

Division of Medicaid State of Mississippi Provider Policy Manual	New: Revised: X Current:	Date: Date: 07/04/04 08/01/07
Section: Transplants	Section: 28.01	
Subject: Introduction	Pages: 1 Cross Reference:	

Medicaid, as authorized by Title XIX of the Social Security Act, is a federal and state program of medical assistance to qualified individuals. Each state designates a state agency as the single state agency for the administration of Medicaid. State law has designated the Division of Medicaid, Office of the Governor, as the single state agency to administer the Medicaid program in Mississippi.

DOM will pay routine Mississippi Medicaid benefits for all covered, medically necessary, and reasonable charges for solid organ and bone marrow/ peripheral stem cell transplants (~~includes peripheral stem cell~~) that are prior approved. All solid organ ~~er~~ and bone marrow/peripheral stem cell transplants, (~~includes peripheral stem cell~~), with the exception of kidney and cornea transplants, must be prior authorized by DOM-regardless of the age of the beneficiary or the diagnosis. All policies in this section are applicable to solid organ transplants and to all inpatient/outpatient bone marrow/peripheral stem cell transplants. (~~includes peripheral stem cell~~) performed inpatient, and bone marrow transplants (~~includes peripheral stem cell~~) performed outpatient. ~~Pancreas transplants are not covered services, nor are bone marrow or peripheral stem cell transplants for breast cancer.~~ Transplant services not covered by DOM include pancreas transplants and bone marrow/peripheral stem cell transplants for breast cancer.

A transplant provider's participation in the Mississippi Medicaid program is entirely voluntary. However, if a provider does choose to participate in Medicaid, the provider must accept the Medicaid payment as payment in full for those services covered by Medicaid. The provider cannot charge the beneficiary the difference between the usual and customary charge and Medicaid's payment. The provider cannot accept payment from the beneficiary, bill Medicaid, and then refund Medicaid's payment to the beneficiary. Services not covered under the Medicaid program can be billed directly to the Medicaid beneficiary.

The Mississippi Medicaid program purchases needed health care services for beneficiaries as determined under the provision of the Mississippi Medical Assistance Act. DOM is responsible for formulating program policy. DOM staff is directly responsible for the administration of the program. Under the direction of DOM, the fiscal agent is responsible for processing claims, issuing payments to providers, and for notifications regarding billing. Medicaid Policy as it relates to these factors is initiated by DOM.

Division of Medicaid	New:	Date:
State of Mississippi	Revised: X	Date: 08/01/07
Provider Policy Manual	Current:	
Section: Transplants	Section: 28.01	
Subject: Introduction	Pages: 1	
	Cross Reference:	

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DOM will pay routine Mississippi Medicaid benefits for all covered, medically necessary, and reasonable charges for solid organ and bone marrow/peripheral stem cell transplants that are prior approved. All solid organ and bone marrow/peripheral stem cell transplants, with the exception of kidney and cornea transplants, must be prior authorized regardless of the age of the beneficiary or the diagnosis. All policies in this section are applicable to solid organ transplants and to all inpatient/outpatient bone marrow/peripheral stem cell transplants. **Transplant services not covered by DOM include pancreas transplants and bone marrow/peripheral stem cell transplants for breast cancer.**

A transplant provider's participation in the Mississippi Medicaid program is entirely voluntary. However, if a provider does choose to participate in Medicaid, the provider must accept the Medicaid payment as payment in full for those services covered by Medicaid. The provider cannot charge the beneficiary the difference between the usual and customary charge and Medicaid's payment. The provider cannot accept payment from the beneficiary, bill Medicaid, and then refund Medicaid's payment to the beneficiary. Services not covered under the Medicaid program can be billed directly to the Medicaid beneficiary.

The Mississippi Medicaid program purchases needed health care services for beneficiaries as determined under the provision of the Mississippi Medical Assistance Act. DOM is responsible for formulating program policy. DOM staff is directly responsible for the administration of the program. Under the direction of DOM, the fiscal agent is responsible for processing claims, issuing payments to providers, and for notifications regarding billing. Medicaid Policy as it relates to these factors is initiated by DOM.

Division of Medicaid State of Mississippi Provider Policy Manual	New: Revised: X Current:	Date: Date: 07/01/04 08/01/07
Section: Transplants	Section: 28.02 Pages: 2	
Subject: Covered Transplant Procedures	Cross Reference:	

Mississippi Medicaid benefits are provided for the following transplants if the transplant facility obtains prior approval (PA) and satisfies all criteria:

Transplant Procedure	Covered	PA Required
Cornea	Yes	No
Heart	Yes	Yes
Heart/Lung	Yes	Yes
Kidney*	Yes	No
Liver	Yes	Yes
Lung - Single	Yes	Yes
Lung - Bilateral	Yes	Yes
Bone Marrow (BMT) or Peripheral Hematopoietic Stem Cell (PSCT): Autologous, Syngeneic, or Allogeneic	Yes	Yes (<u>Inpatient and Outpatient</u>)
Pancreas	No	No
Small Bowel	Yes	Yes

*A kidney transplant done in conjunction with a pancreas transplant will be reimbursed as a kidney transplant only.

Requests for prior approval should must be sent to the Division of Medicaid's Peer-Review Organization (PRO) Utilization Management/Quality Improvement Organization (UM/QIO). Physicians Providers are urged to should submit their requests as soon as it is determined that the patient beneficiary may be a potential candidate for transplant.

All transplant Transplant benefits are contingent upon all of the following:

- ~~The~~ The beneficiary's continued eligibility for Mississippi Medicaid
- ~~the~~ The beneficiary's application for the transplant being approved by DOM's PRO the UM/QIO
- ~~all~~ All inpatient days being certified by DOM's PRO the UM/QIO
- ~~all~~ All conditions of third party liability procedures being satisfied
- ~~all~~ All providers of services completing requirements for participation in the Mississippi Medicaid program, ~~all claims being completed according to the requirements of the Mississippi Medicaid program~~
- All claims being completed according to the requirements of the Mississippi Medicaid program
- ~~all~~ All charges, both facility and physician, relating to procurement/storage ~~must be being billed by the transplant facility on the UB92 current UB claim form under with the appropriate revenue code(s)~~

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- ~~the~~ The transplant facility providing appropriate medical records, progress or outcome reports as requested by DOM, the PRO UM/QIO or the fiscal agent
 - ~~the~~ The transplant procedure being performed at the requesting transplant facility

All terms of the Mississippi Medicaid program, including timely claims filing requirements, are applicable.

Approval ~~will not be given for~~ Transplant procedures/services subject to denial include, but are not limited to the following:

- ~~transplant~~ Transplant procedures/services for which ~~when~~ when medical necessity has not been proven
- ~~transplant procedures which are still investigative, experimental, or still in clinical trial~~ Transplant procedures/services still in clinical trials and/or investigative or experimental in nature
- ~~transplant~~ Transplant procedures/services performed in a facility not approved by DOM,
- ~~inpatient~~ Inpatient or outpatient admissions for transplant procedures/services on which ~~when~~ when certification or re-certification is not obtained from the PRO UM/QIO ~~not certified/re-certified by the UM/QIO~~
- Outpatient admissions for BMT/PSCT procedures/services not certified/re-certified by the UM/QIO

Division of Medicaid State of Mississippi Provider Policy Manual	New: Revised: X Current:	Date: Date: 06/01/03 08/01/07
Section: Transplants	Section: 28.03 Pages: 3	
Subject: Heart Transplants Transplant Coverage Criteria	Cross Reference:	

Age

Less than 66 years of age

Performance Status

New York Heart Association NYHA (NYHA) Class III or IV on maximal medical therapy

Compatibility

Consistent with the transplanting facility's blood and tissue-type compatibility standards

Infections

Controlled for at least 48 hours prior to transplant

Pulmonary

FEV1 of >1.5 liter
PVR of <3 Wood units (if >3, prior to vasodilators, <3 after)
Pulmonary artery systolic pressure <65-70 mm Hg

Other Organs

Absence of irreversible and severe end organ dysfunction (hepatic, renal, peripheral vascular, or cerebrovascular), refractory hypertension, or uncontrolled malignancy

Psychosocial Evaluation

A psychosocial evaluation has been performed for the adult patient candidate or, if the patient candidate is a child, for the family, with the following results:

- ~~if any psychiatric disorder is found to be present in the patient, that disorder is being treated~~
Candidate's psychiatric disorders, if present, are being treated
- the patient's Candidate's social support system has been evaluated and found to be adequate
- the patient Candidate has no previous history of significant non-compliance to medical treatment

Facility

Approved for heart transplants by the Division of Medicaid:

Other

- All other treatments have been attempted or considered and none will prevent progressive disability and/or death
- The candidate and/or guardian legal representative understands the transplant risks and benefits, gives informed consent, and has the capacity to, ~~and will~~ and is willing to comply with needed care, including immunosuppressive therapy
- The candidate has been considered ~~and approved~~ by the center's transplant review team
- ~~For children from 2–6 years of age: the PRO will ask whether childhood immunizations are up to date.~~

Required serologies:

- ~~HIV~~
- ~~Hepatitis A, B, and C~~
- ~~Cytomegalovirus (CMV)~~
- ~~Varicella~~
- Required serology studies have been completed for HIV, Hepatitis (A, B, and C), Cytomegalovirus (CMV), and Varicella

Ask that the following immunizations be administered:

- ~~Hepatitis A (if serology does not indicate immunity)~~
- ~~Hepatitis B (if serology does not indicate immunity)~~
- ~~Pneumococcal~~
- ~~Influenza (yearly for candidates)~~
- Immunizations have been administered as follows:
 - All immunizations for children age two (2) to six (6) are up-to-date in accordance with the most current recommended childhood immunization schedule developed and endorsed by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP)
 - Hepatitis A (if serology does not indicate immunity)
 - Hepatitis B (if serology does not indicate immunity)

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- Pneumococcal
 - Influenza (annually)

Specific Diagnostic Inclusion Criteria

Specific diagnostic inclusion criteria include Any any of the following conditions that is if expected to limit the patient's candidate's survival rate to less than twelve (12) months:

- Congestive, restrictive, or ischemic cardiomyopathy, or
- Valvular, congenital and other organic heart disease, or
- Recurrent and refractory life-threatening ventricular dysrhythmias, or
- Refractory severe angina pectoris

Exclusion Criteria

Exclusion criteria include the following:

- active Active chemical dependency (drugs or alcohol) within the preceding six (6) months
- active-gastrointestinal Gastrointestinal hemorrhage
- severe Severe and irreversible pulmonary (ex: FEV1 < 1 liter) or other non-cardiac organ dysfunction
- recent Recent or unresolved pulmonary infarction (not embolism)
- inability to comply with post-transplant regimen
- uncorrectable Uncorrectable absence of an essential psychosocial support system
- unmanageable Unmanageable psychiatric disorder felt to significantly compromise compliance with post-transplant the post-transplant regimen
- HIV
- Hepatitis B or Hepatitis C
- malignancy (other than skin) within the past five (5) years
- Systemic malignancy

Facility

Facility is approved for heart transplants by the Division of Medicaid. Refer to Section 28.10, Facility Criteria.

Division of Medicaid State of Mississippi Provider Policy Manual	New: Revised: X Current:	Date: Date: 07/01/04 08/01/07
Section: Transplants	Section: 28.04 Pages: 3	
Subject: Bone Marrow Transplant Coverage Criteria	Cross Reference:	

Age

Less than 56 years of age for allogeneic (<66 if fully matched sibling donor)
Less than 66 years of age for autologous

Performance Status

Karnofsky or Lansky >70 or ECOG <3

Compatibility

Allogeneic HLA-MLC match (1 antigen mismatch accepted)

Infections

Controlled for 48 hours prior to transplant

Cardiac

Left ventricular ejection fraction >40%

Pulmonary

FEV1 of >50% of predicted
Dlco >60% of predicted

Psychosocial Evaluation

A psychosocial evaluation has been performed for the adult patient candidate or, if the patient candidate is a child, for the family, with the following results:

- ~~If any psychiatric disorder is found to be present in the patient, that disorder is being treated~~
Candidate's psychiatric disorders, if present, are being treated
- ~~the patient's~~ Candidate's social support system has been evaluated and found to be adequate
- ~~the patient~~ Candidate has no previous history of significant non-compliance to medical treatment

Facility

Approved for bone marrow or peripheral Hematopoietic stem cell transplants by the Division of Medicaid.

Other

- All other treatments have been attempted or considered and none will prevent progressive disability and/or death
- The candidate and/or guardian legal representative understands the transplant risks and benefits, gives informed consent, and has the capacity to, ~~and will~~ and is willing to comply with needed care, including immunosuppressive therapy
- The candidate has been ~~considered and approved~~ by the center transplant review team
- ~~Inquire about immunization status and HIV status.~~
- The candidate's immunization history and HIV status has been obtained

Specific Diagnostic Inclusion Criteria (Allogeneic BMT or PSC PSCT)

- severe Severe aplastic anemia
- pure Pure erythrocyte aplasia
- myelodysplasia Myelodysplasia
- severe Severe hemoglobinopathy (ex: sickle cell, thalassemia)
- selected Selected immunodeficiency syndrome (ex: SCID, Wiskott-Aldrich, Chediak-Higashi)
- genetic Genetic storage disease (ex: Hurler's, Morquio's)
- primary Primary amyloidosis
- paroxysmal Paroxysmal nocturnal hemoglobinuria
- severe Severe platelet dysplasia
- acute Acute lymphocytic leukemia (in first remission if high risk, at early relapse, or in second remission)
- acute Acute myelogenous leukemia (in same clinical states as listed for acute lymphocytic leukemia)
- chronic Chronic lymphocytic leukemia
- chronic Chronic myelogenous leukemia

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- Hodgkin's lymphoma (failed first line therapy or failed at least one standard chemotherapy regimen)
 - non-Hodgkin's Non-Hodgkin's lymphoma (failed or responsive to first line therapy or high risk during first remission)
 - familial Familial hemophagocytic lymphohistiocytosis (FHL) also known as familial erythrophagocytic
 - Lymphohistiocytosis (FEL)

Specific Diagnostic Inclusion Criteria (Autologous BMT or PSC PSCT)

- acute Acute lymphocytic leukemia (in first remission if high risk, at early relapse, or in second remission)
- acute Acute myelogenous leukemia (in same clinical states as listed for acute lymphocytic leukemia)
- chronic Chronic lymphocytic leukemia
- chronic Chronic myelogenous leukemia
- Hodgkin's lymphoma (for failed first line therapy or if failed at least one standard chemotherapy regimen)
- non-Hodgkin's Non-Hodgkin's lymphoma (either failed or responsive to first line therapy or, if high risk, during first remission)
- ~~neuroblastoma~~ Neuroblastoma
- ~~nephroblastoma~~ Nephroblastoma

Exclusion Criteria

- active Active chemical dependency (drugs or alcohol) within the preceding six (6) months
- HIV
- multiple Multiple myeloma (Note: a single autologous transplant may be considered for a patient beneficiary with newly diagnosed or significantly responsive Durie-Salmon Stage II or III disease)
- breast Breast cancer
- Uncorrectable absence of an essential psychosocial support system
- Unmanageable psychiatric disorder felt to significantly compromise the candidate's compliance with the post-transplant regimen

Facility

Facility is approved for bone marrow or peripheral Hematopoietic stem cell transplants by the Division of Medicaid. Refer to Section 28.10, Facility Criteria.

Division of Medicaid State of Mississippi Provider Policy Manual	New: Revised: X Current:	Date: Date: 06/04/03 08/01/07
Section: Transplants	Section: 28.05 Pages: 3 Cross Reference:	
Subject: Lung Transplant Coverage Criteria		

Age

Single lung – less than 66 years of age

Bilateral lung – less than 61 years of age

Heart/Lung – less than 56 years of age

Performance Status

NYHA Class III or IV with rehabilitation potential

Preserved nutritional state

Compatibility

Consistent with the transplanting facility's blood and tissue-type compatibility standards

Infections

Controlled for at least 48 hours prior to transplant (unless the infection is limited to the lung to be removed)

Other organs Organs

Absence of irreversible and severe end organ dysfunction (hepatic, gastrointestinal, renal, peripheral vascular, or cerebrovascular), or uncontrolled malignancy

Psychosocial Evaluation

A psychosocial evaluation has been performed for the adult patient candidate or, if the patient candidate is a child, for the family, with the following results:

- ~~if any psychiatric disorder is found to be present in the patient, that disorder is being treated~~
- Candidate's psychiatric disorders, if present, are being treated
- the patient's Candidate's social support system has been evaluated and found to be adequate

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- the patient Candidate has no previous history of significant non-compliance to medical treatment

Facility

Approved for lung or heart/lung transplants by the Division of Medicaid.

Other

- All other treatments have been attempted or considered and none will prevent progressive disability and/or death
- The candidate and/or guardian legal representative understands the transplant risks and benefits, gives informed consent, and has the capacity to ~~and will~~ and is willing to comply with needed care, including immunosuppressive therapy
- The candidate has been considered and approved by the center's transplant review team
- ~~For children from 2–6 years of age: the PRO will ask whether childhood immunizations are up to date.~~

Required serologies:

- ~~HIV~~
- ~~Hepatitis A, B, and C~~
- ~~Cytomegalovirus (CMV)~~
- ~~Varicella~~
- Required serology studies have been completed for HIV, Hepatitis (A, B, and C), Cytomegalovirus (CMV), and Varicella

Ask that the following immunizations be administered:

- ~~Hepatitis A (if serology does not indicate immunity)~~
- ~~Hepatitis B (if serology does not indicate immunity)~~
- ~~Pneumococcal~~
- ~~Influenza (yearly for candidates)~~
- Immunizations have been administered as follows:
 - All immunizations for children age two (2) to six (6) are up-to-date in accordance with the most current recommended childhood immunization schedule developed and endorsed by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP)

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- Hepatitis A (if serology does not indicate immunity)
 - Hepatitis B (if serology does not indicate immunity)
 - Pneumococcal
 - Influenza (annually)

Specific Diagnostic Inclusion Criteria

- end-stage End-stage fibrotic lung disease unresponsive to alternative therapy with FVC <65% of predicted.
- end-stage End-stage obstructive lung disease with FVC <25% of predicted.
- end-stage End-stage pulmonary hypertension, either primary or secondary – without significant right heart dysfunction (unless heart-lung transplant planned)
- cystic Cystic fibrosis with FVC <40% and FEV1 <30% of predicted.
- bronchiectasis Bronchiectasis
- bronchepulmonary Bronchopulmonary dysplasia
- obliterative Obliterative bronchiolitis

Exclusion Criteria

- active ~~tobacco, alcohol, or illegal drug~~ dependence Active chemical dependence (drugs or alcohol) within the preceding six (6) months
- steroid Steroid therapy >20mg/day (must be off steroids or weanable from them)
- bone Bone marrow failure of any stem line: RBC, WBC, platelets
- severe Severe osteoporosis
- severe Severe chest wall deformity
- cachexia Cachexia (body weight <70% of ideal for height) or obesity (body weight >120% of ideal for height) in CF patients in candidates with Cystic Fibrosis
- no recent Recent pulmonary embolism or current deep venous thrombosis
- viral Viral hepatitis in CF patient candidates with Cystic Fibrosis
- HIV
- Uncorrectable absence of an essential psychosocial support system

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- Unmanageable psychiatric disorder felt to significantly compromise compliance with the post-transplant regimen

Facility

Facility is approved for lung transplants by the Division of Medicaid. Refer to Section 28.10, Facility Criteria.

Division of Medicaid State of Mississippi Provider Policy Manual	New: Revised: X Current:	Date: Date: 06/01/03 08/01/07
Section: Transplants	Section: 28.06 Pages: 3 Cross Reference:	
Subject: Liver Transplant Coverage Criteria		

Age

Less than 65 years of age

Hepatic Status

Child-Pugh Class B or C (Child-Pugh score 7-15). May be considered for candidacy when estimated survival for next year drops to 95% as scored by modified Mayo-Medel

Child-Pugh Class A patients may become candidates if there has been bleeding from portal hypertension or repeated episodes of spontaneous bacterial peritonitis, refractory ascites, or encephalopathy

Model for End Stage Liver Disease (MELD) score

Pediatric End Stage Liver Disease (PELD) score

Compatibility

Consistent with the transplanting facility's blood and tissue-type compatibility standards

Infections

Controlled for at least 48 hours prior to transplant

Other organs Organs

Absence of severe and irreversible end organ dysfunction (cardiac, pulmonary, renal, peripheral vascular, or cerebrovascular) or uncontrolled extrahepatic malignancy

Psychosocial Evaluation

A psychosocial evaluation has been performed for the adult patient candidate or, if the patient candidate is a child, for the family, with the following results:

- ~~if any psychiatric disorder is found to be present in the patient, that disorder is being treated~~
Candidate's psychiatric disorders, if present, are being treated
- ~~the patient's~~ Candidate's social support system has been evaluated and found to be adequate
- ~~the patient~~ Candidate has no previous history of significant non-compliance to medical treatment

Facility

Approved for liver transplants by the Division of Medicaid.

Other

- All other treatments have been attempted or considered and none will prevent progressive disability and/or death
- The candidate and/or guardian legal representative understands the transplant risks and benefits, gives informed consent, and has the capacity to, and will and is willing to comply with needed care, including immunosuppressive therapy
- The candidate has been considered and approved by the center's transplant review team
- For children from 2 – 6 years of age: the PRO will ask whether childhood immunizations are up to date.

Required serologies:

- ~~HIV~~
- ~~Hepatitis A, B, and C~~
- ~~Cytomegalovirus (CMV)~~
- ~~Varicella~~
- Required serology studies have been completed for HIV, Hepatitis (A, B, and C), Cytomegalovirus (CMV), and Varicella

Ask that the following immunizations be administered:

- ~~Hepatitis A (if serology does not indicate immunity)~~
- ~~Hepatitis B (if serology does not indicate immunity)~~
- ~~Pneumococcal~~
- ~~Influenza (yearly for candidates)~~
- Immunizations have been administered as follows:
 - All immunizations for children age two (2) to six (6) are up-to-date in accordance with the most current recommended childhood immunization schedule developed and endorsed by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP)
 - Hepatitis A (if serology does not indicate immunity)
 - Hepatitis B (if serology does not indicate immunity)

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- Pneumococcal
 - Influenza (annually)

Specific Diagnostic Inclusion Criteria

- Chronic progressive liver disease, not otherwise correctable, including cirrhosis due to: alcoholism (if abstinent at least the prior six (6) months), chronic hepatitis C, primary or secondary biliary disease, sclerosing cholangitis, inborn error of metabolism, or other causes
- Non-cirrhotic liver failure due to: biliary atresia, fulminant liver failure, submassive hepatic necrosis, hepatoblastoma, Budd-Chiari syndrome (obstruction of the hepatic veins) – if associated with a treatable disorder
- Hepatocellular carcinoma, in conjunction with chemotherapy, if there is no evidence of extrahepatic metastases

Exclusion Criteria

- active Active chemical dependency (drugs or alcohol) within the preceding six (6) months
- acute Acute alcoholic hepatitis
- uncorrectable Uncorrectable hemodynamic instability
- extensive extensive Extensive and uncorrectable portal vein thrombosis precluding portal inflow to graft
- extrahepatic Extrahepatic malignancy or hepatic malignancy with extrahepatic metastases
- severe Severe terminal diabetic and organ disease
- HIV
- Uncorrectable absence of an essential psychosocial support system
- Unmanageable psychiatric disorder felt to significantly compromise compliance with the post-transplant regimen

Facility

Facility is approved for liver transplants by the Division of Medicaid. Refer to Section 28.10, Facility Criteria.

Division of Medicaid State of Mississippi Provider Policy Manual	New: Revised: X Current:	Date: Date: 06/01/03 08/01/07
Section: Transplants	Section: 28.07	
Subject: Organ Acquisition	Pages: 1	
	Cross Reference:	

~~For all types of transplants, including kidney, all All charges, both facility and physician, (facility and physician) relating to acquisition, whether cadaveric or living donor, must be billed by the transplant facility on the UB92 current UB claim form using the appropriate revenue codes. Transplant facilities must bill all acquisition charges Charges must be billed under the transplant beneficiary's Mississippi Medicaid identification number. Donor related charges may include expenses for: All claims for charges related to the transplant must be billed under the transplant beneficiary's Medicaid identification number.~~

Donor related charges may include the following:

- A search for matching tissue, bone marrow, or organ
- Donor's transportation
- Charges for removal, withdrawal, and preservation/storage
- Donor's hospitalization

~~Subsequent follow-up Medically necessary follow-up care (i.e., outside of the transplant admission) for the living donor outside of the transplant admission, will be covered only if the donor is a Mississippi Medicaid beneficiary. In that case, routine benefits will be paid, and will be reimbursed as routine benefits.~~

Division of Medicaid State of Mississippi Provider Policy Manual	New:	Date:
	Revised: X	Date: 06/01/03
	Current:	08/01/07
Section: Transplants	Section: 28.09	
Subject: Prior Approval	Pages: 1	
	Cross Reference: <u>Third Party Recovery 6.0</u>	

When the medical evaluation process is completed, the transplant facility will contact the Division of Medicaid's Peer Review Organization Contractor to begin the prior approval process.

The PRO will first review the requesting transplant facility information. The facility must be one that meets the approval criteria of DOM. They will then check the eligibility of the beneficiary and ask for any Medicare / third party payer information. If the beneficiary has private insurance, the PRO will request a copy of the approval or denial. If the procedure has been denied, they will proceed with the certification process. If it has been approved, the case will not be reviewed but a file will be established and held.

The PRO will request a letter of medical necessity from the physician that includes an overview of the patient history, any lab, x-rays or other procedures and their results, HIV immunization status, any other medical conditions, and a brief psychosocial history. Specific information must be submitted, as listed in the organ-specific coverage criteria for the type of transplant being requested.

If all the requested information is not submitted, a letter will be sent requesting the omitted information. In order to ensure a complete and timely review, the omitted information must be submitted no later than sixty (60) days after it is requested or a new transplant coverage request will be required. When all requested information is received, the PRO will reopen the review process. The Medical Director will then review each case and complete the final approval or denial that is then sent to DOM.

DOM will determine the amount of reimbursement and communicate with the transplant facility for any necessary arrangements.

Quarterly reports from the facility and/or the physician will be requested by the PRO and must be submitted when requested.

If a transplant facility needs general transplant information before accepting a beneficiary for an evaluation, it is acceptable to contact DOM by telephone or request information in writing.

All solid organ and bone marrow/peripheral stem cell transplants (including peripheral stem cell), with the exception of kidney and cornea transplants, must be prior authorized regardless of the age of the beneficiary or the diagnosis. All policies in this section are applicable to all solid organ transplants and to all inpatient/outpatient bone marrow/peripheral stem cell transplants (including peripheral stem cell) performed inpatient, and bone marrow transplants (including peripheral stem cell) performed outpatient.

The Utilization Management and Quality Improvement Organization (UM/QIO) for the Division of Medicaid is responsible for the evaluation of transplant facilities in accordance with DOM policy. In addition, the UM/QIO verifies beneficiary eligibility and performs a pre-transplant review, including a determination of medical necessity. The transplant facility must contact the UM/QIO after the evaluation process has been completed and it has been determined that the beneficiary is a transplant candidate, but before the transplant admission.

When the UM/QIO has completed the review process, the case will be forwarded to DOM. DOM will determine final approval or denial and issue a letter of agreement or denial to the transplant facility.

Additional information on the prior approval process for transplant may be obtained by accessing the UM/QIO web site <http://www.hsom.org>. Transplant information is covered in the Acute Care Provider

Manual. All procedures and criteria set forth by the UM/QIO are applicable and are approved by the Division of Medicaid. General information needed prior to accepting a beneficiary for transplant evaluation may be obtained by contacting DOM, Bureau of Medical Services.

Third Party Coverage

Transplants on beneficiaries with Medicare coverage do not require prior approval. Claims will be processed as cross-over claims. Refer to Section 6.03, Billing Procedures, in this manual.

If the beneficiary has private insurance and the transplant facility will be billing Medicaid for any of the transplant related hospital charges, prior authorization from the UM/QIO is required.

A copy of the approval/denial by the private insurer must be submitted to the UM/QIO.

- If the procedure has been denied, the UM/QIO will proceed with the certification process.
- If the procedure has been approved and the beneficiary has not exhausted benefits, the UM/QIO will not review the case but a file will be established and held.
- If the procedure has been approved but the beneficiary has or is in danger of exhausting benefits, the UM/QIO will review the case.

Division of Medicaid State of Mississippi Provider Policy Manual	New: Revised: X Current:	Date: Date: 07/01/04 08/01/07
Section: Transplants	Section: 28.10	
Subject: Facility Criteria	Pages: 3 Cross Reference:	

The purpose of the Division of Medicaid's policy is to ensure that Mississippi Medicaid beneficiaries receive care from facilities that can provide the best opportunity for a successful transplant outcome. Similarly-situated individuals are treated alike and any restriction on the facilities that may, or practitioners who may, provide those procedures is consistent with the accessibility of high-quality care to individuals eligible for the procedures.

DOM's Peer Review Organization Contractor is responsible for the evaluation of transplant facilities in accordance with DOM policy. DOM's policy requires that the facility be a Medicare-approved transplant facility. For pediatric or bone marrow transplant facilities which are not reviewed by Medicare standards, the following criteria is applicable:

The applying facility will be required to submit documentation to verify its attainment of all necessary criteria.

The Utilization Management and Quality Improvement Organization (UM/QIO) for the Division of Medicaid is responsible for the evaluation of transplant facilities in accordance with DOM policy.

Adult Transplant Facilities

Adult transplant procedures, except Bone Marrow/Peripheral Stem Cell, must be performed in a Medicare approved transplant facility. Adult Bone Marrow/Peripheral Stem Cell facilities will be evaluated using the criteria listed below.

Pediatric Transplant Facilities and Adult Bone Marrow/Peripheral Stem Cell Transplant Facilities

For pediatric or bone marrow transplant facilities which are not reviewed by Medicare standards, the following criteria is applicable:

The applying facility will be required to submit documentation to verify its attainment of all necessary criteria.

DOM criteria for evaluating pediatric transplant facilities and adult bone marrow/peripheral stem cell transplant facilities are as follows:

1. In its evaluation of transplant facilities, the PRO transplant team will utilize transplant certification, credentialing, and information sources which may include, but will not necessarily be limited to:

Transplant Certification, Credentialing, and Information Sources

- Centers for Medicare and Medicaid Services (CMS) and other regulations
- United Network for Organ Sharing (UNOS) requirements and by-laws
- Organ Procurement and Transplant Network (OPTN) regulations
- National Marrow Donor Program (NMDP)

- The Foundation for the Accreditation of Cellular Therapy (FACT) standards
- Organ Procurement Organizations (OPO)
- Organizations of transplant physicians and surgeons
- Peer-reviewed transplant articles and journals

2. ~~The PRO transplant team will evaluate facilities that request approval to perform pediatric transplant procedures considering the information sources noted above as well as the following criteria:~~

Medical Criteria

- ~~Patient selection—~~ The facility must have adequate and written criteria for patient transplant candidate selection criteria and an a written implementation plan.
- ~~Patient management—~~ The facility must have adequate patient a written transplant candidate management ~~plans and protocols~~ plan/protocol that include includes both evaluative and therapeutic procedures for the waiting period, in-hospital period, and post-transplant phases of treatment.
- ~~Commitment—~~ The facility must make a sufficient commitment of resources and planning to the transplant program to demonstrate the importance of the program at all levels. Indications of this commitment must be broadly evident throughout the facility. The facility must use a multidisciplinary team that includes representatives with expertise in the appropriate organ specialty (ex: hepatology, cardiology, or pulmonology) and the following general areas: transplant surgery, vascular surgery, anesthesiology, immunology, infectious diseases, pathology, radiology, nursing, blood banking, and social services.

Experience Criteria

Number of transplants and survival rates—

- The facility facility's volume of transplants and survival rates must demonstrate both experience and success with clinical solid organ and bone marrow (including peripheral stem cell) transplantation. The facility staff must have performed a reasonable number of successful transplants for each organ type for which DOM approval is sought. For example, according to the useful benchmarks enumerated in CMS' revised "Criteria for Medicare Approval of Transplant Centers" of July 26, 2000 the transplant center may generally be expected to have performed:
 - 12 Twelve (12) or more heart transplants per year with actuarial survival rates of 73% at 1 one (1) year and 65% at 2 two (2) years
 - 12 Twelve (12) or more liver transplants per year with actuarial survival rates of 77% at 1 one (1) year and 60% at 2 two (2) years
 - 10 Ten (10) or more lung transplants per year with actuarial survival rates of 69% at 1 one (1) year and 62% at 2 two (2) years
 - Small bowel transplant facilities (which are not included in the July 26, 2000 publication noted above) should generally have performed 10 ten (10) intestinal transplants, whether or not transplanted in conjunction with another organ, with a demonstrated 1-year one

year actuarial survival of at least 65% using the Kaplan-Meier technique.

Staff—

- The facility must provide documentation to support the current competence of its transplant physicians and transplant surgeons, and, if requested, its organ-specific and general clinical staff. The qualifications and transplant experience of transplant physicians and surgeons specified by UNOS (UNOS bylaws Appendix B – III (2): Liver; (4): Heart; and (5): Lung and Heart-Lung) will be considered appropriate for each specified organ transplant program.

Administrative Criteria

- ~~Organ procurement—~~The facility must be an active member of the OPTN as an appropriate organ transplant facility and abide by its approved rules. The facility must also have an agreement with an OPO.
- ~~Laboratory services—~~The facility must make available, either directly or by specified arrangements, all laboratory services needed to meet the needs of transplant patients candidates/recipients.
- ~~Maintenance of data—~~The facility must agree to maintain and, when requested, periodically submit clinical data, including ~~precertification~~ pre-certification, concurrent review, and other requested information to DOM or to its PRO UM/QIO.
- ~~Where applicable, the facility must agree to contract with DOM on a patient-by-patient basis. Approvals must be renewed at six-month intervals, unless otherwise specified by DOM, until the patient receives the transplant and must be in force at the time of the transplant.~~
- ~~Billing—~~ The facility must agree to submit claims to DOM as specified in its patient-specific agreement with DOM.

Division of Medicaid State of Mississippi Provider Policy Manual	New: Revised: X Current:	Date: Date: 12/01/01 08/01/07
Section: Transplants	Section: 28.11	
Subject: Transportation/Lodging	Pages: 1	
	Cross Reference: Ambulance 8.01-8.16 and NET 12.01-12.17	
	Ambulance 8.0	
	Non-Emergency Transportation (NET) 12.0	

Transportation

For information on transportation of beneficiaries, refer to the Ambulance Section, 8.01-8.16, and the NET Section, 12.01-12.16, in this manual.

Refer to Ambulance, Section 8, and Non-Emergency (NET) Transportation, Section 12, in this manual.

Lodging

For information on lodging, refer to the NET Section, 12.10, in this manual.

Refer to Non-Emergency (NET) Transportation, Section 12, in this manual.

Division of Medicaid State of Mississippi Provider Policy Manual	New: Revised: X Current:	Date: Date: 06/01/03 08/01/07
Section: Transplants	Section: 28.12 Pages: 1	
Subject: Home Health Services	Cross Reference: Home Health 40.0	

The transplant patient who is a Medicaid beneficiary may receive routine home health benefits available to any Medicaid beneficiary. Transplant beneficiaries may be eligible for Home Health benefits.

To qualify for home health benefits under the Medicaid program, a beneficiary must be essentially homebound, under the care of a physician and in need of home health services on an intermittent basis. The Division of Medicaid must review all home health services billed to Medicaid for medical necessity. A Mississippi Medicaid provider must perform the home health services.

For further information on home health benefits refer to the current Mississippi Medicaid Home Health Manual.

Refer to Home Health, Section 40 in this manual.

Division of Medicaid State of Mississippi Provider Policy Manual	New: Revised: X Current:	Date: Date: 06/01/03 08/01/07
Section: Transplants	Section: 28.13 Pages: 1	
Subject: Immunosuppressive Treatment	Cross Reference: Pharmacy 31.0	

~~For those beneficiaries who have immunosuppressive therapy coverage through Medicare, Medicare is considered primary coverage and Medicaid is responsible for coinsurance and the deductible.~~

~~Refer to the current Pharmacy manual for reimbursement of medically necessary drugs covered by Medicaid. Pharmacy, Section 31, in this manual.~~

Note: DOM is only responsible for coinsurance and deductible for dual eligible (Medicare and Medicaid) beneficiaries.

Division of Medicaid State of Mississippi Provider Policy Manual	New: Revised: X Current:	Date: Date: 06/01/03 08/01/07
Section: Transplants	Section: 28.14	
Subject: Documentation Requirements	Pages: 2	
	Cross Reference: General Policy 7.0 Hospital Inpatient 25.0 Hospital Outpatient 26.0	

All professional and institutional providers participating in the Medicaid program are required to maintain records that will disclose services rendered and billed under the program and, upon request, make such records available to representatives of the Division of Medicaid or Office of Attorney General in substantiation of any or all claims. These records should be retained a minimum of five (5) years in order to comply with all state and federal regulations and laws.

In order for DOM to fulfill its obligations to verify services to Medicaid beneficiaries and those paid for by Medicaid, providers must maintain legible and auditable records that will substantiate the claim submitted to Medicaid. At a minimum, the records must contain the following on each patient:

At a minimum, Transplant medical record documentation must contain the following on each beneficiary:

- a comprehensive Comprehensive history and physical assessment/report which includes, but is not limited to the following:
- documentation of treatments Treatments rendered that were unable to prevent progressive disability and/or death
- documentation of the current use, or use in the past six (6) months Use of tobacco, alcohol, and/or illegal drugs currently or within the last six (6) months
- documentation of the absence Absence of severe and irreversible organ dysfunction in organ(s) other than the organ(s) being transplanted
- all relevant Relevant diagnostic studies (ex: x-rays, lab reports, EKG reports, pulmonary function studies, psychosocial reports, nutritional evaluation, performance status) and the results of the studies
- documentation and consult reports Reports, consults or other documentation to substantiate the transplant including documentation of approval for the transplant approval by the center's transplant review team
- copy Copy of signed informed consent form
- refer to Hospital Inpatient, Section 25.15, for further documentation requirements related to the hospitalization.

In addition to the general requirements noted above, providers should refer to documentation requirements found in the following sections of this manual: General Policy, Section 7.03; Hospital Inpatient, Section 25.15, and Hospital Outpatient, Section 26.10.

DOM, the peer review organization contractor, requires that all x-ray images (films, digital images, etc.) be accessible at all times for review. In addition, DOM requires that the films or images be of such quality that they can be clearly interpreted.

~~Providers must maintain proper and complete documentation to verify the services provided. The provider has full responsibility for maintaining documentation to justify the services provided.~~

~~DOM and/or fiscal agent have the authority to request any patient records at any time to conduct a random sampling review.~~

~~If a transplant provider's records do not substantiate services paid for under the Mississippi Medicaid program, as previously noted, the provider will be asked to refund to the Mississippi Medicaid program any money received from the program for such non-substantiated services. If a refund is not received within 30 days, a sum equal to the amount paid for such services will be deducted from any future payments that are deemed to be due the transplant provider.~~

~~Any provider who knowingly or willfully makes, or causes to be made, false statement or representation of a material fact in any application for Medicaid benefits or Medicaid payments may be prosecuted under federal and state criminal laws. A false attestation can result in civil monetary penalties as well as fines, and may automatically disqualify the provider as a provider of Medicaid services.~~

Division of Medicaid State of Mississippi Provider Policy Manual	New: Revised: X Current:	Date: Date: 06/01/03 08/01/07
Section: Transplants	Section: 28.16 Pages: 1	
Subject: <u>Third Party Liability Recovery</u>	Cross Reference: Third Party Recovery 6.1-6.06 6.0	

For Medicaid beneficiaries who have private insurance, a copy of the letter of approval or denial from the private insurer must be submitted. If payment is to be made by private insurance as documented in an approval letter, the case will not be reviewed but a file will be established. If the private insurer submits a denial letter, Medicaid will proceed with the certification process. Refer to sections 6.01-6.06, Third Party Recovery, in this manual.

Mississippi law requires providers participating in the Medicaid program to determine if a beneficiary is covered by a third party source, and to file and collect all third party coverage prior to billing Medicaid. This includes beneficiaries who are Medicare/Medicaid (dual) eligible. Refer to Third Party Liability Recovery, Section 6, in this manual.

Division of Medicaid State of Mississippi Provider Policy Manual	New: Revised: X Current:	Date: Date: 06/01/03 08/01/07
Section: Transplants	Section: 28.17	
Subject: Dual Eligibles	Pages: 1	
	Cross Reference: <u>Beneficiary Information 3.0</u> <u>Third Party Liability-Recovery 6.0</u>	

~~For transplant procedures covered by Medicare, Medicaid will pay the deductible and/or co-insurance. Mississippi Medicaid service limits are applicable unless otherwise specified by the Division of Medicaid.~~

Mississippi law requires providers participating in the Medicaid program to determine if a beneficiary is covered by a third party source, and to file and collect all third party coverage prior to billing Medicaid. This includes beneficiaries who are Medicare/Medicaid (dual) eligible. Refer to Third Party Liability Recovery, Section 6, in this manual.

Providers may file a claim with Medicaid for services not covered by Medicare if the reason for the Medicare denial is other than for medical necessity. Mississippi Medicaid will reimburse the Medicare cost sharing or premium payment for eligible beneficiaries. Refer to Eligibility of Persons, Section 3.1, in this manual.

Division of Medicaid State of Mississippi Provider Policy Manual	New: X Revised: X Current:	Date: 07/04/04 Date: 08/01/07
Section: Transplants	Section: 28.18 Pages: 3 Cross Reference:	
Subject: Small Bowel Coverage Criteria		

Definitions

These ~~The following~~ criteria deal with ~~apply~~ to small bowel (or intestinal) transplantation, whether performed as a solitary procedure (SBT); or performed in conjunction with liver (SB/LT); or with stomach, duodenum, and pancreas, with or without liver (SB/MVT) transplantation.

General Inclusion Criteria

The general indications Indications for SBT are include the combined presence of:

- The loss or absence of sufficient absorptive capacity of the intestinal tract to support life, and
- The demonstrated failure of total parenteral nutrition (TPN)

Concomitant liver or multivisceral transplantation can only be medically justified by documentation of severe and irreversible damage to the individual organ(s) to be replaced.

Age

Less than 65 years of age

Compatibility

Consistent with the transplanting facility blood and tissue-type compatibility standards

Infections

Controlled for at least 48 hours prior to transplant

Other Organs

Absence of severe and irreversible end organ dysfunction (cardiac, central nervous system, pulmonary, renal, peripheral vascular or cerebrovascular)

Psychosocial Evaluation

A psychosocial evaluation has been performed for the adult patient candidate or, if the patient candidate is a child, for the family, with the following results:

- ~~if any psychiatric disorder is found to be present in the patient, that disorder is being treated~~
- Candidate's psychiatric disorders, if present, are being treated

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-
- the patient's Candidate's social support system has been evaluated and found to be adequate
 - the patient Candidate has no previous history of significant non-compliance to medical treatment

Facility

Approved for the proposed small bowel transplant by DOM. DOM may consider in this regard whether the facility has been approved by Medicare for small bowel transplantation or, if not Medicare approved, whether the facility meets the criteria for such approval.

Other

- All other treatments have been attempted or considered and none will prevent progressive disability and/or death
- The candidate and/or guardian legal representative understands the transplant risks and benefits, gives informed consent, and has the capacity to, and will and is willing to comply with needed care, including immunosuppressive therapy
- The candidate has been considered and approved by the center's transplant review team
- For children from 2 – 6 years of age: the PRO will ask whether childhood immunizations are up to date.

Required serologies:

- HIV
- Hepatitis A, B, and C
- Cytomegalovirus (CMV)
- Varicella
- Required serology studies have been completed for HIV, Hepatitis (A, B, and C), Cytomegalovirus (CMV), and Varicella

Ask that the following immunizations be administered:

- Hepatitis A (if serology does not indicate immunity)
- Hepatitis B (if serology does not indicate immunity)
- Pneumococcal
- Influenza (yearly for candidates)
- Immunizations have been administered as follows:
 - All immunizations for children age two (2) to six (6) are up-to-date in accordance with the most current recommended childhood immunization schedule developed and endorsed

by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP)

- Hepatitis A (if serology does not indicate immunity)
- Hepatitis B (if serology does not indicate immunity)
- Pneumococcal
- Influenza (annually)

Specific Diagnostic Inclusion Criteria

Severe and irreversible intestinal insufficiency, congenital or acquired, including, but not limited to the following causes:

- Intestinal atresia
- Gastroschisis
- Microvillus involution disease (intractable diarrhea of infancy)
- Volvulus
- Necrotizing enterocolitis
- Chronic intestinal pseudo-obstruction
- Splanchnic vascular occlusive disease
- Inflammatory bowel disease
- Post-traumatic (including surgical) short bowel syndrome
- Radiation enteritis

And AND

Failure of Total Parenteral Nutrition as documented by:

- Overt or impending liver failure due to TPN-induced hepatic injury, or
- Thrombosis of two or more central venous channels: jugular, subclavian, femoral, or
- Two or more episodes of TPN catheter-induced sepsis in a year or a single episode of line-related fungemia, or
- Frequent episodes of dehydration due to uncontrollable and high volume loss of fluids through the gastrointestinal tract

Exclusion Criteria

- active Active chemical dependency (drugs or alcohol) within the preceding six (6) months
- Profound and progressive neurological dysfunction, e.g., Tay-Sachs
- Non-correctable non-gastrointestinal disease with a lethal prognosis
- Congenital immunodeficiency syndrome

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- Active tuberculosis or active sepsis
 - ~~The uncorrectable~~ Uncorrectable absence of an essential psychosocial support system
 - ~~An unmanageable~~ Unmanageable psychiatric disorder felt to significantly compromise compliance with post-transplant the post-transplant regimen
 - HIV
 - Systemic malignancy

Facility

Facility is approved for small bowel transplants by the Division of Medicaid. Refer to Section 28.10, Facility Criteria.