The Royal College of Pathologists
Pathology: the science behind the cure

14 September 2017

Dear Dr Benneyworth

Thank you for taking the time to read our appeal so carefully and thoughtfully and for granting an appeal on the basis of 'cycle number'. We apologise for not clearly stating our grounds for appeal and we thank you for your understanding, since none of us have previous experience of the appeal process.

We appreciate the opportunity you have given us to respond with some clarifications on our concerns regarding length of stay. Please find our clarifications below.

We believe that it is unreasonable for any person or body to make a final decision on a life-changing or life-saving intervention if the evidence on which the decision is based is incomplete *and* the possible range of interpretation of such evidence that exists is sufficiently broad that adoption of one particular interpretation over another has the possibility to change the decision. To our mind, this also impinges on the "fairness" ground as we believe that it is unfair to patients with relapsed or refractory acute lymphoblastic leukaemia to pick and choose which evidence to consider and which to reject in deciding whether an undoubtedly clinically-active agent (as demonstrated in a phase 3 RCT) will be available for them in the UK.

Your insightful but pragmatic comments relating to the committee decision of which ICER to adopt illustrate the problem we have noted above. You mention that "They concluded that the ratio was not likely to be as much as 1:14". Our concern is to understand how and why the committee concluded that and to know if an alternate conclusion may have changed the outcome and may yet have the possibility to do so. Expert evidence given at the hearing suggested that it would not be uncommon for patients receiving FLAG-based regimens to be hospitalised for 4-6 weeks. By contrast, many of those receiving Inotuzumab may not require admission at all. This is an even greater difference than that suggested by the manufacturer. Since you state – and we agree – that all the modelling approaches presented could be open to criticism, it follows that there should be enhanced care and transparency of reasoning over which approach is selected. You note – regarding the committee – that "They preferred the ERG approach" which appears to indicate a preference for which there was no agreed factual basis. We believe this decision is both unreasonable and unfair to patients who could have been potential future recipients of this drug. We believe this is particularly unfair given that real-world data which could shed light (independent of the manufacturer or the ERG) on this aspect of decision making could easily be collected.

Rachael Hough, Ajay Vora, Adele Fielding

On behalf of the Royal College of Pathologists, Royal College of Physicians and Association of Cancer Physicians

The Royal College of Pathologists
4th floor, 21 Prescot Street, London, E1 8BB, UK
Tel: 020 7451 6700, Fax: 020 7451 6701, www.rcpath.org
Registered Charity in England and Wales no. 261035