National Institute for Health and Care Excellence

Centre for Health Technology Evaluation

Immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99) [ID346]

Immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99) [ID346]
The British Association for Paediatric Nephrology response to the Assessment Report

Issue 1 2.2.3

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
List of non-transplant centres	Omit Newcastle as non-transplant centre; transplants are undertaken in Newcastle	none

Issue 2 4.3.2.3

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
Comparison of graft function in the two arms of the study reported by Trompeter states comparison is between TAC and AZA	Significantly higher function in the TAC arm compared with the CSA arm	none

Issue 3 4.3.2.3 summary

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
Lower graft function was associated with TAC	Lower graft function was associated with CSA	Probably none

(please cut and paste further tables as necessary)

Issue 4 Page 240

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
Hypomagnesaemia reported by Trompeter, assumed to last until end of trial (4 years)	Omit assumption that hypomagnesaemia is persistent – it is usually transient and resolves within a few months. We have very few patients who need supplements for more than 6 months. The Trompeter paper does not have adequate duration of follow-up for this assumption to stand	Slight reduction in cost

Issue 5 Page 280

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
MMF is predicted to be effective in regimens containing CSA but not IR TAC	In the TWIST trial the purposed of the study was to eliminate the use of steroids with a beneficial effect on growth in height. This TA does not make much mention of the benefit of steroid withdrawal. A significant number of paediatric renal units now use the TWIST which is one of the few scientific studies undertaken in paediatric renal transplantation. Any recommendation arising from the TA needs to include reference to the use of MMF as part of the TWIST study as it has been demonstrated to be effective in reducing steroid side effects and improving growth.	May be significant

Issue 6 7.1.2.2

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
…was found in TAC v AZA at up to 4 years	The trial referred to in reference 74 compared TAC and CSA,	none

follow-up[74]	not AZA; furthermore, the follow-up only extended to 1 year, nit 4 years	

Issue 7 Page 322

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
MMF is cost effective only if used in combination with CSA	Some reference to MMF and steroid withdrawal is necessary	significant

Issue 8

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)

Issue 9

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
Give full details of the problem detected, if necessary, with explanation of why the issue is considered to be a problem.	Give details of any amendments/corrections made in sufficient detail to allow these to be reproduced	Insert ICER resulting from amended model. If the model has not been re-run, if appropriate, describe your expectations of how the problem might have an impact on the result