Decision Memo for Ventricular Assist Devices (VADs) as a Bridge to Heart Transplantation (CAG-00162N)

Decision Summary

CMS intends to issue an NCD which indicates that, consistent with CIM §65-15, ventricular assist devices, when used as a bridge to transplant, are reasonable and necessary. CIM §35-87 will be modified to remove the prohibition against this indication. Other indications for or prohibitions against the use of ventricular assist devices in either CIM §65-15 or 35-87 are not affected by this determination.

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Decision Memo

This decision memorandum does not constitute a national coverage determination (NCD). It states CMS's intent to issue an NCD. Prior to any new or modified policy taking effect, CMS must first issue a manual instruction giving specific directions to our claims-processing contractors. That manual issuance, which includes an effective date, is the NCD. If appropriate, the Agency must also change billing and claims processing systems and issue related instructions to allow for payment. The NCD will be published in the Medicare Coverage Issues Manual. Policy changes become effective as of the date listed in the transmittal that announces the Coverage Issues Manual revision.

TO: Administrative File: CAG #00162N
Ventricular Assist Devices (VADs) Used as a Bridge to Heart Transplantation

FROM:

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SUBJECT: Coverage Decision Memorandum for Ventricular Assist Devices (VADs) Used as a Bridge to Heart Transplantation to correct CIM 35-87 which incorrectly contradicts CIM 65-15 for using VADs as a bridge to transplant.

DATE: October 30, 2002

This memorandum serves two purposes: (1) provides a brief background and reviews the history of Medicare coverage of Heart Transplantation and ventricular assist devices, and (2) outlines the agency's intention to correct its policy under the statutory authority of section 1862 (a)(1)(A) of the Social Security Act (the Act).

Background

CMS has two coverage policies concerning cardiovascular procedures, CIM 35-87 Heart Transplants and CIM 65-15 Artificial Hearts and Related Devices, which have been modified over the last several years to reflect the current evidence at that time. These independent modifications have resulted in a recently recognized conflict between the two instructions. It is the agency's intent to make a national coverage decision to correct these instructions.

CIM 65-15 is a national coverage decision allowing the use of ventricular assist devices for support of blood circulation postcardiotomy and as a bridge to transplant. The decision to allow the use of VADs as a bridge to transplant was announced in a November 1995 instruction.

Prior to the 1995 change in CIM 65-15, CMS had made several changes to its heart transplantation coverage outlined in CIM 35-87. The last change of CIM 35-87, in 1987, included the following paragraph: "Medicare does not cover the use of artificial hearts or ventricular assist devices, either as a permanent replacement for a human heart or as a temporary life-support system until a human heart becomes available for transplant…"

This prohibition to the use of VADs as a bridge to transplant was not noted when creating the positive coverage decisions in CIM 65-15. This decision memorandum announces our intention to issue an NCD, which will correct this discrepancy.

Public Comment

CMS has received comments from the American College of Cardiology (ACC). The ACC has strongly endorsed the change in the wording of Medicare policy for CIM §35-87 to make it consistent with CIM §65-15.

CIM Analysis

The older NCD, CIM §35-87, was developed based upon the scientific evidence at that time that did not demonstrate the clinical effectiveness of VADs. The subsequent NCD, CIM §65-15, used more current evidence that did demonstrate the clinical effectiveness of VADs as a bridge to transplant. An unintentional procedural error left CIM §35-87 unchanged and in conflict with the newer CIM §65-15. There is no additional evidence since the publication of CIM §65-15 that would indicate that VADs are no longer clinically effective. Therefore, CMS determines that VADs as a bridge to transplant are reasonable and necessary and the prohibition in CIM §35-87 should be removed.

Decision

CMS intends to issue an NCD which indicates that, consistent with CIM §65-15, ventricular assist devices, when used as a bridge to transplant, are reasonable and necessary. CIM §35-87 will be modified to remove the prohibition against this indication. Other indications for or prohibitions against the use of ventricular assist devices in either CIM §65-15 or 35-87 are not affected by this determination.

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