CCG response: The CCG is looking into this question and a response will be made available at the October 2018 Governing Body meeting.

Question from Shirley Murgraff, member of the public to the Friday 28 September 2018 CCG Governing Body:

1. Can the Governing Body clarify the CCG and North East London Commissioning Alliance position on the use of the drugs Avastin and Lucentis, following the High Court judgement outlined in https://www.mirror.co.uk/news/greedy-drug-companies-lose-legal-13285139?

CCG response: For clarification, Avastin®, Lucentis® and Eylea® are not drugs prescribed in primary care. Lucentis® and Eylea® are commissioned by CCGs from Trusts with specialist ophthalmology services and administered via intravitreal injection (into the eye) by suitably qualified physicians who are experienced in administering intravitreal injections.

The indication for use under discussion is wet age-related macular degeneration, a relatively common condition that can lead to blindness. All 3 drugs belong to a similar class of drugs – known as VEGF inhibitors. Lucentis® and Eylea® have a current licence for wet AMD but Avastin® is not licensed for wet AMD, it is however licensed for the treatment of various cancers (including of the colon, rectum, cervix and breast).

There has been long standing interest from CCGs across the country (and PCTs before that) in commissioning the use of Avastin® as the preferred choice of anti-VEGF treatment for wet AMD, but this has not been progressed due to legal threats from the manufacturers that stand to lose profit from a wholesale switch from Lucentis® / Eylea®.

NHS Clinical Commissioners has been working over the last 3years to influence:

- The General Medical Council – to provide a specific exception to their standard guidance, to support physicians wishing to prescribe Avastin® off-licence for wet AMD;
- The Secretary of State for Health to ask NICE to consider the status of the current Technology Appraisal guidance and authorise NICE to undertake an multiple treatment appraisal looking the comparative cost effectiveness of Avastin® with Lucentis® and Eylea®;
- Simon Stevens at NHS England to support the case for change and to support clinical commissioners who wish to make local commissioning decisions to prescribe Avastin 'off-licence' on the grounds that it is safe and a cost effective treatment.

The Royal College of Ophthalmologists have welcomed the ruling but acknowledge the need to work with the Department of Health and Social Care, regulatory bodies and commissioners to secure efficient pathways for patients.

Until earlier this year, NICE guidance made positive recommendations for Lucentis® and Eylea® only in the management of wet AMD. In January this year, NICE concluded that there are "...no clinically significant differences in effectiveness and safety..." between Avastin and the current market authorised medicines, ranibizumab (Lucentis) and

aflibercept (Eylea) for the treatment of this condition. Furthermore, Avastin is the most cost-effective treatment compared to the others available, with the potential to release millions of pounds of vital funding locally which can be reinvested in other frontline NHS services.

NICE's review and conclusion that there are no clinically significant differences in effectiveness and safety between Avastin (unlicensed for wet AMD) and the licensed alternatives Lucentis® and Eylea® was a most welcome 1st step. The Court ruling this month also gives further assurance to commissioners in that the Court dismissed the case brought by Norvatis and Bayer against the North East England CCGs' policy to include Avastin as an option for the management of wet AMD.

This is not however the final step with regards to routine use of Avastin® for wet AMD. The legislative framework as I understand it, does not yet permit the use of an unlicensed product where there is not a "special clinical need" in cases where there is a current licensed option available. The Department of Health and Social Care, NHS England and the relevant regulatory bodies: - the Medicines and Healthcare products Regulatory Agency and the General Medical Council will have to issue updated guidance to facilitate the routine use of Avastin® for wet AMD.

Through our contracts team, we have made contact with Islington CCG as the host commissioner for Moorfields Hospital (where currently all known charges for wet AMD drugs for City & Hackney patients originate from) with regards to discussions with Moorfields following on from the ruling. Islington CCG has confirmed it will be formally notifying Moorfields of its plans to scope the use of Avastin® in the treatment of wet AMD, subject to NHSE Guidance, during 2019-20.

A referral has also been made to the Regional Medicines Optimisation Committees (RMOC) – for the RMOCs to consider providing guidance to commissioners and Trusts across NHS England.

The four Regional Medicines Optimisation Committees for England make recommendations, pursue actions, and co-ordinate activities related to any aspect of Medicines Optimisation. There is a committee for each NHS England region which brings together decision makers and clinicians across each geography.

Although there are 4 committees, the RMOCs operate against a single framework, with each group being part of a greater national system. Their role and function has been co-developed by NHS England and NHS Clinical Commissioners on behalf of Clinical Commissioning Groups, in partnership with NHS hospital representatives, primary care providers, the National Institute for Health and Care Excellence, NHS Improvement and representative bodies of the branded and generic pharmaceutical industry. Dr Haren Patel, Prescribing Lead GP is a member of the London RMOC.

Further information is available on request.