NICE National Institute for Health and Care Excellence

National Institute for Health and Care Excellence

Centre for Health Technology Evaluation

Pro-forma Response

External Assessment Centre Report factual check

HeartFlow FFR_{CT} for the computation of fractional flow reserve from coronary CT angiography

Please find enclosed the assessment report prepared for this assessment by the External Assessment Centre (EAC).

You are asked to check the assessment report from KiTec to ensure there are no factual inaccuracies contained within it. If you do identify any factual inaccuracies you must inform NICE by 9am, **28 May** using the below proforma comments table. All your comments on factual inaccuracies will receive a response from the EAC and when appropriate, will be amended in the EAC report. This table, including EAC responses will be presented to the Medical Technologies Advisory Committee and will subsequently be published on the NICE website with the Assessment report.

21 May 2015

Issue 1

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Page 20- "The sponsor claims that the radiologists performing CCTA can also interpret FFR_{CT} analyses along with trained general, interventional, or imaging cardiologists. However, since FFR_{CT} analysis is a centralised service the EAC considers this claim to be irrelevant."	HeartFlow suggests the following part of this phrase be removed: "However, since FFR_{CT} analysis is a centralised service the EAC considers this claim to be irrelevant."	We believe that this statement is not factually accurate. HeartFlow provides the FFR_{CT} results as a centralised service, but a trained physician is required to interpret the results and determine how best to manage each individual patient. While the generation of results is a centralised service performed at HeartFlow, the interpretation of these results is not centralised. It is performed by physicians involved with patient care.	The EAC accepts the sponsor's clarification on this matter and has incorporated the proposed amendment in the text. The section now reads: '*The sponsor claims that the radiologists performing CCTA can also interpret the reported FFRCT analyses along with trained general, interventional, or imaging cardiologists. The EAC agrees that while the generation of results is a centralised service performed at HeartFlow, the interpretation of these results is not centralised. It is performed by clinicians involved with patient care*.'

Issue 2

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Page 113 "The sponsor states that only this population (pre-test likelihood of 10-90%) has been considered for the cost model, however, the EAC found that the cost of pre-test	Page 113 "While the sponsor's model includes patients outside the scope (pre-test likelihood of 10-90%), the sponsor does not recommend any change in treatment for these patients. We have excluded these patients from our revised	The language used in the EAC report in these two instances may lead one to believe that HeartFlow's inclusion of these patients (<10% & >90% pre-test likelihood of disease) caused the model to show undue value of FFR_{CT}, In actuality it is the	The EAC accepts the sponsor's clarification on this matter and has incorporated the proposed amendments in the text.

likelihoods of <10% & >90% were also included. Clearly these populations needs to be excluded to accurately estimate the cost-savings of the technology compared to current practice." Page 124 "In their submission, the sponsor states that patients with pre-test likelihood of <10% and >90% are not considered. However, on scrutiny of the electronic model, costs have been estimated for these populations and are included in the final per patient cost estimations. The EAC has excluded these patients and re-estimated the costs."	model and results." Page 124 "In their submission, the sponsor states that patients with pre-test likelihood of <10% and >90% are not considered. However, on scrutiny of the electronic model, costs have been estimated for these populations and are included in the final per patient cost estimations. Since the sponsor does not suggest any change in treatment for such patients, excluding them results in further increase in average cost savings due to FFR_{CT}. The EAC has excluded these patients and re-estimated the costs."	opposite. Removing these patients (as appropriately done in EAC's analysis) increases the estimated average costs saved by utilizing FFR_{CT}.	