



MEDICARE PROPOSES COVERAGE WITH EVIDENCE DEVELOPMENT FOR ARTIFICIAL HEART DEVICES

The Centers for Medicare & Medicaid Services (CMS) today proposed coverage with evidence development of artificial heart devices. CMS proposes to cover artificial heart devices in Medicare beneficiaries who are enrolled in Food and Drug Administration (FDA)-approved studies.

“Our proposal relaxes a long-standing non-coverage policy, gives access to our beneficiaries and promotes evidence development through FDA approved studies of this advanced technology,” said CMS Acting Administrator Kerry Weems.

Artificial hearts are mechanical replacement devices that are used in patients with severe, bi-ventricular heart failure. Because these patients are extremely sick and at imminent risk of death, the device can be used to enable a patient to live until a donor heart becomes available for transplant or, for a non-transplant patient, to extend his or her life. Since the device requires a portion of the patient’s own heart be removed, an artificial heart patient must be supported by his or her device through the end of life or until heart transplantation.

The use of artificial heart technology has not been available to Medicare beneficiaries due to a 1986 non-coverage policy. Since the 1986 policy, two artificial heart device manufacturers have run clinical trials studying the safety and health outcomes of using their devices in these very sick patients. CMS believes there is now sufficient scientific evidence on the use of artificial hearts to allow coverage of these devices for beneficiaries in the carefully controlled clinical environment of an FDA-approved study. Providing coverage with evidence development allows CMS to provide faster and more effective coverage with more informed clinical decision making.

“This device may be able to help patients that otherwise have no treatment options available to them,” Weems said.

CMS plans to issue a final national coverage determination in early May 2008. CMS invites public comments on its proposed decision, which is available on the CMS Web site at <https://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=211>. Instructions for the submission of comments may be found at https://www.cms.hhs.gov/InfoExchange/02_publiccomments.asp.

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