Right Honourable Jeremy Hunt MP: Secretary of State for Health

Department of Health
Richmond House, 79 Whitehall, London SW1A 2NS

Cc. Professor David Haslam: Chair of NICE

National Institute for Health and Care Excellence
10 Spring Gardens, London, SW1A 2BU

23 February 2015

Dear Secretary of State,

**Re: Consideration of Treatment Options for Chronic Eye Conditions in the NHS**

The NHS is currently facing the greatest financial challenge since its creation in 1948 and this pressure will continue for the foreseeable future. In the recent report, "The NHS five year forward view", NHS England has described an annual £30 billion gap between available funding and predicted demand for health services by 2020. This comes after five years of the lowest ever growth in NHS funding and austerity measures designed to meet the £20 billion "Nicholson challenge".

The CCGs have the responsibility for commissioning the majority of NHS healthcare and for ensuring that every pound is spent to best effect. This involves clinicians in CCGs making complex decisions on the allocation of resources and the relative availability of treatments. When considering these decisions the clinicians leading commissioning organisations have the responsibility for balancing the needs of the individual with the needs of the wider community.

You will be well aware that CCG's are bound by the requirement to provide drugs recommended by NICE where NICE Technology Appraisal guidance exists. Whilst CCGs recognise and value the benefits of NICE's role in the NHS, sometimes an unintended consequence of Technology Appraisal guidance can be to effectively enforce prioritisation of resources away from other effective treatments in favour of those recommended by NICE. We believe that in the case of Technology Appraisal Guidance TA155 and TA294 relating to the treatment of chronic eye conditions with ranubizumab (Lucentis) and aflibercept (Eylea), this re-prioritisation of resources has now become disproportionate.

There is no doubt that the advent of medicines to treat chronic degenerative eye conditions is something to be celebrated, and that many people's sight has been saved as a result. However, we believe that in the case of these products a number of factors have conspired to create afinancial situation that has now become untenable for CCGs and indeed for the NHS at large, and we are writing to you to both raise the profile of the issues and to request your support to progress a central solution to resolve this situation.

The issues relate to the position of the NHS regarding another product that can be used successfully to treat these conditions, bevacizumab (Avastin). Avastin is licenced for use in bowel cancer but it has been used "off licence" to treat wet AMD (and a range of other chronic eye conditions) in a wide range of settings since 2005. Genentech, the manufacturer of Avastin, subsequently developed the related product Lucentis, and successfully obtained a

licence for this latter product to be used in patients with wet AMD, and subsequently a range of other eye conditions. Roche, which now owns Avastin, has decided not to apply for a licence for the use of Avastin to treat any eye conditions.

Thus once Lucentis became available in the UK and received positive NICE appraisal as the only product licenced in the market for this indication, it became the default option for treatment. None of this would matter if it were not for the fact that Genentech (as above, subsequently purchased by Roche) priced Lucentis at between 10-20 times as much as the original drug Avastin. This has huge consequences for the finances of the NHS as the incidence of these chronic eye conditions is increasing each year due to an aging population and the treatment can extend to the lifetime of many patients. Whilst it is hard to give a precise figure of the actual excess cost that the NHS is paying each year we can be certain that it will run into hundreds of millions of pounds. We believe the subsequent pricing of the product Eylea is an example of 'me too' pricing, the precedent having been set by the price of Lucentis in the market.

There have been a number of significant events in this story over the last few years. In 2012 two trials (CATT in the USA and IVAN in the UK) published their results after two years of study. They demonstrated comparable effectiveness between Avastin and Lucentis. In September 2014 a Cochrane Review was published that noted comparable safety between both drugs.

Avastin is widely used in the USA to treat a range of eye conditions, and in recent months theItalian and French governments have taken action at central government level to ensure that Avastin is available in place of Lucentis across their respective nationally funded health systems. In May 2014 Italy's Ministry of Health said it was seeking €1.2bn in damages from Roche and Novartis for colluding to prevent doctors using Avastin to treat wet AMD, taking the lead from an earlier antitrust investigation that resulted in the levying of a €182.5m fine. Meanwhile, France and the EU have both indicated interest in pursuing their own further investigations into the companies' dealings regarding these products.

A recent editorial in the BMJ titled, "What is stopping the NHS from using Avastin for macular degeneration and other retinal disorders? Government must act to remove the hurdles" was published on 19 November 2014. The editorial stated:

*Commissioners are expected to enact NICE guidance, and NICE has not considered Avastin. This makes it difficult to commission the use of Avastin and to deprive patients of NICE sanctioned treatment. Furthermore, the General Medical Council (GMC) states that doctors should prescribe unlicensed drugs only if "there is no suitably licensed medicine that will meet the patient's need. "Without unequivocal GMC and NICE support, ophthalmologists are understandably concerned that they may be assuming unacceptable personal liability by using an unlicensed drug when a licensed alternative exists. Where these concerns don't exist, ophthalmologists are happy to prescribe Avastin. For example, Avastin is the market leading drug for neovascular AMD in the US. Closer to home, in Guernsey, where NICE guidance does not apply, Avastin is the only therapy commissioned for the treatment of neovascular AMD.…..*"*Until Avastin has been appraised (by NICE) the GMC must also be unambiguous in supporting doctors who use the off-label drug instead of licensed alternatives."*

To conclude, we believe the current situation in England places clinical commissioners and clinicians treating these conditions in an invidious position. If they commission or use Avastin, a drug with the potential to provide safe and effective treatment at a cost that is many hundreds of millions of pounds less to the NHS at large, they will find themselves in conflict with NICE and the GMC. We have written to the GMC to ask for their support in providing a specific exception to their standard guidance to support practitioners who wish to prescribe Avastin for use in the eye, and to Simon Stevens to ask for his support at a national level for Clinical Commissioners who wish to make local commissioning decisions to prescribe Avastin in place of the NICE mandated products Lucentis and Eylea.

The Royal College of Ophthalmologists has issued a recent statement in which it states that '...The current situation is divesting the NHS of funds that could be put to better use.... The college would therefore welcome an urgent review of this issue by the UK's regulatory bodies to consider how this unusual situation can be remedied.' Their full statement is available at http://tinyurl.com/pz7soxx

**We the undersigned, as the commissioners of the services are therefore calling upon you as Secretary of State for Health to:**

1) Ask NICE to consider amendments to the current status of Technology Appraisal Guidance TA155 and TA294 in light of the issues described in this letter

2) Authorise NICE to undertake a Multiple Technology Appraisal (MTA) review looking at the comparative cost effectiveness of Avastin, Lucentis and Eylea

And, given the necessary time that it will take to conduct this MTA we request that you:

3) Support Clinical Commissioners who wish in the meantime to make local commissioning decisions to prescribe Avastin in place of the NICE mandated products Lucentis and Eylea, on the grounds that this is a safe and cost effective alternative treatment that can save the NHS hundreds of millions of pounds, which can be reinvested in patient care.

4) Provide assurance to Clinical Commissioners that the Department of Health will underwrite the costs of any legal action that may result from the implementation of local commissioning decisions relating to the use of Avastin in NHS pathways

Yours sincerely

CCG Chief Clinical Officers & Clinical Chairs

Dr Phil Pue, Chief Clinical Officer
**NHS Airedale, Wharfedale & Craven CCG**

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**NHS Aylesbury Vale CCG**

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