

1	<p>Treatment & Condition</p> <p>Aflibercept for treating diabetic macular oedema</p>
2	<p>Associated appraisal body & Summary of ruling</p> <p>NICE technology appraisal guidance 346 (July 2015)</p> <p>Aflibercept solution for injection is recommended as an option for treating visual impairment caused by diabetic macular oedema only if:</p> <ul style="list-style-type: none"> • the eye has a central retinal thickness of 400 micrometres or more at the start of treatment and • the company provides aflibercept with the discount agreed in the patient access scheme.
3	<p>Number of people in Northern Ireland expected to take up service/therapy</p> <p>There is an estimated 1.4m people living in Northern Ireland (aged 18 years and over (NISRA, 2013). Recent data from the Quality and Outcome Framework indicates that the prevalence of diabetes in individuals aged 17 years and older in Northern Ireland is 4.3% (QOF data, 2014).</p> <p>Aflibercept is one of a group of medicines licensed and NICE-approved for the treatment of visual impairment caused by diabetic macular oedema:</p> <ul style="list-style-type: none"> • Ranibizumab (Lucentis®) – NICE TA279 • Dexamethasone (Ozurdex®) – NICE TA349 • Fluocinolone (Iluvien®) – NICE TA301 <p>Using data from NISRA, QOF and the NICE costing template (TA346), it is estimated that there are 264 incident cases of visual impairment attributable to DMO in Northern Ireland. Of these, 145 people are predicted to be eligible for treatment with aflibercept only and 13 people will require combination therapy with aflibercept and laser treatment.</p>
4	<p>Patient Access Scheme availability</p> <p>The Department of Health and Bayer Pharma have agreed that aflibercept will be available to the NHS with a patient access scheme which makes it available with a discount. The size of the discount is commercial in confidence.</p>
5	<p>Costs</p>
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>The list price of aflibercept is £816 per vial. The total cost for treating a patient in the first year is £6,936 (based on 8.5 aflibercept injections). The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of aflibercept, with the discount applied at the point</p>

	<p>of purchase or invoice. The level of the discount is commercial in confidence.</p> <p>After the first 12 months, the treatment interval may be extended based on visual and anatomic outcomes. The schedule for monitoring should be determined by the treating physician. Aflibercept should be discontinued if the patient is not benefiting from continued treatment.</p>
5.2	<p>Infrastructure costs per patient per annum</p> <p>It is recognised from the NICE guidance that there may be infrastructure requirements associated with the introduction of this therapy. The HSCB will work with the Belfast and Western Trusts to identify any infrastructure requirements as part of the wider projected growth in macular services regionally.</p>
5.3	<p>Current in year costs</p> <p>The service will be introduced as part of the existing macular services provided by the Belfast and Western Trusts. In-year costs of implementing this therapy will be available from the funding already allocated to Trusts for the predicted growth in patients numbers in this area.</p>
5.4	<p>Recurrent overall costs per annum</p> <p>The annual cost of the new drug regime is similar to other existing therapies. In-year 2015/16 costs will be covered from funding already allocated to Trusts.</p>
5.5	<p>Opportunities for cost savings and how these will be secured</p> <p>It is unlikely that implementation of NICE TA346 will result in any cost savings.</p>
6	<p>Expected implementation period</p> <p>There is no impediment to immediate implementation for new patients.</p>
7	<p>Commissioning arrangements</p> <p>At present, this regime is available on a cost per case basis. This was on the basis of a recommendation by the Scottish Medicines Consortium (SMC 1003/14 October 2014). HSCB will now move to formal commissioning of this regime.</p>
8	<p>Monitoring arrangements</p> <p>The HSC Board will incorporate monthly monitoring arrangements for this regime within the existing arrangements in place with Belfast and Western Trusts.</p> <p>A monitoring report will be submitted to the Specialist Services Commissioning Team on a regular basis for formal review.</p>
9	<p>DHSSPS Legislative/Policy Caveats</p> <p>This advice does not override or replace the individual responsibility of health</p>

	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.
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