



Paul Murphy, T.D.  
Dáil Éireann,  
Leinster House,  
Kildare Street,  
Dublin 2.

23rd June 2022

PQ: 32660/22

**To ask the Minister for Health the reason that a rule (details supplied) is in place for the drug PCSK9 inhibitor. -Paul Murphy**

**Details supplied:** *that if a patient has not previously had an MI (myocardial infarction) this drug is not covered on their medical card nor are they entitled to avail of a reimbursement through the High Tech Scheme, despite the fact that this treatment has a cost of 500 euro per month?*

Dear Deputy Murphy,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 32660/22), which you submitted to the Minister for Health for response.

The HSE is committed to providing access to as many medicines as possible in as timely a fashion as possible from the resources available (provided) to it.

The HSE robustly assesses applications for pricing and reimbursement to make sure that it can stretch available resources as far as possible and to deliver the best value in relation to each medicine and ultimately more medicines to Irish citizens and patients.

HSE decisions on which medicines are reimbursed by the taxpayer are made on objective, scientific and economic grounds. On occasion, the HSE, in stretching constrained resources, will make a decision to establish a Managed Access Protocol to identify those who would benefit most when making a decision to support reimbursement on a patient specific basis.

Reimbursement of PCSK9 inhibitors, alirocumab (Praluent®) and evolocumab (Repatha®) is supported under the High Tech Arrangement via a Managed Access Protocol overseen by the HSE-Medicines Management Programme.

Under the Managed Access Protocol for PCSK9 Inhibitors, reimbursement is supported for the following subgroups of the licensed population:

- a) adults with a confirmed diagnosis of myocardial infarction +/- revascularisation procedures, non-haemorrhagic stroke or peripheral arterial disease (i.e. secondary prevention), or who have undergone coronary artery bypass graft, with a LDL-C persistently  $\geq 3.5$  mmol/L
- b) adults with a confirmed diagnosis of heterozygous familial hypercholesterolaemia (HeFH) with a LDL-C persistently  $\geq 4$  mmol/L.

Both (a) and (b) would be despite optimum use of lipid-lowering therapy (atorvastatin/rosuvastatin + ezetimibe) or in the setting of confirmed intolerance to lipid-lowering therapy.

The Managed Access Protocol, which outlines in detail the criteria that must be satisfied in order for a patient to be approved for reimbursement of a PCSK9 inhibitor under the High Tech Arrangement, is available on the website of the HSE-Medicines Management Programme:

<https://www.hse.ie/eng/about/who/cspd/ncps/medicines-management/managed-access-protocols/pcsk9-inhibitors/>

Yours sincerely,



Suzanne Doyle  
Primary Care Eligibility & Reimbursement Service