Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil
Bealach amach 5, M50, An Bóthar Thuaidh, Fionnghlas
Baile Átha Cliath 11, D11 XKF3
Fón: (01) 864 7100 Facs: (01) 834 3589

Health Service Executive, Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: (01) 864 7100 Fax: (01) 834 3589

28th August 2024

Circular 014/24

RE: Reimbursement of Nilemdo® (Bempedoic Acid) and Nustendi® (Bempedoic Acid/Ezetimibe)

Dear Doctor,

The HSE has approved reimbursement for Nilemdo® (Bempedoic Acid) 180 mg tablets and Nustendi® (Bempedoic Acid/Ezetimibe) 180 mg/10 mg tablets under Community Drug Schemes from 1 September 2024. These products are approved for reimbursement on the basis of managed access for their licensed indications.

Due to the potential budget impact, PCRS has introduced a reimbursement application system to ensure appropriate patients have access to treatment. Applications are submitted via the PCRS Doctor Application Suite > Claiming > Special Drug Request.

Please see attached letter and supporting information from Prof Michael Barry, Clinical Lead of the HSE Medicines Management Programme (MMP) in relation to reimbursement of Nilmedo® and Nustendi®.

Yours faithfully,

Shaun Flanagan

Primary Care Reimbursement Service

Re: Reimbursement of Bempedoic Acid (Nilemdo®) and Bempedoic Acid + Ezetimibe (Nustendi®)

28 August 2024

Dear Colleagues,

Bempedoic acid 180 mg film-coated tablets (Nilemdo®) and bempedoic acid 180 mg plus ezetimibe 10 mg film-coated tablets (Nustendi®) are available for reimbursement under the Community Drug Schemes from 1 September 2024. Reimbursement of these medicinal products is conditional on a HSE-Managed Access Protocol (MAP) being put in place that enables individual reimbursement approval for individuals who meet the criteria outlined in the MAP.

A summary of the reimbursement criteria, as outlined in the MAP, is enclosed for your information. Full details of the MAP for bempedoic acid can be accessed on the HSE-Medicines Management Programme (MMP) website:
www.hse.ie/eng/about/who/cspd/medicines-management/managed-access-protocols/.

GPs and hospital prescribers, once user-registered with the HSE-Primary Care Reimbursement Service (PCRS), will be authorised to submit an application on an individual patient basis, through the special drug request (SDR) section on the 'GP Application Suite' or under 'Services for Hospitals' on the PCRS website (www.hse.ie/eng/staff/pcrs/online-services/). The application for reimbursement support should be made by the prescriber responsible for the initiation of treatment.

My thanks for your ongoing support in promoting safe, effective and cost-effective prescribing.

With best wishes,

Michael Barry.

Professor Michael Barry,
National Clinical Lead,
HSE-Medicines Management Programme.
www.hse.ie/mmp

Reimbursement Information – Bempedoic Acid film-coated tablets (Nilemdo®) & Bempedoic Acid plus Ezetimibe film-coated tablets (Nustendi®)

Medicines Management Programme

Adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia who:

- do not reach the LDL-C target levels for their total cardiovascular risk category, **and**
- have confirmed adherence to the maximum-tolerated dosages of statins and ezetimibe.

Very-high-risk cardiovascular risk category[a]

- LDL-C persistently ≥ 1.4 mmol/L[c] → **Reimbursement supported**
- LDL-C persistently < 1.4 mmol/L[c] → **Reimbursement not supported**

High-risk cardiovascular risk category[b]

- LDL-C persistently ≥ 1.8 mmol/L[c] → **Reimbursement supported**
- LDL-C persistently < 1.8 mmol/L[c] → **Reimbursement not supported**

Cardiovascular risk category	People with any of the following:
[a]**Very-high-risk**	• Documented ASCVD, either clinical or unequivocal on imaging • DM with target organ damage[¥], or at least three major risk factors, or early onset of Type 1 DM of long duration (> 20 years) • Severe CKD (eGFR < 30 ml/minute/1.73 m^2) • A calculated SCORE ≥ 10% for 10-year risk of fatal CVD • FH with ASCVD or with another major risk factor
[b]**High-risk**	• Markedly elevated single risk factors, in particular total cholesterol > 8 mmol/L, LDL-C > 4.9 mmol/L, or blood pressure > 180/110 mmHg • FH without other major risk factors • DM without target organ damage[¥], with DM duration ≥ 10 years or another additional risk factor • Moderate CKD (eGFR 30 – 59 ml/minute/1.73 m^2) • A calculated SCORE ≥ 5% and < 10% for 10-year risk of fatal CVD

[c]**Two LDL-C levels** must be provided to demonstrate that LDL-C is **persistently** above the specified thresholds:

- The **current LDL-C level** must have been taken in the 30-day period prior to the date of application for reimbursement approval.
- The **previous LDL-C level** should have been taken at least three months prior to the current LDL-C level.
- **The current LDL-C level must be reflective of confirmed adherence to ezetimibe 10 mg daily for a minimum of three months and one of the following**:*
  - adherence to high-dose statin therapy for a minimum of three months
  - adherence to maximum-tolerated statin therapy for a minimum of three months, where the individual was unable to tolerate high-dose statin therapy
  - statin intolerance
  - contraindication to statin therapy.
- A copy of the blood test results showing the **current LDL-C level** must be provided as part of the application for reimbursement approval.

see the HSE-Managed Access Protocol for further details

A Managed Access Protocol (MAP) is in place through the Health Service Executive (HSE)-Medicines Management Programme (MMP): https://www.hse.ie/eng/about/who/cspd/medicines-management/managed-access-protocols/.
Prescribers, once user-registered with the Primary Care Reimbursement Service (PCRS), are required to apply for reimbursement approval on an individual patient basis through the PCRS online application system (www.pcrs.ie). This can be accessed for GPs via the 'GP Application Suite' and for hospital prescribers via 'Services for Hospitals'.

Abbreviations: ASCVD: Atherosclerotic cardiovascular disease; CKD: Chronic kidney disease; CVD: Cardiovascular disease; DM: Diabetes Mellitus; eGFR: estimated glomerular filtration rate; FH: Familial hypercholesterolaemia; LDL-C: Low-density lipoprotein-cholesterol; SCORE: Systematic coronary risk estimation. [¥]Target organ damage is defined as microalbuminuria, retinopathy, or neuropathy.

Version 1 August 2024