NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

TYRX Absorbable Antibacterial Envelope for preventing infection from pacemakers and implantable defibrillators

Draft scope

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of TYRX within its CE mark for preventing infection from pacemakers and implantable defibrillators.

Background

Pacemakers and implantable cardioverter-defibrillators are used to regulate heart rate in people with cardiac arrhythmias. Between April 2015 and March 2016, 34,000 pacemakers and 13,000 ICDs were implanted (both new and replacements) in England[1]. Some pacing devices are inserted within a porcine or polymer 'pouch' to prevent device migration. Around 20% of implants will be replacement of existing devices. It is estimated that 3 to 4% of people undergoing surgery will develop an infection. Patients considered to have a high risk of surgical site infection are those with diabetes, renal insufficiency, on anticoagulants or daily corticosteroids, immunosuppression and those with a previous pacing device which requires early replacement.

Current British guidelines for the diagnosis, prevention and management of implantable cardiac electronic device infection recommended intravenous antimicrobial prophylaxis 1 hour prior to skin incision[2]. Antibiotic regimens vary with all patients receiving pre-operative prophylaxis and some receiving an additional post-operative dose.

The technology

The TYRX Absorbable Antibacterial Envelope (Medtronic) CE mark notes that it is intended to be used in patients having a pacemaker or implantable defibrillator. It is an antibiotic-coated bio-absorbable polymer mesh into which any pacemaker or defibrillator can be placed before it is implanted. The knitted glycoprene II mesh envelope anchors the CIED to the chest wall to

prevent device migration and an absorbable tyrosine-based polyarylate polymer antimicrobial agent coating delivers rifampicin and minocycline, each at a concentration of 102 μg/cm^2 for 7 days which is intended to reduce the risk of surgical site infection. The technology is available in 2 sizes: medium (6.3 cm x 6.9 cm) intended for use with a pacemaker and large (7.6 cm x 8.5 cm) intended to hold an implantable defibrillator. Expert advice has indicated that TYRX would be used with current antibiotic prophylaxis.

Intervention(s)	TYRX Absorbable Antibacterial Envelope
Population(s)	People requiring a pacemakers or implantable cardioverter-defibrillators for the treatment of arrhythmias.
Comparators	Standard management without the TYRX device
Outcomes	The outcome measures to be considered include: • device related surgical site infection (SSI) • hospital re-admissions • hospital length of stay • antibiotic usage • number of invasive procedures including replacement surgeries • mortality • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective.

Other considerations	If the evidence allows the following subgroups will be considered: • High risk of infection Guidance will only be issued in accordance with the CE marking. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations and NICE Pathways	Related Technology Appraisals: Dual‑chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block (2014) NICE technology appraisal guidance 324. Review date TBC. Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure (2014). NICE Technology Appraisal 314. Review date TBC. Terminated appraisals None Appraisals in development (including suspended appraisals) None Related Guidelines: Healthcare-associated infections: prevention and control in primary and community care (2012) NICE guideline CG139 Review date TBC. Acute heart failure: diagnosis and management (2014) NICE guideline CG187 Review date TBC. Atrial fibrillation: management (2014) NICE guideline CG180 Review date TBC. Chronic heart failure in adults: management (2010). NICE clinical guideline 108 Review date TBC. Surgical site infections: prevention and treatment (2008). NICE clinical guideline 74 Review date Feb 2017. Guidelines in development Chronic heart failure in adults: diagnosis and management NICE guideline. Publication expected August 2018

	Atrial fibrillation: management NICE guideline. Publication expected: September 2020. Related Interventional Procedures: Subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death (2017) NICE interventional procedures guidance 603 Insertion of a subcutaneous implantable cardioverter defibrillator for prevention of sudden cardiac death (2013) NICE interventional procedures guidance 454 Laser sheath removal of pacing leads (2004) NICE interventional procedures guidance 63 Related medical technologies guidance: ENDURALIFE powered CRT-D devices for treating heart failure (2017) NICE medical technologies guidance 33. Related Public Health Guidance/Guidelines: Healthcare-associated infections: prevention and control (2011) NICE guideline PH36 Related Quality Standards: Healthcare-associated infections (2016) NICE quality standard 113 Acute heart failure (2015) NICE quality standard 103 Atrial fibrillation (2015, updated 2018) NICE quality standard 93 Acute coronary syndromes (including myocardial infarction) (2014) NICE quality standard 68 Infection prevention and control (2014) NICE quality standard 61 Surgical site infection (2013) NICE quality standard 49 Chronic heart failure in adults (2011, updated 2016) NICE quality standard 9 Related NICE Pathways: Heart rhythm conditions (2018) NICE pathway

	Acute heart failure (2016) NICE pathway Chronic heart failure (2017) NICE pathway Prevention and control of healthcare-associated infections (2016) NICE pathway
Related National Policy	NHS England (2016) IM4 Complex Cardiac Implantable Electronic Devices (CIED) Optimisation NHS England (2015) Cardiac Surgery - Adults NHS England (2013) Cardiology: Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronisation Therapy (CRT) (Adult) NHS England (2013) 2013/14 NHS standard contract for cardiology: implantable cardioverter defibrillator (ICD) and cardiac resynchronisation therapy (CRT) (adult). Reference: A09/S/a NHS England (2013) 2013/14 NHS standard contract for cardiology: electrophysiology and ablation services (adult). Reference: A09/S/b NHS England (2017) Manual for Prescribed Specialised Services 2017/18. https://www.england.nhs.uk/wp-content/uploads/2017/10/prescribed-specialised-services-manual-2.pdf National Service Framework Coronary Heart Disease - archived Department of Health and Social Care, NHS Outcomes Framework 2016-2017 (published 2016): Domains https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017

Questions for consultation

How should a surgical site infection be defined?

How should high risk of infection requiring a pacemaker or defibrillator be defined?

Do all patients receiving a pacemaker or defibrillator have it inserted within a pouch?

Are alternative ‘pouches’ used in the placement of pacing devices?

What is the current antibiotic prophylaxis regimen for patients having a pacing device without TYRX? Are patients at high risk of a surgical site infection

treated? Would the antibiotic prophylaxis regimen be different for patients having TRYX?

Are the outcomes listed appropriate? Should outcome related to device migration be included (for example lead displacement)?

Are there any subgroups of people in whom TYRX is expected to be more clinically effective and cost effective or other groups that should be examined separately? Should people who are having a replacement of a cardiac implantable electronic device be included as a subgroup?

Where do you consider TYRX will fit into the existing NICE pathways, heart rhythm conditions and chronic heart failure?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which TYRX is licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

Do you consider TYRX to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a ‘step-change’ in the management of the condition)?

Do you consider that the use of TYRX can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction).

References

1. National Institute of Cardiovascular Outcomes Research (NICOR) (2017) National Audit of Cardiac Rhythm Management Devices: April 2016 – March 2016. London: Pad Creative.

2. Sandoe, J.A.T. Barlow, G., Chambers, J.B. et al. (2015), Guidelines for the diagnosis, prevention and management of implantable cardiac electronic device infection. Report of a joint Working Party project on behalf of the British Society for Antimicrobial Chemotherapy (BSAC, host organization), British Heart Rhythm Society (BHRS), British Cardiovascular Society (BCS), British Heart Valve Society (BHVS) and British Society for Echocardiography (BSE), Journal of Antimicrobial Chemotherapy, vol 70, pp325-359.

