HCFA Rulings

Department of Health and Human Services

Health Care Financing Administration

Ruling No. 87-1 Date: April, 1987

HCFA Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

HCFA Rulings are binding on all HCFA components, the Provider Reimbursement Review Board and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This Ruling provides criteria that facilities must comply with in order to obtain approval for payment for heart transplants. It rescinds HCFAR 80-1, which excluded heart transplants from coverage under Medicare. Coverage as a result of this Ruling may be effective as early as October 17, 1986 under some circumstances, as specified in the effective date section.

HCFAR 87-1-1

MEDICARE PROGRAM

Hospital Insurance Benefits (Part A)

Criteria for Medicare Coverage of Heart Transplants

HCFAR 87-1

Purpose: This Ruling rescinds HCFA Ruling HCFAR 80-1 that excluded coverage of heart transplants under the Medicare program. It also provides public notice of HCFA's new coverage policy for heart transplants.

Citations: Sections 1102, 1862(a)(1) and 1871 of the Social Security Act (42 U.S.C. 1302, 1395y(a)(1) and 1395hh), 52 FR 10935.[1]

Ruling: HCFAR 80-1 that excludes heart transplants from coverage under the Medicare program is rescinded. Facilities that wish to obtain coverage of heart

[1] Editor's note: This Ruling appeared in the Federal Register of April 6, 1987 (52 FR 10935) as part of a Notice of Ruling. Additional background information and pertinent history are available in that document. The Ruling is printed without change except for correction of obvious typographical errors. We especially note correct wording of criteria 5.d. and 5.e. under section A, "Criteria for Facilities."

transplants for their Medicare patients must submit an application and supply documentation showing their initial and ongoing compliance with each of the criteria. For facilities which are approved, Medicare will cover under Part A (Hospital Insurance) all medically reasonable and necessary inpatient services. Payment for these services generally will be made under the Diagnosis Related Group (DRG) classification code #103, "Heart transplants". Organ acquisition costs will be paid separately on a cost-reimbursement basis. Physician services, related to the transplant,

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as well as non-hospital services related to pre-and post-transplant care, will be covered under Part B (Supplementary Medical Insurance) and reimbursed on the basis of reasonable charges. In accordance with the provisions of section 9335(c) of OBRA, post-transplant care for covered transplants includes outpatient, self-administrable immunosuppressant drugs, such as cyclosporine, for a period of up to one year beginning with the date of discharge from the inpatient hospital stay during which the transplant was performed. If a Medicare beneficiary receives a covered heart transplant from an approved facility, reasonable and necessary services for followup care and for complications are covered, even if such services are furnished by a hospital that is eligible for Medicare reimbursement but is not specifically approved by Medicare for heart transplantation.

Medicare will not cover transplants or re-transplants in facilities which have not been approved as Medicare transplant facilities. If a Medicare beneficiary receives a heart transplant from a facility that is not approved by Medicare for heart transplantation, we will not cover any inpatient services associated with the transplantation procedure. Neither will we cover physician services associated with the transplantation procedure. Thus, payment will not be made for the performance of the transplant or for any other services which are incorporated into a global fee. However, after a beneficiary has been discharged from a hospital (which has not been approved by Medicare as a heart transplant center) in which he or she receives the heart transplant, medical and hospital services required as a result of the prior non-covered transplant may be covered in

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a facility otherwise eligible for Medicare reimbursement when they are reasonable and necessary in all other respects. Thus, coverage will be provided for subsequent inpatient stays or outpatient treatment (exclusive of self-administrable immunosuppressive drugs) ordinarily covered by Medicare even if the need for treatment arose because of a previous non-covered heart transplant procedure. These services also will be covered for Medicare beneficiaries who were not beneficiaries at the time they received a heart transplant regardless of whether or not the transplant was performed at an approved facility.

Once a facility applies for approval and is approved as a heart transplant facility for Medicare purposes, it is obliged to report immediately to HCFA any events or changes which would affect its approved status. Specifically, a facility

must report any significant decrease in its experience level or survival rates, the transplantation of patients who do not meet its patient selection criteria, the loss of key members of the transplant team, or any other major changes that could affect the performance of heart transplants at the facility. Changes from the terms of approval may lead to withdrawal of approval for Medicare coverage of heart transplants performed at the facility.

A facility that we approve as meeting the criteria set forth in this notice may seek Medicare payment from its Medicare intermediary for heart transplants performed on Medicare patients. For facilities receiving Medicare payment under the Medicare prospective payment system, we will use the DRG classification #103, "Heart transplants". We have

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established a relative weight of 14.9944 for DRG 103 and a 51 day outlier threshold.

Heart acquisition costs will be reimbursed as a cost pass through.

The criteria that we will require facilities to meet in order to receive Medicare payment for heart transplantations follow.

A. Criteria for Facilities
   1. Patient selection. A facility must have adequate written patient selection criteria and an implementation plan for their application. (Guidelines for patient selection criteria appear in section D. of this ruling.)
   2. Patient management. A facility must have adequate patient management plans and protocols that include the following:
      a. Detailed plans for therapeutic and evaluative procedures for the acute and long-term management of a patient, including commonly encountered complications. The basis for confidence in these plans must be stated.
      b. The logistics of the plans for patient management and evaluation during the waiting and immediate post-discharge, as well as in-hospital, phases of the program.
      c. The logistics of the plans for long-term management and evaluation, including education of the patient, liaison with the patient's attending physician, and the maintenance of active patient records for five years.
   3. Commitment. A facility must make a sufficient commitment of resources and planning to the heart transplant program

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to carry through its application. Indications of this commitment could include the following:
      a. Commitment of the facility to the heart transplant program is at all levels and broadly evident throughout the facility. (A cardiac transplantation program requires a major commitment of resources. These may

intermittently include many other departments as well as the principal sponsoring departments.)

b. The facility has both the expertise and the commitment for participation in medical, surgical, and other relevant areas, particularly cardiology, cardiovascular surgery, anesthesiology, immunology, infectious diseases, pulmonary diseases, pathology, radiology, nursing, and social services. The facility must identify individuals in these areas in order to achieve an identifiable and stable transplant team. Responsible medical/surgical members of the team must be board certified or eligible in their respective disciplines or have demonstrated transplantation competence irrespective of board status.
   1) The component teams must be integrated into a comprehensive team with clearly defined leadership and corresponding responsibility.
   2) The facility must have an active cardiovascular medical and surgical program. (General indicators

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of this type of program would be a minimum of 500 cardiac catheterizations and coronary arteriograms annually, with the ability and willingness to do these procedures on an emergency basis, and a surgical group that has demonstrated low mortality rates in an active open heart surgical program involving at least 250 procedures a year.) The surgical team responsible for transplantation must be an identified, stable group.
   3) The anesthesia service must identify a team for transplantation that must also be available at all times.
   4) The infectious diseases service must have both the professional skills and laboratory resources needed to discover, identify, and manage the complications from a whole range of organisms, many of which are uncommonly encountered in the usual infectious diseases laboratory.
   5) The nursing service must identify a team or teams trained not only in hemodynamic support of the patient, but also in the special problems of managing immunosuppressed patients.
   6) Pathology resources must be available for studying and reporting promptly the pathological responses to transplantation.

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   7) Adequate social service resources must be available.
   8) Mechanisms must be in place for managing the heart transplant program which assure that --
      (A) Patient selection criteria are consistent with those set forth in the facility's written patient selection criteria;
      (B) The facility is responsible for the ethical, and medical considerations involved in the patient selection process and application of patient selection criteria.

9) Adequate plans exist for organ procurement meeting legal and ethical criteria, as well as yielding viable transplantable organs in reasonable numbers.

4. Facility plans. The facility must have overall facility plans, commitments, and resources for a program that will assure a reasonable concentration of experience; specifically, 12 or more cardiac transplantation cases per year. This level of activity must be shown feasible and likely on the basis of plans, commitments, and resources.

5. Experience and survival rates. The facility must demonstrate experience and success with a clinical organ transplantation program involving immunosuppressive technique. The evaluation of a facility's experience and survival rates will be made on patients transplanted since January 1, 1982.

The facility must have an established cardiac transplantation program with documented evidence of 12 or more patients in each of the two preceding 12-month periods and twelve patients prior to that but since January 1, 1982. Such programs are deemed to have the potential for acceptable data bases for estimating survival.

The applicant facilities will be required to report experience and survival rates as of a given point in time. That point in time must be within 90 days of the date we receive the application and will be referred to as the fiducial date. The fiducial date for experience and survival results must be the same and it must be stated.

Survival rates may be influenced by many factors, including random chance and patient selection. However, most authorities agree that a patient who is not free of adverse prognostic factors warrants cardiac transplantation only if he or she has a reasonable prognosis and the donor heart cannot be used in a patient who is a good candidate with at least a moderately urgent need and who is in reasonable geographic proximity. Initially, the facility must demonstrate actuarial survival rates of 73 percent for one year and 65 percent for two years for patients who have had heart transplants since January 1, 1982 at that facility. In reporting their actuarial survival rates, facilities must use the Kaplan-Meier technique. The

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following definitions and rules also must be used:

a. The date of transplantation must be the starting date for calculation of the survival rate.
b. For those dead, the date of death is used if known. If the date of death is unknown, it must be assumed as one day after the date of the last ascertained survival.

c. For those who have been ascertained as surviving within 60 days before the fiducial date, survival is considered to be the date of last ascertained survival, except for patients described in paragraph (e) below.
d. Any patient who is not known to be dead but whose survival cannot be ascertained to a date that is within 60 days before the fiducial date, must be considered as ''lost to followup" for the purposes of this analysis.
e. Any patient transplanted between 61 and 120 days before the fiducial date must be considered as "lost to followup" if he or she is not known to be dead or his or her survival has not been ascertained for at least 60 days before the fiducial date. Any patient transplanted within 60 days before the fiducial date must be considered as "lost to followup" if he or she is not known to be dead or his or her survival has not been ascertained on the fiducial date.
f. A facility must submit its survival analyses using the assumption that each patient in the ''lost to followup"

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category, (according to the criteria A.5.d. or e. above) died one day after the last date of ascertained survival. However, a facility may submit an additional analysis that reflects each patient in the "lost to followup" category as alive at the date of the last ascertained survival.

In addition to reporting actuarial survival rates, the facility must submit the following actual information on every Medicare and non-Medicare patient who received a heart transplant between January 1, 1982 and the date of the application:

- Transplant number.
- Age.
- Sex.
- Date of transplant.
- Date of most recent ascertained survival.
- Date of death.
- The category of each patient (that is: living, dead, or "lost to followup" according to the criteria A.5.d. or e. above).

Unique patient identifiers are not needed. The facility may submit additional information on any of the cases that it would like the expert consultants to consider in their reviews.

Although we are not requiring that these data be submitted in a particular format, our review will be facilitated if the data are submitted as follows:

- Data are tabulated in seven columns, with data for each patient appearing as one line and listed in the sequence of date of transplant.
- The fiducial date should appear on each page.

- The transplant numbers listed may be existing heart transplant numbers used by the applicant facility. If so, the basis for any missing numbers should be explained.
- The tabulation should include no more that these required data. If more data are provided, they should be through additional tables or supplemental explanation.

6. Maintenance and submission of data. The facility must agree to maintain and routinely submit to HCFA in a standard format prescribed by HCFA, summary data about patients selected, protocols used and short-and long-term outcome on all patients undergoing cardiac transplantation, not only those for whom payment under Medicare is sought. (Such data are necessary to provide a data base for an ongoing assessment of cardiac transplantation and to assure that approved facilities maintain appropriate patient selection criteria, adequate experience levels and satisfactory patient outcomes.) In addition, facilities must agree to notify HCFA immediately of any change related

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to the facility's transplant program that could affect the health or safety of patients selected for covered Medicare heart transplants or which would otherwise alter specific elements in their application. For example, a facility must report any significant decrease in its experience level or survival rates, the loss of key members of the transplant team, or the transplantation of patients who do not meet the facility's patient selection criteria.

Facilities not approved for Medicare covered heart transplants are not required to maintain summary data in standard format. However, if and when these facilities apply for Medicare approval, they will be required to submit such data for all patients receiving a heart transplant beginning 30 days after being notified of our data requirements. We plan to issue instructions to all hospitals regarding the required summary data in the near future.

7. Organ procurement. The facility must operate or participate in an organ procurement program to obtain donor organs.
   a. If a cardiac transplantation center utilizes the services of an outside organ procurement agency to obtain donor organs, it must have a written arrangement covering these services. The cardiac transplantation center must notify the Secretary in writing within 30 days of terminating such arrangements.

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   b. "Organ procurement agency" is defined as an organization that meets the criteria of section 371(b) of the Public Health Service Act.

8. Laboratory services. The facility must make available, directly or under arrangements, laboratory services to meet the needs of patients. Laboratory

services are performed in a laboratory facility approved for participation in the Medicare program.

B. Process for Review and Approval of Facilities

The approval of facilities will be based on a careful review of the materials submitted regarding their experience, survival rates, and expertise, as well as their commitment to the heart transplant program. We will conduct the review with the aid and advice of individual non-Federal, expert consultants in relevant fields. Generally, the consultants will have the responsibility of reviewing applications at the request of HCFA, making recommendations to HCFA on a timely basis concerning qualified facilities, and supporting each recommendation with written documentation. Consensus of the consultants is not required. The individual consultants will report to us on their findings with respect to individual applications and will provide the basis for decisions as to the approval or disapproval of such applications.

In approving facilities, we will compare the facility's submission against the criteria specified in this notice. The approval granted will be for a three year period and extensions of approval will require submission of a continuation application and will not be automatic.

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In addition to reviewing applications, the individual expert consultants may propose specific changes to the coverage criteria. Finally, in certain limited cases, exceptions to the strict criteria proposed may be warranted if there is justification and if the facility ensures our objectives of safety and efficacy. Under no circumstances will exceptions be made for facilities whose transplant programs have been in existence for less than two years, and applications from consortia will not be approved. In these two cases, disapprovals will be made by HCFA and will not require prior reviews by the expert consultants. Additionally, exceptions on the basis of geographic considerations will not be granted.

C. Application Procedure

In order to facilitate the approval of qualified facilities, we announced in the proposed notice that we would begin accepting and reviewing applications from facilities that believed they were qualified based on the proposed criteria. Because the applications will be approved only on the basis of the criteria published in this final notice, facilities, which have submitted applications prior to the publication date of this final ruling (April 6, 1987), have the opportunity to submit any necessary revision and additions to their applications.

A facility that seeks retroactive approval must show that it met the experience and survival criteria on the date to which it seeks retroactive approval, as well as show its experience and survival to the stated fiducial date.

The applications procedure is as follows:

1. An original and two copies of the application must be submitted on 8 1/2 by 11 inch paper, signed by a person authorized to do so. The facility must be a participating hospital under Medicare and must specify its provider number, and the name and telephone number of an individual we could contact should we have questions regarding the application.
2. Information and data must be clearly stated, well organized and appropriately indexed to aid in its review against the criteria specified in this notice. Each page must be numbered.
3. To the extent possible, the application should be organized into eight sections corresponding to each of the eight major criteria and addressing, in order, each of the sub-criteria identified.
4. The application should be mailed to the address below in a manner which provides the facility with documentation that it was received by us.

   Administrator
   Health Care Financing Administration
   c/o Office of Executive Operations
   Room 777 East High Rise
   6325 Security Blvd.
   Baltimore, Maryland 21207

D. Guidelines for Patient Selection Criteria

Included in section A., Criteria for Facilities, is the requirement that a facility must have adequate written patient selection criteria and an implementation plan for their application.

Such criteria should include or be comparable to, but need not be limited to, the guidelines below that indicate the type of factors or areas we would like to see addressed. We expect to disapprove any facility that departs so significantly from the guidelines that Medicare beneficiaries would be placed at risk.

1. Patient selection criteria must be based upon both a critical medical need for transplantation and a maximum likelihood of successful clinical outcome.
2. The patient must have a very poor prognosis (for example, less than a 25 percent likelihood of survival for six months) as a result of poor cardiac status, but must otherwise have a good prognosis.
3. All other medical and surgical therapies that might be expected to yield both short- and long-term survival (for example, 3 or 5 years), comparable to that of cardiac transplantation, must have been tried or considered.
4. Many factors must be recognized at the present time to exert an adverse influence on the outcome after cardiac transplantation. The manner and extent to which adverse risk is translated into contraindication varies. A patient who meets patient selection criteria under section D. 2., 3., and 5.,

and is free of the adverse factors under this section 4a. and b., is considered a good candidate for cardiac transplantation. Some experts would not require freedom from all adverse

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factors under this section 4b. We recognize that some who may not be considered "good candidates" may also benefit, but the likelihood or extent of benefit is significantly less.

a. Strongly adverse factors include:
   (1) Advancing age; for example, a patient beyond 53 to 57 years of age (the mid-50's). Until not long ago, limited experience with patients over age 50 showed that these patients had both impaired capacity to withstand post-operative and immunosuppressive complications and lessened survival. More recently, carefully selected patients through age 55 have had good survival experience; but experience with patients beyond age 55 is limited. The selection of any patient for transplantation beyond age 50 must be done with particular care to ensure an adequately young "physiologic" age and the absence or insignificance of coexisting disease.
   (2) Severe pulmonary hypertension (because of the limited work capacity of the typical donor right ventricle which is an important consideration in orthotopic cardiac transplantation). Generally, pulmonary vascular resistance above 5 Wood units or pulmonary artery systolic pressure over 65 mm Hg is

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a serious adverse factor. However, these patients may be acceptable if a pulmonary vasodilator drug reduces both pulmonary vascular resistance below 3 Wood units and pulmonary artery systolic pressure below 50 mm Hg.
   (3) Renal or hepatic dysfunction not explained by the underlying heart failure and not deemed reversible (because of the nephrotoxicity and hepatotoxicity of cyclosporine). For patients who are to receive azathioprine and high-dose corticosteroid rather than cyclosporine, a slightly higher level of hepatic or renal dysfunction is acceptable, but substantial dysfunction is still a contraindication (because of the likelihood of early exacerbation postoperatively and because of interference with immunosuppressive regimens).
   (4) Acute severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of one or more vital end-organs (because of a substantially less favorable prognosis for survival than for the average transplant recipient).
   (5) Symptomatic peripheral or cerebrovascular disease (because of accelerated progression in some patients after cardiac transplantation and on chronic corticosteroid treatment).

(6) Chronic obstructive pulmonary disease or chronic bronchitis (because of poor postoperative course and likelihood of exacerbation of infection with immunosuppression).
(7) Active systemic infection (because of the likelihood of exacerbation with initiation of immunosuppression).
(8) Recent and unresolved pulmonary infarction, pulmonary roentgenographic evidence of infection, or of abnormalities of unclear etiology (because of the likelihood that this represents pulmonary infection).
(9) Systemic hypertension, either at transplantation or prior to development of end-stage heart disease, that required multi-drug therapy for even moderate control (for example, multidrugs to bring diastolic pressure below 105 mm Hg) for patients who would be on cyclosporine protocols (because of the substantial exacerbation of hypertension with cyclosporine and the difficulty of its management).
(10) Any other systemic disease considered likely to limit or preclude survival and rehabilitation after transplantation.

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(11) Cachexia, even in the absence of major end organ failure (because of the significantly less favorable survival of these patients).
(12) The need for or prior transplantation of a second organ such as lung, liver, kidney, or marrow (because this represents the coexistence of significant disease, and because multi-organ transplantation must still be considered experimental).
(13) A history of a behavior pattern or psychiatric illness considered likely to interfere significantly with compliance with a disciplined medical regimen (because a lifelong medical regimen is necessary, requiring multiple drugs several times a day, with serious consequences in the event of their interruption or excessive consumption).
(14) The use of a donor heart, that may have had its effectiveness compromised by such factors as the use of substantial vasopressors prior to its removal from the donor, its prolonged or compromised maintenance between the time of its removal from the donor and its implantation into the patient, or pre-existing disease.

b. Other factors given less adverse weight by some experts but considered importantly adverse by others include:

(1) Insulin-requiring diabetes mellitus, in the judgment of most experts (because the diabetes is often accompanied by occult vascular disease and because the diabetes and its complications are exacerbated by chronic corticosteroid therapy; even current cyclosporine immunosuppression regimens require chronic long-term corticosteroid, though at a lower dose, and high dose corticosteroid is used in the treatment of acute rejection).
(2) Asymptomatic severe peripheral or cerebrovascular disease (because of accelerated progression in some patients after cardiac transplantation and on chronic corticosteroid treatment).
(3) Documented peptic ulcer disease (because of the likelihood of early postoperative exacerbation).
(4) Current or recent history of diverticulitis (which must be considered a source of active infection that may be exacerbated with the initiation of immunosuppressant).

5. Plans for long-term adherence to a disciplined medical regimen must be feasible and realistic for the individual patient.

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Effective Dates: October 17, 1986 for those facilities which would have qualified as heart transplant facilities when the transplant was performed and whose applications are received by HCFA by July 6, 1987. The effective date of coverage for heart transplants performed at facilities applying after July 6, 1987 is the date the facility receives approval as a heart transplant facility from HCFA.

Dated: March 20, 1987

William L. Roper, M.D.
Administrator, Health Care
Financing Administration

US Government Printing Office: 1987-181- 2701 60262