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Appendix 3: Consensus of the Welsh Retinal Group Meeting, June 29th 2007

Treatment of 'Wet' Age-Related Macular Degeneration

Welsh Retina Group

June 2007

The Welsh Retina Group met on 29 June 2007 in Cardiff.

All consultant ophthalmologists specialising in the management of retinal diseases (including macular degeneration) in Wales were invited.

The following consultants attended the meeting:-

[Redacted names of consultants]

The following were unable to attend in person but submitted their views by email:

[Redacted names of consultants]

This document represents the consensus of the group regarding:

- **Interim NICE guidance on 'Ranibizumab (Lucentis) and pegaptanib (Macugen) for age-related macular degeneration'**
- **Treatment of 'wet' macular degeneration in Wales pending final NICE guidance**
- **The role of Avastin**
- **Clinical trial to compare the safety and efficacy of Lucentis and Avastin**

Response of Welsh Retina Group to the interim NICE guidance on 'Ranibizumab and pegaptanib for age-related macular degeneration'

We are disappointed by the very restrictive interim guidance on treatment of 'wet' macular degeneration published by NICE. If applied in its current form it is clear to us that many patients who could benefit will be denied treatment.

We find it difficult to explain to our patients how the Scottish Medicines Consortium, after reviewing the same data arrived at such a different conclusion.

We understand that difficult and sometimes unpopular decisions regarding the affordability of new treatments have to be made. Limited resources must be spent wisely and equitably. We recognise our own bias as clinicians dealing with people suffering the effects of 'wet' macular degeneration on a daily basis. However we expect the organisation entrusted to make those decisions on behalf of the National Health Service to maintain the highest standards of scientific rigour and fairness.

We were surprised therefore to find that the appraisal consistently overestimated the cost of treatment and underestimated the cost of blindness.

1. The major factor determining cost is the number of treatments required. The cost effectiveness model assumes 24 treatments over two years. Current evidence suggests that similar visual outcomes are obtained with 14 treatments in the same period. This is acknowledged in paragraph 4.2.3.12. However in the concluding paragraph 4.3.14 the cost of monthly injections is quoted.
2. If 24 treatments were administered (paragraph 4.3.10) but over a longer period than two-years, it is likely that the visual gain would be maintained. However the cost effectiveness model assumes that vision declines at a similar rate to the natural history of the disease beyond two-years (paragraph 4.3.8). We concede that the frequency of assessment and treatment required beyond the second year is unknown and that this ongoing cost is not included in the model.
3. The cost effectiveness model fails to take account of early cessation of treatment. In clinical practice treatment would not be continued if the visual acuity drops consistently below 6/60.
4. The assumption that treatment is provided on a day case basis artificially inflates the cost (paragraph 4.2.3.13). Most centres are planning to administer the treatment in a clean room in outpatients.
5. The model underestimates the costs related to blindness (paragraph 4.3.13).
6. We too recognise the need to make effective use of NHS resources (paragraph 4.3.1). We are very concerned by the potential shortfall in capacity (physical space and manpower) in many units. However this should not be used as an excuse for centrally limiting access to an effective treatment. Local services must evolve to meet the demands of the population they serve.

Consensus of Welsh Retina Group on the treatment of 'wet' AMD in Wales pending final NICE guidance

Based on the available evidence Lucentis is the most effective treatment. There are three options in order of preference:

1. Lucentis for any patient with active subfoveal choroidal neovascularisation secondary to 'wet' AMD. Provided the visual acuity is better than 6/96 (or 20/320), the lesion is less than or equal to 12 disc areas in size and there is no permanent damage to the fovea.
2. Lucentis for the better seeing (second) eye in any patient with active subfoveal choroidal neovascularisation secondary to 'wet' AMD. Provided the visual acuity is better than 6/96 (or 20/320), the lesion is less than or equal to 12 disc areas in size and there is no permanent damage to the fovea. Photodynamic therapy can still be applied to first eyes in line with current guidelines on the grounds that the outcome will be better than the natural history of the disease and that close monitoring may detect early signs of a problem in the fellow eye.
3. Lucentis in line with interim NICE guidance. That is a classic or predominantly classic subfoveal choroidal neovascular membrane secondary to 'wet' AMD in the better seeing (second) eye. Provided the visual is better than 6/96 (or 20/320), the lesion is less than or equal to 12 disc areas in size and there is no permanent damage to the fovea. PDT will still be applied to first eyes on the grounds that the outcome is better than the natural history and close monitoring may detect early signs of a problem in the fellow eye.

We prefer option 1. This is the approach adopted recently by the Scottish Medicines Consortium. Our main concern is limited capacity in terms of physical space and manpower. Rapid expansion would be required from the outset.

Option 2 is more realistic within the constraints of the service but does require expansion within a few months to sustain. This policy has been adopted by a number of regions in England (e.g. Yorkshire and the Humber Specialised Commissioning Group & North Derbyshire, South Yorkshire and Bassetlaw Commissioning Consortium). It is open to criticism by patient support groups. However we believe it can be justified on the grounds that a proven treatment is being provided to those in greatest need.

The third option is unsatisfactory. It is the way we appear to be heading at the moment. Many patients who could benefit will be denied sight saving treatment. This option may appeal to LHBS and Trust Boards for several reasons. Fiscal – all LHBS are in financial deficit, the interim guidance is so restrictive that it minimises expenditure. Justifiable – insofar as NICE interim guidance is being met before it becomes a statutory obligation. Deniable – critics will be referred to the 'experts' at NICE. "Our hands are tied. Don't blame us, blame them." Expedient – Trusts can delay making difficult decisions about increasing capacity. Our greatest concern is a protracted appeal to NICE guidance. The scope for wide regional variation has already been amply demonstrated and ultimately brings the National Health Service into disrepute.

The role of Avastin

We have serious concerns regarding the generalised use of Avastin. Despite a body of professional opinion to suggest this drug is **probably** safe and effective it remains unlicensed.

GMC guidance regarding the use of medicines for purposes for which they are not licensed clearly states that our primary concern is to always act in the best interest of our patient. We are not satisfied that the 'off-label' drug Avastin will better serve our patient's needs than the licensed alternative, Lucentis. We feel there is insufficient evidence to demonstrate its safety and efficacy. We advise against its generalised use within the National Health Service in Wales.

Clinical trial to compare the safety and efficacy of Lucentis and Avastin

We support the principle of a study to compare the safety and efficacy of Lucentis and Avastin. This evidence is essential before Avastin can be safely recommended for use in the NHS.

The quickest and most cost effective way for Wales to be involved in this research would be to participate in the IVAN trial (A randomised controlled trial of alternative treatments to inhibit VEGF in age-related choroidal neovascularisation).

The IVAN study has been under development for about six months and the final permissions have just been granted. The only Welsh unit to be listed as a potential study centre is the University Hospital of Wales. However at present even this unit lacks the capacity and manpower to participate.

Each centre has to recruit 30 subjects and provide a weekly research clinic for two to three years for their treatment. The clinic must have an accredited optometrist as well as nursing and medical staff. The protocol includes administering detailed quality of life questionnaires.

Although the research element of the study attracts additional funding the number of patients to be recruited is far short of that required to provide a 'service' for the local population. The protocol is time consuming. The same resources could be utilised more efficiently to provide a service.

Preliminary results will be available in about two years but it will probably be nearer to four years before there is any definitive answer.