Advice Statement 001/2016

| What is the clinical effectiveness, safety and cost effectiveness of the MitraClip® transcatheter mitral valve repair system in patients with moderate to severe or severe mitral regurgitation for whom surgery is not the best option (patients who are at high surgical risk or who are non-surgical candidates)? |

This advice has been produced following completion of [evidence note 58](#) by Healthcare Improvement Scotland. The evidence note was based on a EUneHTA rapid review following consultation with the Scottish Cardiac Society.

### Background

Mitral regurgitation (MR) is characterised by backward flow of blood from the left ventricle to the left atrium during the contraction phase of the cardiac cycle. Left untreated, moderate to severe mitral regurgitation can result in congestive heart failure and eventually lead to death.

MitraClip® System is a transcatheter mitral valve repair system for reconstruction of the insufficient mitral valve in patients with MR. The procedure is performed using venous access thereby avoiding open heart surgery and cardiopulmonary bypass.

Surgical repair, where feasible, is considered to be the gold standard treatment for severe chronic MR. This Advice Statement considers the MitraClip® intervention in patients with moderate to severe or severe mitral regurgitation, for whom surgery is not the best option (patients who are at high surgical risk or who are non-surgical candidates). In a systematic review of 12 studies the mean age of patients receiving MitraClip® ranged from 70 to 78 years. No robust data on the size of the eligible patient population were identified. Extrapolating commissioning data from NHS England, expert opinion estimates that around 20 patients per year would be identified in Scotland.

### Clinical effectiveness

- No evidence was identified directly comparing the outcomes of medical therapies with MitraClip® implantation in this patient group.
- A systematic review of low-quality evidence, comprising non-comparative prospective observational studies, suggests that MitraClip® is a feasible option to improve symptoms of MR in patients with moderate to severe or severe MR who are considered to be at high surgical risk.
- One small, methodologically-limited, comparative study reported a 1-year survival benefit of MitraClip® implantation in 78 patients with MR at high surgical risk (≥12% estimated risk of surgical mortality) when compared with a cohort of 36 patients receiving standard medical care. The comparator group was identified retrospectively and after the outcomes of the MitraClip® intervention group were known, and included
patients ineligible for the prospective part of the study. The study had high risk of bias.

- Three randomised controlled trials investigating the safety and effectiveness of the MitraClip® system are ongoing.

**Safety**
- In uncontrolled observational studies assessed as being of acceptable methodological quality, in-hospital mortality was around 4% (two studies), 30-day mortality ranged from 1.75% to 5.6% (four studies) and 1-year mortality ranged from 10% to 22.8% (three studies). Study authors generally concluded that the MitraClip® procedure can be safely performed.

**Cost effectiveness**
- The cost effectiveness of MitraClip® compared with medical therapies is uncertain. One United Kingdom (UK) model based on the aforementioned small comparative study demonstrated MitraClip® to be cost effective from a 5-year time horizon onwards. The robustness of the results is compromised owing to the absence of randomised comparative data on the survival benefits, small patient numbers and the high risk of bias in the study.
- The cost of the MitraClip® device is £20,000 including VAT. This is the per procedure cost regardless of the number of clips required. This cost does not include other healthcare resources required to perform the procedure, for example staffing and theatre time.

**Context**
- In 2009 the National Institute for Health and Care Excellence interventional procedure guidance [IPG309](#) recommended that the procedure should only be used with special arrangements for clinical governance, consent and research for patients who are well enough for surgical mitral valve leaflet repair to treat their MR, or in the context of research for patients who are not well enough for surgical mitral valve leaflet repair to treat their MR.
- Three centres in NHS England (Manchester, Bristol and London) are undertaking the procedure within the Commissioning through Evaluation programme. The mitraclip registry collects data on all procedures performed in the UK since the introduction of the technique. The registry is managed by the National Institute for Cardiovascular Outcomes Research (NICOR) with clinical direction and strategy provided by the UK Mitraclip group.

**Conclusion**
- Use of MitraClip® for the treatment of moderate to severe or severe MR in patients for whom surgery is not the best option (patients who are at high surgical risk or who are non-surgical candidates) should only be considered on an individual patient basis and in the context of appropriate data collection, such as the NICOR registry, and clinical audit.

**Advice context:**

*The status of SHTG Advice Statements is ‘required to consider’.*

*No part of this advice may be used without the whole of the advice being quoted in full. This advice represents the view of the SHTG at the date noted.*

*It is provided to inform NHS boards in Scotland when determining the place of health technologies for local use. The content of this Advice Statement was based upon the evidence and factors available at the time of*
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Chair
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