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30 September 2011

Dear [redacted]

Appeal Against Final Appraisal Determination: Dasatinib, high-dose imatinib and nilotinib for the treatment of imatinib-resistant chronic myeloid leukaemia (CML) (part review of NICE technology appraisal guidance 70), and dasatinib and nilotinib for people with CML for whom treatment with imatinib has failed because of intolerance

Thank you for your letter dated 26 September 2011.

1.3 Considering Dasatinib as Combination Therapy in the Blast Phase of CML is unfair

I have considered your comments, and referred to the passages in the FAD which you highlight, but it is still my view that there is no evidence of any such consideration. The committee say in the FAD

...It noted that treatment for the blast-crisis phase is different from that used in the other phases, with interventions generally used as adjuvant treatment to intensive chemotherapy for acute leukaemia. The Committee was aware that no evidence using the interventions in this way had been submitted. To the extent that dasatinib could be considered a stand-alone treatment, the Committee concluded that the evidence was particularly limited.... the Committee concluded that dasatinib could not

be considered a cost-effective use of NHS resources for the treatment of blast-crisis phase CML.

The committee is saying that it saw no evidence relating to use as adjuvant treatment (ie, in combination). They do not discuss such use and in the absence of any evidence relating to such use I do not consider that they would have discussed it. They go on in the next sentence to refer to dasatinib as a stand alone treatment, and then discuss that. Finally, they conclude that dasatinib (and not "*dasatinib in combination with*...") is not cost effective for treatment of blast phase CML.

My view is that there are no grounds on which a panel could conclude that the consideration you complain of took place or affected the appraisal, and therefore this is not a valid appeal point.

1.4 The Review and Approval of Novartis' Patient Access Scheme During an On-Going Multiple Technology Appraisal Is Procedurally Unfair

In light of your further comments I agree this point should be considered by the appeal panel.

1.5 The Decision Not to Apply The End-of-Life Criteria is Unfair

I am afraid I do not think your approach to the EoL criteria is arguable. When considering whether the criterion in para 2.1.2 is satisfied, para 2.3.1 directs the committee that the estimates of extension to life must be robust. Para 2.3.1 is not a separate consideration to be applied after paras 2.1 and 2.2, it sets the bar when applying 2.1. In this case the committee did not accept that the estimates were robust, and accordingly did not move on to consider para 2.2. That is a correct application of the process.

If the conclusion that the estimates were not robust is unjustified, then the effect would be that para 2.2 would have had to have been considered, but the appeal panel will be considering that possibility under your ground 2.3.

I do not accept this is a valid appeal point.

Ground 2

2.1 Relying on outputs of the SHTAC Model and utilising these to form the basis of guidance to the NHS is Perverse

Thank you for your comment. I should make clear that your document may be supplemental to your appeal letter, but it should not contain new material not seen by the Committee. As you are aware an appeal panel does not consider new evidence.

2.5 Ultra-orphan

I am afraid that I do not agree that the fact that guidance is draft is irrelevant. It is relevant that the guidance was drafted some years ago, and has never been adopted by NICE. The inescapable inference is that it is not NICE policy. Had it been it would have been adopted.

If there were an issue, it would be an issue of what treatments are referred to NICE, which is not a matter within the appeal panel's remit (or indeed NICE's remit overall). It is well known that NICE applies the same methodology and standards across appraisals, and even so appellants often seek to take issue with NICE for alleged lack of consistency. Within that framework I do not see that there is any arguable unreasonableness.

I do not agree that this is a valid appeal point.

Ground 3

3.2 The Acceptance of the Novartis Patient Access Scheme is in Breach of the PPRS

In light of my comment under point 1.4 above I now agree this is a valid ground 3 argument.

Conclusion

This is the final decision on initial scrutiny. The valid appeal points are 1.1, 1.2, 1.4, 1.6, 2.1, 2.2, 2.3, 2.4, 3.1, and 3.2.

Yours sincerely

[redacted]
Appeals Committee Chair
National Institute for Health and Clinical Excellence