CHAPTER 4
SECTION 24.1

HEART-LUNG AND LUNG TRANSPLANTATION

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I. CPT[1] PROCEDURE CODES

32850 - 32854, 33930 - 33935

II. DRGs

495 for lung transplant.

III. POLICY

A. Heart-lung and single and double lung transplantation requires preauthorization.

B. Living donor lobar lung transplantation requires preauthorization.

1. A TRICARE Prime enrollee must have a referral from his/her Primary Care Manager (PCM) and an authorization from the contractor before obtaining transplant-related services. If network providers furnish transplant-related services without prior PCM referral and contractor authorization, penalties will be administered according to TRICARE network provider agreements. If Prime enrollees receive transplant-related services from non-network civilian providers without the required PCM referral and contractor authorization, Managed Care Support (MCS) contractors shall reimburse charges for the services on a Point of Service basis. Special cost-sharing requirements apply to Point of Service claims.

2. For Standard and Extra patients residing in a Managed Care Support (MCS) region, preauthorization authority is the responsibility of the MCS Medical Director or other designated utilization staff.

C. The designated preauthorizing authority shall only use the criteria contained in this policy when preauthorizing lung and heart-lung transplantations.

D. The designated preauthorizing authority may also preauthorize advanced life support for air ambulance and a certified advanced life support attendant for a heart-lung or lung transplantation patient who has received preauthorization.

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E. Affirmative Patient Selection Criteria. Benefits are allowed for single and double lung and living donor lobar lung transplantation when the transplant is performed at a TRICARE or Medicare-certified lung transplant center or TRICARE-certified pediatric consortium lung transplant center. Benefits are allowed for heart-lung transplantation when the transplant is performed at a TRICARE or Medicare-certified heart, lung, or heart-lung transplant center or TRICARE-certified pediatric consortium heart, lung or heart-lung transplantation center. The beneficiaries must meet the following criteria:

1. Have irreversible, progressively disabling, end-stage pulmonary or cardiopulmonary disease.

2. Have tried or considered all other medical and surgical therapies that might have been expected to yield both short and long-term survival comparable to that of transplantation.

3. Have a realistic understanding of the range of clinical outcomes that may be encountered.

4. Demonstrate plans for a long-term adherence to a disciplined medical regimen are feasible and realistic.

F. In addition to meeting the above patient selection criteria, the following adverse factors must be absent or minimized:

1. Acutely ill patients (i.e., with serious exacerbation of chronic end-stage disease or with nonchronic end-stage disease) or those who currently require mechanical ventilation for more than a very brief period (because there is difficulty in adequate assessment, a propensity for infection and likelihood for poor results).

2. Significant systemic or multi-system disease (because the presence of multi-organ involvement limits the possibility of full recovery and may compromise the function of the newly transplanted organ(s)).

3. Extrapulmonary site of infection (because of the probability of recrudescence once immunosuppression is instituted).

4. Hepatic dysfunction, even secondary to right ventricular failure, such as bilirubin exceeding 2.5 mg/ml (because of hepatotoxicity of many post-transplant medications and complications due to coagulopathies, hepatic encepalopathy, infection, poor wound healing, and increased postoperative mortality).

5. Renal dysfunction, such as preoperative serum creatinine greater than 1.5 mg/dl or a 24-hour creatinine clearance less than 50 ml/min, except that with severe pulmonary hypertension creatinine clearance as low as 35 ml/min may be acceptable if intrinsic renal disease is excluded. (Cyclosporine is nephrotoxic).

6. Systemic hypertension that requires multidrug therapy for even moderate control (for example, multidrugs to bring diastolic pressure below 105 mm Hg), either at

transplantation or at the development of end-stage heart-lung disease (because of substantial exacerbation of hypertension with post-transplantation drug regimen).

7. Cachexia, even in the absence of major end organ failure (because of the significantly less favorable survival of these patients).

8. Obesity, with weight being an increasingly severe adverse factor as the patient exceeds by 20 percent of ideal weight for height and sex (because of more difficult post-operative mobilization and impaired diaphragmatic function, as well as the difficulty of weight control once corticosteroid immunosuppressant is instituted).

9. 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 of excessible consumption).

10. Active cigarette smoking (abstinence of a minimum of four months prior to transplantation is recommended).

11. Previous thoracic or cardiac surgery or other bases for pleural adhesions may be a serious adverse factor depending upon site of thoracotomy/sternotomy, the degree of adhesions and the type of transplant anticipated (because of scar tissue and the propensity for inadequately controlled bleeding).

12. Age greater than or equal to 65 years.

13. Recent or current history of gastrointestinal problems (because of common post-operative gastrointestinal problems and hemorrhage).

14. Chronic corticosteroid therapy that cannot be tapered and discontinued prior to transplantation has been considered a serious adverse factor by many (because of the increased risk of tracheal or bronchial dehiscence in the early post-operative period).

15. With chronic pulmonary infection (as with bronchiectasis, chronic or cystic fibrosis), single lung transplantation is contraindicated (because of the great likelihood of the infection extending from the contaminated native lung into the transplanted lung) and the patient must meet the criteria and benefit/risk considerations of double lung or heart-lung transplantation.

16. With significant heart disease (for example, substantial irreversible right ventricular disease or significant coronary artery disease) the patient must meet the criteria and benefit/risk considerations for heart-lung transplantation; lung transplantation and concurrent repair of the cardiac abnormality may be appropriate in unusual circumstances, as in some situations with Eisenmenger's syndrome.

17. Primary or metastatic malignancies of the lung.

G. Services and supplies related to heart-lung or lung transplantation are covered for:

1. Evaluation of potential candidate's suitability for heart-lung or lung transplantation, whether or not the patient is ultimately accepted as a candidate for transplantation.

2. Pre- and post-transplant inpatient hospital and outpatient services.

3. Pre- and post-operative services of the transplant team.

4. The donor acquisition team, including the costs of transportation to the location of the donor organ and transportation of the team and the donated organ to the location of the transplantation center.

5. The maintenance of the viability of the donor organ after all existing legal requirements for excision of the donor organ have been met.

6. Donor costs.

7. Blood and blood products.

8. FDA approved immunosuppression drugs to include off-label uses when reliable evidence documents that the off-label use is safe, effective and in accordance with nationally accepted standards of practice in the medical community (proven).

9. Complications of the transplant procedure, including inpatient care, management of infection and rejection episodes.

10. Periodic evaluation and assessment of the successfully transplanted patient.

11. Cardiac rehabilitation.

12. Pulmonary rehabilitation for pre- and post-lung and heart-lung transplants

13. Transportation of the patient by air ambulance and the services of a certified life support attendant.

14. DNA-HLA tissue typing in determining histocompatibility.

H. TRICARE may cost-share for epoprostenol (FLOLAN®) for the management of severe secondary pulmonary hypertension, including those for patients with pulmonary hypertension secondary to the scleroderma spectrum of diseases, whether or not they have been authorized for and are awaiting lung transplantation.

IV. POLICY CONSIDERATION

A. In those cases where the beneficiary fails to obtain preauthorization, benefits may be extended if the services of supplies otherwise would qualify for benefits but for the failure to obtain preauthorization. If preauthorization is not received, the appropriate preauthorizing

authority is responsible for reviewing the claims to determine whether the beneficiary's condition meets the clinical criteria for the heart-lung or lung transplantation benefit. Charges for transplant and transplant-related services provided to TRICARE Prime enrollees who failed to obtain PCM referral and contractor authorization will be reimbursed only under Point of Service rules.

B. Benefits will only be allowed for transplants performed at a TRICARE or Medicare-certified heart, heart-lung or lung transplantation center. Benefits are also allowed for transplants performed at a pediatric facility that is TRICARE-certified as a heart, heart-lung, or lung transplantation center on the basis that the center belongs to a pediatric consortium program whose combined experience and survival data meet the TRICARE criteria for certification. The contractor is the certifying authority for transplant centers within its region. Refer to Chapter 11, Section 7.1 for organ transplant center certification requirements.

C. Heart-lung, and lung transplantation will be paid under the DRG.

D. Claims for transportation of the donor organ and transplant team shall be adjudicated on the basis of billed charges, but not to exceed the transport service's published schedule of charges, and cost-shared on an inpatient basis. Scheduled or chartered transportation may be cost-shared.

E. Charges made by the donor hospital will be cost-shared on an inpatient basis and must be fully itemized and billed by the transplant center in the name of the TRICARE patient.

F. Acquisition and donor costs are not considered to be components of the services covered under the DRG. These costs must be billed separately on a standard CMS 1450 UB-04 claim form in the name of the TRICARE patient.

G. When a properly preauthorized transplant candidate is discharged less than 24-hours after admission because of extenuating circumstances, such as the available organ is found not suitable or other circumstances which prohibit the transplant from being timely performed, all otherwise authorized services associated with the admission shall be cost-shared on an inpatient basis, since the expectation at admission was that the patient would remain more than 24 hours.

H. Heart-lung and lung transplants performed on an emergency basis in an unauthorized heart-lung or lung transplant facility may be cost shared only when the following conditions have been met:

1. The unauthorized center must consult with the nearest TRICARE or Medicare-certified heart-lung or lung transplantation center regarding the transplantation case; and

2. It must be determined and documented by the transplant team physician(s) at the certified heart-lung or lung transplantation center that transfer of the patient (to the certified heart-lung or lung transplantation center) is not medically reasonable, even though transplantation is feasible and appropriate.

V. EXCLUSIONS

A. Expenses waived by the transplant center, (e.g., beneficiary/sponsor not financially liable).

B. Services and supplies not provided in accordance with applicable program criteria (i.e., part of a grant or research program; unproven procedure).

C. Administration of an unproven immunosuppressant drug that is not FDA approved or has not received approval as an appropriate "off label" drug indication.

D. Pre- or post-transplant nonmedical expenses, (e.g., out-of-hospital living expenses, to include hotel, meal, privately owned vehicle for the beneficiary or family members).

E. Transportation of an organ donor.

F. AlloMap® molecular expression testing for cardiac transplant rejection surveillance.

VI. EFFECTIVE DATES

A. February 28, 1991, for heart-lung and lung transplantation.

B. May 1, 1996, for epoprostenol.

C. June 1, 1997, for living donor lobar lung transplantation.

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