Cost-effectiveness of evolocumab in patients with high atherosclerotic cardiovascular risk in Sweden

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Background/Introduction: Elevated low-density lipoprotein cholesterol (LDL-C) is one of the most important modifiable risk factors for atherosclerotic cardiovascular disease (ASCVD). Evolocumab, a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor, is indicated for the reduction of CV risk by lowering LDL-C.

Purpose: Assess the cost-effectiveness of evolocumab added to standard of care (SoC), maximally tolerated lipid-lowering treatment, in two patient populations for which evolocumab is reimbursed in Sweden: (1) patients with ASCVD with LDL-C ≥ 2.5 mmol/L on SoC, and (2) heterozygous familial hypercholesterolemia (HeFH) patients without ASCVD with LDL-C ≥ 3.0 mmol/L on SoC.

Methods: A previously published Markov model was adapted to the Swedish context. The model incorporated real-world CV event (CVE) rates (myocardial infarction, ischemic stroke and CV death). In patients with ASCVD, a CVE rate of 6.3/100 patient-years was obtained from Swedish national registries. In HeFH patients without ASCVD, a CVE rate of 4.5/100 patient-years was obtained from a national screening program in the Netherlands. ASCVD patient characteristics were obtained from Swedish national registries. HeFH patient characteristics were obtained from the RUTHERFORD-2 clinical trial. The model used an evolocumab LDL-C reduction of 59%, as observed in the FOURIER CV outcomes clinical trial, and the relationship between LDL-C lowering and CVE reduction from the Cholesterol Treatment Trialists’ Collaboration (CTTC) 2010 meta-analysis (base case) or FOURIER (scenario). An annual evolocumab list price (before discount) of SEK 48,759 [€ 4,632] (1 SEK = € 0.095) was considered. Costs and health outcomes were evaluated over a lifetime horizon from a societal perspective.

Results: In the base case, for patients with ASCVD with LDL-C ≥ 2.5 mmol/L on SoC, the addition of evolocumab was associated with: a 0.30 reduction in the lifetime per-patient CVE rate, increased costs of SEK 413,835 and increased quality-adjusted life years (QAL Y) of 0.67, yielding an incremental cost-effectiveness ratio (ICER) of SEK 615,393 [€ 58,462] per QAL Y gained. In the base case, for HeFH patients without ASCVD with LDL-C ≥ 3.0 mmol/L on SoC, the addition of evolocumab was associated with: a 0.57 reduction in the lifetime per-patient CVE rate, increased costs of SEK 701,200 and increased QAL Y of 1.39, yielding an ICER of SEK 503,710 [€ 47,852] per QAL Y gained. In the scenario analysis, ICER were SEK 539,846 [€ 51,285] and SEK 462,961 [€ 43,981] per QAL Y, respectively.

Conclusions: These results indicate the addition of evolocumab to SoC may be considered cost-effective in Sweden. Indeed, based on these data, the Swedish Dental and Pharmaceutical Benefits Agency (TLV) recently granted expanded reimbursement for evolocumab (submission 2138/2018), which led to a positive national recommendation in the patient populations described above.