

## **Briefing on behalf of the North East and North Cumbria NHS Clinical Commissioning Groups on the use of Avastin for Age-related macular degeneration (AMD)**

This briefing provides stakeholders in the North East and North Cumbria information from the region's NHS clinical commissioning groups about the decision to offer local patients with wet age-related macular degeneration (AMD) a choice of clinically-effective alternative drugs for their treatment.

Allowing patients a choice of safe and clinically effective drugs means the region's NHS has the opportunity to save money. An alternative drug is available to treat wet AMD, which is a tenth of the price of the main drugs currently used.

Our conservative estimates suggest that the new policy could save the region's NHS up to £13.5 million a year within the next five years. To put that in perspective, £13.5 million could pay for an extra 270 nurses or 266 heart transplants – every year. In a financially stretched NHS, that could be life-changing for thousands of our patients.

### **What is wet age-related macular degeneration (AMD)?**

Age-related macular degeneration (AMD) is a painless eye condition that causes you to lose central vision, usually in both eyes. In AMD, this vision becomes increasingly blurred, which means:

- Reading becomes difficult
- Colours appear less vibrant
- People's faces are difficult to recognise

Macular degeneration develops when the part of the eye responsible for central vision (the macula) is unable to function as effectively as it used to. There are two main types – dry AMD and wet AMD. Wet AMD is more serious.

### **What are the drugs used to treat this condition?**

Avastin is a licensed medication which large scale, international clinical trials have demonstrated is safe and clinically effective to treat wAMD patients.

This includes NICE (although NICE guidelines are not mandatory).

Avastin is a tenth of the cost of both of the alternatives, Eylea and Lucentis, both of which can be marketed for wAMD patients because they have a "licence" for this use.

NHS patients in the North East and North Cumbria are now being offered a choice of drug treatment. If a wAMD patient chooses to be treated with Eylea or Lucentis, the NHS will provide that drug to the patient.

If a wAMD patient chooses to be treated with Avastin, that decision will free up NHS money which will be used to pay for doctors, nurses and drugs to treat other NHS patients.

### **What is the issue re drug licencing?**

Avastin does not have a licence – which is a commercial marketing authorisation – for treating wAMD patients because, despite the mountain of evidence that it is clinically effective for wAMD use, Roche have not applied for a licence for this use.

Licences are issued to make sure drugs are marketed responsibly – the terms of a licence do not apply to the way doctors use a drug.

It is common practice for clinicians to use drugs 'off-label' – i.e. not for the indication described in their marketing. This is the case with dozens of common paediatric drugs.

The drug companies have a vital role to play in our healthcare system but they make decisions about when to apply for drug licences according to their own commercial interests. In contrast, the NHS has a duty to put the best interests of the NHS and all of its patients first.

### **What are the cost savings?**

Our conservative estimates suggest that the new policy could save the region's NHS up to £13.5 million a year within the next five years. To put that in perspective, £13.5 million could pay for an extra 270 nurses or 266 heart transplants – every year. In a financially stretched NHS, that could be life-changing for thousands of our patients.

### **I've heard that some clinicians are saying they are concerned about using Avastin for wet AMD?**

We do understand that there may be some caution among clinicians about using Avastin instead of Eylea or Lucentis. However, large-scale medical trial evidence internationally supports Avastin as a safe, effective clinical option for wet AMD.

Avastin is widely used across Europe and in the US for wAMD patients, including by the Veterans' Health Administration (which cares for 21 million veterans).

The region's clinical commissioning groups have taken specialist level legal advice, and we are confident that we are acting lawfully - in the same way that clinicians providing Avastin to private wAMD patients are acting lawfully.

Our legal position is strongly supported by a preliminary decision of the European Court handed down in September 2017.

The CCGs are offering to support NHS ophthalmologists in the region to ensure they have confidence in the legal basis of the decision and to offer patients choice, since this will benefit the wider NHS.

### **Have other areas of the country made this decision to offer choice?**

North East and North Cumbria is not the first part of the country to take this step – other individual CCGs have done so. However, we may be the largest geography as together we have a strong history of partnership working in the best interests of local people and the 12 CCGs have decided to work collectively on this issue as we have a duty to act “efficiently, effectively and economically”. We believe that this policy delivers on that duty.

Other CCGs are working on the issue and have a variety of approaches which encourage using Avastin for wAMD patients.

### **What information is there available for patients about this?**

We have already been working with interest groups on patient leaflet to explain this issue and to help patients decide on which drug they wish to have for wAMD, and provided information for NHS ophthalmologists to help have an informed discussion with patients. This leaflet will be made available as soon as possible in print and in audio format.

All the clinical commissioning groups will have information on their websites, and we will update key charities, groups and organisations such as Healthwatch.

### **Further information for clinicians and NHS organisations**

Avastin is not licensed for wAMD patients because Roche, which also owns the legal rights to Lucentis, has not applied for a licence to treat patients with this drug.

There is very strong international, peer-reviewed evidence that Avastin is clinically effective for wet AMD patients. This includes NICE (although NICE guidelines are not mandatory).

Avastin is widely used across Europe and in the US for wAMD patients, including by the Veterans' Health Administration (which cares for 21 million veterans). It is also widely used by clinicians in the UK for patients who are treated privately.

Licences are issued to make sure drugs are marketed responsibly – the terms of a licence do not apply to the way doctors use a drug and it's common practice for clinicians to use drugs 'off-label' – i.e. not for the indication described in their marketing. This is the case with dozens of common paediatric drugs.

The European Court has recently supported the Italian courts which fined Roche and Novartis (which markets Lucentis in Europe) for market abuse by misleading doctors in suggesting that Avastin was not clinically effective for wet AMD patients as part of an attempt to persuade Italian doctors to use Lucentis instead.

Roche could apply to license Avastin for this use if it wished. The decision not to do so appears to be a straightforward commercial decision made by Roche to maximise their revenue from Lucentis.

Commercial decisions by drug companies about what drugs to licence for what conditions should not restrict the drugs the NHS can use when other drugs are proved as clinically effective.

We understand that there may be some caution among clinicians but we are confident on the legal basis. We wish to reassure clinicians that Avastin is routinely used in private practice in the UK, and more widely around the world, and no one has ever been referred to the GMC.

Also, the test for the GMC is “fitness to practise”. No clinician could be held “unfit” to practise as a result of following a CCG approved policy to give patients a choice between clinically effective drugs.

Our primary obligation is to act in the best interest of the NHS and patients, and we are offering clear legal support to NHS ophthalmologists in the region so they can have confidence in the legal basis of the decision.

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