin
- Start ezetimibe 10mg daily for 28 days
- Initiate bempedoic acid 180mg daily in combination with ezetimibe (Nustendi®) if confirmed statin intolerance or ezetimibe alone does not achieve LDL-C reduction target (<2mmol/L)
- Consider initiation of inclisiran if LDL-C remains >2.6 mmol/L

*defined as person reported intolerance to recommended high intensity statin treatment

5. Prescribing and Supply Information

Dose	Nustendi® (Bempedoic acid/Ezetimibe) 180mg/10mg tablet: One tablet daily Nilemdo® (Bempedoic acid) 180 mg tablet: One tablet daily
Duration	Long term with response to lipid panel, including LDL-C
Supply	Can be initiated in both primary and secondary care
Key Special warnings and precautions including Pregnancy, breastfeeding	**Contraindications**: - Hypersensitivity to active substance of excipients - Pregnancy and breast feeding - Concomitant use with simvastatin – simvastatin dose should be limited to 20mg daily (or 40mg daily for patients with severe hypercholesterolaemia and high risk for cardiovascular complications, who have not achieved their treatment goals on lower doses and when the benefits are expected to outweigh the potential risks) **Warnings**: **Contraception measures in women of child-bearing potential** - Before initiating treatment in women of child-bearing potential, appropriate advice on effective methods of contraception should be provided, and effective contraception initiated. - Patients taking oestrogen-based oral contraceptives should be advised about possible loss of effectiveness due to diarrhoea and/or vomiting. Patients should be advised to immediately contact their physician and stop treatment if they are planning to become pregnant or if they become pregnant. **Increased serum uric acid** - Bempedoic acid may raise the serum uric acid level due to inhibition of renal tubular OAT2 and may cause or exacerbate hyperuricaemia and precipitate gout in patients with a medical history of gout or predisposed to gout. Treatment should be discontinued if hyperuricaemia accompanied with symptoms of gout appear. This list is not exhaustive – please refer to the most up-to-date resources such as BNF and Summary of Product Characteristics
Renal impairment	There is limited experience with bempedoic acid in patients with severe renal impairment (defined as eGFR < 30 mL/min/1.73 m^2), and patients with ESRD on dialysis. Additional monitoring for adverse reactions

	(including but not exclusive to uric acid, haemoglobin and LFTs) may be warranted in these patients when bempedoic acid is administered.
Hepatic impairment	Patients with severe hepatic impairment (Child-Pugh C) have not been studied. Periodic liver function tests should be considered for patients with severe hepatic impairment.
Monitoring	Baseline blood test monitoring: Full lipid profile, LFTs, renal function, uric acid and FBC (including Hb) and then repeated following 3 months. If stable to periodically monitor blood test at 6-12 month intervals. Actions at 3 months: **Lipid profile** – similar to statins, aiming for targets set in guidance (Primary prevention – reduction of >40% non-HDL-C, Secondary prevention aiming for LDL-C targets ≤2.0mmol/L (or non-HDL-C ≤2.6mmol/L) **LFTs** – similar to statins, treatment to be discontinued if transaminases rise >3x upper limit of normal. **Haemoglobin** – a decrease in haemoglobin has been observed in clinical trials, usually occurring in the first 4 weeks of treatment. If a decrease from baseline of 20g/L or figures fall below lab refence ranges – stop treatment and investigate causes. If bempedoic acid is the cause, Hb values usually return to baseline after 4 weeks. **Urate Levels** – Patients with elevated levels and accompanying symptoms of gout should stop treatment.
Criteria for referral back to Parent Team	If LDL is not achieved to guideline target, then to seek advice and guidance to explore further treatment options. If bempedoic acid has to be stopped due to monitoring criteria above – please refer to lipid team for further treatment options. Considerations for treatment would include optimising current statin therapy or if for advanced injectables if for secondary prevention.
Interactions	- When bempedoic acid co-administered with simvastatin – dose should be limited to 20mg daily (or 40mg daily for patients with severe hypercholesterolaemia and high risk for cardiovascular complications, who have not achieved their treatment goals on lower doses and when the benefits are expected to outweigh the potential risks) due to 2 fold increase in simvastatin exposure - Bempedoic acid may lead to a moderate increase in other statins including atorvastatin, pravastatin and rosuvastatin – although no requirement for dose alterations required. - The safety and efficacy of ezetimibe administered with fibrates has not been established. If cholelithiasis is suspected in a patient receiving bempedoic acid in combination with ezetimibe, and fenofibrate, gallbladder investigations are indicated, and this therapy should be discontinued. - Caution should be exercised when initiating bempedoic acid or bempedoic acid in combination with ezetimibe, in combination with ciclosporin and ciclosporin concentrations should be monitored. - If bempedoic acid or bempedoic acid in combination with ezetimibe is added to warfarin or other coumarin anticoagulants,

	the International Normalised Ratio (INR) should be appropriately monitored. This list is not exhaustive – please refer to the most up-to-date resources such as BNF and Summary of Product Characteristics
Any specific or important counselling points	Elevated Urate Levels - Advise patients of the risk of elevated serum uric acid levels, including development of gout. - Inform patients that serum uric acid levels may be monitored during treatment with bempedoic acid. - Patients with signs or symptoms of hyperuricemia should contact their clinician if symptoms occur. Each Nilemdo® OR Nustendi® tablet should be taken orally with or without food. The tablet should be swallowed whole.

6. Prescribing Support

Referrals and enquiries sent via email are to be answered within **5 working days** of receipt.

Team	Email Address
Barts Health	
Lipid Clinic, Barts, St Bartholomew's Hospital	bartshealth.cardiologylipids@nhs.net
Homerton	
Dept. of Pathology, Homerton Hospital,	Consultant chemical pathologist, Pathology admin contact details -0208 510 7309
Barking, Havering and Redbridge University Hospitals	
Cardiology Lipid Management, Barking, Havering and Redbridge NHS trust	Currently run by a Barts Health Consultant – please contact Dr Fizzah Choudry via their secretary