LDL-cholesterol targets and lipid-lowering therapies – a plea to medical schemes and the Council for Medical Schemes

To the Editor: The Lipid and Atherosclerosis Society of Southern Africa (LASSA) is concerned about the under-treatment of patients with dyslipidaemia, especially those with established atherosclerotic cardiovascular disease (ASCVD) or at very high risk for ASCVD, and particularly patients with familial hypercholesterolaemia (FH), which is highly prevalent in communities with founder effects in South Africa (SA).

Current dyslipidaemia guidelines have not been adopted by medical schemes in SA. The Council for Medical Schemes (CMS) still prescribes an outdated algorithm.[1] LASSA subscribes to the current European Society of Cardiology (ESC)/European Atherosclerosis Society (EAS) lipid guidelines as updated in 2025, with low-density lipoprotein (LDL)-cholesterol (LDL-C) targets of <1.8 mmol/L and <1.4 mmol/L, respectively, for patients at high or very high ASCVD risk.[2] Many patients with severe hypercholesterolaemia require dual or triple combination lipid-lowering therapies to reach these targets. Proprotein convertase subtilisin/kexin type 9 (PCSK9)-inhibitor therapy, in the form of monoclonal antibodies or an siRNA, are available in SA, but are not funded by medical schemes because they are not listed in the CMS algorithm. Patients with severe heterozygous or homozygous FH who are inadequately controlled with conventional therapy are particularly disadvantaged as LDL-C reductions that can be achieved by additional PCSK9-inhibition could translate to large reductions in absolute risk.[3]

Given the large potential benefit of PCSK9-directed therapy in patients with very high LDL-C, we report with great concern that funding of such therapy was recently declined for a young homozygous FH patient who had undergone two coronary bypass operations and an aortic valve replacement. On high-intensity statin plus ezetimibe, his LDL-C remained >5 mmol/L. The medical scheme refused to fund a PCSK9-inhibitor despite evidence that such treatment lowered the LDL-C by an additional 30%. The patient's complaint was initially upheld by the CMS, but an appeal to the CMS Appeal Board argued that such therapy was 'not available in the public sector', and that PCSK9 monoclonal antibodies as biologicals were 'not covered under the member's benefit option'. The appeal was upheld on, in our opinion, the erroneous grounds that the patient had not reached the LDL-C target, and that the patient's option did not provide for 'biologics'. We contend that additional LDL-C lowering would benefit this patient. Furthermore, the Medical Aid Schemes Act 131 of 1998 states that provision must be made for appropriate additional therapies without penalty to the member when formulary drugs are ineffective.

Insufficiently treated patients with homozygous FH have an extremely poor prognosis that may be worse than in patients with, for example, cancers or rheumatoid arthritis, for which biologicals are often funded. Aggressive lowering of LDL-C early in life reduces the lifelong LDL-C burden and prolongs life.

In another case, a medical scheme, after much delay, agreed to fund <10% of the cost of evolocumab for a patient with heterozygous FH whose LDL-C remained >5 mmol/L on a combination of statins and ezetimibe, but achieved 2.2 mmol/L after the addition of self-funded evolocumab. Most SA patients cannot afford monthly co-payments of several thousand rands; consequently, limited approvals are *de facto* denials.

We suggest establishing a policy such as the National Institute for Health and Care Excellence (NICE) guidelines,[4] which set criteria for the use of PCSK9-directed treatment, essentially recommending PCSK9-directed additional treatment if the LDL-C remains >5 mmol/L or >3.5 mmol/L, respectively, in primary and secondary prevention of ASCVD. As not all conditions will respond to this treatment, we advise setting up a network of national reference lipid clinics, with a dedicated central laboratory, to ensure that an accurate diagnosis and optimal evidence-based therapeutic recommendations can be made for patients with severe disorders of lipid and lipoprotein metabolism.[5] The cost of the medication can further be reduced by VAT exemption, and by the pharmaceutical industry lowering the price of life-saving medications.

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