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Sent via email

James Whale Fund for Kidney Cancer
46-48 King Street
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23 December 2010

Dear Mr Turkentine

Final Appraisal Determination: Everolimus for the second line treatment of advanced and/or metastatic renal cell carcinoma

Thank you for lodging the James Whale Fund for Kidney Cancer's appeal against the above Final Appraisal Determination, by email on 22 December.

Introduction

The Institute's appeal procedures provide for an initial scrutiny of points that an appellant wishes to raise, to confirm that they are at least arguably within the permitted grounds of appeal ("valid"). The permitted grounds of appeal are:

- Ground 1: The Institute has failed to act fairly
- Ground 2: The Institute has formulated guidance which cannot reasonably be justified in the light of the evidence submitted.
- Ground 3: The Institute has exceeded its powers.

This letter sets out my initial view of the points of appeal you have raised: principally whether they fall within any of the grounds of appeal, or whether further clarification is required of any point. Only if I am

satisfied that your points contain the necessary information and arguably fall within any one of the grounds will your appeal be referred to the Appeal Panel.

Initial View

Your email reads:

The James Whale Fund for Kidney Cancer wishes to Appeal against the initial decision of NICE not to recommend the Drug Everolimus as a 2nd line treatment of Kidney Cancer for the following reasons: The outlook for metastatic kidney cancer patients who have failed initial treatment (sunitinib in the UK) is bleak. Everolimus is the only agent with positive randomized data in the 2nd line setting. Trails have shown the drug is well tolerated and has an impressive progression free survival advantage (HR 0.3). In Trails patients were able to cross over into the active treatment arm for compassionate reasons invalidating any overall survival analysis. Everolimus is established worldwide as an essential part of kidney cancer management. The absence of 2nd line therapy in the UK puts patients at a disadvantage in terms of outcome. We know Clinicians feel this will have a negative impact on survival in audits which are ongoing.

I do not think that your email can amount to a valid ground of appeal. I understand and accept your concern for patients, and also accept the point that the drug has evidence in its favour, has clinical benefits, and is in use in other countries. But none of these points amount to a procedural unfairness, guidance which cannot be justified, or the Institute exceeding its powers.

Ordinarily the institute allows for comment on initial scrutiny before making a final decision, and so I must do so here. However, particularly as your appeal was received well after the appeal deadline, I wish to stress that any comment must be on why the email set out above should be held to be a valid ground of appeal. If I feel that you are instead advancing new arguments not contained in your email of 22 December I will have to reject them.

The final date on which I can receive any further comments is **5pm on Monday 17 January**. I must emphasise that in this case any correspondence on this matter received after 5pm on that date will not be considered.

Conclusion

As your email does not contain any appeal points, I cannot pass your appeal to the Appeal Panel for consideration at this time.

I can however tell you that appeals have been lodged by other parties, and as appeals are held in public, it will be possible for you to attend and listen to (but not take part in) the appeal. Again, if you wish to make any further comment I would be grateful to receive it by **no later than 5pm on Monday 17 January**.

Yours sincerely

Maggie Helliwell
Appeals Committee Chair
National Institute for Health and Clinical Excellence