Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: January 27, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

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Health Care Financing Administration

[BPD–812–NC]

RIN 0938–AG83

Medicare Program; Criteria for Medicare Coverage of Lung Transplants

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice announces a Medicare national coverage decision for lung and heart-lung transplantations. Lung transplantation refers to the transplantation of one or both lungs from a single cadaver donor. Heart-lung transplantation refers to the transplantation of one or both lungs and the heart from a single cadaver donor.

We have determined that, under certain circumstances, lung transplants and heart-lung transplants are a medically reasonable and necessary service when furnished to patients with progressive end-stage pulmonary or cardiopulmonary disease and when furnished by Medicare participating facilities that meet specific criteria, including patient selection criteria.

DATES: This notice is effective February 2, 1995. For information on how this notice effects Medicare payment for lung and heart-lung transplants, see sections E and F of this notice.

ADDRESSES: *Applications.* A facility seeking Medicare coverage and payment for lung transplantation should mail 10 copies of the application to the address below in a manner which provides the facility with documentation that it was received by us: Director, Office of Hospital Policy, Room 189 East High Rise, 6325 Security Boulevard, Baltimore, Maryland 21207.

Comments. Comments will be considered if we received them at the appropriate address, as provided below, no later than 5 p.m. on April 3, 1995.

Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–812–NC, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room 132, East High Rise Building, 6325 Security Building, Baltimore, MD 21207.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD–812–NC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

If you wish to submit comments on the information collection requirements contained in this rule, you may submit comments to: Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

FOR FURTHER INFORMATION CONTACT: Claude Mone, (410) 966–5666.

SUPPLEMENTARY INFORMATION:

I. Background

Administration of the Medicare program is governed by the Medicare law, title XVIII of the Social Security Act (the Act). The Medicare law provides coverage for broad categories of benefits, including inpatient and outpatient hospital care, skilled nursing facility (SNF) care, home health care, and physicians' services. It places general and categorical limitations on the coverage of the services furnished by certain health care practitioners, such as dentist, chiropractors and podiatrists, and it specifically excludes some categories of services from coverage, such as cosmetic surgery, personal comfort items, custodial care, routine physical checkups, and procedures that are not reasonable and necessary for diagnosis or treatment of an illness or injury.

The Act also provides direction as to the manner in which payment is made for Medicare services, the rules governing eligibility for services, and the health, safety, and quality standards to be met in institutions furnishing services to Medicare beneficiaries. The Medicare law does not, however, provide an all-inclusive list of specific items, services, treatments, procedures, or technologies covered by Medicare. Thus, except for the examples of durable medical equipment in section 1861(n) of the Act, and some of the medical and other health services listed in section 1861(s) and 1862(a) of the Act, the Act does not specify medical devices, surgical procedures, or diagnostic or therapeutic services that should be covered or excluded from coverage.

The intention of the Congress, at the time the Medicare Act was enacted in 1965, was that Medicare would provide health insurance to protect the elderly or disabled from the substantial costs of acute health care services, principally hospital care. The program was designed generally to cover services ordinarily furnished by hospitals, SNFs, and physicians licensed to practice medicine. The Congress understood that questions as to coverage of specific services would invariably arise and would require specific coverage decisions by those administering the program. It vested in the Secretary the authority to make those decisions.

Section 1862(a)(1)(A) of the Act prohibits payment for any expenses incurred for items or services ''which are not reasonable or necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.'' We have interpreted this statutory provision to exclude from Medicare coverage those medical and health care services that have not been demonstrated by acceptable clinical evidence to be safe and effective. Effectiveness in this context is defined as the probability of benefit to individuals from a medical item, service, or procedure for a given medical problem under average conditions of use, that is, day-to-day medical practice.

To date, the Medicare program has not issued a national coverage policy on lung or heart-lung transplantation. In the absence of national coverage policy, the contractors that process Medicare claims are authorized to develop Medicare coverage policy for their service area using medical literature, the advice of medical consultants and local medical societies, and their private line business practices.

Several contractors have determined lung transplantation to be a Medicare covered service prior to this notice, and a small number of contractors have covered heart-lung transplant. However, most of these contractors do not have a clearly defined coverage policy that would allow a beneficiary to know in advance if the procedure would be covered. Rather, they review each case individually after it has occurred and determine coverage without published