Association of British Healthcare Industries

Nicole Fisher
Project Manager- Committee C
National Institute for Health and Care Excellence
Level 1A, City Tower
Piccadilly Plaza
Manchester M1 4BT

12th August 2014

Dear Nicole,

Dual-chamber pacemakers for treating symptomatic bradycardia due to sick sinus syndrome without atrioventricular block, (part review of Technology Appraisal 88)

The Association of British Healthcare Industries (ABHI) on behalf of the following manufacturers; Biotronik, Boston Scientific, Medtronic, Sorin Group, St Jude Medical, wish to thank NICE for the opportunity to comment on the TAG report for the TA88. Our comments are confined to four areas:

Industry Submission

The Assessment Report notes that a submission was not received from manufacturers. NICE will be aware that on 2nd January 2014, ABHI confirmed that industry would not be making a submission, but would be commenting at each phase of consultation. The decision not to submit a model, and instead support the review by the TAG was based largely by the fact that single chamber atrial pacing AAI(R) is rarely used in the UK – owing to technological advances and in the light of DANPACE. This is confirmed by the clinical expert opinion provided to TAG. The MTA Methods Guide clearly advises that a manufacturer's submission is not a compulsory element and it would appear that the TAG was not made aware of our intentions. We apologise if this has in anyway hindered their work planning.

Costs Used in the Model and Pacemaker Pricing Information

The Assessment Report notes that device pricing information was not provided by manufacturers. ABHI were unable, in the timeframe requested, to facilitate an aggregate, average pricing estimate because of the governance requirements associated with the release of commercially sensitive data from multiple manufacturers. We have now accomplished this task and have provided that information to you separately.

However, as the acquisition prices of single and dual chamber pacemakers are included within national tariffs, ABHI are in support of the modelling approach undertaken by the TAG. As HRGs EA03Z & EA05Z (Table 2) capture the full cost of pacemaker implantation, including the device itself, the use of HRGs in the model is the most appropriate way to determine cost-effectiveness and budget impact. These are after all, the actual costs that Commissioners incur. It should also be noted that there is a greater differential between tariff costs than between device costs, making a tariff-based model more conservative towards dual chamber devices.

HRG	Name	Tariff
EA03Z	Pace 1 - Single Chamber or Implantable Diagnostic Device	£2,259
EA05Z	Pace 2 - Dual Chamber	£3,208

Table 2. Admitted patient care & outpatient procedure elective tariff values 2014-15

Risk of Developing Heart Failure and Age

The Assessment Report notes that, based on a sub-group analysis of DANPACE, patients younger than 75 years may be at a lower risk of developing heart failure with single chamber atrial pacing compared with dual chamber pacing, whilst patients aged more than 75 years were at higher risk of developing heart failure with single chamber atrial pacing. It should be noted however, that algorithms that reduce unnecessary ventricular pacing by maintaining the patients' intrinsic AV conduction where possible, are in routine practice and continue to develop.

As patients with sick sinus syndrome without AV block may subsequently develop AV block, managing this transition phase is crucial. Newer pacemaker algorithms are helpful in this transition phase[1,2,3]. Minimising ventricular pacing is beneficial sick sinus syndrome without AV block, while dual chamber pacing is necessary when the patient develops AV block[1,2,3]. We would therefore ask the Committee to recognise the overall clinical and cost-effectiveness results when developing their recommendations and also be mindful of the need for clinicians to be able to take the risks and benefits for individual patients into account, including the risk of developing heart failure, when applying guidance.

Budget and Service Impact

The '*UK NATIONAL AUDIT OF CARDIAC RHYTHM MANAGEMENT DEVICES 2012*' shows that AAIR and AAI modes accounted for **only 165 implants** in the UK, equivalent to <0.5% of the total implant numbers (Table 3).

Atrial based modes	2012		2011
DDDR	26701	67.49%	66.90%
DDD	830	2.10%	2.40%
AAIR	132	0.33%	0.01%
AAI>DDD	42	0.11%	0.01%
AAIR>DDDR	40	0.10%	0.00%
AAI	33	0.08%	0.00%
DDI	10	0.03%	0.02%
AAIsafeR	2	0.01%	0.00%
DDIR	1	0.00%	0.01%
Ventricular based modes	**2012**		**2011**
VVIR	11057	27.95%	29.80%
VVI	285	0.72%	0.50%
VDD	67	0.17%	0.26%
VDDR	12	0.03%	0.03%

Table 3: 13 commonest pacing modes in the UK (2012 National Audit of CRDM Devices)

It is clear that the technological advances in pacing therapy and associated algorithms available across the range of manufacturers has mitigated the need and use for AAI(R). Given the risk of developing AV block at some point in the patient's disease pathway, this has led to the current position where practice is already consistent with the findings of the Assessment Report.

Subject to the Committee's recommendation that dual-chamber pacemakers for treating symptomatic bradycardia due to sick sinus syndrome without AV block are an acceptable use of the NHS finite resources, new guidance to this effect is unlikely to result in any dramatic shift in clinical practice. The maximum budget impact is likely to be HRG EA03 to EA05 tariff uplift x patient population, i.e. £1,151 x 165 = £191,066.

Yours Sincerely

[redacted]

[redacted]

Association of British Healthcare Industries (ABHI)

On Behalf of
Biotronik
Boston Scientific
Medtronic, Inc.
Sorin Group
St Jude Medical

References

1. Stockburger M. Et al. "Long-term clinical effects of ventricular pacing reduction with a hangeover mode to minimize ventricular pacing in a general pacemaker population" CARDIOSTIM 2014 Annual Scientific Sessions, in Nice, France. Paper accepted at European Heart Journal.

2. Davy JM et al. "Near elimination of ventricular pacing in SafeR mode compared to DDD modes: a randomized study of 422 patients" Pacing Clin Electrophysiol. 2012 Apr;35(4):392-402. doi: 10.1111/j.1540-8159.2011.03314.x. Epub 2012 Feb http://www.ncbi.nlm.nih.gov/pubmed/22309303.

3. Sweeney MO, et al., Minimizing Ventricular Pacing to Reduce Atrial Fibrillation in Sinus-Node Disease. (The Search AV Extension and Managed Ventricular Pacing for Promoting Atrioventricular Conduction (SAVE PACe) Trial) N Engl J Med 2007; 357:1000-1008 September 6, 2007DOI: 10.1056/NEJMoa071880