ROTHERHAM BOROUGH COUNCIL - REPORT TO MEMBERS

1.	**Meeting:**	**Health Select Commission**
2.	**Date:**	**8th December 2011**
3.	**Title:**	**To look at offering Avastin (off-label) as a first choice treatment for wet age-related macular degeneration.**
4.	**Directorate:**	**NHS Rotherham**

5. Summary

The Clinical Commissioning Group is considering adopting off-label Avastin as the first line treatment of wet age-related macular degeneration (wet AMD) instead of the currently licensed first line treatment recommended by NICE which is Lucentis®.

Public Health has reviewed the evidence base which indicates that both options are similarly safe and effective; however, before making any decision, a consultation is being undertaken with relevant stakeholders including patients, public, clinicians and managers to establish the feasibility of commissioning a service based on Avastin.

The Health select commission is invited to comment on the consultation process and offer its view on the option that the CCG is considering.

6. Recommendations

The Health Select Commission Members:

- **Note the findings of the evidence review**
- **Comment on the consultation process**
- **Feedback its view on the option being considered**

7. Proposals and Details

Background to the treatment
Wet Aged-related Macular Degeneration (AMD)

Wet AMD is the most common cause of visual loss in people over the age of 60 years and there are approximately 26,000 new cases in the UK each year. Rotherham's wet age related macular degeneration (AMD) service was established in October 2008. Every week they receive between 4 and 6 new referrals. Lucentis® is currently given on a monthly basis.

Avastin

Avastin continues to be widely used off-label world-wide to treat a number of eye conditions, including wet AMD. In the US, practice pattern reports from the American Academy of Ophthalmology and the American Association of Retinal Specialists suggest that most US patients receive Avastin rather than Lucentis® for the treatment of wet AMD (Tufail et al, 2010: ABC).

In August 2008 National Institute Clinical Evidence (NICE) issued guidance on Lucentis®, recommending this as a possible treatment for people with wet AMD. Avastin was not considered as it wasn't licensed for the treatment of eye conditions but for certain cancers. NICE are currently reviewing Avastin.

Avastin and Lucentis® are both monoclonal antibodies that act as anti-VEGF and were developed by Genentech which is now a wholly owned subsidiary of Roche. The older drug, Avastin, has been in use for longer which allows more time for long term side effects to manifest themselves and it is reassuring that they have not done so. The newer drug, Lucentis®, has been through a more systematic process of testing within the licensing process.

Labelled drugs

Means that the drug has been licensed for a specific purpose, as a condition of the license, the manufacturer produced a 'label' explaining the indications, risks, and benefits.

'Off' Label drugs

Means that a drug might be labelled for one purpose but can be used:

1. For treating another condition/indication.
2. For a different age group, e.g. to treat children, because many medicines are not licensed for children.
3. For a different dose or route or method of administration.
4. For patients who cannot take licensed formulations.
5. Are administered through a set protocol.

Once a device or medication has been licensed, health professionals may use it 'off label' for other purposes if they:

• are well informed about the product,
• base its use on firm scientific method and sound medical evidence,
• maintain records of its use and effects.
A drug company can choose not to license a drug for another purpose even if it proves to be effective.

NHS Rotherham Procedures

At NHS Rotherham, there are general processes and agreements via Medicine Management Committee that cover GPs for using off-label drugs. If Avastin was chosen as a first choice treatment the liability would be considered as part of a service specification and NHS Rotherham through Medicine Management Committee for approval.

An evidence review (safety and effectiveness), which included most recent comparative clinical and current practice in the UK, was presented at NHS Rotherham's Commissioning Executive and Medicines Management Committee, the summary is stated below:

"Overall Avastin and Lucentis® are very similar both in terms of outcomes and side effects. Both drugs appear to improve visual acuity and this compares favourably to previous treatments. We are still unclear about the long term effects and safety profile of Avastin or Lucentis®" (HH & SS July 2011).

Consultation Process

A number of steps have been taken to move the consultation process forward, these are outlined below:

1. Provider consultation has also been carried out with key clinicians. Further actions agreed to take processes forward.
2. Have collected examples of other PCTs patient literature and commissioning processes.
3. Linked with the South Yorkshire and Humber wider group.
4. Plans to establish a consultation and seek public/ patient opinion and stakeholders to share findings with key stakeholders and committees. Written a public consultation list of questions to pilot, and then roll out to various groups in the New Year.

Actions resulting from Consultation

- Established a safe supply of Avastin.
- Potential liability processes agreed if required.

Progress to date

NHS Rotherham is currently undertaking a consultation process to investigate both clinicians and patients' views of the use of Avastin as the first choice for the treatment of AMD. The Commissioning Executive and the Medicine Management Committee at NHS Rotherham are fully supportive of a move towards Avastin as the first choice treatment for AMD. There has been agreement that NHS Rotherham is

able to indemnify the provider against any potential litigation from treating patients with an off-label drug.

Clinicians delivering the wet AMD service at Rotherham Foundation Trust (RFT) are supportive of the use of Avastin for the treatment of wet AMD as long as a number of conditions are met.

However, they currently feel that we are not at an appropriate stage in discussions to consult with their patients. Therefore we need to establish patient opinion on the use of Avastin via other routes.

The options/recommendations resulting from this consultation will help dictate the next steps in commissioning decisions.

8. Finance

The key source of potential savings is reduced drug costs. A reimbursement scheme for Lucentis exists where the manufacturer pays the cost of the drug if more than 14 injections are used per eye, enabling a mechanism to stop treatment when it is no longer deemed necessary (i.e. vision has stabilised). There is no such corresponding scheme for Avastin; therefore treatment may need to continue indefinitely, if an improvement in vision is sustained. Although from current evidence injections haven't continued.

Therefore the amount of any potential savings will be sensitive to:

- Differences in the need for follow-up
- Drug costs
- Costs of additional investigations
- Whether a proportion or all cost savings would be reinvested into eye health.

Switching to Avastin may release significant amounts of resource; however, this will not be done at the expense of quality of care or patient safety.

9. Risks and Uncertainties

The review is being undertaken to consider the best options for service users and the people of Rotherham, taking into consideration financial implications and the need to ensure NHS budgets are being invested most effectively. It is uncertain as yet as to what final decision will be made, but all the responses from this consultation will feed into the process and help inform any future decisions.

Risks

- Patients might choose to be treated at Sheffield and ask for Lucentis, if we did adopt Avastin as first choice. Therefore Rotherham would have to pay for Lucentis, although Sheffield is undertaking an IVAN clinical trial (where Avastin is used as treatment).
- Ophthalmologists may be reluctant to use Avastin.
- Lack of long term evidence of the safety profile of either drug.
- Patients might have a negative reaction to Avastin.

- The public may object to the use of Avastin.
- RNIB have a working relationship with Novartis who market Lucentis. This may influence the consultation with the public.
- Novartis is looking to expand the indications for the use of Lucentis.

There are differences between the treatment regimes that the current evidence base supports for the two drugs. Therefore, any potential savings from switching to the use of Avastin may be short lived as a result of the potential increased duration of treatment and associated follow-up and investigation costs. Limited evidence on the effectiveness of long-term usage of Avastin.

10. Background Papers and Consultation

Evidence review
Evidence review tables
Paper for Commissioning Executive/Medicine Management Committee

Further details or the above papers can be requested from:

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