NICE TA 301 – Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema after an inadequate response to prior therapy (rapid review of technology appraisal guidance 271)

1 Summary of NICE TA 301

TA 301 updates and replaces NICE technology appraisal guidance 271 issued in January 2013.

Fluocinolone acetonide intravitreal implants are recommended as an option for treating chronic diabetic macular oedema after inadequate response to prior therapy only if:

- the implant is to be used in an eye with an intraocular (pseudophakic) lens and
- the manufacturer provides fluocinolone acetonide intravitreal implant 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 Costing Template that accompanies NICE TA301 estimates that in year 1 approximately 45 people in Northern Ireland will receive a fluocinolone acetonide intravitreal implant.

From year 2 the number of new patients eligible to receive a fluocinolone acetonide intravitreal implant will be approximately five per year.

3 Costs

3.1 Cost per patient per annum

On the basis of the information included in the costing template, the annual costs of introducing NICE TA301 are as follows:

<table>
<thead>
<tr>
<th>No. of patients</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1 45 patients (prevalent population)</td>
<td>£273k</td>
</tr>
<tr>
<td>Year 2 5 patients (incident population)</td>
<td>£39k</td>
</tr>
<tr>
<td>Year 3 5 patients (incident population plus further follow up)</td>
<td>£40k</td>
</tr>
</tbody>
</table>

The manufacturer of fluocinolone (Alimera Sciences) has agreed a patient access scheme with the Department of Health which makes fluocinolone available with a discount applied to all invoices. The level of the discount is commercial-in-confidence.
3.2 In year cost per patient per annum (for new and prevalent cases)

It is not anticipated that there will be any in-year 2013/14 costs associated with the introduction of this treatment. Subject to the submission and agreement of investment proposals by Belfast and Western Trusts, it is expected that this therapy will be introduced in the first quarter of 2014/15.

3.3 Cost savings and how these will be secured

The implementation of NICE TA301 is not anticipated to generate any cost savings.

3.4 Recurrent overall cost

Based on the standard NICE costing template for this net additional treatment costs are estimated as follows:

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Recurrent cost from year 3 is £40k.

4 Expected implementation period

It is expected that subject to submission and agreement of investment proposals by Belfast and Western Trusts, that this therapy will be introduced in the first quarter of 2014/15 on a cost per case basis.

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 DMO. This information will include:

- Number of patients commenced on treatment
- Number of new and review attendances
- Number of fluocinolone intravitreal implants injected.
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.

### 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.