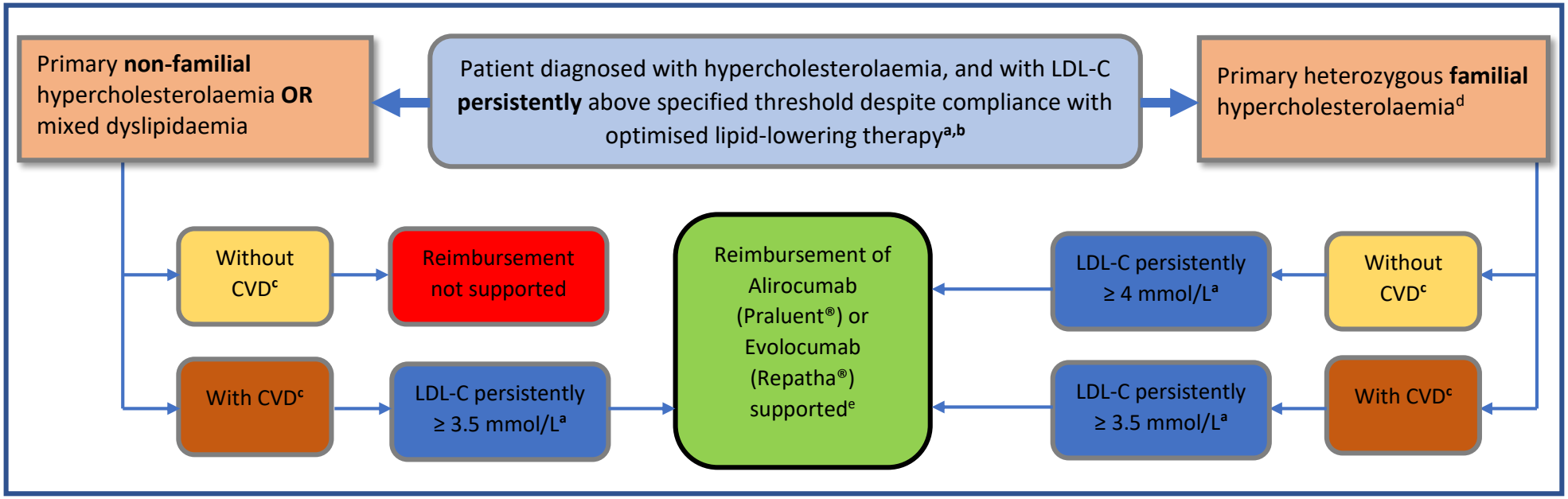
PCSK9 Inhibitors for the treatment of primary hypercholesterolaemia and mixed dyslipidaemia under the High Tech Arrangement

Medicines Management Programme
Prescribing and Cost Guidance



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

- The current level must have been taken in the 30-day period prior to the date of application for reimbursement approval
- The other level should have been taken between three to six months prior to the current level
- The current level must be reflective of one or more of the following:
  - adherence to treatment with optimised lipid-lowering therapy for a minimum of three months
  - statin and/or ezetimibe intolerance
  - contra-indication to statin and/or ezetimibe therapy.

[b]Optimised lipid-lowering therapy is defined as confirmed adherence for a minimum of three months to treatment with ezetimibe 10 mg daily, and atorvastatin ≥ 40 mg daily or rosuvastatin ≥ 20 mg daily.

[c]CVD is defined as a prior diagnosis of myocardial infarction (with or without revascularisation procedures), non-haemorrhagic stroke or peripheral arterial disease or having undergone coronary artery bypass graft.

[d]Evidence should be provided to support the diagnosis of familial hypercholesterolaemia:

- Results of genetic testing, and/or
- Classification of definite familial hypercholesterolaemia under the Dutch Lipid Clinic Network Score or Modified UK Simon Broome criteria.

[e]Reimbursement of evolocumab is supported for a maximum of 26 Repatha® 140 mg pre-filled pens per year i.e. the patient should be prescribed a dose of 140 mg of evolocumab every two weeks. Reimbursement of the dose of 420 mg of evolocumab once monthly is not supported.

Approved prescribers are required to apply for reimbursement approval through the online application system.
The *HSE-Managed Access Protocol for PCSK9 Inhibitors* is available at https://www.hse.ie/eng/about/who/cspd/ncps/medicines-management/.

Abbreviations: CVD: Cardiovascular disease; LDL-C: Low-density lipoprotein-cholesterol; PCSK9: Proprotein convertase subtilisin/kexin type 9

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