



## CCGs win right to offer patients Avastin for wet AMD

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BMJ

A group of 12 clinical commissioning groups in the north of England have won a legal battle to offer patients a choice to use off-label bevacizumab to treat wet age related macular degeneration, which they say will save the NHS millions of pounds.

In November last year the drug companies Novartis and Bayer brought legal proceedings against the CCGs because they had decided to offer bevacizumab (Roche's Avastin), which is not licensed for treatment of wet AMD, alongside ranibizumab (Lucentis, marketed by Novartis) and aflibercept (Bayer's Eylea), which are approved by the UK National Institute for Health and Clinical Excellence for treating the condition in the NHS.<sup>1</sup>

The companies opposed the policy on four grounds: they said that the supply of bevacizumab was unlawful because it was not licensed for ophthalmic use; it undermined drug regulation; it undermined patients' right to have a NICE approved drug; and the patient information sheet accompanying the policy was misleading.

However, in the High Court Mrs Justice Whipple dismissed the application for judicial review on all grounds and found in favour of the CCG's policy. She said that the companies' arguments that the NHS could not consider bevacizumab unless Roche applied for a licence for it as an eye treatment was an "absurd proposition." She said, "It would give unbounded power to the pharmaceutical companies to decide which medicines to make available for which purposes."

She added, "That would be seriously detrimental to the wider public interest in maintaining a cost effective public health system."

David Hambleton, a former consultant geriatrician and lead for the North East and North Cumbria CCG Forum, said that the group was delighted to be able to offer patients bevacizumab as an alternative treatment. "Novartis and Bayer have argued long and hard for the more expensive drugs they'd rather sell to be the only ones available to people suffering from this condition, but, thankfully, the court has recognised that there is no medical basis to that argument.

"This is great news for patients with this condition and for the wider NHS. It's a victory for common sense over commercial interests."

It's not the first time that the NHS has faced legal proceedings over bevacizumab for eye disease. In 2011-12 the Southampton, Hampshire, Isle of Wight, and Portsmouth Primary Care Trust consortium tried to implement such a policy. But Novartis forced a judicial review.<sup>2</sup>

A series of investigations by *The BMJ* subsequently found that doctors had been deterred from prescribing off-label bevacizumab through a combination of legal threats, misinformation, anticompetitive behaviour, and lobbying.<sup>3</sup>

*The BMJ's* investigations raised questions about the General Medical Council's prescribing guidance to doctors and that of the Medicines and Healthcare Products Regulatory Agency (MHRA). Both organisations deterred use of an off-label drug on the grounds of cost when licensed alternatives were available and told *The BMJ* that that was the law.

NICE guidelines state that bevacizumab provides the best value for money for treating macular degeneration.<sup>4</sup> But it also says that cost should not be a factor in prescribing decisions and that the GMC's guidance should be considered. Bevacizumab can be prescribed for AMD only if a "person has a specific need and no other licensed product meets that need," it says.

The MHRA has also since argued that it was a drug regulator's job to determine the safety and effectiveness of a drug, and not that of NICE, and that because bevacizumab had to be split into vials before it was used it was unlicensed for wet AMD.

However, Mrs Justice Whipple found that wasn't the case. "Treating clinicians can lawfully choose Avastin for ophthalmic use on grounds of cost," she ruled.

"The EMA [European Medicines Agency] does not have exclusive competence to determine whether Avastin is clinically effective and safe for ophthalmic use. NICE and the CCGs also have competence in that arena."

She "invited the MHRA to review its guidance." She also did not find the different ways of purchasing bevacizumab to be unlawful.

The MHRA said that it "will be considering the judgment and any implications arising from it."

The decision has been broadly welcomed by health leaders and doctors' organisations.

Charlie Massey, chief executive of the GMC, had previously told *The BMJ* that he did not see the prescription of bevacizumab as an issue of fitness to practise. He welcomed the High Court's decision, adding, "It's important that doctors work in partnership with patients and give them sufficient information about the medicine they propose to prescribe to allow them to make an informed decision."

The Royal College of Ophthalmologists said that it was "delighted" with the ruling. Andrew Lotery, the college's scientific chair, said, "This is a great day for the NHS and patients. The ruling is extremely welcome, as the royal college

has long petitioned on the use of Avastin as an effective treatment for wet AMD. Our members—ophthalmologists overseeing the treatment of patients with eye disease—can now feel assured that they can offer the best treatment for their patient’s individual needs. We expect that the release of funds in the use of Avastin will be secured to improve patient care within the hospital eye service.”

Julie Wood, chief executive of NHS Clinical Commissioners, also said that she was delighted. “The potential cost savings from switching to the cheaper Avastin, with no impact on patient outcomes, are huge, and when resources in the NHS are so stretched we must ensure that maximum value is delivered for every NHS pound.

“We now call on the Department of Health and Social Care and NHS England to take all steps in acting on this judgment and actively support the implementation of similar pathways across the country for the benefit of patients, the public, and taxpayers.”

Novartis said that it was “a bad day for patients, doctors, and the NHS” and that the judgment undermined drug regulation. It said it was “unethical” that patients were being asked to make this choice and that it would place a “burden on already overstretched doctors.”

It is considering appealing the judgment, as is Bayer.

- 1 Cohen D. CCGs face legal threat for offering off-label drug for wet AMD. *BMJ* 2017;359:j5021. 10.1136/bmj.j5021 29089307
- 2 Torjesen I. Novartis takes legal action over trusts’ advice to use bevacizumab for wet AMD. 2012;344:e2959.
- 3 Cohen D. Why have UK doctors been deterred from prescribing Avastin? *BMJ* 2015;350:h1654. 10.1136/bmj.h1654 25834024
- 4 National Institute for Health and Clinical Excellence. Age-related macular degeneration: NICE guideline NG82. Jan 2018. <https://www.nice.org.uk/guidance/NG82>.

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