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

6th July 2022

PQ: 32662/22

To ask the Minister for Health the reason that low-density lipoprotein needs to be consistently above 4mmol/L; and the research that this is based on given that the European Society of Cardiology advise a target of 1.4mmol/L in cases of high-risk coronary artery disease. -Paul Murphy

Dear Deputy Murphy,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference: 32662/22), which you submitted to the Minister for Health for response.

Reimbursement of the 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 ≥ 3.5 mmol/L
b) adults with a confirmed diagnosis of heterozygous familial hypercholesterolaemia (HeFH) with a LDL-C persistently ≥ 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/

The reimbursement criteria outlined in the Managed Access Protocol, are based on scientific data from the major clinical trials that provide the clinical evidence for the efficacy and safety of these medicines. The criteria also take into account the Health Technology Assessment carried out by the National Centre for Pharmacoeconomics, and the recommendations of the HSE-Drugs Group in relation to the reimbursement approval of these medicines.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service