11 June 2012

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Dear Sirs

Final Appraisal Determination: Belimumab for the treatment of systemic lupus erythematosus

Thank you for your letter of 30 May. This is my final decision on initial scrutiny.

1.3 The Appraisal Committee’s finding that belimumab has not been shown to represent a cost-effective use of NHS resources compared with rituximab, acts to protect continued use of a product which is not authorised for the condition under consideration, contrary to the medicines licensing regime and the European Court decision in Case C-185/10 European Commission v. Republic of Poland

I have indicated that I regard this as a valid ground, and the issue is whether it should be considered under ground 3 rather than ground 1.

As you know, ground 1 of the grounds of appeal looks to procedural fairness. I have carefully considered the points you make but they all seem to me to be points of substance rather than procedure. There seems to be no suggestion that what was done has come as a surprise, that evidence was relied on that was not disclosed to you, or anything of that sort. Rather the argument is that issuing a negative recommendation based on cost would be unlawful, or more broadly "wrong". I am afraid I do not see how that can be said to be a matter of procedural fairness, and it seems likely to confuse the appeal hearing if it is viewed in that light.
Although you do not make the point, I can see that it may be arguable that even if a recommendation based on cost was made and was not unlawful, it might nevertheless not be justifiable on the evidence. It could be the case that cost is in principle relevant (I stress I have no view on that) but that it is unreasonable to rely on it either generally or in this case. If the arguments do develop in that direction I am sure the appeal panel would also consider the point in that light. With that caveat, it remains my view that the correct approach to this issue is to consider whether it is within NICE's powers at all.

Conclusion

All your appeal points are valid, but point 1.3 should be considered under ground 3 rather than ground 1.

Yours sincerely

Chair
National Institute for Health and Clinical Excellence