NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

TYRX Absorbable Antibacterial Envelope for preventing infection from cardiac implantable electronic devices

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of TYRX within its CE mark for preventing infection from cardiac implantable electronic devices.

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 1 to 2% 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.

Collatamp G is a collagen sheet impregnated with gentamicin. Its CE marked indications for use are for local haemostasis of capillary, parenchymatous and seeping haemorrhages in areas with a high risk of infection. It is sometimes used to wrap around the CIED before it is implanted reduce the rate of surgical site infections and is therefore a relevant comparator.

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 (including cardiac resynchronisation devices which either pace or defibrillate). 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 which would be used with current antibiotic prophylaxis.

Intervention(s)	TYRX Absorbable Antibacterial Envelope
Population(s)	People requiring a new or replacement pacemaker or implantable defibrillator (including cardiac resynchronisation devices which either pace or defibrillate) for the treatment of heart failure and arrhythmias.
Comparators	Standard management without the TYRX device, that is pre-operative intravenous antibiotics with or without Collatamp G.
Outcomes	The outcome measures to be considered include: • device related infection • hospital re-admissions • hospital length of stay • antibiotic usage • number of device related re-intervention procedures (including extraction and 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. **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 The NHS Long Term Plan, 2019. NHS Long Term Plan. NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019) Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domains 1 and 2. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017

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.