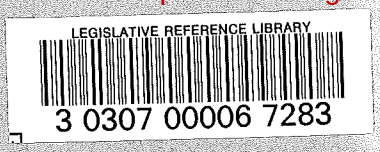

Advisory Committee on
Organ and Tissue Transplants

Annual Report to the Legislature and Department of Human Services

January 1, 1992

State of Minnesota
Committee on Transplants
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MS-0025/DT 11-91

State of Minnesota
Department of Human Services
Human Services Building
444 Lafayette Road
St. Paul, Minnesota 55155

January 1, 1992

The Honorable Don Samuelson
State Senator
Room 124, State Capitol
75 Constitution Avenue
St. Paul, Minnesota 55155

Dear Senator Samuelson:

Laws of Minnesota 1990, chapter 256B, article 6, section 29 directed the Department of Human Services (DHS) to appoint and convene a 12-member advisory committee on organ and tissue transplants for reimbursement by medical assistance (MA). The advisory committee is to submit an annual report to chairs of the Health and Human Services Divisions of the House Appropriations and Senate Finance Committees and Commissioner of the Department of Human Services. Attached, pursuant to legislation, is the second annual report of the Advisory Committee on Organ and Tissue Transplants.

The advisory committee's recommendations address transplant procedures and facilities that should be added to those covered by Minnesota MA. The Committee recommended the following transplant procedures and facilities, detailed in the attached report.

TRANSPLANT	CRITERIA	FACILITY
Heart-lung	Primary pulmonary hypertension	Must meet United Network for Organ Sharing criteria
Lung	Cadaveric donors only	Must meet United Network for Organ Sharing criteria
Pancreas	Uremic diabetic recipients of kidney transplants	Must meet United Network for Organ Sharing criteria
Allogeneic bone marrow	Stage III or IV Hodgkin's disease	Must meet United Society of Hematology and Clinical Oncology standards
The Committee also recommends that all facilities paid by Minnesota Medical Assistance to perform bone marrow transplants meet the American Society of Hematology and Clinical Oncology standards for bone marrow transplant facilities.		

Legislation creating the advisory committee also directs DHS to periodically recommend to the Legislature criteria for MA coverage of transplants and certification of transplant facilities. DHS agrees in principle with recommendations of the Committee. A copy of budget projections is enclosed. At this time we do not know whether these expenditures will be included in the Governor's Supplemental Budget Request. It appears that we may once again have to propose reduction in expenditures. We will consider these recommendations in light of other priorities.

Once again, members of the Advisory Committee on Organ and Tissue Transplants contributed invaluable experience and knowledge to organ transplant policy development in the MA program. DHS thanks them for their time and effort and excellent report of recommendations.

If you have need of additional information, please do not hesitate to contact Mary Kennedy, Director, Health Care Management Division, at 297-3200.

Sincerely,

NATALIE HAAS STEFFEN
Commissioner

Enclosures 2

TRANSPLANT PROCEDURES
BUDGET ESTIMATE

The following are estimates of additional Medical Assistance program costs that may be incurred if transplant procedures listed below are added to program coverage. Both federal and state shares are shown.

Estimated expenditures for heart-lung and lung transplants are based on national utilization and adjusted for Medical Assistance (one transplant annually) at 1991 average charges.

Estimated expenditures for pancreas transplants are based on payments on those procedures during calendar year 1988, before 1989 legislation eliminated them from coverage. Expenditures were increased 17 percent from 1988 to account for increases in hospital reimbursement rates. It is not anticipated that increases in demand for pancreas transplants will have occurred since 1988 since increases in eligibility have taken place in the categories of children and pregnant women where there is a low incidence of organ transplantation.

The cost estimate for the allogeneic bone marrow transplant for Hodgkin's disease is based on one additional bone marrow transplant per year at present costs.

Estimated expenditures also are separated into spending estimates for adults and children (under age 21) to show forecasted spending due to new requirements of the Early and Periodic Screening, Diagnosis, and Treatment program (see page 5 of attached report). Adult and child spending was calculated based on representation of the two groups in the total Medical Assistance fee-for-service population. Approximately three fourths of the population is 20 years of age or younger.

STATE FISCAL YEAR 1993
(in 000's)

PROCEDURE	FEDERAL EXPENDITURES	STATE EXPENDITURES	TOTAL
Heart-Lung	$65	$55	$120
Adults	(16)	(14)	(28)
Children	(49)	(41)	(92)
Lung	$43	$37	$80
Adults	(10)	(8)	(18)
Children	(33)	(29)	(62)
Pancreas	$19	$17	$36
Adults	(4)	(4)	(8)
Children	(15)	(13)	(28)
Allogeneic Bone Marrow	$26	$22	$48
Adults	(6)	(5)	(11)
Children	(20)	(17)	(37)
TOTAL	$153	$131	$284
Adults	(36)	(31)	(67)
Children	(117)	(100)	(217)

Advisory Committee on
Organ and Tissue Transplants

Annual Report to the Legislature and Department of Human Services

SUMMARY

Purpose

This is the second annual report of the Advisory Committee on Organ and Tissue Transplants presented to the Legislature and Department of Human Services. The report includes recommendations on specific transplant procedures that should be considered for funding under the State's Medicaid (Medical Assistance) program. The report also recommends criteria for approving procedures and facilities.

The Advisory Committee on Transplants first annual report, submitted April 9, 1991, made recommendations for approval of transplants and transplant facilities that have been carried over into this 1992 report. The 1992 committee report also makes additional recommendations on procedures and facilities beyond those in the 1991 report. All recommendations are summarized in the "Recommendations" section below.

Background

Laws of Minnesota 1989 restricted transplant procedures covered by Medical Assistance to those covered by Medicare (Minnesota Statutes 256B.0625, subdivision 27). This law eliminated coverage of pancreas, heart-lung, lung, adult liver, and certain bone marrow transplants previously considered for coverage on an individual basis.

Objections ensued over transplant coverage restrictions implemented by the 1989 law. Consequently, the Legislature passed Laws of Minnesota 1990, chapter 256B, article 6, section 29 directing the Department of Human Services to appoint and convene a 12-member advisory committee on organ and tissue transplants. The statute requires the Advisory Committee on Organ and Tissue Transplants to submit an annual report of recommendations on transplant procedures and facilities the Legislature should add to Medical Assistance coverage to chairs of the Health and Human Services Divisions of the House Appropriations and Senate Finance Committees and the Commissioner of the Department of Human Services. In addition to the charge to the Committee, legislation directed the Department of Human Services to periodically recommend to the Legislature criteria for Medical Assistance coverage of transplants and certification of transplant facilities.

On April 9, 1991, the Department of Human Services transmitted the first annual report of the Advisory Committee on Transplants to the Legislature. The Committee in its report recommended addition of four types of transplant procedures. The Legislature did not act on committee recommendations and procedures were not added to coverage during the 1991 legislative session.

Recommendations of this Report

This second annual report of the Advisory Committee on Transplants recommends addition of the following transplant procedures for Medical Assistance coverage:

TRANSPLANT	CRITERIA	FACILITY
Heart-lung	Primary pulmonary hypertension	Must meet United Network for Organ Sharing criteria
Lung	Cadaveric donors only	Must meet United Network for Organ Sharing criteria
Pancreas	Uremic diabetic recipients of kidney transplants	Must meet United Network for Organ Sharing criteria
Allogeneic bone marrow	Stage III or IV Hodgkin's disease	Must meet United Society of Hematology and Clinical Oncology standards
The Committee also recommends that all facilities paid by Minnesota Medical Assistance to perform bone marrow transplants meet the American Society of Hematology and Clinical Oncology standards for bone marrow transplant facilities.		

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CONTENTS

INTRODUCTION

Medicaid Coverage

Minnesota Medical Assistance. Recipients of Medical Assistance (Medicaid) in Minnesota are covered for heart, liver, bone marrow, and kidney transplants. Appendix 1 is a copy of Medical Assistance coverage criteria from the Medical Assistance and General Assistance Medical Care Provider Manual.

During calendar year 1990 Medical Assistance paid all or part of the costs of 14 bone marrow transplants and 34 kidney transplants (Table 1). Table 1 also shows the number of those transplants where Medicare or another third-party payer contributed toward costs ("Medicare/Third-Party Payers"). Medicare's renal dialysis program pays for many costs associated with kidney transplants for Medical Assistance recipients who are eligible for Medicare. Twenty-eight (28) of the 34 kidney transplant recipients had Medicare coverage. In those instances, Medical Assistance paid only the 20 percent beneficiary co-payment and deductible.

Although heart transplants were covered in 1990, Medical Assistance did not expend any funds for that procedure, presumably because the procedure was not indicated or a donor organ was not available. (One recipient obtained a heart transplant during 1989.) A decrease in the frequency of payments on liver transplants from three in 1989 to zero in 1990 probably is due to enactment of 1989 legislation eliminating Medical Assistance coverage of liver transplants for adults.

Medical Assistance expenditures for all transplant surgeries was approximately $490,000 for services provided during calendar year 1989 and $679,000 for calendar year 1990. These figures include payments to hospitals and physicians for the inpatient stay only. Not included are costs of other hospitalizations due to complications and outpatient costs of lab work, drugs, and physician visits. Also not accounted for are medical costs not incurred because of the curative effect of the transplant.

Table 1. Minnesota Medical Assistance transplant procedure frequency and expenditures (in 000s of dollars), calendar year 1990.

PROCEDURE	MEDICAL ASSISTANCE FREQUENCY	MEDICARE/THIRD-PARTY PAYER CONTRIBUTED	MEDICAL ASSISTANCE EXPENDITURES
Allogeneic bone marrow	8	0	$362
Autologous bone marrow	6	2	$180
Kidney	34	28	$137
Liver	0	---	---
Heart	0	---	---
TOTAL MEDICAL ASSISTANCE EXPENDITURES			$679

Federal Medicaid requirements. As a condition of participation, federal regulations require state Medical Assistance (Medicaid) programs that choose to cover transplants to administer coverage under a federally-approved state plan. The state plan must include compliance with the following standards:

1. Similarly situated individuals must be treated alike.

2. Restrictions on facilities or practitioners must assure high quality of care.

3. Services must be reasonable in amount, duration, and scope to achieve their purpose.

Federal law also prohibits Medicaid programs from use of race, color, sex, national origin, or handicapping condition as a reason for not covering a transplant.[1]

As long as state Medicaid programs stay within the above requirements, however, they have leeway in designing transplant coverage. In addition to deciding whether to cover transplants at all, states may establish medical necessity criteria for coverage. For

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[1]U.S. Department of Health & Human Services, "A Guide to State Organ Transplant Activities in the United States" (December 1990): 4

instance, states may impose limitations on transplant procedures that are covered. A particular transplant may be restricted to certain diagnoses or clinical conditions, ages, or other patient selection criteria as long as the criteria are reasonable. General exclusions, such as "coverage limited to nonexperimental procedures", are not permissible.

In addition, states may choose to limit facilities and practitioners that provide transplant services. Facilities and practitioners that are selected must demonstrate excellence, and all recipients, regardless of place of residence, must have equal access to care. State Medicaid programs also may cover transplant services up to specified dollar or inpatient hospital length of stay limits as long as each recipient receives the same level of service. Limits must be of a reasonable amount that will assure effective treatment.

State Medicaid program transplant coverage. Medicaid programs vary according to which transplants are covered. Appendix 2 is a copy of a chart illustrating solid organ transplant procedure coverage in the 50 states and District of Columbia in 1990. Over half of all states and D.C. covered kidney, heart, and liver transplants, whereas less than half covered heart-lung, lung, and pancreas. (Similar data are not available for bone marrow transplants.)

States vary on coverage criteria for individual transplants.[2] Most states use specific medical criteria to select patients for transplants and may contract with medical advisory groups for decision-making. Other states rely on specially designated transplant facilities for appropriate patient selection. About half of the states have developed their own standards for coverage of transplants while other states rely on criteria already established by Medicare.

States that elect to include the medically needy population in their Medicaid program usually provide that group with the same transplant coverage provided to the categorically needy. Except for liver transplants, age of the transplant recipient rarely is a criterion for state Medicaid program transplant coverage, although transplant facilities may consider age and other factors when recommending someone for a transplant. About 11 of the 48 states that covered liver transplants in 1990 limited coverage to children under the age of 21, probably because those states followed Medicare criteria.

Ten states have maximums on Medicaid dollars that may be spent on a transplant. For instance, Pennsylvania covers all six solid organ transplant procedures, but places a dollar limit on the hospital benefit ($48,416 for heart-lung and $53,558 for liver). Alabama covers liver and kidney transplants although only children are covered for liver

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[2]U.S. Department of Health & Human Services, "A Guide to State Organ Transplant Activities in the United States" (December 1990): 1-4

transplants and up to a maximum benefit of $125,000. The adult inpatient hospital stay for kidney transplants has a 14 day annual limit. It appears that Alabama is the only state with a limit on hospital length of stays. At this time Minnesota Medical Assistance does not place maximum benefit amounts on transplant services, although payments to hospitals are limited to lump-sum amounts calculated for approximately 40 diagnostic categories. Physician payments, such as transplant surgery fees, currently are based on the median of usual and customary charges from 1982.

Recent Changes in Transplant Coverage

During the past year, two changes in federal law increased Minnesota Medical Assistance transplant coverage.

Adult liver transplants. On April 12, 1991, the Federal Register announced that Medicare will begin coverage of adult liver transplants. This resulted in addition of adult liver transplants to Minnesota Medical Assistance transplant benefits because Medical Assistance, by state law, must follow Medicare transplant coverage. Medical Assistance liver transplant procedures must be performed in Minnesota facilities that have applied to the Health Care Financing Administration for approval to perform liver transplant surgery.

Medicare guidelines include adult liver transplants for beneficiaries with end-stage liver disease, life expectancy without a transplant of less than 12 months, and no medical or surgical alternatives to transplantation. Coverage is limited to the following seven conditions:

1. Primary biliary cirrhosis.
2. Primary sclerosing cholangitis.
3. Post-necrotic cirrhosis, hepatitis B surface antigen negative.
4. Alcoholic cirrhosis.
5. Alpha-1 antitrypsin deficiency disease.
6. Wilson's disease.
7. Primary hemochromatosis.

Patients may not have hepatic, extrahepatic, or metastatic malignancies; significant or advanced cardiac, pulmonary, renal, nervous system, or other systemic disease; systemic

infection; active alcohol or drug abuse; history of behavior or psychiatric illness likely to interfere significantly with treatment; or acute severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of one or more vital organs. Conditions such as Budd-Chiari syndrome and fulminant hepatic failure are not covered. Live liver transplants and liver transplants in conjunction with transplantation of another organ also are excluded from coverage.

In addition, facilities must meet criteria for approval by Medicare to perform liver transplants. Facility criteria include a 77 percent one-year and 60 percent two-year survival rate and a minimum of 12 liver transplants performed per year. The facility must demonstrate that it has adequate patient selection and management criteria. In cases involving alcoholic cirrhosis, patient selection must include evidence of sufficient social support to assure assistance in alcohol rehabilitation and immunosuppressive therapy following the operation. The facility also must require a period of abstinence prior to surgery, although Medicare does not specify the length of time abstinence is required.

When Medicare added adult liver transplant coverage it did not change coverage of liver transplants for children. Pursuant to Medicare coverage regulations instituted in 1983, Medical Assistance covers liver transplants for children under age 18 with extrahepatic biliary atresia or any other form of end-stage liver disease. Liver transplants in children with a malignancy extending beyond the margins of the liver or those with persistent viremia are excluded from coverage. However, the Omnibus Budget Reconciliation Act of 1989 requires state Medicaid programs to cover all medically necessary organ transplants for children under age 21. This requirement, described below, has the potential to expand liver transplant coverage for children.

Transplants for Children. The Omnibus Budget Reconciliation Act of 1989 requires state Medicaid programs to furnish all medically necessary diagnosis and treatment services to treat conditions detected by periodic screening provided to children under the age of 21 as part of the Medicaid Early and Periodic Screening, Diagnosis and Treatment program. Federal regulations have yet to be published, but a recent communication from the Department of Health and Human Services to state Medicaid agencies directed states to provide medically necessary services regardless of whether the services are covered in the state plan. The federal communication also specified that states must provide medically necessary organ transplants as part of this new requirement. See Appendix 3 for a copy of the federal communication.

This provision of the 1989 Omnibus Budget Reconciliation Act takes precedence over state law limiting Medical Assistance transplant coverage to services covered by Medicare. Minnesota Medical Assistance now must consider approval of a transplant for a recipient who is 20 years of age or younger based on medical necessity. Minnesota also must change its state plan on transplants to conform with this requirement.

MEDICAL NECESSITY

Criteria for Coverage

The Advisory Committee on Transplants developed and used the following criteria to evaluate a transplant procedure for medical necessity and make recommendations for coverage by the Medical Assistance program.

1. **Proven effectiveness of procedure.** Transplants are performed as treatment and an alternative to other treatments in which the outcome often is unsatisfactory, and rarely are performed purely for research or experimental purposes. The Committee does not support Medical Assistance funding of transplants performed on an experimental or research basis. In addition, the Committee does not recommend transplant procedures for coverage unless evidence is available that clearly indicates the procedure has been demonstrated to be medically effective. Published outcome data for each procedure must be available (see number 2. below for survival criteria.) A number of procedures sufficient to allow for an evaluation of effectiveness must have been performed. Transplant centers performing the procedure, on a trial or therapeutic basis, must meet standards of excellence established by appropriate medical authorities for performing the designated transplant procedure.

2. **Life expectancy after surgery.** Graft and host survival statistics on specific transplant procedures must be available and considered. Survival rates for the first year following surgery are most significant. Consideration also must be given to the total number of transplants performed in each specific area and experience over time. Procedures must have at least a 50 percent graft survival rate for the first year following surgery.

3. **Status of patient.** Individual patient factors such as health status and alcohol and other drug consumption affect transplant outcomes. Transplants would be inappropriate in someone who will die shortly whether the transplant is or is not

done, but usually the probability of survival of a particular patient only can be estimated. Medical Assistance funds should not be used to pay for transplants performed as a "last hope" when they do not otherwise meet criteria for coverage. Patient evaluation and monitoring for the appropriateness of transplant surgery is best conducted by transplant facilities with standards of excellence. This is the primary reason for stressing that facilities are chosen carefully.

4. **Quality of life.** There should be a higher probability that a satisfactory quality of life can be achieved with a transplant than without. In some cases, it could be less expensive to provide alternative care to the transplant, but the quality of life and productivity of the individual may be so much lower that cost should not be the only factor considered.

5. **Other considerations.** The Committee also considered the following issues in its discussion of transplant procedures that should be covered by Medical Assistance, although the issues did not directly affect the decision to recommend certain transplants for coverage. These issues are important to include in any discussion on transplant coverage.

   a. **Cost.** The Committee did not base recommendations on cost of transplants, because this was not part of its charge from the Legislature. Cost has to be considered in the context of society as a whole, although cost estimates should be calculated as part of any recommendation to cover additional transplants.

   b. **Cost of care without a transplant.** Costs arise for persons who need transplants whether or not the transplant is provided. Cost also must be looked at within the context of transplants that already are provided. Transplants may be more or less expensive than alternative treatments depending on the individual patient and transplant procedure. For some transplants, there are no viable alternative treatments and so the patient dies.

   c. **Comparability to other plans.** A discussion of other state Medicaid program coverage and criteria starts on page three. It is important to examine transplant coverage by other programs and third party payers to understand criteria used and determine if those criteria are appropriate for decisions on Minnesota Medical Assistance coverage. The Committee will continue to study public and private funding of transplants to gain an understanding of the rationales used for coverage. However, care must be taken when comparing other third party payer coverage with Medical Assistance. For instance, Blue Cross and Blue Shield of Minnesota began to provide coverage for some transplants while they were still considered to be investigative. The criteria have to be looked at very carefully, particularly the administrative decisions which ultimately lead to the decision to provide coverage for a class of transplants.

Criteria for Facility Approval

Facilities and practitioners that perform transplants must meet high quality standards in order to guarantee that all transplants done are medically necessary and assure quality care. The following are criteria transplant facilities should meet to obtain approval for providing transplants to Medical Assistance recipients.

1. The facility must meet criteria established by appropriate medical authorities for performing the designated transplant procedure. For instance, bone marrow transplant facilities should meet the American Society of Hematology and Clinical Oncology standards for bone marrow transplant facilities. Professional society criteria must be examined carefully, however, and compared to criteria established by third party payers.

2. Transplant centers must have available protocols for patient selection and management, evidence of facility commitment and planning, transplant procedure experience and survival rates, sufficient laboratory services, and any other required facility feature or skill applicable to the particular transplant. In addition to verifying existence of protocols for patient selection, etc., Medical Assistance should regularly review each transplant facility's application of its procedures and protocols to guarantee that appropriate standards are upheld. Patient selection is an extremely important feature of a transplant program. Patients should be selected based on medical criteria as well as on their ability to comply with their post-operative treatment regimen, critical to treatment success and cost-effectiveness.

The Department of Human Services should certify facilities based on the above criteria and limit facilities that perform transplants to those that demonstrate standards of excellence. Transplant centers should be approved with the option of withdrawing approval if performance drops below acceptable standards. This is in compliance with federal Medicaid regulations that require states to monitor facilities chosen to perform transplants.

Transplants should not occur outside of the state of Minnesota. There are three chief reasons to not pay for transplant procedures in other states: 1) The qualifications of the center that performs the transplant are key to successful transplant outcomes. At least two high quality transplant centers are located in Minnesota for each transplant procedure that is currently covered or recommended for coverage. There is no need to examine and continually monitor out-of-state transplant centers for addition to the list of approved centers. 2) Medical Assistance must provide transportation, meals, and lodging for transplant patients, live donors, and family members. It is unnecessary for the State to incur those expenses, and risk paying for prolonged hospital stays and emergency medical transportation for Minnesota residents in other states. 3) Minnesota has an excellent medical system and has consistently been a leader in the area of organ transplantation.

When a transplant patient is referred to a center out of the state because the procedure is not covered in Minnesota, the procedure probably is in an investigative stage and should not be approved. The transplant facility must be able to provide evidence to meet criteria for coverage starting on page six. It is highly unlikely that these criteria will be met.

RECOMMENDATIONS ON TRANSPLANT PROCEDURES AND FACILITIES

First Annual Report Recommendations

The following transplant procedures were recommended for coverage in the March 1991 report of the Advisory Committee on Transplants. The Committee maintains that these procedures meet medical necessity criteria for coverage by the Medical Assistance program and recommends that the Legislature add them to existing transplant coverage. In addition, since, in the opinion of the Committee the following transplants are medically necessary for the indications given, the Department of Human Services should cover the procedures for recipients under age 21 according to 1989 Omnibus Budget Reconciliation Act provisions for diagnosis and treatment of children.

Pancreas transplants. Pancreas transplants are indicated for uremic diabetic recipients of kidney transplants. The pancreas transplant may occur simultaneously with a kidney transplant or following kidney transplantation. Facilities that may perform pancreas transplants must be approved for performing pancreas transplants by the United Network for Organ Sharing. At this time, approved Minnesota facilities are the Mayo Clinic and University of Minnesota Hospital.

Heart-lung transplants. The Advisory Committee on Transplants recommends coverage of heart-lung transplants for persons with primary pulmonary hypertension. Facilities must meet criteria currently in final stages of development by the United Network for Organ Sharing.

Allogeneic bone marrow transplants for Hodgkin's disease. Allogeneic bone marrow transplants should be covered for stage III or IV Hodgkin's disease. Allogeneic bone marrow transplants are those in which the transplant recipient receives bone marrow from a donor who may be related or unrelated to the patient. This recommendation adds an indication for allogeneic bone marrow transplants, already covered for other indications (see Appendix 1). Since autologous bone marrow transplants (use of patient's own bone marrow) for treatment of stage III or IV Hodgkin's disease are covered, allogeneic bone marrow transplants to treat the same condition should be covered as well. It appears that omission of allogeneic bone marrow transplants for Hodgkin's disease may have been an oversight by Medicare.

Additional Recommendations

In addition to transplant procedures and facilities recommended in the 1991 report, the Committee recommends the following:

Lung transplants. The Committee re-examined the issue of lung transplants and is satisfied that lung transplants meet criteria for coverage. Therefore the Committee recommends coverage of lung transplants that use lungs from cadaveric donors. Facilities should meet United Network for Organ Sharing criteria for performing heart-lung and lung transplants.

American Society of Hematology and Clinical Oncology standards for bone marrow transplant facilities. At this time the Department of Human Services reimburses any hospital in the state of Minnesota for bone marrow transplants if the facility is accredited by the Joint Commission of Health Organizations. This is consistent with Medicare regulations.

The Department of Human Services should limit bone marrow transplant facilities to those that meet the American Society of Hematology and Clinical Oncology standards for bone marrow transplant centers. Bone marrow transplantation is a rapidly growing area and the number of bone marrow transplant facilities also is greatly expanding. The growth rate for facilities is due partly to the fact that bone marrow transplantation requires limited technology. More stringent standards are necessary to assure quality of care.

OTHER ISSUES

The Advisory Committee on Transplants discussed further the areas of pancreas transplants not performed in conjunction with or following a kidney transplant and autologous bone marrow transplants for treatment of brain and other solid tumors.

Autologous bone marrow transplants for treatment of brain and other solid tumors. At this time available outcome data on treatment of brain tumors, Ewing's sarcoma, and other solid tumors through autologous bone marrow transplantation do not meet criteria for coverage established by the Committee. The Committee will continue to review results of the treatment protocol that uses autologous bone marrow "rescue" in conjunction with high-dose chemotherapy for possible coverage by Minnesota Medical Assistance.

Pancreas transplants alone. The Committee did not recommend coverage of pancreas transplants performed alone (not in conjunction with or following a kidney transplant) because of the difficulty in defining appropriate patient selection criteria for this type of transplant procedure. Therefore even though the current success rate for pancreas transplants performed alone is sufficiently high to meet criteria for coverage established by the Committee, the Committee agreed to table a recommendation for coverage until next year.

6901.01 Covered Services

As of July 1, 1989, the Legislature limited MA coverage of organ and tissue transplants to those procedures covered by the Medicare program. MA therefore, covers cornea, heart, liver, bone marrow, and kidney transplant procedures. Transplant coverage includes: preoperative evaluation; recipient and donor surgery; follow-up care for the recipient and live donor; and retrieval of organs and tissues.

6901.02 Providers

To receive reimbursement for a heart or liver transplant, the hospital must be approved by Medicare. A pediatric hospital that has met Health Care Financing Administration approval criteria for performing a heart or liver transplant on a child also may perform those transplants.

Kidney, cornea, and bone marrow transplants must be performed in a facility that is participating as a provider of services in the Medicare program, and that meets statutory requirements for providing transplants to MA recipients, when available.

6901.03 Coverage of Eligibility Groups

Transplant coverage applies to any person eligible for MA as either categorically or medically needy, or any person eligible for GAMC. GAMC recipients should be referred to their county human services agency for application to MA. See specific transplant procedure criteria below.

6901.04 Prior Authorization

Liver transplants, transplants for children under the age of 21 other than for approved conditions, and transplants that are to be performed in out-of-state facilities require prior authorization. The transplant facility must submit the prior authorization form with a medical report attached. The medical report must include the following information:

- Diagnosis including ICD-9 diagnosis code
- Proposed treatment
- Sufficient information to show medical necessity of proposed treatment
- Any additional information that is pertinent. For out-of-state hospitals this includes experience of the transplant facility in terms of numbers performed and outcome.

If a transplant is to be performed out of the state, the provider must get prior authorization according to the instructions for out-of-state services described in the Prior Authorization chapter. Local trade area (border state) hospitals are not classified as out-of-state hospitals.

6901.05 Transplants for Children

Transplants not specifically listed in this chapter as covered will be considered for coverage in children under the age of 21 pursuant to the Omnibus Budget Reconciliation Act of 1989. Transplants will be approved on the basis of medical necessity and must be demonstrated to be medically effective. Include documentation with the prior authorization request that details the patient condition and plan of care, evidence to support medical effectiveness of the procedure, and experience of the transplant facility, i.e. number of procedures performed in a year and first-year survival rates.

6901.06 Heart Transplant Coverage

Cardiac transplants are covered when performed in a facility on the Medicare list of approved heart transplant

centers. Artificial heart transplants and ventricular assist devices are not covered. Prior authorization is required for transplants at facilities that are not on the Medicare-approved list.

6901.07 Liver Transplant Coverage

Liver transplants in children (ages 17 and under) with extrahepatic biliary atresia or any other form of end-stage liver disease are covered. Liver transplants for children with a malignancy extending beyond the margins of the liver or those with persistent viremia and live liver transplants are not covered.

Liver transplants are covered for adults with the following conditions:

A. Primary biliary cirrhosis.

B. Primary sclerosing cholangitis.

C. Postnecrotic cirrhosis, hepatitis B surface antigen negative.

D. Alcoholic cirrhosis.

E. Alpha-1 antitrypsin deficiency disease.

F. Wilson's disease.

G. Primary hemochromatosis.

Adult liver transplants are covered retroactively to March 8, 1990, with prior authorization and provided that the recipient was eligible for MA and the facility that performed the transplant is approved by Medicare to perform liver transplants. See 6901.04 for prior authorization information requirements.

Liver transplants require prior authorization including those covered by other third-party payers. Liver transplants for recipients with Medicare coverage do not require prior authorization.

6901.08 Bone Marrow Transplant Coverage

Allogeneic bone marrow transplants are covered for the following:

A. Treatment of leukemia or aplastic anemia when it is reasonable and necessary for the individual patient to receive this therapy.

B. Treatment of severe combined immunodeficiency disease (SCID).

C. Treatment of Wiskott-Aldrich syndrome.

Autologous bone marrow transplants are covered for the following:

A. Acute leukemia in remission with a high probability of relapse and no HLA-matched donor.

B. Resistant non-Hodgkin's lymphomas or those presenting with poor prognostic features following an initial response.

C. Recurrent or refractory neuroblastoma.

D. Advanced Hodgkin's disease who have failed conventional therapy and have no HLA-matched donor.

Autologous bone marrow transplants are not covered for the following conditions:

A. Acute leukemia in relapse.

B. Chronic granulocytic leukemia.

C. Solid tumors (other than neuroblastoma).

6901.09 Kidney Transplant Coverage

Kidney transplants must be performed in a hospital that is participating as a provider of services in the Medicare program. Kidney transplants require prior authorization if they will be performed in an out-of-state facility.

6901.10 Donor Coverage

The organ donor is covered for medically necessary inpatient hospital days and other services directly related to the transplant. Donor charges should be billed to the recipient MA number. Donor travel expenses will be reimbursed by the recipient county of residence according to MA travel reimbursement policy. Patients should contact their county case worker to arrange travel.

6901.11 Billing

The costs of organ and tissue procurement should be included on the inpatient hospital billing form. Hospital days of stay for the donor are included in the DRG payment for the donee (MA recipient). All charges for the donor should be billed using the donee MA identification number.

6901.12 Other Payers

Liable third-party payer coverage and research and grant monies must be used to the fullest extent before MA payment will be made for a transplant. If payment is denied by a third-party payer, the denial and documentation of efforts to secure payment must be submitted with the claim. If appeals are available through the insurer, the Department will ask the client to pursue these appeals.

Providers must obtain prior authorization for transplants that require it even though private insurance will pay part of the bill.

Legal References Minnesota Statutes, section 256B.0625, subd. 27

Exhibit 1-MEDICAID COVERAGE OF SOLID ORGAN TRANSPLANTS

	HEART	*HEART/ LUNG*	*KIDNEY*	*LIVER*	*LUNG*	*PANCREAS*
ALABAMA			X	X		
ALASKA			X	X		
ARIZONA	X		X	X		
ARKANSAS	X		X	X		
CALIFORNIA	X		X	X		
COLORADO	X	X	X	X		
CONNECTICUT	X	X	X	X		
DELAWARE	X	X	X	X		X
D.C	X		X	X		
FLORIDA	X		X	X		
GEORGIA			X	X		
HAWAII			X	X		
IDAHO			X			
ILLINOIS	X		X	X		
INDIANA	X	X	X	X		X
IOWA	X		X	X		
KANSAS	X		X	X		
KENTUCKY	X	X	X	X	X	X
LOUISIANA	X	X	X	X	X	X
MAINE	X	X	X	X	X	
MARYLAND	X	X	X	X	X	
MASSACHUSETTS	X	X	X	X	X	X
MICHIGAN	X	X	X	X	X	X
MINNESOTA	X		X	X		
MISSISSIPPI	X	X	X	X	X	X
MISSOURI	X		X	X		
MONTANA	X		X	X		

	HEART	*HEART/ LUNG*	*KIDNEY*	*LIVER*	*LUNG*	*PANCREAS*
NEBRASKA	X		X	X		
NEVADA			X	X		
NEW HAMPSHIRE			X	X		
NEW JERSEY	X	X	X	X		
NEW MEXICO	X	X	X	X	X	
NEW YORK	X	X	X	X		
N. CAROLINA	X	X	X	X	X	
N. DAKOTA	X	X	X	X	X	X
OHIO	X	X	X	X	X	X
OKLAHOMA			X	X		
OREGON	X	X	X	X		
PENNSYLVANIA	X	X	X	X	X	X
RHODE ISLAND	X	X	X	X		
S. CAROLINA	X		X	X		
S. DAKOTA	X		X	X		
TENNESSEE	X		X	X		
TEXAS	X		X	X		
UTAH			X	X		
VERMONT	X	X	X	X	X	X
VIRGINIA			X			
WASHINGTON	X	X	X	X	X	
W. VIRGINIA	X		X	X		
WISCONSIN	X	X	X	X	X	X
WYOMING						
TOTALS	**40**	**23**	**50**	**48**	**15**	**12**

Source: IHPP, 1990

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

Region V
105 West Adams
Chicago, Ill 60603

June, 1991

CHICAGO REGIONAL STATE LETTER NO: 37-91

SUBJECT: Revisions to the State Plan Preprint Due to Provisions of the Omnibus Budget Reconciliation Act of 1989 (OBRA 89) - **INFORMATIONAL**

The Medicaid Bureau of the Health Care Financing Administration (HCFA) is currently drafting new State plan preprint pages to reflect the OBRA 89 provisions related to Early and Periodic Screening, Diagnosis and Treatment (EPSDT). However, it will be several months before these pages are published. In the meantime, the Medicaid Bureau provided the following guidance for State plan revisions to comply with the OBRA 89 EPSDT requirements.

Item 4.b. of Attachments 3.1-A and 3.1-B should be revised to indicate that the State meets the new requirement in section 1905(r) of the Social Security Act (the Act) that all medically necessary diagnosis and treatment services will be furnished to EPSDT recipients to treat conditions detected by periodic and interperiodic screening services, even if the services are not included in the State plan. The plan revision should include a list of each 1905(a) service which is not currently provided under the State plan but must now be available to EPSDT recipients if medically necessary.

In addition, because State Medicaid programs must now provide any medically necessary organ transplants to children under age 21, States should amend their plans to comply with the requirements of section 1903(i) of the Act. Therefore, page 27 and Attachment 3.1-E should be revised with appropriate organ transplant information. Organ transplants should also be added to the list of services provided to EPSDT recipients in Item 4.b. of Attachments 3.1-A and 3.1-B.

States must also make revisions to the reimbursement sections of their plans. Specifically, Attachment 4.19-B should be revised to include reimbursement methodologies and assurances for the additional Medicaid services not otherwise covered under the State plan, which are required to be provided to EPSDT recipients if medically necessary. It is unacceptable to merely indicate that payment for these services will be based on existing Medicare and

Medicaid reimbursement methodologies. The State must identify the particular service by name and indicate the specific reimbursement methodology to be used. If the State chooses to use a reimbursement methodology that is employed for some other service, specific identification of the service and the location in the plan of its reimbursement methodology must be provided. If a State chooses to follow Medicare payment methodologies, the specific service and the specific Medicare payment methodology to be utilized must also be provided.

Regulations at 42 CFR 447.201(b) require that the State plan describe the policy and methods to be used in setting payment rates for each type of service included in the State's Medicaid plan. Therefore, revisions of the reimbursement sections of the plan for non-cost based methodologies should include a full discussion of the charge structure and how it is related to payment for the services. For both non-cost based and cost based methodologies the State must provide the appropriate information and assurances required by 42 CFR 447, Subparts B, C, and D.

Finally, you should evaluate the amount, duration and scope of services currently provided in your approved plan and make appropriate revisions to remove arbitrary limits on services furnished to EPSDT recipients. Section 1905(r)(5) of the Act is clear that all services or treatments which are "medically necessary" to correct or lessen health problems detected or suspected by the screening services must be provided to individuals under age 21. Therefore, States must indicate in the plan that limits on services or treatments are not applicable to EPSDT recipients. For example, if a State has placed a limit on the number of inpatient days covered under Medicaid, the plan must specify that the limitation does not apply to EPSDT recipients.

If you have any questions please contact Barbara J. England, Medicaid Policy Specialist, at (312) 353-8720 or your Medicaid Program Specialist.

Charles W. Hazlett
Associate Regional Administrator
Division of Medicaid

Originating Component: Medicaid Operations Branch
Division of Medicaid