HSCB Service Notification for the managed entry of new medicines and technologies

Health and Social Care Board

1 Treatment & Condition

Evolocumab for treating primary hypercholesterolaemia and mixed dyslipodaemia

2 Associated appraisal body & Summary of ruling

NICE Technology Appraisal Guidance (TA394) June 2016.

Evolocumab is recommended as an option for treating primary hypercholesterolaemia or mixed dyslipidaemia, only if:

- The dosage is 140 mg every 2 weeks by subcutaneous injection.
- Low-density lipoprotein concentrations are persistently above the thresholds specified in table 1 despite maximal tolerated lipid-lowering therapy. That is, either the maximum dose has been reached, or further titration is limited by intolerance (as defined in NICE's guideline on familial hypercholesterolaemia).
- The company provides evolocumab with the discount agreed in the patient access scheme.

Table 1 Low-density lipoprotein cholesterol concentrations above which evolocumab is recommended

	Without CVD	**With CVD**	
		High risk of CVD [1]	**Very high risk of CVD [2]**
Primary non-familial hypercholesterolaemia or mixed dyslipidaemia	Not recommended at any LDL-C concentration	Recommended only if LDL-C concentration is persistently above 4.0 mmol/litre	Recommended only if LDL-C concentration is persistently above 3.5 mmol/litre
Primary heterozygous-familial hypercholesterolaemia	Recommended only if LDL-C concentration is persistently above 5.0 mmol/litre	Recommended only if LDL-C concentration is persistently above 3.5 mmol/litre	

[1] High risk of CVD is defined as a history of any of the following: acute coronary syndrome (such as myocardial infarction or unstable angina needing hospitalisation); coronary or other arterial revascularisation procedures; chronic heart disease; ischaemic stroke; peripheral arterial disease.

[2] Very high risk of CVD is defined as recurrent cardiovascular events or cardiovascular events in more than 1 vascular bed (that is, polyvascular disease).

Abbreviations: CVD, cardiovascular disease; LDL-C, low-density lipoprotein

	cholesterol. This guidance is not intended to affect the position of patients whose treatment with evolocumab was started within the NHS before this guidance was published. Treatment of those patients may continue without change to whatever funding arrangements were in place for them before this guidance was published until they and their NHS clinician consider it appropriate to stop.
3	**Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)* It is anticipated that 230 patients will take up this therapy.
4	**Patient Access Scheme availability** The company has agreed a PAS that will provide a simple discount to the list price of evolocumab. The level of discount is commercial in confidence. The HSCB will keep this under review. NICE has considered that the subgroups for which evolocumab is recommended have severe hypercholesterolaemia and a high risk of CVD, so treatment should continue in secondary care where simple patient access schemes apply.
5	**Costs** *(before PAS if applicable)* Evolocumab costs £170.10 for a 140-mg prefilled pen or syringe
5.1	**Drug cost per patient per annum (for new and prevalent cases)** The annual cost of treatment per patient is estimated to be £4,400 per annum (before PAS)
5.2	**Infrastructure costs per patient per annum**
5.3	**Current in year costs** In year costs will depend on when implementation begins. Assuming uptake from 1 September 2016 the in year costs (before PAS) will be approximately £500k.
5.4	**Recurrent costs** The costing template under standard assumptions estimates the cost (before PAS) of introducing this technology as £1m.
5.5	**Opportunities for cost savings and how these will be secured** It is anticipated that evolocumab will lead to fewer cardiovascular events, such as myocardial infarction and stroke, compared with current treatments. This may translate into savings for commissioners.

6	**Expected implementation period** There is no barrier to immediate implementation of this guidance.
7	**Commissioning arrangements** This regime will be formally commissioned vis the Medicines Management Commissioning Team. Given the small number of patients in NI likely to be eligible for this treatment, it is expected that a decision to commence this therapy will be taken in secondary care settings.
8	**Monitoring arrangements** The prescribing trends for this drug will be monitored by medicine management advisers where appropriate. The Medicines Management Commissioning Team will track trends in the use of this drug.
9	**DHSSPS Legislative/Policy Caveats** This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.