Ventricular Assist Devices as Destination Therapy

Perry Bridger, MHS
Coverage and Analysis Group
Division of Medical & Surgical Services

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Overview

- Brief background of CHF in the Medicare population
- History and timeline of Medicare coverage of VADs for destination therapy
- Recent coverage determination request
- Voting and discussion questions to the panel

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CMS Review Team

- Perry Bridger, MHS – Lead Analyst
- Madeline Ulrich, MD, MS – Lead Medical Officer
- Kimberly Long– Executive Secretary
- Steve Phurrough, MD, MPA
- Joanna Farrell
- Stuart Caplan, RN, MAS

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CHF in the Medicare Population

- 80% of those diagnosed with CHF are over age 65
- Prevalence of CHF in the Medicare population is estimated to be as high as 10%
- Leading cause of hospitalization in Medicare

*ACC/AHA 2001

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Current CMS Coverage

- Medicare covers the implantation of VADs for support of blood circulation postcardiotomy with FDA approval for that use.
- LVADs may also be covered as a bridge to transplant in patients who have been approved as heart transplant candidates.
- Medicare does not cover LVADs “when used as an artificial heart.”

(CIM section 65-15)

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NCD Request

- Letter requesting expanded coverage of VADs from the REMATCH investigators received by CMS on July 16, 2002.
- Request formally accepted for national coverage determination on August 9, 2002.
- Referred to MCAC on October 31, 2002.

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FDA Approval

- On November 6, 2002, Thoratec, Inc. was the first to receive FDA approval for an “expanded indication of use” for the Thoratec Heartmate SNAP VE LVAS for end-stage, non-transplantable patients.
- “[This device] is now also indicated for use in patients with New York Heart Association Class IV end stage left ventricular failure who have received optimal medical therapy for at least 60 of the last 90 days, and who have a life expectancy of less than two years, and who are not eligible for cardiac transplantation.”

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Content of Request

- "Revise and update Medicare coverage policy for VADs to include destination therapy consistent with the current scientific and clinical literature."
- Based on evidence presented in the REMATCH trial.
- Requestors are investigators of the REMATCH trial:
  - Eric A. Rose, MD (Principal Investigator)
  - James W. Long, MD, Ph.D.
  - Leslie W. Miller, MD
  - Lynne Warner Stevenson, MD

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Evidence Review

- REMATCH
- Other supporting materials

REMATCH

- RCT: optimal medical therapy vs. LVAD
- LVAD: 68 OMM: 61
- Endpoint: death from any cause
- Inclusion criteria:
  - NYHA Class IV ≥ 90 days
  - LVEF ≤ 25%
  - Peak O2 ≤ 12ml/kg (changed to 14)
  - Ineligible for cardiac transplantation

MCAC Panel Materials

- CMS summary of evidence
- Copies of all articles reviewed in the summary of evidence
- Thoratec manuals - Instruction for Use, Patient Handbook, and Patient Information Booklet
- Updated data on REMATCH patients supplied by Thoratec
- Additional information on Medicare heart transplant policies
- Questions for the panel

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Panel Voting Question

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Voting Question: Quality of the Evidence

- Is the quality of the evidence adequate to draw conclusions about the net health outcomes in Medicare beneficiaries comparable to patients enrolled in the Randomized Evaluation of Mechanical Assistance for the Treatment of Heart Failure (REMATCH) trial who undergo LVAD implantation?

Considerations for Quality of the Evidence

- Are the study endpoints and patient selection criteria appropriate?
- Are the management and extent of complications adequately described?
- Do the follow-up survival data for the REMATCH trial suggest any meaningful difference in patient survival compared to the data at the time the study reached its primary endpoint?

Magnitude of Net Health Outcomes

- If the quality of the evidence is adequate, does it demonstrate any positive net health outcomes and if so what is the size of the improvement in net health outcomes of LVADs compared to optimal medical management for these patients?

MCAC Categories of Effectiveness

- Breakthrough technology
- Substantially more effective
- More effective
- As effective but with advantages
- As effective and with no advantages
- Less effective but with advantages
- Less effective and with no advantages
- Not effective

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Discussion Questions

Discussion Question 1

REMATCH showed increased survival in device recipients, but the survival advantage diminished over time and was associated with severe complications and increased hospitalization.

- Do the demonstrated extension of life and the limited improvement in the quality of life justify the risks of LVAD implantation?

Discussion Question 2

One REMATCH inclusion criterion was that a candidate for LVAD implantation for destination therapy could not be a heart transplant candidate.

- Should the evaluation to determine transplant candidacy be performed only by a heart transplant center that has been approved for Medicare reimbursement?

Discussion Question 3

- Initially, should there be specific facility (e.g. Medicare approved transplant center only or other transplant center) and personnel requirements (surgeon and team experience) that must be met to provide the patient with an optimal chance of successful LVAD implantation (e.g., adequate pre/post operative care, follow-up care, psychological support for patient/family, and end-of-life care)?

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Discussion Question 4

REMATCH results are based on LVAD implantation in 68 patients. Complete, timely, and accurate LVAD implant and outcomes data for destination therapy patients is critical to future Medicare coverage review and policy refinements.

- Should mandatory data reporting be required as a condition for Medicare reimbursement?

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Discussion Question 5

There have been improvements in both LVAD design and medical management of end-stage heart failure patients since the start of the REMATCH trial.

- Have these improvements affected the applicability of the REMATCH results?

THANK YOU