

**NICE TA 274 – Ranibizumab for treating diabetic macular oedema (this updates and replaces TA 237)**

<p><b>1</b></p>	<p><b>Summary of NICE TA 274</b></p> <p>NICE recommends ranibizumab as a possible treatment for visual impairment due to diabetic macular oedema (DMO), only if the eye has a central retinal thickness of 400 micrometres or more at the start of treatment and the manufacturer provides ranibizumab with the discount agreed in the patient access scheme (as revised in 2012).</p>
<p><b>2</b></p>	<p><b>Number of people in Northern Ireland expected to take up service/therapy (new cases per year)</b></p> <p>The clinical assumptions in NICE costing template accompanying TA 274 are based on expert opinion. Using the NICE costing template assumptions, and diabetes prevalence rate of 5.1% (Source: QoF data 2012), it is estimated that the total number of patients in the incident population in Northern Ireland will be 134. Around 35% of patients are assumed to require treatment for both eyes. The annual requirement will therefore be around 181 new eyes to be treated.</p> <p>This service will be introduced as part of the existing macular services provided by Belfast and Western Trusts. Information available from the two Trusts indicates that a cohort of existing diabetic patients with a visual impairment due to DMO (26%) will meet the NICE criteria for accessing these therapies. For Northern Ireland this would equate to approximately 270 patients or 360 eyes.</p> <p>Information available from other centres already providing a service for patients with DMO (Moorfields and Kings College) show a higher percentage of prevalent DMO patients with central retinal thickness over 400 microns than that used in NICE assumptions. The HSC Board will therefore introduce detailed monitoring arrangements with the Belfast and Western Trust. The projected numbers will be subject to review over the next 12-24 months.</p>
<p><b>3</b></p>	<p><b>Costs</b></p>
<p><b>3.1</b></p>	<p><b>Cost per patient per annum</b></p> <p>The provision of a service for patients with DMO to access ranibizumab will include the costs of the drug and the infrastructure requirements associated with the delivery of the overall service to include the initial OCT screening, treatment and monitoring appointments.</p> <p>The list price of ranibizumab is £742.17. A discount is available in the patient access scheme. The patient pathway is complex and involves a series of monthly</p>

appointments for monitoring and/or treatment as required. The cost per patient will vary depending on individual response to treatment and the number of injections required by each patient.

It is estimated that on average patients will receive 7 treatment injections in year 1, 4 injections in year 2 and 3 injections in year 3.

The projected additional funding required for the treatment of 134 new patients per annum based on the proposed care pathway are set out in the table 1 below.

**Table 1**

	<b>Current Treatment Cost</b>	<b>Cost of patient treatment</b>	<b>Net Additional funding required</b>
	<b>£000's</b>	<b>£000's</b>	<b>£000's</b>
Year 1	125	855	730
Year 2	125	1,345	1,220
Year 3	125	1,705	1,580

The average cost per patient in each of the three years is as follows:

Year 1 - £5,448

Year 2 - £3,657

Year 3 - £2,687

Non recurrent funding of approximately £4.5m will be required for the treatment of the projected 270 prevalent cases (360 eyes) over the three year pathway. The HSC Board will identify funding from slippage for the treatment of these cases.

**3.2 In year cost per patient per annum (for new and prevalent cases)**

As outlined in 3.1, the full year effect average cost per patient per annum for new and prevalent cases is as follows:

Year 1 - £5,448

Year 2 - £3,657

Year 3 - £2,687

It is anticipated that a service will be in place by September 2013 (initially provided by an Independent Sector provider). This will reduce the in-year average cost per patient in year 1 (2013/14) to approximately £2,750.

A total of £1.5m will be required to introduce the service during 2013/14. This includes the in-year costs associated with commencement on treatment of both new and prevalent patients.

3.3	<p><b>Cost savings and how these will be secured</b></p> <p>As outlined in table 1 in section 3.1 above, the current laser treatment costs for patients with this condition are estimated at £125k per annum. The cost of introducing a service for the use of ranibizumab for this cohort of patients has been offset to reflect this saving.</p> <p>A Patient Access Scheme is also available against the cost per vial of ranibizumab. The size of this discount is commercial in confidence. However, the HSC Board will work with the two Trusts to ensure that both Trusts avail of this access scheme.</p>
3.4	<p><b>Recurrent overall cost</b></p> <p>Table 1 above in section 3.1 sets out the net recurrent costs associated with the introduction of this service on the basis of a three year patient pathway. The net recurrent cost after a three year period is £1,580,000. This is based on current clinical evidence which suggests that the numbers on treatment will plateau after year three.</p>
4	<p><b>Expected implementation period</b></p> <p>The HSC Board has been working with both Belfast and Western Trusts on the requirements for the introduction of this service. It is anticipated that both Trusts will have a service in place by January 2014. In the interim it is proposed that an Independent Sector provider will deliver a service from September 2013 for a period of up to six months.</p>
5	<p><b>Commissioning arrangements</b></p> <p>Belfast and Western Trusts have been invited to submit Business Cases for establishment of this service as part of the wider macular service provision.</p> <p>Following agreement on the detail of the Business cases submitted by both Belfast and Western Trusts, and the IS sector tender from Belfast Trust, this treatment will be consolidated into the commissioning arrangements in place for macular services during 2013/14.</p>
6	<p><b>Monitoring arrangements</b></p> <p>The HSC Board will introduce detailed monthly monitoring arrangements with both Belfast and Western Trusts to include information on:</p> <ul style="list-style-type: none"> <li>• number of patients commenced on treatment</li> <li>• number of ranibizumab injections administered</li> </ul> <p>The HSC Board will work with both Trusts to establish new PAS codes which will allow Diabetic Macular Oedema activity to be recorded separately on PAS.</p>

	Ongoing meetings between the HSC Board, PHA and both Trusts will continue as the service is established.
<b>7</b>	<b>DHSSPS Legislative/Policy Caveats</b>  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.