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Clinical Commissioning Policy:

Transcatheter Edge to Edge Repair (percutaneous mitral valve leaflet repair) for moderately severe or severe secondary mitral regurgitation due to left ventricular dysfunction and/or dilatation (adults) [2254]

Summary

Transcatheter Edge to Edge Repair TEER (percutaneous mitral valve leaflet repair) is not recommended for patients with heart failure, and secondary mitral regurgitation due to LV dysfunction.

The policy is restricted to adults. In those age groups not included in the policy there is insufficient evidence to confirm safety, and this intervention is therefore not recommended to be used. Those aged under 18 years old are managed by congenital heart services.

Patients with primary degenerative mitral regurgitation are a distinct population from the patients in this policy. TEER (Percutaneous mitral valve leaflet repair) for primary mitral regurgitation is covered by the separate NHS England policy: Percutaneous mitral valve leaflet repair for primary degenerative mitral regurgitation URN 1714.

Committee discussion

Clinical Panel considered the evidence base and the recommendation was made to progress the policy. Please see Clinical Panel reports for full details of Clinical Panel's discussion. The Clinical Priorities Advisory Group committee papers can be accessed here: Transcatheter Edge to Edge Repair (percutaneous mitral valve leaflet repair) for moderately severe or severe secondary mitral regurgitation due to left ventricular dysfunction and/or dilatation

What we have decided

NHS England has carefully reviewed the evidence to treat moderately severe or severe secondary mitral regurgitation due to left ventricular (LV) dysfunction. NHS England recognises that the published evidence identifies that, at present, there is sufficient evidence to commission this treatment. However, following the relative prioritisation process undertaken in May 2024, NHS England has concluded that, balanced against other relative priorities that were also considered during this process, Transcatheter Edge to Edge Repair (percutaneous mitral valve leaflet repair) for moderately severe or severe secondary mitral regurgitation due to left ventricular dysfunction and/or dilatation (adults) will not be funded at this time within the resources available.

The evidence review can be accessed here: Transcatheter Edge to Edge Repair (percutaneous mitral valve leaflet repair) for moderately severe or severe secondary mitral regurgitation due to left ventricular dysfunction and/or dilatation

Links and updates to other policies

There is no current commissioning policy for the interventional management of secondary mitral regurgitation.

The following documents have informed this policy:

- The NICE Heart Valve Disease guidelines (NG208) of 2021 recommend TEER be considered for adults with heart failure and severe SMR who remain symptomatic on medical management and for whom surgery is unsuitable. (NICE, 2021)
- The 2021 ESC/EACTS guidelines for Valvular Heart Disease and 2021 (Vahanian et al., 2021)
- The management of secondary mitral regurgitation in patients with heart failure: a joint position statement from the Heart Failure Association (HFA), European Association of Cardiovascular Imaging (EACVI), European Heart Rhythm Association (EHRA), and European Association of Percutaneous Cardiovascular Interventions (EAPCI) of the ESC (Coats et al, 2021)

Plain language summary

About secondary mitral valve regurgitation due to LV dysfunction and/or dilatation

The heart has four valves which, when they work correctly, ensure the one-way flow of blood through the different chambers of the heart and to the major blood vessels. Mitral regurgitation (MR) is a type of heart valve disease where the valve between the left heart chambers does not close completely, leading to blood leaking backwards through the valve.

The cause of mitral regurgitation is broadly divided into degenerative (or ‘primary mitral regurgitation’ where the valve itself is structurally abnormal) and functional (or ‘secondary mitral regurgitation’ where the valve is structurally normal, but another condition affects the structure and/or function of the heart so that the valve cannot close properly). This policy focusses on adults with secondary mitral regurgitation due to LV dysfunction and/or heart failure.

Heart failure describes situations where the heart muscle works less well and its ability to pump blood is reduced. In patients with heart failure affecting the left side of the heart, the left ventricle (LV) does not function well and may enlarge, which is known as dilation. This can prevent the mitral valve from properly closing, which causes MR. This type of MR that is a consequence of LV dysfunction but with a structurally normal mitral valve is known as secondary mitral regurgitation (SMR). One third of patients with heart failure and reduced LV function will have moderate or severe SMR.

People with SMR have symptoms because of both the underlying heart failure, and because of the valve itself is not working correctly. Symptoms of heart failure can include increasing breathlessness and swelling of the legs. Symptoms may get progressively worse despite medicines given for heart failure, which may result in recurrent hospitalisation and eventually death.

About current treatment

Current standard of care treatment involves optimising the heart failure using medications. There are two additional options for some patients:

1. Cardiac resynchronisation therapy (CRT) may also be used for selected patients. CRT involves implanting a special type of pacemaker under the skin and wired to the heart, which stimulate the chambers on the left and right side of the heart to pump at the same time, which improves the heart's efficiency.

2. Some patients with severe functional mitral regurgitation, after appropriate consideration and assessment by a heart multi-disciplinary team, may be treated with mitral valve surgery.

About Transcatheter Edge-to-Edge Repair (percutaneous mitral valve leaflet repair)

Both terms (TEER and percutaneous mitral valve leaflet repair) refer to the same intervention, which is a less invasive method than surgery for treating mitral regurgitation. This intervention, done under general anaesthesia, delivers a clip to the heart via a tube inserted into a blood vessel in the groin. The procedure is monitored using a camera placed in the oesophagus (swallowing tube) to help guide the clip towards the mitral valve. The clip attaches to the edges of the valve which allows the valve to close better.

Epidemiology and needs assessment

The incidence of heart failure in Europe is about 5 per 1000 person/years in adults and prevalence is 1–2% in adults: increasing from around 1% for those <55 years to >10% for those aged over 70 years (NICE, 2018b). It is estimated that about 650,000 people in the UK have heart failure (British Heart Foundation, 2022). Heart failure accounts for 5% of all emergency hospital admissions and ~1 million bed days each year (Conrad et al., 2018).

The number of patients that meet the clinical criteria for TEER requires extrapolation of available epidemiological data and is difficult to estimate accurately but is summarised in the following series of informed assumptions for the population of England:

- The prevalence of heart failure is approximately 1% (550,000 people in England)
- About 50% (225,000 people) have a reduced left ventricular ejection fraction (LVEF)
- Moderate to severe mitral regurgitation is present in approximately 33% of patients with heart failure and a reduced LVEF (74,250 people)
- Approximately 50% of these (37,125 people) will have serious co-morbidities/frailty and intervention will carry excessive risk or be futile.
- Of the remaining 37,125 patients, a proportion will be symptomatic despite maximally tolerated guideline medical therapy (including cardiac resynchronisation therapy devices if indicated)
- About 15-25% of this proportion will fulfil clinical and anatomical criteria for transcatheter edge to edge repair (NICE, 2018)
- Ultimately, it is estimated that about 5,000 patients may be eligible for TEER at any time in England.

Although the overall prevalence of heart failure is fairly constant, the population of patients with heart failure is dynamic with a high incidence and high mortality and thus consideration of incidence is important. By extrapolation from these considerations, and

from the calculations above, clinical consensus estimates that an annual provision for TEER in England of approximately 500 cases per year is required to manage patients with secondary mitral regurgitation who might be eligible for this intervention.

Policy review date

This document will be reviewed when information is received which indicates that the policy requires revision. If a review is needed due to a new evidence base then a new Preliminary Policy Proposal needs to be submitted by contacting england.CET@nhs.net.

Our policies provide access on the basis that the prices of therapies will be at or below the prices and commercial terms submitted for consideration at the time evaluated. NHS England reserves the right to review policies where the supplier of an intervention is no longer willing to supply the treatment to the NHS at or below this price and to review policies where the supplier is unable or unwilling to match price reductions in alternative therapies.

Equality statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Definitions

Percutaneous	Made, done, or effected through the skin.
Transcatheter	Refers to any procedure performed through the lumen (central cavity) of a catheter that is inserted, in this case, into a large blood vessel in the groin
Mitral Valve	One of the four heart valves, with two cusps or flaps, that allows one-way movement of blood through the heart chambers
Leaflet	Valves are made of leaflets, which are thin but strong flaps of tissue that come together to close the valve
Echocardiography	A type of ultrasound scan used to look at the heart and nearby blood vessels. It is done with a hand-held wand (probe) placed on the chest, known as transthoracic, or into the swallowing tube, known as transoesophageal echocardiography.
Regurgitation	Backflow through a valve

Ejection fraction	a measurement, expressed as a percentage, of how much blood the left ventricle pumps out with each contraction.
Coronary artery bypass graft	An open heart surgical procedure used to treat coronary heart disease. It diverts blood around narrowed or clogged parts of the major arteries to improve blood flow and oxygen supply to the heart.
NYHA	New York Heart Association. A commonly used functional classification system that places patients in one of four categories based on limitations of physical activity as below: I No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation or shortness of breath. II Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, shortness of breath or chest pain. III Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, shortness of breath or chest pain. IV Symptoms of heart failure at rest. Any physical activity causes further discomfort.

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