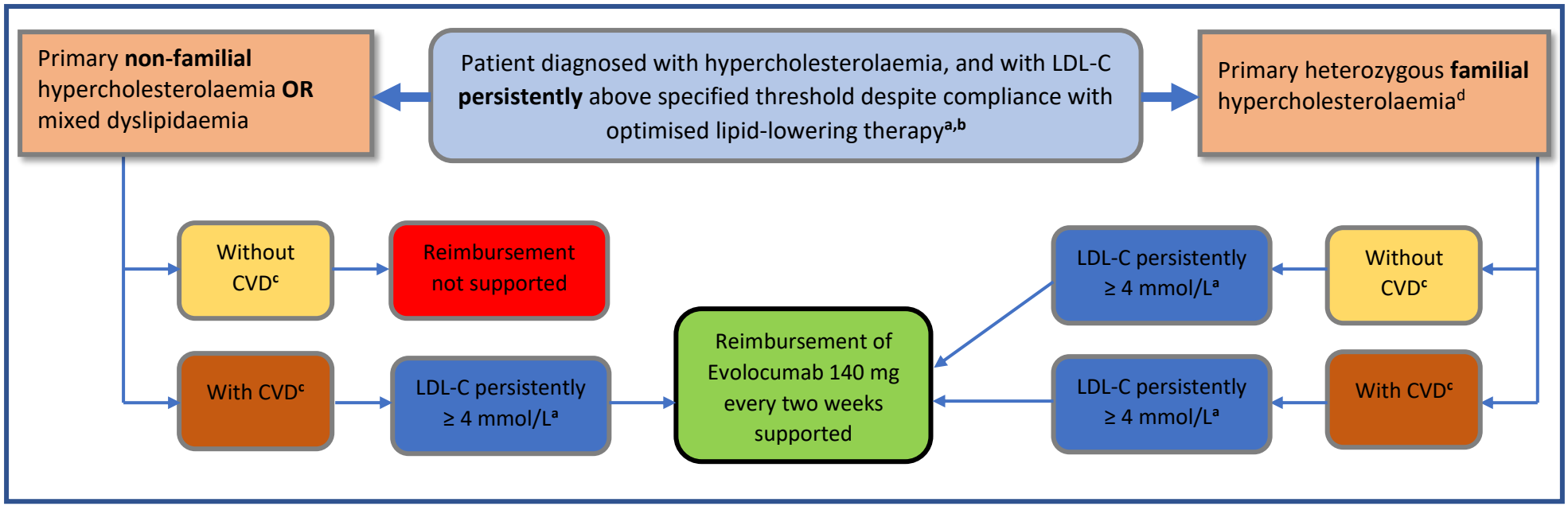
Evolocumab for the treatment of primary hypercholesterolaemia and mixed dyslipidaemia under the High Tech Arrangement

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 must be taken between three to six months prior to the current level
- The current level must be reflective of:
  - adherence to treatment with optimised lipid-lowering therapy for a minimum of three months, or
  - statin intolerance, or
  - contra-indication to statin 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) 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.

Approved prescribers are required to apply for reimbursement approval on an individual patient basis.
The *HSE-Managed Access Protocol for Evolocumab (Repatha®)* and the *Individual Reimbursement Approval Application Form* are available at https://www.hse.ie/eng/about/who/cspd/ncps/medicines-management/pcsk9-inhibitors/.

Abbreviations: CVD: Cardiovascular disease; LDL-C: Low-density lipoprotein-cholesterol.

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