

910598

Report of The  
Advisory Committee on  
Organ and Tissue Transplants

**Findings and Recommendations for  
Medical Assistance Coverage of  
Transplant Procedures**

**ANNUAL REPORT**

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*State of Minnesota  
Committee on Transplants  
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St. Paul, Minnesota 55155-3853*

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Pursuant to MS 256B.0629

March 31, 1991  
MS-0025/DT 4-91

## EXECUTIVE SUMMARY

Laws of Minnesota 1990, chapter 256B, article 6, section 29 directed the Department of Human Services 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 the 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 (DHS). This report is the Advisory Committee on Organ and Tissue Transplants' first Annual Report to the Legislature.

The recommendations of the Advisory Committee, per legislation, address transplant procedures and facilities that should be considered for addition to those covered by Minnesota MA. The following additional transplant procedures, detailed in the report, are recommended:

<u>Transplant</u>	<u>Criteria</u>	<u>Facilities</u>
HEART-LUNG	Primary pulmonary hypertension	Abbott-Northwestern Mayo Clinic U of M Hospital
LIVER	Nonmalignant liver and biliary tract disease	Mayo Clinic U of M Hospital
PANCREAS	Uremic diabetic recipients of kidney transplants	Mayo Clinic U of M Hospital
ALLOGENEIC BONE MARROW	Stage III or IV Hodgkin disease	MN hospitals with bone marrow transplant programs approved by Medicare



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## **I .**

### **BACKGROUND AND LEGISLATION**

A law on organ and tissue transplants, passed during the 1989 legislative session, established clear coverage restrictions for persons receiving transplant benefits from the Minnesota Medical Assistance (MA) program. The significance of this new law, Minnesota Statutes 256B.0625, was that it limited MA coverage of transplant procedures to those covered by Medicare (see Appendix B). Adoption of Medicare standards resulted in elimination of MA reimbursement, as of July 1, 1989, for pancreas, heart-lung, lung, adult liver, and certain types of bone marrow transplants.

The Legislature and Department of Human Services (DHS) sought enactment of legislation to provide the MA program with guidelines on organ and tissue transplant procedures that should receive public funding. Prior to this law, DHS lacked statutory authority to deny requests for transplant approval. DHS also lacked the resources to conduct research into transplant procedure effectiveness and keep abreast of developments in the area in order to determine appropriate coverage. The statute adopted Medicare standards because Medicare is a public health insurance program with clear transplant coverage criteria based on Medicare's assessment of organ and tissue transplant effectiveness.

#### **Advisory Committee on Organ and Tissue Transplants:**

In response to concerns that use of Medicare transplant standards exclusively prevents access to medically necessary and effective transplant procedures, during the following (1990) legislative session the Legislature established the Advisory Committee on Organ and Tissue Transplants (Minnesota Statutes 256B.0629 -- Appendix C). The Legislature created the 12-member Committee to offer advice and recommendations to DHS and the Legislature on efficacy of transplant procedures, current practice standards, availability of qualified transplant facilities, and issues related to transplants such as ethics, law, and economics. Members were chosen from a variety of areas as mandated by law, and appointed by the DHS Commissioner on March 1, 1991 (Appendix A).

Committee activities include:

- Collecting information on transplants currently not covered.
- Obtaining information on transplant procedures from Minnesota transplant providers.
- Developing guidelines for addition of noncovered transplant procedures.
- Recommending, in an annual report, transplant procedures and facilities to add to existing MA coverage.

The Committee's annual report is to be submitted to the chairs of the health and human services appropriations divisions of the House Appropriations Committee and the Senate Finance Committee, and to the DHS Commissioner. Only the Legislature may approve additional transplant procedures and facilities, and may only approve those procedures and facilities recommended by the Transplant Committee or DHS.

## **II .**

### **TRANSPLANT COVERAGE UNDER MINNESOTA MEDICAL ASSISTANCE**

#### **Eligibility:**

In Minnesota, MA recipients are eligible for transplant coverage whether they qualify for MA as categorically or medically needy. According to Social Security standards, a recipient of a solid organ or bone marrow transplant is automatically determined to be disabled for at least one year, and is eligible for MA if income criteria are met.

Individuals on General Assistance Medical Care (GAMC) who need a transplant also meet disability criteria and become eligible for MA. GAMC is a state-funded health program for persons who meet MA income criteria, but do not qualify for MA because they do not fit a MA eligibility category, such as having a disability or receiving Aid to Families with Dependent Children (AFDC). DHS instructs providers and local human services agencies to require GAMC transplant candidates to apply for MA so federal funding may be obtained. Children's Health Plan recipients do not receive inpatient hospitalization benefits, but would likely qualify for MA in the event that transplant surgery is necessary.

#### **Covered Procedures:**

Table 1 shows transplant procedures covered by Minnesota MA before and after enactment of the July 1, 1989 organ and tissue transplant coverage legislation. Although the chart shows coverage of allogeneic and autologous bone marrow transplants both prior to and after July 1, 1989, enactment of transplant legislation eliminated coverage of some bone marrow transplants. Medicare specifies diagnoses covered and excluded for bone marrow transplants (Appendix D -- Medicare Coverage Issues Manual, Bone Marrow Transplantation).

Table 1

**TRANSPLANT COVERAGE  
MINNESOTA MEDICAL ASSISTANCE**

<u>Procedure</u>	<u>MN MA Before 7/1/89</u>	<u>MN MA (Medicare) After 7/1/89</u>
Heart-lung	Yes	No
Lung	Yes	No
Heart	Yes	Yes
Allogeneic Bone Marrow	Yes	Yes for certain diagnoses
Autologous Bone Marrow	Yes	Yes for certain diagnoses
Liver	Yes	Only Children
Pancreas	Yes	No
Renal	Yes	Yes

Medicare is in the process of finalizing criteria for coverage of adult liver transplants. The period for public comment has passed, and Medicare now is addressing comments received from the public. MA will cover adult liver transplants according to Medicare regulations as soon as final regulations are published. Liver transplants that meet Medicare criteria and were performed in Medicare-approved facilities will be covered by Medicare and Minnesota MA if performed on or after March 8, 1990, the date of the first Federal Register notice announcing the intent of Medicare to cover adult liver transplants.

Consistent with Medicare coverage, MA transplant coverage includes preoperative evaluation, recipient and donor surgery and hospitalization, follow-up care for the recipient and live donor, and retrieval of organs and tissues. MA recipients also receive drug coverage beyond that covered by Medicare. For those transplants not covered by MA at this time, MA pays for necessary care both prior to hospitalization for the transplant surgery and after hospital discharge.



**Approved Facilities:**

The July 1, 1989 law that changed transplant procedures covered by MA also affected facilities that could perform transplant surgeries. It required that MA coverage comply with "all applicable laws, rules, and regulations governing (1) coverage by the Medicare program..." This limits providers to those facilities that meet Medicare standards. Medicare requirements for transplant facilities vary according to the type of transplant procedure.

Medicare approves specific facilities to perform heart transplants based on success rates, numbers of heart transplants performed, and other factors. The University of Minnesota Hospital and Clinic and Abbott Northwestern Hospital are Minnesota facilities approved by Medicare to perform heart transplants. In addition to the national listing of approved heart transplant facilities, Medicare regulations allow for approval of additional facilities, including pediatric hospitals, that meet certain criteria.

Kidney, bone marrow, and liver transplants must be performed by Medicare-certified hospitals. Liver transplants currently are the only transplant procedure that require prior authorization by Medicare and Minnesota MA.

**Payment:**

MA reimbursement rates (maximum allowed fees) are legislatively mandated. Transplant hospitals receive a lump-sum payment based on the diagnosis related group (DRG) reimbursement method which currently is facility-specific. Fee maximums for professional services are based on charges from the base year of 1982, per legislation. MA reimbursement may be obtained only if the recipient is eligible at the time services are rendered and any available private insurance or Medicare benefits are exhausted.

**Frequency:**

A very small percent of the total population will ever need organ or tissue transplantation. This also is true of MA recipients. Below (Table 3) are frequencies for MA transplant recipients for calendar years (CY) 1988 through 1990. These data are based on claims submitted with *Physicians' Current Procedural Terminology* (CPT) procedure codes for transplant surgeries performed during those calendar years. Therefore, hospitalizations are not reported here if the surgery procedure was not billed to MA.

The subheading "MA Primary" in Table 3 means MA was the sole payer. "MA Partial" includes many types of payments. For example, in some cases MA paid only part of the bill due to private insurance or Medicare coverage. In other cases it appears that the provider was not paid for the transplant surgery procedure itself because of failure to obtain prior authorization when required.

Figures for autologous bone marrow transplants likely are subsumed in 1988 and 1989 allogeneic transplant figures because CPT did not publish a specific procedure code for autologous bone marrow transplants until 1990.

**Table 3**  
**MEDICAL ASSISTANCE TRANSPLANT FREQUENCY**

<u>Procedure</u>	<u>CY88</u>	<u>CY89</u>	<u>CY90</u>
HEART-LUNG*	0	0	0
LUNG*	0	0	0
HEART			
MA Primary	1	2	0
MA Partial	2	0	0
ALLOGENEIC BONE MARROW			
MA Primary	4	3	3
MA Partial	3	1	4
AUTOLOGOUS BONE MARROW			
MA Primary	--	--	2
MA Partial	--	--	0
LIVER**			
MA Primary	1	2	0
MA Partial	1	1	0
PANCREAS*			
MA Primary	6	1	0
MA Partial	0	0	0
KIDNEY			
MA Primary	3	4	5
MA Partial	46	15	26

\* Dropped from coverage 7/1/89.

\*\* Dropped from coverage for adults 7/1/89.

A slight decrease in frequency of some transplant procedures occurred after enactment of the 1989 statute that adopted Medicare coverage standards. All prior authorization requests for procedures not covered by Medicare, if initiated before the July 1, 1989 cut-off, were considered for coverage under previous criteria. If approved, MA paid the claim even though the procedure was dropped from coverage as of July 1, 1989.

**Costs:**

Limitations on MA coverage of transplant procedures to those procedures covered by Medicare reduce MA expenditures for inpatient hospital stays and surgeon and anesthesiologist payments for the transplant surgery and other inpatient physician services. MA continues to pay costs of care both before and after the hospital stay for the transplant procedure even though the transplant surgery and inpatient stay is not covered. This is consistent with Medicare regulations.

Therefore, all associated transplant costs are not "saved" when the transplant procedure itself is excluded from coverage. Often, payments for services provided over a 12-month period that includes an inpatient stay for a transplant are greater for the services provided before and after the inpatient stay than for the transplant procedure itself. For instance, MA paid out a total of \$103,354 over a 12-month period for one heart transplant patient. This included two inpatient stays in addition to the transplant surgery stay. MA expenditures for the heart transplant surgery and hospitalization were \$39,974 (38% of total expenditures).

MA expenditures for transplants are shown in Table 4. Amounts are payments for the transplant surgery inpatient stay, including the hospital DRG and physician payments, made during calendar years 1988 through 1990. The costs represent total payments made during those years, but not necessarily for services provided during that time period. Providers have up to 12 months to submit claims.

Table 4

## MEDICAL ASSISTANCE TRANSPLANT EXPENDITURES

<u>Procedure</u>	<u>CY88</u>	<u>CY89</u>	<u>CY90</u>	<u>TOTAL</u>
Heart	\$81,525	\$47,261	\$4,160	\$132,946
Allogeneic Bone Marrow	97,224	215,351	197,240	509,815
Autologous Bone Marrow	---	---	18,162	18,162
Liver	125,722	65,976	110,685	302,383
Pancreas alone	14,953	18,467	4,354	37,774
Kidney and Pancreas/Kidney	110,499	129,746	145,264	385,509
TOTAL	<u>\$430,957</u>	<u>\$476,838</u>	<u>\$476,719</u>	<u>\$1,384,516</u>

**MA Transplant Denials:**

Since enactment of the 1989 legislation that limited MA transplant coverage to Medicare-covered procedures, DHS has specifically denied coverage of two transplants. Both denials were of autologous bone marrow transplants for patients with cancer. Transplant coverage for these conditions was denied consistent with the Medicare exclusion of autologous bone marrow transplants for solid tumors, other than neuroblastoma (Appendix D).

Both patients appealed the MA denials. In one case, the appeal was dismissed because the hospital agreed to provide the transplant gratis. In the second case, although the appeal referee upheld the DHS denial, DHS entered into a stipulated agreement to pay for the transplant after the case was appealed to district court. The patient's counsel cited precedence established in the U.S. Court of Appeals for the Eighth Circuit regarding state Medicaid agency use of Medicare criteria to deny transplants. In *Meusberger v. Palmer*, the Eighth Circuit Court ordered the Director of the Iowa Department of Human Services to pay for the plaintiff's pancreas transplant. The court held that Iowa had arbitrarily excluded coverage of pancreas transplants because Medicare considered them to be experimental, where in fact, they were not. The Minnesota DHS decided that, pending recommendations from the Advisory Committee on Transplants, further legal action would not be pursued.

### III.

#### OTHER STATE MEDICAID COVERAGE

All states must meet basic requirements in their Medicaid State Plan for transplant program approval from the Health Care Financing Administration (HCFA). HCFA does not require that state MA programs provide organ transplants, however, and leaves to the states decisions on which procedures, if any, to cover. For a state to receive Federal Financial Participation (FFP) for transplants, the state must operate under an approved State Plan that specifies how transplant coverage will be administered (Appendix E -- MN State Plan, Standards for Coverage of Organ Transplants). States must meet the following basic standards for federal approval:

- \* Similarly situated individuals. States must apply established coverage criteria equally to all eligible recipients. For example, HCFA ruled that the state of Oregon violated federal law because it used a finite sum of money for all transplants and denied transplant coverage when the budgeted amount was depleted. This denied access to similarly situated individuals.
- \* Facility and Practitioner Restrictions. Restrictions on access to facilities and practitioners must be consistent with high quality standards.
- \* Sufficiency of Services. Any limits applied to transplants, such as dollars or days, must be reasonable and assure quality care.

States also may cover transplants only for the categorically needy, and choose not to cover the medically needy. Coverage of the categorically needy includes coverage for recipients of Aid to Families with Dependent Children (AFDC), Minnesota Supplemental Assistance (MSA), and certain other groups such as pregnant women. However, eliminating coverage for the medically needy excludes those who have sufficient medical expenses to reduce their income to MA income limits. Minnesota MA transplant coverage includes both categorically and medically needy eligibility groups.

A 1990 survey conducted by the Intergovernmental Health Policy Project (IHPP) in Washington D.C. found that among the 50 state MA programs and the District of Columbia, all but one (Wyoming) cover at least one type of transplant (Appendix F -- Medicaid Coverage of Organ Transplant Procedures). Forty-nine states and the District of Columbia cover kidney transplants, 48 cover liver, 46 bone marrow, 40 heart, 23 heart-lung, 15 lung, and 12 pancreas.<sup>1</sup>

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<sup>1</sup>Laudicina, Susan S., "A Guide to State Organ Transplant Activities in the United States" (December 1990): 4-5.

Many variations in administration of transplant programs are found among states, however. Although age rarely is a factor, states vary on whether they cover transplants for the medically needy population (about one third do not). Criteria for coverage of transplants also differs among states. All states require prior authorization for some transplant procedures.

## **IV.**

### **OTHER TRANSPLANT FUNDING**

Private insurance plans, both indemnity and health maintenance organizations, cover transplant procedures, but differ in procedures covered and benefit amounts. Blue Cross and Blue Shield of Minnesota requires prior authorization for bone marrow, heart, heart-lung, liver, pancreas, and lung transplants. The state insurance mandates do not address requirements for insurers in this area.

The Minnesota Comprehensive Health Association (MCHA) is a state high-risk health insurance plan for Minnesota residents unable to obtain standard health coverage. Twenty-four states have a similar type of plan. Minnesota's plan contains a six-month pre-existing condition clause, and requires prior authorization for coverage of liver, heart, heart-lung, lung, pancreas, kidney, and bone marrow transplants. Candidates for a transplant are reviewed by the plan review committee. The MCHA plan pays for covered services only after all other insurance benefits, including Medicare, are exhausted, with the exception of Medical Assistance. MA recipients may enroll in MCHA.

The 1990 IHPP transplant survey found that six state governments conduct formal public education programs on organ transplantation and the importance of organ donation. These programs usually are administered by the state health department. A Minnesota statute requires medical providers to inform potential organ donors and their families about organ donation, but at this time, Minnesota does not have a formal public education initiative.

## V.

### DISCUSSION AND RECOMMENDATIONS

The following sections encompass recommendations of the Advisory Committee on Organ and Tissue Transplants for coverage of transplant procedures and approval of facilities that perform transplants. The Committee recommends that efforts should be made to ensure that decisions on health care benefits, including transplants coverage, are made on the best, current scientific knowledge available rather than the idiosyncracies of any given situation. Consideration should be given to recommendations on uniform coverage in the report of the Health Care Access Commission.

Another general recommendation of the Committee is that the issue of possible disincentives to work created by lack of coverage of post-transplant care costs be reviewed. The Committee is concerned that individuals may be discouraged from returning to work after a transplant because MA benefits would be lost. If a transplant recipient does not obtain a job with benefits that cover costs of follow-up medical care, especially drugs such as immunosuppressive therapy, the costs of such care may keep the individual from returning to work and other activities. The Committee recommends that alternative funding of post-transplant costs, particularly costs of drugs, be explored.

#### A. Limitations of Medicare Criteria

The Medicare beneficiary population is primarily made up of persons over the age of 65, with a significant disabled population. An extremely small number of children receive Medicare benefits; only children under the age of 21 whose parents are retired or disabled and receive Medicare themselves. By contrast, the Minnesota MA program is comprised primarily of younger individuals. MA covers a disproportionate number of children, particularly those with disabilities. MA also is made up of many individuals over the age of 65 who have lower income or are institutionalized, and disabled persons. However, the general MA population differs significantly from the Medicare population.

Even though a person who undergoes a transplant will qualify for Social Security disability, many organ and tissue transplant candidates under the age of 65 do not receive Medicare benefits prior to the date of transplant surgery because of a 24 to 36-month waiting period from the onset of disability. Kidney transplants are an exception because the waiting period after determination of disability is only 12 months, so most MA recipients who undergo kidney transplantation also are eligible for Medicare at the time of the transplant. Aside from kidney transplants, the disability waiting period reduces the number of adults under age 65 covered for transplants by Medicare, and although persons over the age of 65 can be candidates for

transplants, longevity and health status also lower the number of Medicare transplant recipients. The relatively low need of transplants among the Medicare population may act to reduce public pressure on Medicare to add new transplant procedures and to result in less responsiveness by Medicare to adding procedures even when the procedures are shown to be efficacious.

These differences in demographics between MA and Medicare groups present a drawback when Medicare transplant coverage criteria are used to determine MA coverage. Medicare services are established to provide for the needs of a predominantly older population, and for the chronically disabled. The Medicare program does not focus on the needs of younger individuals, especially children, nor does it typically serve the nondisabled population under 65 who develop the need for a transplant.

A second limitation of Medicare criteria for MA transplant coverage is the response time of Medicare, governed by the Health Care Financing Administration (HCFA) of the federal Department of Health and Human Services (HHS). Because HCFA makes coverage decisions on a national scale and the fiscal impact of adding services is greater, the internal and public processes HCFA uses to review procedures for possible addition result in a lag in decision-making compared to advances in the transplant field. For instance, on March 8, 1990, HCFA announced its intent to cover adult liver transplants. At this time, HCFA still is reviewing public comments. A full year has elapsed since HCFA publicly recognized that adult liver transplants are efficacious, but coverage has yet to be established.

Finally, state MA programs that adopt Medicare transplant coverage are encountering problems in the courts. The Eighth Circuit Court decision discussed on page 11 of this report represents a court case where exclusive use of Medicare criteria by the state MA agency was viewed as arbitrary in light of evidence that showed the transplant procedure to be medically effective. Courts are making decisions based on medical necessity when encountering appeals of transplant denials from both the private and public sectors.<sup>2</sup> This infers that MA transplant coverage criteria should be as up-to-date as possible and based on current scientific knowledge.

In summary, applicability of Medicare transplant coverage standards to Minnesota MA is limited by three major factors:

1. Medicare and MA populations differ demographically and vary in requirements for health care.
2. Medicare coverage changes occur at the federal level and are slow to respond to advances in the transplant field.

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<sup>2</sup>McGivney, Wlm. T., Brown, Elizabeth, "Coverage, Technology Assessment, and the Courts", *AMA Tech* (Feb. 1991): 1-8.



3. Recent court cases have struck down state MA programs for exclusive use of Medicare transplant coverage standards.

#### **B. Guidelines for Transplant Approval**

The legislative mandate to the Advisory Committee on Transplants is to develop guidelines for addition of transplant procedures currently not covered by Minnesota Medical Assistance, and to recommend transplant procedures and facilities to add to existing coverage. The Committee considered several criteria when it discussed possible addition of transplant procedures.

Although the Committee discussed and considered all seven areas listed below, the decision to recommend a transplant for coverage was based primarily on available, current scientific information on the effectiveness of the transplant procedure. The Committee also did not emphasize the consideration of costs of transplant procedures or sources of funding for them, since this would go beyond the scope of the Committee's mandate. However, the Committee recognizes that the issue of health care costs is very important and that a substantial portion of the State's population are uninsured or underinsured. The Advisory Committee on Transplants recommends that consideration be given to the breadth of coverage available to all Minnesota residents as well as the depth of services available to some.

The Committee considered the following guidelines when recommending a transplant for coverage by MA:

1. **Life-expectancy after surgery.** 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. The Committee did not recommend additions to transplant coverage if the transplant procedure had less than a 50 percent overall survival rate for the first year following surgery.
2. **Quality of life.** There should be a higher probability that a satisfactory quality of life can be achieved with a transplant than without.
3. **Status of patient.** Individual patient factors such as health status, alcohol consumption and other life-style patterns 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. Patient evaluation and monitoring for the appropriateness of transplant surgery is best conducted by the transplant facility. Therefore, the Committee recommends that MA-covered transplants are performed at facilities with standards of excellence (see part V.D.)

4. **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 expensive than alternative treatments or less expensive depending on the individual patient and transplant procedure. For some transplants, there are no viable alternative treatments, and so the patient dies. For others, 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. **Comparability to other plans.** The Committee compared transplant coverage by private insurance, Blue Cross and Blue Shield, MCHA, and other state Medicaid programs. Private and public insurance and state MA programs coverage all vary considerably.
6. **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. Often, utilization of transplants is low due to unavailability of donor organs or a small number of patients who are appropriate candidates.
7. **Experimental nature of procedure.** Transplants are performed as treatment and an alternative to other treatments in which the outcome often is unsatisfactory, and rarely are performed on an experimental basis. The term "experimental" means that the procedure is performed purely for research purposes. The Committee does not support MA funding of transplants performed on an experimental basis. The Committee also discussed the terms "experimental" and "investigational" and will continue work on definitions of the terms and differences between them.

#### **C. Recommendations on Transplant Procedures to Cover**

The Advisory Committee on Transplants agrees that transplant procedures currently covered by Medicare and Minnesota Medical Assistance are effective and medically indicated. The following procedures currently are covered:

##### **Heart**

Allogeneic Bone Marrow for the following conditions only:

- leukemia or aplastic anemia
- severe combined immunodeficiency disease (SCID)
- Wiskott-Aldrich syndrome

Autologous Bone Marrow for the following only:

- acute leukemia in remission with high probability of relapse and no HLA-matched donor
- resistant non-Hodgkin's lymphomas or those presenting with poor prognostic features following an initial response
- recurrent or refractory neuroblastoma
- advanced Hodgkin's disease who failed conventional therapy and have no HLA-matched donor

Liver for children under age of 21

Kidney

**Additional Transplants Recommended:**

The Committee on Transplants recommends that the following transplant procedures be considered for addition to services covered by the Minnesota Medical Assistance program. Given the short time-frame of preparing this report, further review will be undertaken in several areas before the next Annual Report is submitted.

Recommended for coverage for limited indications:

<u>Transplant</u>	<u>Criteria</u>	<u>Facilities</u>
HEART-LUNG	Primary pulmonary hypertension	*Abbott-Northwestern *Mayo Clinic *U of M Hospital
LIVER	Nonmalignant liver and biliary tract disease	*Mayo Clinic *U of M Hospital
PANCREAS	Uremic diabetic recipients of kidney transplants	*Mayo Clinic *U of M Hospital
ALLOGENEIC BONE MARROW	Stage III or IV Hodgkin disease	MN hospitals with bone marrow transplant programs approved by Medicare

Heart-lung

Heart-lung transplants are indicated for persons with primary pulmonary hypertension. Abbott-Northwestern Hospital, Mayo Clinic, and University of Minnesota Hospital and Clinic are facilities recommended to perform heart-lung transplants. These facilities have well-established programs and cooperate on donor availability and patient priorities.

The Committee will review indications for heart-lung transplants and develop more specific facility criteria for the next Annual Report.

#### Liver

The Committee recommends coverage of liver transplants for nonmalignant liver and biliary tract disease in adults (already covered in children). Mayo Clinic and the University of Minnesota Hospital and Clinic are recommended facilities. Specific facility selection criteria will be developed for the next Annual Report.

#### Pancreas

Pancreas transplants are indicated for uremic diabetic recipients of kidney transplants (simultaneous with kidney or occurring after a kidney transplant). Mayo Clinic and University of Minnesota Hospital and Clinic are recommended facilities.

Further study is needed on the pancreas transplant that does not occur with a kidney transplant. The Committee also will develop more specific facility criteria next year.

#### Allogeneic bone marrow for Hodgkin disease

Allogeneic bone marrow transplants should be covered for stage III or IV Hodgkin 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 recipient. Autologous bone marrow transplants for Hodgkin disease currently are covered. Autologous transplants utilize the patient's bone marrow. Minnesota facilities that currently have bone marrow transplant programs and are approved by Medicare may provide these transplants.

#### **Deferred for Future:**

Additional indications for allogeneic and autologous bone marrow transplants require further review by the Committee. The Committee has requested input from an oncologist on this rapidly growing area, and also will refine transplant facility criteria.

A recommendation for coverage of lung transplants also was deferred for more study and discussion prior to submission of the next committee report.

#### **D. Recommendations on Transplant Facilities**

Transplants must be performed by facilities and staff that meet standards of excellence in the field. The Advisory Committee on Transplants recommends that transplant facilities meet minimal criteria for approval to perform transplant procedures covered by Minnesota MA. This will guarantee that the most appropriate selection of patients and use of transplant funds occur.

All transplant facilities should be evaluated according to the following criteria:

- \* Patient selection criteria. Includes written protocols, health and life-style assessments, and monitoring.
- \* Patient management. Plans for patient management and evaluation, pre and post-transplant care, and follow-up.
- \* Facility commitment and planning. Includes presence of graduate medical education, written plans and protocols, organ procurement, sufficient transplant volume.
- \* Experience and survival rates. Including surgeon experience, patient survival after first year, number of procedures performed.
- \* Laboratory services. Availability in-house or readily accessible.

MA recipients also should be assured of adequate access to all covered transplant procedures. It is the position of the Committee that there are an adequate number of high-quality transplant facilities within the state of Minnesota, and that MA recipients should rarely, if ever, need to go outside the State for a transplant.

The following transplant facilities currently are approved by MA because they meet Medicare approval criteria:

Heart -- University of Minnesota Hospital and Clinic  
Abbott Northwestern

Bone marrow, kidney, liver -- any hospital meeting Medicare approval (approved by the Joint Accreditation of Health Organizations); liver transplants (child) require prior authorization.

The Committee recommended transplant facilities that should be approved to perform the recommended additional transplants in part V.C. The Committee's efforts over the next year will focus on refinement of facility selection criteria and recommendations of specific facilities that meet established standards.

ADVISORY COMMITTEE ON ORGAN AND TISSUE TRANSPLANTS

\*Arthur Caplan, Ph.D.

Director, Center for Biomedical Ethics  
University of Minnesota

Craig Christianson, M.D.

Medical Director  
UCare Minnesota

Barbara Elick, BSN

Chief Transplant Coordinator  
University of Minnesota Hospital and Clinic

Marty Halvorson, LMFT

Director of Pastoral Care and Clinical Pastoral Education  
Methodist Hospital, Minneapolis

Ruud Krom, M.D., Ph.D.

Consultant in Surgery, Mayo Clinic  
Director, Liver Transplant Program  
Mayo Clinic

Grace Nelson

Chair, Public Policy Committee  
Minnesota Senior Federation

Del Ohrt, M.D.

Vice President and Medical Director  
Blue Cross & Blue Shield of MN

Ralph Peterson

Transplant Patient Support Group

Lois Quam, Health Economist

Director of Research, United Health Care  
Chair, Health Care Access Commission

David Sutherland, M.D., Ph.D.

Professor, General & Transplant Program  
Director, Pancreas Transplant Program  
University of Minnesota Hospital and Clinic

Pamela Wheelock

Executive Budget Officer, Budget Division  
Minnesota Department of Finance

Pamela Zembal, MSN

Manager of Quality Compliance, HMO Section  
Minnesota Department of Health

\*Agreed to participate, but was not available for meetings and did not provide an alternate.

DEPARTMENT OF HUMAN SERVICES STAFF PARTICIPANTS

Mary Kennedy  
Director, Health Care Management Division

Patricia MacTaggart  
Asst. Director, Health Care Management Division

Kathleen Cota  
Supervisor, Health Services Policy Section

Christine Dobbe  
Program Consultant, Health Care Management Division

1 part 9505.0315, subpart 1, item F, provided to nonambulatory  
2 persons who do not need a wheelchair lift van or  
3 stretcher-equipped vehicle, may be reimbursed at a lower rate  
4 than special transportation provided to persons who need a  
5 wheelchair lift van or stretcher-equipped vehicle.

6       Sec. 57. Minnesota Statutes 1988, section 256B.0625, is  
7 amended by adding a subdivision to read:

8       Subd. 26. [SPECIAL EDUCATION SERVICES.] Medical assistance  
9 covers medical services identified in a recipient's  
10 individualized education plan and covered under the medical  
11 assistance state plan. The services may be provided by a  
12 Minnesota school district that is enrolled as a medical  
13 assistance provider or its subcontractor, and only if the  
14 services meet all the requirements otherwise applicable if the  
15 service had been provided by a provider other than a school  
16 district, in the following areas: medical necessity,  
17 physician's orders, documentation, personnel qualifications, and  
18 prior authorization requirements. Medical assistance coverage  
19 for medically necessary services provided under other  
20 subdivisions in this section may not be denied solely on the  
21 basis that the same or similar services are covered under this  
22 subdivision.

23       Sec. 58. Minnesota Statutes 1988, section 256B.0625, is  
24 amended by adding a subdivision to read:

25       Subd. 27. [ORGAN AND TISSUE TRANSPLANTS.] Medical  
26 assistance coverage for organ and tissue transplant procedures  
27 is limited to those procedures covered by the Medicare program,  
28 provided those procedures comply with all applicable laws,  
29 rules, and regulations governing (1) coverage by the Medicare  
30 program, (2) federal financial participation by the Medicaid  
31 program, and (3) coverage by the Minnesota medical assistance  
32 program.

33       Sec. 59. [256B.0642] [FEDERAL FINANCIAL PARTICIPATION.]

34       The commissioner may, in the aggregate, prospectively  
35 reduce payment rates for medical assistance providers receiving  
36 federal funds to avoid reduced federal financial participation



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1 determines that the recipient's needs exceed the amount approved  
2 for the appropriate level of care as determined in paragraph  
3 (c), the home care provider may refer the case to the department  
4 for a level III determination. Based on the client needs,  
5 physician orders, diagnosis, condition, and plan of care, the  
6 department may give prior approval for care that exceeds level  
7 II described in paragraph (c). The amount approved shall not  
8 exceed the maximum cost for the appropriate level of care as  
9 determined in paragraph (c), clause (1), which will be the  
10 maximum ICF/MR rate for intermediate care facilities for persons  
11 with mental retardation or related conditions, or the maximum  
12 nursing home case mix payment, or the highest hospital cost for  
13 the state.

14 The department has 30 days from receipt of the request to  
15 complete the level III determination, during which time it may  
16 approve the higher level while reviewing the case.

17 Case reviews or approval of home care services in levels II  
18 and III may result in assignment of a case manager.

19 (e) [PRIOR APPROVAL REQUIRED IN FOSTER CARE SETTING.] Any  
20 home care service provided in an adult or child foster care  
21 setting must receive prior approval by the department.

22 Subd. 6. [RECOVERY OF EXCESSIVE PAYMENTS.] The  
23 commissioner shall seek monetary recovery from providers of  
24 payments made for services which exceed the limits established  
25 in this section.

26 Sec. 52. [256B.0629] [ADVISORY COMMITTEE ON ORGAN AND  
27 TISSUE TRANSPLANTS.]

28 Subdivision 1. [CREATION AND MEMBERSHIP.] By July 1, 1990,  
29 the commissioner shall appoint and convene a 12 member advisory  
30 committee to provide advice and recommendations to the  
31 commissioner concerning the eligibility of organ and tissue  
32 transplant procedures for reimbursement by medical assistance  
33 and general assistance medical care. The committee must include  
34 representatives of the transplant provider community, hospitals,  
35 patient recipient groups or organizations, the department of  
36 human services, the department of finance, and the department of

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1 health, at least one representative of a health plan regulated  
2 under chapter 62A, 62C, or 62D, and persons with expertise in  
3 ethics, law, and economics. The terms and removal of members  
4 shall be governed by section 15.059. Members shall not receive  
5 per diems but shall be compensated for expenses. The advisory  
6 committee does not expire as provided in section 15.059,  
7 subdivision 6.

8 Subd. 2. [FUNCTION AND OBJECTIVES.] The advisory committee  
9 shall meet at least twice a year. The committee's activities  
10 include, but are not limited to:

11 (1) collection of information on the efficacy and  
12 experience of various forms of transplantation not approved by  
13 medicare;

14 (2) collection of information from Minnesota transplant  
15 providers on available services, success rates, and the current  
16 status of transplant activity in the state;

17 (3) development of guidelines for determining when and  
18 under what conditions, organ and tissue transplants not approved  
19 by medicare should be eligible for reimbursement by medical  
20 assistance and general assistance medical care;

21 (4) providing recommendations, at least annually, to the  
22 commissioner on: (i) organ and tissue transplant procedures,  
23 beyond those approved by medicare, that should also be eligible  
24 for reimbursement under medical assistance and general  
25 assistance medical care; and (ii) which transplant centers  
26 should be eligible for reimbursement from medical assistance and  
27 general assistance medical care.

28 Subd. 3. [ANNUAL REPORT.] The advisory committee shall  
29 present an annual report to the commissioner and the chairs of  
30 the health and human services appropriations divisions of the  
31 house appropriations committee and the senate finance committee  
32 by January 1 of each year on the findings and recommendations of  
33 the committee.

34 Subd. 4. [RESPONSIBILITIES OF THE COMMISSIONER.] The  
35 commissioner shall periodically:

36 (1) Recommend to the legislature criteria governing the

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1 eligibility of organ and tissue transplant procedures for  
2 reimbursement from medical assistance and general assistance  
3 medical care. Procedures approved by medicare are automatically  
4 eligible for medical assistance and general assistance medical  
5 care reimbursement. Additional procedures are eligible for  
6 reimbursement only upon approval by the legislature. Only  
7 procedures recommended by the task force and the commissioner  
8 may be considered by the legislature.

9 (2) Recommend to the legislature criteria for certifying  
10 transplant centers within and outside of Minnesota where  
11 Minnesotans receiving medical assistance and general assistance  
12 medical care may obtain transplants. Additional centers may be  
13 certified only upon approval of the legislature. Only centers  
14 recommended by the task force and the commissioner may be  
15 considered by the legislature.

16 Sec. 53. [256B.0643] [VENDOR REQUEST FOR CONTESTED CASE  
17 PROCEEDING.]

18 Unless otherwise provided by law, a vendor of medical care,  
19 as defined in section 256B.02, subdivision 7, must use this  
20 procedure to request a contested case, as defined in section  
21 14.02, subdivision 3. A request for a contested case must be  
22 filed with the commissioner in writing within 60 days after the  
23 date the notification of an action or determination was mailed.  
24 The appeal request must specify:

25 (1) each disputed action or item;

26 (2) the reason for the dispute;

27 (3) an estimate of the dollar amount involved, if any, for  
28 each disputed item;

29 (4) the computation or other disposition that the appealing  
30 party believes is correct;

31 (5) the authority in statute or rule upon which the  
32 appealing party relies for each disputed item;

33 (6) the name and address of the person or firm with whom  
34 contacts may be made regarding the appeal; and

35 (7) other information required by the commissioner.

36 Nothing in this section shall be construed to create a right to

Biofeedback therapy is covered under Medicare only when it is reasonable and necessary for the individual patient for muscle re-education of specific muscle groups or for treating pathological muscle abnormalities of spasticity, incapacitating muscle spasm, or weakness, and more conventional treatments (heat, cold, massage, exercise, support) have not been successful. This therapy is not covered for treatment of ordinary muscle tension states or for psychosomatic conditions. (See HCFA-Pub. 14-3, §§2200ff, 2215, and 4161; HCFA-Pub. 13-3, §§3133.3, 3148, and 3149; HCFA-Pub. 10, §§242 and 242.5 for special physical therapy requirements. See also 35-20 and 65-8.)

#### 35-29 OXYGEN TREATMENT OF INNER EAR/CARBON THERAPY

(Effective for services performed on and after August 1, 1978).—NOT COVERED

Oxygen (95 percent) and carbon dioxide (5 percent) inhalation therapy for inner ear disease, such as endolymphatic hydrops and fluctuant hearing loss, cannot be considered reasonable and necessary. The therapeutic benefit deriving from this procedure is highly questionable.

#### 35-30 BLOOD PLATELET TRANSFUSIONS AND BONE MARROW TRANSPLANTATION

##### A. Blood Platelet Transfusions

(Effective for services performed on or after August 1, 1978.)

Blood platelet transplants are safe and effective for the correction of thrombocytopenia and other blood defects. If such treatment is reasonable and necessary for the individual patient, it is covered under Medicare.

##### B. Allogeneic Bone Marrow Transplantation

Allogeneic bone marrow transplantation is a procedure in which a portion of a healthy donor's bone marrow is obtained and prepared for intravenous infusion to restore normal marrow function in recipients having an inherited or acquired marrow deficiency or defect.

THE FOLLOWING USES OF ALLOGENEIC BONE MARROW TRANSPLANTATION ARE COVERED UNDER MEDICARE:

(Effective for services performed on or after August 1, 1978.)

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

(Effective for services performed on or after June 3, 1985.)

2. For the treatment of severe combined immunodeficiency disease (SCID).
3. For the treatment of Wiskott - Aldrich syndrome.

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### C. Autologous Bone Marrow Transplantation

(Effective for services performed on or after 04/28/89.)

Autologous bone marrow transplantation is a technique for restoring bone marrow stem cells using the patient's own previously stored marrow.

1. Covered Conditions.—Autologous bone marrow transplantation (ICD-9-CM code 41.01, CPT-4 code 38240) is considered reasonable and necessary under §1862(a)(1) of the Medicare law for the following conditions and is covered under Medicare for patients with:

- o Acute leukemia in remission (ICD-9-CM code NEC V 10.60) who have a high probability of relapse and who have no HLA - matched donor (codes lymphoid V10.61, monocytic V10.63, myeloid V 10.62, NEC V10.69);

- o Resistant non-Hodgkin's lymphomas (ICD-9-CM codes 202.80 - 202.88) or those presenting with poor prognostic features following an initial response;

- o Recurrent or refractory neuroblastoma (see ICD-9-CM Neoplasm by site, malignant); or

- o Advanced Hodgkin's disease (ICD-9-CM code 201) who have failed conventional therapy and have no HLA-matched donor.

2. Noncovered Conditions.—Insufficient data exist to establish definite conclusions regarding the efficacy of autologous bone marrow transplantation for the following conditions:

- o Acute leukemia in relapse (ICD-9-CM codes 204.0, 205.0, 206.0, and 208.0);

- o Chronic granulocytic leukemia (ICD-9-CM code 205.1); or

- o Solid tumors (other than neuroblastoma) (ICD-9-CM codes 140-199).

In these cases, autologous bone marrow transplantation is not considered reasonable and necessary within the meaning of §1862(a)(1) of the Medicare law and is not covered under Medicare for these conditions.

### 35-31 TREATMENT OF DECUBITUS ULCERS

An accepted procedure for healing decubitus ulcers is to remove dead tissue from the lesions and to keep them clean to promote the growth of new tissue. This may be accomplished by hydrotherapy (whirlpool) treatments. Hydrotherapy (whirlpool) treatment for decubitus ulcers is a covered service under Medicare for patients for whom this form of treatment is reasonable and necessary. Some other methods of treating decubitus ulcers, the safety and effectiveness of which have not been established, are not covered under the Medicare program. Some examples of these types of treatments are: ultraviolet light, low intensity direct current, topical application of oxygen, and topical dressings with Balsam of Peru in castor oil.

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#### STANDARDS FOR COVERAGE OF ORGAN TRANSPLANTS

- o Medical Assistance coverage of organ and tissue transplant procedures is limited to those procedures covered by the Medicare program plus cornea transplants; thereby assuring that services are reasonable in amount, duration, and scope to achieve their purpose.
- o Consistent with Medicare coverage, Medical Assistance transplant coverage includes preoperative evaluation; recipient and donor surgery; follow-up care for the recipient and live donor; and harvesting and procurement of organs and tissues.
- o To receive reimbursement for a heart transplant, the hospital must meet one of the following criteria:
  - o be on the approved list of Medicare heart transplant facilities; or
  - o ensure standards of safety and efficacy and have had a transplant programs in effect for at least two years; or
  - o be a pediatric hospital that has met HCFA approval criteria for performing a heart transplant on a child.

Kidney, bone marrow, and cornea transplants must be performed in a hospital that is participating as a provider of services in the Medicare program and which meets Minnesota Department of Human Services standards of safety and efficacy.

Liver transplants must be performed in a hospital which meets Minnesota Department of Human Services standards of safety and efficacy.

These restrictions on the facilities and practitioners which may provide organ and tissue transplants help to assure that the designated providers render high quality care for which access is assured through local agency health care access plans.

- o Bone marrow transplants, liver transplants, and transplants performed in out-of-state facilities require prior authorization. The prior authorization process is defined in Minnesota Rules, Parts 9505.5000 to 9505.5105, which is contained in Supplement 3 to Attachments 3.1-A and B. This rule was promulgated to assure the appropriate and consistent disposition of prior authorization requests; thereby assuring that similarly situated individuals are treated alike.
- o Transplant procedures which are not covered by Medicare, but for which the prior authorization process was initiated for a Medical Assistance recipient before July 1, 1989, and which would have been covered by Medical Assistance before July 1, 1989, are covered by Medical Assistance.

## 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
DISTRICT OF COLUMBIA	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		

## EXHIBIT 1 (Continued)

## MEDICAID COVERAGE OF SOLID ORGAN TRANSPLANTS

	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		
NORTH CAROLINA	X	X	X	X	X	
NORTH 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		
SOUTH CAROLINA	X		X	X		
SOUTH 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	
WEST VIRGINIA	X		X	X		
WISCONSIN	X	X	X	X	X	X
WYOMING						
TOTALS	40	23	50	48	15	12

Source: IHPP, 1990.