Service Notification in response to DHSSPS endorsed NICE Technology Appraisals

Health and Social Care Board

NICE TA 305 – Aflibercept for treating visual impairment caused by macular oedema secondary to central retinal vein occlusion

1	**Summary of NICE TA 305** Aflibercept solution for injection is recommended as an option for treating visual impairment caused by macular oedema secondary to central retinal vein occlusion only if the manufacturer provides aflibercept solution for injection with the discount agreed in the patient access scheme.
2	**Number of people in Northern Ireland expected to take up service/therapy (new cases per year)** The NICE Costing Template that accompanies TA 305 estimates that 176 people in Northern Ireland would be eligible to receive treatment for visual impairment caused by macular oedema secondary to central retinal vein occlusion. The current standard treatment for visual impairment caused by macular oedema secondary to central retinal vein occlusion is dexamethasone or anti-VEGF drugs, such as ranibizumab. However, clinicians are more likely to use ranibizumab than dexamethasone because it is believed to have fewer side effects. Aflibercept has a similar adverse event profile to ranibizumab and is an alternative to either ranibizumab or dexamethasone.
3	**Costs**
3.1	**Cost per patient per annum** The list price of aflibercept 40 mg/ml solution for injection is £816 per 0.1ml vial (excluding VAT; 'British national formulary' [BNF] edition 66). The manufacturer of aflibercept solution for injection has agreed a patient access scheme with the Department of Health which makes aflibercept solution for injection available with a discount applied to the list price. The level of discount is commercial in confidence. Aflibercept is administered as a single 2 mg intravitreal injection. After the initial injection, treatment is given monthly. If there is no improvement in visual and anatomic outcomes over the course of the first 3 injections, continued treatment is not recommended. Monthly treatment continues until visual and anatomical outcomes are stable for 3 monthly assessments. Thereafter the need for continued treatment should be reconsidered. The summary of product characteristics states that monitoring is recommended at the injection visits and that the monitoring schedule should be determined by the doctor responsible for the patient's care based on the response of the condition to treatment. Hence, if a patient receives one injection per month, the annual cost of treatment per patient is £9792 (before application of the discount associated with the patient access scheme).

3.2	**In year cost per patient per annum (for new and prevalent cases)** In year costs will subject to patient uptake. However, based on the NICE costing template, a start date of July 2014 and regular growth over the year, in year costs are estimated as will be approximately £28,000. (Before PAS discount)
3.3	**Cost savings and how these will be secured** The implementation of NICE TA 305 is not anticipated to generate any cost savings.
3.4	**Recurrent overall cost** The NICE costing template estimates the cost of implementation as £76,000 using default assumptions and drug cost before the PAS discount scheme.
4	**Expected implementation period** It is expected that this therapy will be available for use in NI during the second quarter of 2014/15. This introduction will subject to confirmation of the level of funding available and submission and agreement of Business Cases by Belfast and Western Trusts.
5	**Commissioning arrangements** Belfast and Western Trusts will be invited to submit Business Cases for the introduction of this treatment as part of wider macular service provision. Following agreement on the detail of the Business Cases submitted by both Belfast and Western Trust, this treatment will be consolidated into the commissioning arrangements in place for macular services.
6	**Monitoring arrangements** The HSC Board will incorporate detailed monthly monitoring arrangements for this regime within the existing arrangements with Belfast and Western Trusts for monitoring patients with macular oedema secondary to central retinal vein occlusion. This information will include: • Number of new and review attendances • Number of patients commenced on treatment • Number of aflibercept intravitreal injections given. A monitoring report will be submitted to the Specialist Services Commissioning Team on a regular basis for formal review and comment by the team. Ongoing meetings between the HSC Board, PHA and both Trusts will continue.
7	**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.