

Rules of **Department of Social Services**

Division 70—Division of Medical Services Chapter 2—General Scope of Medical Service Coverage

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Title 13—DEPARTMENT OF SOCIAL SERVICES

Division 70—Division of Medical Services

Chapter 2—General Scope of Medical Service Coverage

13 CSR 70-2.020 Scope of Medical Services for General Relief Recipients (Rescinded December 30, 2005)

AUTHORITY: section 207.020, RSMo 1986. This rule was previously filed as 13 CSR 40-81.181. Emergency rule filed July 15, 1981, effective Aug. 1, 1981, expired Oct. 10, 1981. Original rule filed July 15, 1981, effective Oct. 11, 1981. Amended: Filed April 17, 1987, effective Sept. 11, 1987. Emergency rescission filed June 7, 2005, effective July 1, 2005, expired Dec. 27, 2005. Rescinded: Filed June 15, 2005, effective Dec. 30, 2005.

13 CSR 70-2.100 Title XIX Procedure of Exception to Medical Care Services Limitations

PURPOSE: This rule establishes the basis, procedure and criteria where the state Medicaid agency may grant an exception to benefit limitations otherwise imposed by the state's Medicaid program.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.

(1) Under the requirements of this rule, the Division of Medical Services (DMS) may approve and authorize payment for the provision to a Medicaid-eligible recipient of an essential medical service or item that would otherwise exceed the benefit limitations of the medical assistance program. An administrative exception may be made on a case-by-case basis to limitations and restrictions. The director of the DMS will have the final authority to approve payment on a request made to the exception process. These deci-

sions will be made with appropriate medical or pharmaceutical advice and consultation.

- (2) Requirements for consideration and provision of a service as an exception to the normal limitations of Medicaid coverage are as follows:
- (A) A physician, resident, intern, extern, nurse clinician, nurse practitioner or registered nurse (RN) acting on the behalf of the physician must certify that medical treatment or items of service which are covered under the Medicaid Program and which, under accepted standards of medical practice, are indicated as appropriate to the treatment of the illness or condition, have been used and found to be medically ineffective in the treatment of the recipient for whom the exception is being requested or inappropriate for that specific recipient;
- (B) All third-party resource benefits must be exhausted before the Medicaid program will pay for any treatment or service;
- (C) Any drug requested has been approved by the Food and Drug Administration (FDA) and is being prescribed for an FDA-approved indication and route of administration or medical literature must exist justifying the effectiveness of the drug or that specific diagnosis or for that specific route of administration:
- (D) Any medical, surgical or diagnostic service requested which is provided by a physician must be listed in the most recent publication of the *Physicians' Current Procedural Terminology*, Fourth Edition (CPT-4);
- (E) Any individual for whom an exception request is made must be eligible for Medicaid on the date(s) the item or services are provided or in the case of retroactive eligibility approval can be granted if requested;
- (F) The provider of the service must be an enrolled provider in the Medicaid program on the date(s) the item or services are provided;
- (G) The item or services for which an exception is requested must be of a type and nature which falls within the broad scope of a medical discipline included in the Medicaid program and which does not represent a departure from the accepted standards and precepts of good medical practice;
- (H) Requests must be made and approval granted before the requested item or services are provided, or not more than one (1) state working day following the provision of the service. Retroactive approval of coverage may be granted in cases in which the recipient's eligibility for Medicaid is established;
- (I) All requests for exception consideration must be initiated by the attending physician the resident, intern, extern, nurse clinician, nurse practitioner or RN acting in the physi-

cian's behalf for an eligible recipient and must be submitted as prescribed in policy of the DMS;

- (J) Requests for exception consideration, by whatever means received, must support and demonstrate that one (1) or more of the following conditions are met:
- 1. The item or service is required to sustain the recipient's life;
- 2. The item or service would substantially improve the quality of life for a terminally ill patient;
- 3. The item or service is necessary as a replacement due to an act occasioned by violence of nature without human interference, such as a tornado or flood; or
- 4. The item or service is necessary to prevent a higher level of care;
- (K) All exception requests must represent cost-effective utilization of Medicaid funds. When an exception item or service is presented as an alternative, lesser level-of-care than the level otherwise necessary, the exception must be less program costly; and
- (L) Reimbursement of services and items approved under this exception procedure shall be made in accordance with the Medicaid-established fee schedules or rates for the same or comparable services. For those services for which no Medicaid-established fee schedule or rate is applicable, reimbursement will be determined by the state agency considering costs and charges.
- (3) Consideration under this rule shall not be applicable to requests for services under the following circumstances such as, but not limited to:
- (A) Requests for General Relief recipients for noncovered services or program areas;
- (B) Services that would be provided by individuals whose specialty is not covered by the Medicaid program, such as chiropractic services;
 - (C) Orthodontics;
 - (D) Inpatient hospital services;
 - (E) Air transportation;
- (F) Alternative services such as personal care, adult day health care, homemaker/chore, hospice and respite care, regardless of authorization by the Division of Aging;
- (G) Psychological testing or counseling provided by professionals other than psychiatrists:
- (H) Waiver of Medicaid program requirements for documentation, applicable to services requiring a second surgical opinion, voluntary sterilization, hysterectomies or legal abortions;
- (I) Failure to obtain prior authorization as required for a service otherwise covered by Medicaid;



- (J) Delivery or placement of custom-made items following the recipient's death or loss of eligibility for the service;
- (K) Previous denial by the Medicaid state agency of a request for exception consideration where the current request fails to present information of significance in overcoming the deficiency upon which the original request was denied:
- (L) Requests for additional reimbursement for items or services otherwise covered by the Medicaid program;
 - (M) Over-the-counter drugs;
- (N) Providing additional covered drugs when recipient has used his/her five (5) prescriptions per month;
- (O) Qualified Medical Benefits services (QMB);
- (P) Medicaid waiver services such as Children's Waiver, Acquired Immunodeficiency Syndrome (AIDS) Waiver, Community Psychiatric Rehabilitation Waiver or Mentally Retarded Developmental Disabled Waiver; and
 - (Q) Transplants.

AUTHORITY: sections 207.020, 208.153 and 208.201, RSMo 2000.* This rule was previously filed as 13 CSR 40-81.195. Original rule filed May 15, 1987, effective Oct. 11, 1987. Amended: Filed June 4, 1990, effective Dec. 31, 1990. Amended: Filed Oct. 2, 2006, effective April 30, 2007.

*Original authority: 207.020, RSMo 1945, amended 1961, 1965, 1977, 1981, 1982, 1986, 1993; 208.153, RSMo 1967, amended 1967, 1973, 1989, 1990, 1991; and 208.201, RSMo 1987.

13 CSR 70-2.200 Medicaid Program Benefits for Human Organ and Bone Marrow Transplants and Related Medical Services

PURPOSE: This rule establishes, via regulation, the Department of Social Services'/Division of Medical Services' guidelines regarding Medicaid coverage and reimbursement for human organ or bone marrow transplants and related medical services. These policies will be administered by the Division of Medical Services with the assistance and guidance of its Transplant Advisory Committee.

(1) Administration. Through its Medicaid program, the Department of Social Services (DSS)/Division of Medical Services (DMS) will provide limited coverage and reimbursement for the transplantation of human organs or bone marrow and the related medical services, including, but not necessarily limited to, treatment and necessary pre-transplant

- and post-operative care for the specific procedures defined here and as further defined by the DSS/DMS and included in the provider program manuals.
- (A) The recipient must be Medicaid-eligible on each date on which services are rendered
- (B) Medicaid shall be the payor of last resort and all other appropriate funding sources must be exhausted prior to obtaining Medicaid reimbursement.
- (2) Conditions and Limitations.
- (A) The procedures of transplantation and the related medical services must be prior authorized by DSS/DMS.
- (B) Medicaid benefits may be provided for transplantation of the following:
 - 1. Bone marrow;
 - 2. Heart:
 - 3. Kidney;
 - 4. Liver; and
- 5. Lung (effective for dates of service October 1, 1991 and after that date.)
- (C) Transplants which include multiple organs, at least one (1) of which is covered under subsection (2)(B), may be covered at the recommendation of the Transplant Advisory Committee.
- (D) Each request for coverage will be handled on a case-by-case basis. A separate Prior Authorization Request must be submitted for each individual recipient and transplant.
- (E) In order to be considered for approval, each proposed transplant case must meet all of the requirements of procedures and protocols specific to the service as defined by DSS/DMS. These procedures and protocols will be developed with input by the DMS' Transplant Advisory Committee.
- (F) Approved organ transplants can only be performed in a facility which submits documentation approved by DMS as complying with the following criteria:
- 1. The transplant facility must qualify for membership in the national transplantation network and must provide a copy of a current effective certification from the United Network for Organ Sharing (UNOS) granting approval to perform a specific transplant(s). The certification from UNOS will be considered appropriate verification and documentation for DMS transplant facility approval;
- 2. When the period for initial certification expires, the transplant facility must provide DMS evidence that continued approval from UNOS allowing participation to perform the transplant(s) has been granted;
- 3. Each type of Missouri Medicaid-covered organ transplant will be subject to sepa-

- rate UNOS certification for each type of organ transplant;
- 4. The transplant facility must notify DMS of each new transplant surgeon who becomes a member of the transplant team. The transplant surgeons must be current Missouri Medicaid participating providers;
- 5. The transplant facility must name the organ procurement organization (OPO) presently utilized by the facility. The transplant facility must furnish a copy of the notification from Health Care Financing Administration (HCFA) which designates the facility's OPO as an acceptable organ procurement source;
- 6. The transplant facility must provide DMS with a yearly report of the number of patients receiving transplants at the facility and the average charge for the inpatient transplant stay (by type of the transplant(s) performed) as defined by DMS in the provider program manual;
- 7. Those facilities seeking certification as a Medicaid-approved Kidney Transplant Center must furnish a copy of their current Medicare certification indicating active participation in the Medicare Renal Transplant Program; and
- 8. The facility must submit a copy of its Protocol for Transplantation Cases and Patient Selection Criteria for the type(s) of transplant(s) for which it is requesting transplant facility approval.
- (G) Approved bone marrow transplants can only be performed in a facility which submits documentation approved by DMS as complying with the following bone marrow transplant facility criteria. An autologous only transplant facility must meet criteria items one through twelve (1–12) of the following:
- 1. A physician(s) with expertise in pediatric and/or adult bone marrow transplantation, hematology and oncology;
- Identified nursing unit with protective isolation unit for bone marrow transplantation;
- 3. Blood bank with Pheresis capability and the capability to supply required blood products or association with a qualified blood bank;
- Physicians with expertise in infectious disease, immunology, pathology and pulmonary medicine;
- Capability of providing cardiac/respiratory intensive care and renal dialysis;
- 6. Performance of at least thirteen (13) bone marrow transplants a year or demonstrated an ability to care for prolonged marrow failure by treating twenty-two (22) marrow failure patients per year;



- 7. Capability for marrow cryopreservation and purging techniques or affiliation with a facility which has these capabilities;
- 8. Capability to provide psychosocial support to patients and their families;
- 9. Close affiliation with academically based institutions to insure that all components of comprehensive care for patients undergoing bone marrow transplantation are present in the facility. The mere presence or availability of the components one through eight (1–8) is not adequate. The facility must demonstrate that a coordinated bone marrow transplantation program is in place and directed by a physician trained in an institution with a well established bone marrow transplantation program;
- 10. The capacity and commitment to conduct a systematic evaluation of outcome and cost (refer to paragraph (2)(F)6.);
- 11. Once approved, continuing approval of the facility requires evidence of a record of success and safety with bone marrow transplantation, and that the program continues to meet the previously mentioned criteria;
- 12. The facility must submit a copy of its Protocol for Transplantation Cases and Patient Selection Criteria for the type of bone marrow transplants to be performed at the facility. Once approved as a facility each new type of bone marrow transplant or diagnosis added for treatment by the facility must be documented by submitting the new protocol and patient selection criteria;
- 13. Physicians with expertise in infectious disease, immunology, pathology (of Graft vs. Host Disease) and pulmonary medicine;
- 14. Tissue typing laboratory with capability to perform typing for HLA-A, B, C, D/DR, and MLC;
 - 15. Cytogenetic laboratory; and
- 16. Adequate laboratory facility to assay drug levels including Cyclosporine A.
- (H) All providers of transplantation and related services must sign a Missouri Medicaid Provider Participation Agreement in order to receive reimbursement.
- (I) In the case of a medical emergency, submittal of the required facility documentation may be waived for a period of ninety (90) days. During that period, the facility must submit the appropriate documentation as described in subsections (2)(F) or (2)(G) and (2)(J) and (3)(A)—and they shall be financially at risk regarding state approval for any transplant related services rendered prior to the approval of its application.
- (J) The transplant facility or surgeon must submit medical documentation that verifies that the transplant candidate has met the facility's Patient Selection Criteria documented by

the facility's Protocol for Transplantation Cases.

- (K) All transportation and housing costs incurred in connection with transplant procedures will be treated as noncovered services.
- (L) The transplant procedures and related services outlined previously will be reimbursable when they are performed/provided by a qualified provider who participates in the Missouri Medicaid program. In cases involving procedures that are to be performed outside of Missouri, however, the Transplant Advisory Committee, at its discretion, may require an eligible client's physician to file a statement indicating why the transplant procedure must be performed at an out-of-state facility.
- (M) DSS/DMS will reimburse qualified providers for a presurgery assessment at established Medicaid reimbursement rates.

(3) Procedure.

- (A) The physician or transplant facility must make a written request to DSS/DMS for coverage of the transplant. This request must include, at a minimum, the following information:
 - 1. Diagnosis;
 - 2. Pertinent medical history;
- 3. Alternative treatments performed and results.
 - 4. Recommended transplant procedure;
 - 5. Prognosis:
- 6. Results of a presurgery assessment and copies of medical documentation verifying that the patient has completed the selected facility's Protocol for Transplantation. Cases and meets the Patient Selection Criteria; and
- 7. Name of the selected transplant center. In cases involving out-of-state facilities, a statement from the patient's physician explaining why the transplant procedure must be performed there. (Note: Those statements may be requested at the discretion of the DMS Transplant Advisory Committee).
- (B) The request for transplantation will be reviewed by DMS and the transplant facility advised in writing of the decision. An agreement will be issued on a case-by-case basis for approved transplants.

(4) Reimbursement.

(A) Facility.

1. Reasonable charges will be paid by the Medicaid program up to a maximum cap amount for the type of transplant authorized as listed in subparagraph (4)(A)1.A. The cap will cover the costs associated with the transplant for the patient's hospitalization from the date of the transplant procedure until the date of discharge except as further defined in para-

graph (4)(A)2. These charges will include organ procurement, donor costs or both, inpatient surgery costs and all postsurgical hospital costs as defined in the provider program manual.

A. Type	Maximum	
of Transplant	Cap Amount	
Kidney	\$ 39,000	
Heart	\$100,000	
Bone Marrow	\$100,000	
Liver	\$100,000	
Lung	\$100,000	
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- B. Reimbursement for multiple organ transplants involving a transplant covered in subsection (2)(B), may not exceed the maximum of highest coverage for highest single transplant, that is, heart/kidney = \$100,000 cap.
- 2. Payment for all other transplant-related medical services provided prior to the date of the transplant surgery or subsequent to the date of discharge will be made at established Medicaid reimbursable rates, excluding the period and reimbursement set out in subparagraph (4)(A)1.A. and otherwise subject to the limitations as defined in the appropriate provider program manuals.
- (B) Physician. Payment for the physician's services for the actual transplant surgery will be determined through a medical review by the DMS physician consultant.

AUTHORITY: sections 208.153 and 208.201. RSMo Supp. 1990.* This rule was previously filed as 13 CSR 40-81.035. Emergency rule filed April 2, 1986, effective April 12, 1986, expired Oct. 10, 1986. Original rule filed April 2, 1986 effective June 28, 1986. Rescinded and readopted: FIled Jan. 17, 1990, effective April 26, 1990. Emergency amendment filed July 25, 1991, effective Aug. 5, 1991, expired Dec. 2, 1991. Emergency amendment filed Sept. 27, 1991, effective Oct. 7, 1991, expired Feb. 3, 1992, Amended: Filed Oct. 9, 1991, effective April 9, 1992. Emergency amendment filed Jan. 17, 1992, effective Feb. 4, 1992, expired June 2, 1992.

*Original authority: 208.153, RSMo 1967, amended 1967, 1973, 1989, 1990, 1991 and 208.201, RSMo 1987.