

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 16, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03–1589 Filed 1–23–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3113–N]

Medicare Program; Meeting of the Medicare Coverage Advisory Committee—March 12, 2003

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a public meeting of the Medicare Coverage Advisory Committee (the Committee). The Committee provides advice and recommendations to us about clinical issues. Among other things, the Committee advises us on whether adequate evidence exists to determine whether specific medical items and services are reasonable and necessary under Medicare law. The Committee will discuss and make recommendations concerning the quality of the evidence and related issues for the use of a left ventricular assist device as “destination” (permanent) therapy in end-stage heart failure patients who are not eligible for a heart transplant. Notice of this action is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)).

DATES: *The Meeting:* The public meeting announced will be held on Wednesday, March 12, 2003 from 7:30 a.m. until 3:30 p.m., E.S.T.

Deadline for Presentations and Comments: Interested persons may present data, information, or views orally or in writing, on issues pending before the committee. Written presentations and comments must be submitted to the Executive Secretary by February 20, 2003, 5 p.m., E.S.T.

Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to notify the Executive Secretary

by February 26, 2003 (see **FOR FURTHER INFORMATION CONTACT**).

ADDRESSES: *The Meeting:* The meeting will be held at the Baltimore Convention Center, Room 338–339, One West Pratt Street, Baltimore, MD 21201.

Presentations and Comments: Submit formal presentations and written comments to Kimberly Long, Executive Secretary, by telephone at 410–786–5702 or by e-mail at klong@cms.hhs.gov; Office of Clinical Standards and Quality; Centers for Medicare & Medicaid Services; 7500 Security Boulevard; Mail Stop C1–09–06; Baltimore, MD 21244.

Web site: You may access up-to-date information on this meeting at www.cms.gov/coverage.

Hotline: You may access up-to-date information on this meeting on the CMS Advisory Committee Information Hotline, 1–877–449–5659 (toll free) or in the Baltimore area (410) 786–9379.

FOR FURTHER INFORMATION CONTACT: Kimberly Long, Executive Secretary, by telephone at (410) 786–5702 or by e-mail at klong@cms.hhs.gov.

SUPPLEMENTARY INFORMATION: On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) to describe the Medicare Coverage Advisory Committee (the Committee), which provides advice and recommendations to us about clinical issues. A revised charter was signed by the Secretary on November 22, 2002 (67 FR 79124). This notice announces the following public meeting of the Committee.

Meeting Topic

The Committee will discuss the evidence, hear presentations and public comment, and make recommendations regarding the use of a left ventricular assist device as “destination” (permanent) therapy in end-stage heart failure patients who are not eligible for a heart transplant. Background information about this topic, including panel materials, is available on the Internet at <http://www.cms.hhs.gov/coverage>.

Procedure and Agenda

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. The Committee may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations, you must notify the Executive Secretary named in the **FOR FURTHER INFORMATION CONTACT** section, and submit the following by the *Deadline for Presentations and*

Comments date listed in the **DATES** section of this notice: a brief statement of the general nature of the evidence or arguments you wish to present, and the names and addresses of proposed participants. A written copy of your presentation must be provided to each Panel member before offering your public comments. We will request that you declare at the meeting whether or not you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

After the public and CMS presentations, the Committee will deliberate openly on the topic. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topic. At the conclusion of the day, the members will vote and the Committee will make its recommendation.

Authority: 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 14, 2003.

Robert A. Streimer,

Acting Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99E–5112]

Determination of Regulatory Review Period for Purposes of Patent Extension; NOVOSEVEN

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for NOVOSEVEN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.