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

1	**Treatment & Condition** Aflibercept for treating visual impairment caused by macular oedema after branch retinal vein occlusion.
2	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA409 Aflibercept is recommended as an option within its marketing authorisation for treating visual impairment in adults caused by macular oedema after branch retinal vein occlusion, only if the company provides aflibercept with the discount agreed in the patient access scheme. The current first line treatment for visual impairment caused by macular oedema secondary to BRVO is, for those whom laser is suitable, laser photocoagulation and, for those in whom laser treatment is unsuitable, Ranibizumab interaviteal injection or Dexamethasone intravitreal implant. Treatment with Ranibizumab or Dexamethasone are also provided as second line treatments for those in whom laser treatment has was not beneficial. Aflibercept offers an additional treatment option for patients.
3	**Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)* The NICE Resource Impact Template (RIT) that accompanies TA409 estimates current and future numbers of patients requiring treatment for visual impairment caused by macular oedema after branch retinal vein occlusion. The model suggests a growth in total patient numbers from 376 in 2017/18 to 1,520 in 2021/22. Aflibercept is an additional treatment option alongside current standard treatment options for for treating visual impairment in adults after branch retinal vein occlusion.
4	**Patient Access Scheme availability** The manufacturer of Aflibercept solution for injection (Bayer) 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.
5	**Costs** *(before PAS if applicable)*
5.1	**Drug cost per patient per annum (for new and prevalent cases)** The list price of Aflibercept 40 mg/ml solution for intravitreal injection is £816 per 0.1ml vial. Aflibercept is administered as a single 2 mg intravitreal injection into the affected eye. 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 when the patient visits for injections and the monitoring schedule should be determined by the doctor responsible for the patient's care based on the response of the condition to treatment. The NICE Resource Impact Template (RIT) estimates the average annual cost of treatment (drug plus administration and monitoring costs etc.) per patient when one eye is treated as £9,034 in the first year of treatment, £3,905 in the second year of treatment and £3,011 in subsequent years (before application of the discount associated with the patient access scheme).
5.2	**Infrastructure costs per patient per annum** The implementation of NICE TA409 is unlikely to result in significant change in infrastructure requirements. The HSC Board will work with the Belfast and Western Trusts to identify how the requirements compare to current infrastructure needs.
5.3	**Current in year costs** Aflibercept is an additional treatment option alongside current standard treatment options. Any costs in 2016/17 should be addressed by the funding made available to Belfast and Western Trusts for the growth in the use of therapies for treating macular conditions.
5.4	**Recurrent overall costs per annum** *(including additional costs)* Aflibercept is an additional treatment option alongside current standard treatment options. The recurrent costs of full uptake of this additional treatment option for 1,520 patients by 2021/22 is £1.5m before application of the patient access scheme which is commercial in confidence. The projected costs will be included in the HSC Board financial planning assumptions for predicted uptake of this regime from 2017/18.
5.5	**Opportunities for cost savings and how these will be secured** The implementation of NICE TA409 is not anticipated to generate any cost savings.
6	**Expected implementation period** There is no impediment to immediate implementation of this guidance.
7	**Commissioning arrangements** This treatment will be formally commissioned from the Belfast and Western Trusts by the HSCB/PHA via the Specialist Services Commissioning Team. This regime will be consolidated into the commissioning arrangements in place for macular services.

8	**Monitoring arrangements** The HSC Board will incorporate information on this regime into the existing monthly monitoring arrangements with Belfast and Western Trusts for monitoring patients with the range of macular conditions. This information will include: • Number of new and review attendances • Number of patients commenced on treatment • Number of aflibercept intravitreal injections administered 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.
9	**DoH (NI) 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.