NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Furosemide micro-pump for treating oedema associated with heart failure

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of furosemide micro-pump within its marketing authorisation for treating oedema associated with heart failure.

Background

Heart failure is an umbrella term for conditions that affect the efficiency of the heart pumping blood around the body. Heart failure currently affects approximately 900,000 people in the UK[1]. Heart failure is a common cause of admission to hospital with over 70,000 admissions in England in 2014/15[2]. According to the National Heart Failure Audit Annual Report 2014-2015, approximately half of hospital admissions where the primary diagnosis was heart failure were associated with moderate or severe oedema[1].

Oedema is the medical term for fluid retention. In heart failure, oedema may be experienced as peripheral oedema (usually in the lower limbs) or pulmonary oedema (a build-up of fluid in the lungs leading to difficulty breathing).

NICE Guideline 108 for managing chronic heart failure notes that diuretics should be routinely used for the relief of congestive symptoms and fluid retention (oedema). These include loop diuretics (such as furosemide or bumetanide) or thiazide-based diuretics. For patients with acute heart failure, NICE Guideline 187 states that intravenous diuretic therapy should be used. For patients already taking a diuretic, a higher dose diuretic than that taken on admission should be considered.

The technology

Furosemide micro-pump (Sc2Wear furosemide micro-pump patch, ScPharmaceuticals) is a controlled-release reformulation of the diuretic furosemide for treating heart failure. The furosemide micro-pump delivers the drug subcutaneously through a wearable patch device.

Furosemide micro-pump does not currently have a marketing authorisation in the UK for treating oedema in heart failure. It has been studied in 1 completed and 1 ongoing randomised controlled trial in patients with oedema related to their heart failure. Another randomised controlled trial is expected to be completed in 2018. In both completed trials furosemide micro-pump was compared with furosemide administered intravenously and included people

with peripheral oedemas and excluded people requiring hospitalisation or with worsening symptoms.

Furosemide has a marketing authorisation in the UK as an oral and parenterally administered diuretic for many indications including oedema associated with heart failure, cirrhosis of the liver and renal disease, as well as peripheral oedema as a result of mechanical obstruction or venous insufficiency.

Intervention(s)	Furosemide micro-pump
Population(s)	People with oedema associated with heart failure
Comparators	Oral or intravenous administration of furosemide and other diuretics used for oedema associated with heart failure (including but not limited to bumetanide, torasemide, bendroflumethiazide and metolazone)
Outcomes	The outcome measures to be considered include: • urine output and fluid balance • weight • symptoms of heart failure (such as breathlessness) • adverse effects of treatment • health-related quality of life • mortality.
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	Guidance will only be issued in accordance with the marketing authorisation. 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	**Related Guidelines:**

recommendations and NICE Pathways	Acute heart failure: diagnosis and management (2014) NICE Guideline 187 Chronic heart failure in adults: management (2010) NICE Guideline 108 **Guidelines in development:** Chronic heart failure in adults: diagnosis and management. (Review of NICE Guideline 108) Expected to be published March 2018 **Related Quality Standards:** Acute heart failure (2015) NICE Quality Standard QS 103 Chronic heart failure in adults (2011) NICE Quality Standard QS9 **Related NICE Pathways:** Acute heart failure (2016) NICE Pathway Chronic heart failure (2016) NICE Pathway
Related National Policy	**National Service Frameworks:** Coronary heart disease - archived Department of Health, NHS Outcomes Framework 2015-2016, Dec 2014. Domains 2-3.

Questions for consultation

Would furosemide micro-pump be used in the NHS to treat people with peripheral oedema only, as in the clinical trials?

Have all relevant comparators for furosemide micro-pump been included in the scope? Which treatments are considered to be established clinical practice in the NHS for oedema associated with heart failure?

Are the outcomes listed appropriate? In particular is 'symptoms of heart failure (such as breathlessness) an appropriate outcome?

Where do you consider furosemide micro-pump will fit into the existing NICE Pathways for acute heart failure and chronic heart failure?

The main proposed benefit of technology is that patients could be treated in the community/primary care. What monitoring and support would be required and is this likely to be possible?

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 furosemide micro-pump will be 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 furosemide micro-pump 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 furosemide micro-pump 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.

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. HQIP, BSH and NICOR (2016) National Heart Failure Audit Annual Report 2014-2015

2. Hospital Episode Statistics (2015) Hospital episode Statistics, Admitted Patient Care – England 2014-15: Diagnosis