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

Health and Social Care Board

1	**Treatment & Condition** *(Title)* Dexamethasone intravitreal implant (Ozurdex®) for treating diabetic macular oedema (TA349)
2	**Associated appraisal body & Summary of ruling** *(to include indication, restrictions, other relevant information)* NICE technology appraisal guidance 349 (July 2015) Dexamethasone intravitreal implant is recommended as an option for treating diabetic macular oedema only if: • the implant is to be used in an eye with an intraocular (pseudophakic) lens, and • the diabetic macular oedema does not respond to non-corticosteroid treatment, or such treatment is unsuitable.
3	**Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)* Dexamethasone intravitreal implant is one of a group of medicines licensed and NICE-approved for the treatment of visual impairment caused by diabetic macular oedema: • Ranibizumab (Lucentis®) – NICE TA279 • Aflibercept (Eylea®) – NICE TA346 • Fluocinolone (Iluvien®) – NICE TA301 Dexamethasone will be given to people with an intraocular (pseudophakic) lens who are unsuitable for, or who have not responded to, non-corticosteroid treatment. Non-corticosteroid treatments include aflibercept and ranibizumab. Based on a pro rata calculation from the Costing Statement that accompanies TA349, 24 people in Northern Ireland may be eligible for dexamethasone intravitreal implant each year. There will also be a requirement associated with treating the prevalent population not previously treated with fluocinolone. NICE estimate that this will be implemented over a three year period.
4	**Patient Access Scheme availability** Dexamethasone intravitreal implant is not subject to a patient access scheme.

5	**Costs** *(before PAS if applicable)*
5.1	**Drug cost per patient per annum (for new and prevalent cases)** Dexamethasone intravitreal implant is given as an injection into the eye. Each implant delivers 700 micrograms dexamethasone to the back of the eye over a period of 6 months or more. The implant remains in the vitreous for up to 270 days before fully dissolving. The summary of product characteristics states that, after initial treatment, re-treatment can be performed after approximately 6 months if the patient experiences decreased vision with or without an increase in retinal thickness with recurrent or worsening diabetic macular oedema. The summary of product characteristics states that patients should be monitored following an injection of dexamethasone intravitreal implant. The list price of dexamethasone intravitreal implant is £870.00 per 700 microgram implant. In the company's model, dexamethasone intravitreal implant was assumed to have a total cost of £986.68 for treating unilateral disease and £1944.19 for bilateral disease.
5.2	**Infrastructure costs per patient per annum** 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.
5.3	**Current in year costs** The service will be introduced as part of the existing macular services provided by the Western and Belfast Trust. In-year costs of implementing this therapy will be available from the funding already allocated to Trusts, accounting for the predicted growth in patients numbers in this area.
5.4	**Recurrent overall costs per annum** *(including additional costs)* Based on a pro rata calculation from the Costing Statement that accompanies TA349, 24 people in Northern Ireland may be eligible for dexamethasone intravitreal implant each year. The annual cost of implementing this guidance for the incident population is estimated as £118,000 in Northern Ireland. The recurrent costs will be included in the HSC Board financial planning assumptions for predicted growth in this area from 2016/17. There will also be a non-recurring cost for treating the prevalent population not previously treated with fluocinolone. NICE estimate that this will be implemented over 3 years at a cost of £500k in year 1, £500k in year 2 and £400k in year 3.

5.5	**Opportunities for cost savings and how these will be secured** Use of dexamethasone intravitreal implant could improve a patient's quality of life and reduce the cost burden of visual impairment due to diabetic macular oedema. However, it is not possible to quantify any savings to the HSC as a result of implementing this technology.
6	**Expected implementation period** There is no impediment to immediate implementation for new patients.
7	**Commissioning arrangements** This therapy will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis. Investment Proposal Templates will be completed by each Trust and the final profile of resources and revised monitoring arrangements agreed.
8	**Monitoring arrangements** The HSC Board will incorporate detailed monthly monitoring arrangements for this regime within the existing arrangements for Belfast and Western Trusts. This will include: 1. Number of patients commenced on this treatment regime 2. Number of implants administered A monitoring report will be submitted to the Specialist Services Commissioning Team on a regular basis for formal review.
9	**DHSSPS Legislative/Policy Caveats** *(NICE guidance only)* 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.