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13.1 GENERAL INFORMATION

Through its MO HealthNet Program, the Department of Social Services, MO HealthNet Division provides limited coverage for the transplantation of human organs or bone marrow/stem cell and the medical services related to the transplant, including, but not necessarily limited to, evaluation, treatment and necessary post-operative care, for the specific procedures defined herein and further defined by the MO HealthNet Division provider manuals for specific program areas (hospital, physicians, etc.).

13.1.A TRANSPLANT SERVICES

Hospital, physician and other related medical services are covered for the following types of transplants when performed in a MO HealthNet approved transplant facility, for patients who meet the patient selection criteria, and have been prior authorized by the MO HealthNet Division.

- Stem Cell from cord blood, peripheral blood or bone marrow
- Heart
- Lung
- Liver
- Kidney
- Small Bowel
- Pancreas in combination with kidney or following a kidney transplant
- Multiple Organ (must include an organ transplant listed above)

13.1.B NONDISCRIMINATION

Providers must comply with the 1964 Civil Rights Act, as amended; Section 504 of the Rehabilitation Act of 1973; the Age Discrimination Act of 1975; the Omnibus Reconciliation Act of 1981 and the Americans with Disabilities Act of 1990 and all other applicable Federal and State Laws that prohibit discrimination in the delivery of services on the basis of race, color, national origin, age, sex, handicap/disability or religious beliefs.
Further, all parties agree to comply with Title VII of the Civil Rights Act of 1964 which prohibits discrimination in employment on the basis of race, color, national origin, age, sex, handicap/disability, and religious beliefs.

13.1.C PARTICIPANT NONLIABILITY

MO HealthNet covered services rendered to an eligible participant are not billable to the participant if MO HealthNet would have paid had the provider followed the proper policies and procedures for obtaining payment through the MO HealthNet Program as set forth in 13 CSR 70-4.030.

13.1.D RETENTION OF RECORDS

MO HealthNet providers must retain for 5 years, from the date of service, fiscal and medical records that coincide with and fully document services billed to the MO HealthNet Agency, and must furnish or make the records available for inspection or audit by the Department of Social Services or its representative upon request. Failure to furnish, reveal and retain adequate documentation for services billed to the MO HealthNet Program may result in recovery of the payments for those services not adequately documented and may result in sanctions to the provider’s participation in the MO HealthNet Program. This policy continues to apply in the event of the provider’s discontinuance as an actively participating MO HealthNet provider through change of ownership or any other circumstance.

13.1.E ADEQUATE DOCUMENTATION

All services provided must be adequately documented in the medical record. The Code of State Regulations, 13 CSR 70-3.030, Section (1)(A) defines “adequate documentation” and “adequate medical records” as follows:

Adequate documentation means documentation from which services rendered and the amount of reimbursement received by a provider can be readily discerned and verified with reasonable certainty.

Adequate medical records are records which are of the type and in a form from which symptoms, conditions, diagnoses, treatments, prognosis and the identity of the patient to which these things relate can be readily discerned and verified with reasonable certainty. All documentation must be made available at the same site at which the service was rendered.

13.1.F EMERGENCY SERVICES

Emergency services are services required when there is a sudden or unforeseen situation or occurrence or a sudden onset of a medical condition manifesting itself by acute symptoms of
sufficient severity (including severe pain) that the absence of immediate medical attention could reasonably be expected to result in:

1. Placing the patient’s health in serious jeopardy; or
2. Serious impairment to bodily functions; or
3. Serious dysfunction of any bodily organ or part.

13.1.G OUT-OF-STATE, NONEMERGENCY SERVICES

All nonemergency, MO HealthNet covered services that are to be performed or furnished out-of-state for eligible MO HealthNet participants and for which MO HealthNet is to be billed, must be prior authorized before the services are provided. Services that are not covered by the MO HealthNet Program are not approved.

Out-of-state is defined as not within the physical boundaries of the State of Missouri nor within the boundaries of any state that physically borders on the Missouri boundaries. Border-state providers of services (those providers located in Arkansas, Illinois, Iowa, Kansas, Kentucky, Nebraska, Oklahoma and Tennessee) are considered as being on the same MO HealthNet participation basis as providers of services located within the State of Missouri.

A Prior Authorization Request form is not required for out-of-state nonemergency services. To obtain prior authorization for out-of-state, nonemergency services, a written request must be submitted by the Missouri referring physician to:

MO HealthNet Division
Pharmacy and Clinical Services
Transplant Unit
P.O. Box 6500
Jefferson City, MO 65102

or faxed to (573) 526-4650.

The written request must include:

1. A brief past medical history.
2. Services attempted in Missouri.
3. Where the services are being requested and who will provide them.
4. Why services can’t be done in Missouri
NOTE: The out-of-state medical provider must agree to complete an enrollment application and accept MO HealthNet reimbursement. Prior authorization for out-of-state services expires 180 days from the date the specific service was approved by the state.


The following are exempt from the out-of-state prior authorization requirement:

1. All Medicare/MO HealthNet crossover claims.
2. All Foster Care children living outside the State of Missouri. However, nonemergency services that routinely require prior authorization continue to require prior authorization by out-of-state providers even though the service was provided to a Foster Care child.
3. Emergency ambulance services.
4. Independent laboratory services.

13.2 REQUIREMENTS FOR PROVIDER PARTICIPATION

To participate in the MO HealthNet Transplant Program, transplant providers must satisfy the following requirements:

• The transplant facility is an enrolled MO HealthNet hospital provider;
• The transplant facility is an approved MO HealthNet transplant facility;
• The transplant surgeon is an enrolled MO HealthNet provider; and
• Any physician who is a member of the transplant team or who is a consultant or otherwise involved in treating the transplant patient, for which reimbursement is expected, is an enrolled MO HealthNet provider. The MO HealthNet Division does not have provisions to provide payment to a provider other than the physician performing the service.

Additional information on provider conditions of participation can be found in Section 2 of this provider manual.

13.2.A TRANSPLANT FACILITY PARTICIPATION REQUIREMENTS

The MO HealthNet Transplant Program requires covered transplants to be performed in a facility approved by the MO HealthNet Division (MHD) as a MO HealthNet transplant facility. To be considered for approval as a MO HealthNet transplant facility, the facility must have been approved by the MO HealthNet Division as a MO HealthNet hospital provider and must sign a “MO HealthNet Provider Participation Agreement.”
In order to qualify for approval in the MO HealthNet Transplant Program, a facility must meet all of the criteria specific to the transplant service (heart, lung, liver, kidney, pancreas, small bowel, multiple organ or bone marrow/stem cell). Transplant facility participation requirements were developed by MHD with the assistance of its Transplant Advisory Committee.

A facility must be approved by MHD for each type of bone marrow/stem cell or organ transplant to be performed. A facility may apply for approval to perform any or all of the transplant services.

The MO HealthNet Division advises the facility in writing as to whether the application is approved or denied.

The facility must submit documentation, which substantiates that the facility complies with the appropriate criteria to:

MO HealthNet Division
Pharmacy and Clinical Services
Transplant Unit
P.O. Box 6500
Jefferson City, MO 65102-6500

13.2.B ORGAN TRANSPLANT FACILITY 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 specific transplant(s). The certification from UNOS is considered appropriate verification and documentation for organ transplant facility approval.

2. Each type of MO HealthNet covered organ transplant is subject to separate UNOS certification.

3. When the period for initial UNOS certification expires, the transplant facility must provide evidence that continued approval from UNOS allowing participation to perform the transplant(s) has been granted.

4. The transplant facility must provide the C.V. of all members of the transplant team at the time of application and must notify MHD of each new primary transplant surgeon who becomes a member of the transplant team. The primary transplant surgeons must be enrolled as MO HealthNet participating providers. Other physicians who wish to receive reimbursement for services must also be enrolled as MO HealthNet participating providers.
5. The transplant facility must provide the name of the Organ Procurement Organization (OPO) presently utilized by the facility. The transplant facility must also furnish a copy of the notification from Centers for Medicare & Medicaid Services (CMS) which designates the facility’s OPO as an acceptable organ procurement source.

6. 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.

13.2.B(1) Kidney Transplant Facility

A facility seeking certification as an approved MO HealthNet kidney transplant center must furnish a copy of its current Medicare certification indicating active participation in the “Medicare Renal Transplant Program.”

The Medicare certification must be submitted in addition to the organ transplant facility participation criteria items 1 through 6.

13.2.B(2) Organ Transplant Facility Application Process

A facility may contact the MO HealthNet Division—Pharmacy and Clinical Services Transplant Unit (573) 751-6963 for further information regarding the organ transplant facility application process.

13.2.C BONE MARROW/STEM CELL TRANSPLANT FACILITY CRITERIA

The initial provisional approval for a bone marrow/stem cell transplant center is for a period of one to three years. The ASC/ASCO criteria are used for final approval.

MHD advises the facility in writing whether the application is approved or denied.

An autologous only transplant center must meet criteria 1 through 10 of the following. An allogeneic transplant center must meet all 14 criteria listed below.

Autologous/Allogeneic Criteria

1. Physician(s) with expertise in pediatric and/or adult bone marrow/stem cell transplantation, hematology and oncology. (List staff members and qualifications);

2. Identified nursing unit with facility defined protective isolation unit for bone marrow/stem cell transplantation;
3. Blood bank with pheresis capability and the capability to supply required blood products, or association with a qualified blood bank;

4. Physicians with expertise in infectious disease, immunology, pathology and pulmonary medicine. (List staff members and qualifications);

5. Capability of providing cardiac/respiratory intensive care and renal dialysis;

6. Performed at least 13 bone marrow/stem cell transplants a year or demonstrated an ability to care for prolonged marrow failure by treating 20 adult or 10 pediatric marrow failure patients per year.

7. Capability for marrow cryopreservation and purging techniques, if appropriate, or affiliation with a facility with these capabilities;

8. Capability to provide psycho-social support to patients and their families;

9. Close affiliation with academically based institutions to ensure that all components of comprehensive care for patients undergoing bone marrow/stem cell transplantation are present in the facility. The mere presence or availability of components 1 through 8 is not adequate. The facility must demonstrate that a coordinated bone marrow/stem cell transplantation program is in place and directed by a physician trained in an institution with a well established bone marrow/stem cell transplantation program.

10. Submit a copy of its “Protocol for Transplantation Cases” and “Patient Selection Criteria” for the type of bone marrow/stem cell transplants to be performed at the facility. Once approved as a facility, each new type of bone marrow/stem cell transplant or diagnosis added for treatment by the facility must be documented by submitting the new protocol and patient selection criteria;

**Additional Allogeneic Criteria**

11. Physicians with expertise in infectious disease, immunology, pathology (of Graft vs. Host Disease), and pulmonary medicine. (List staff members and qualifications);

12. Tissue typing laboratory with capability to perform typing for HLA, A, B, C, DR, and MLC;

13. Cytogenetic laboratory; and

14. Adequate laboratory facility to assay drug levels including Cyclosporin A.
13.2.C(1) Bone Marrow/Stem Cell Transplant Facility Application

The MO HealthNet Division has compiled a Bone Marrow Facility Application which addresses all criteria and protocols required for approval as a bone marrow/stem cell transplant facility.

An application may be requested by writing:

MO HealthNet Division
Pharmacy and Clinical Services
Transplant Unit
P.O. Box 6500
Jefferson City, Missouri 65102-6500

or by calling the MO HealthNet Division, Pharmacy and Clinical Services at (573) 751-6963.

13.2.D APPROVED MO HEALTHNET TRANSPLANT FACILITIES

Below is a complete listing of facilities approved by MO HealthNet to perform transplants for MO HealthNet or MO HealthNet Managed Care participants. Note that facilities are listed by the type of transplant for which they have requested approval. Some facilities are approved for several types of transplants. Some facilities may be certified as a Medicare transplant facility.

Requests for transplants involving out-of-state transplant facilities (facilities not located in Missouri or a state physically bordering Missouri; i.e. Kansas, Tennessee, etc.) may require the referring physician to submit a statement to the MO HealthNet Division indicating why the transplant patient must have the procedure performed at an out-of-state facility.

**BONE MARROW/STEM CELL**

Barnes-Jewish Hospital (Adult)—St. Louis, MO
Cardinal Glennon Children’s Hospital—St. Louis, MO
Children’s Mercy Hospital of K.C.—Kansas City, MO
Kansas University Medical Center—Kansas City, KS
St. Jude Children’s Research Hospital—Memphis, TN
St. Louis Children’s Hospital—St. Louis, MO
St. Louis University—St. Louis, MO
St. Lukes Cancer Institute of Kansas City—Kansas City, MO
University of Nebraska—Omaha, NE

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Barnes-Jewish Hospital*—St. Louis, MO
Cardinal Glennon Children’s Hospital*—St. Louis, MO
St. Louis Children’s Hospital*—St. Louis, MO
St. Louis University—St. Louis, MO
St. Lukes Hospital of K.C.*—Kansas City, MO
University of Nebraska*—Omaha, NE

KIDNEY

Barnes-Jewish Hospital*—St. Louis, MO
Cardinal Glennon Children’s Hospital*—St. Louis, MO
Children’s Mercy Hospital of K.C.*—Kansas City, MO
Kansas University Medical Center*—Kansas City, KS
St. Louis Children’s Hospital*—St. Louis, MO
St. Louis University*—St. Louis, MO
St. Lukes Hospital of K.C.*—Kansas City, MO
University of Missouri-Columbia*—Columbia, MO
University of Nebraska*—Omaha, NE

KIDNEY/PANCREAS

Barnes-Jewish Hospital*—St. Louis, MO
Kansas University Medical Center*—Kansas City, KS
St. Louis University*—St. Louis, MO
University of Nebraska*—Omaha, NE

LIVER

Barnes-Jewish Hospital*—St. Louis, MO
Cardinal Glennon Children’s Hospital*—St. Louis, MO
Children’s Mercy Hospital of K.C.—Kansas City, MO
Kansas University Medical Center*—Kansas City, KS
St. Louis Children’s Hospital*—St. Louis, MO
St. Louis University*—St. Louis, MO
University of Nebraska*—Omaha, NE

LUNG

Barnes-Jewish Hospital*—St. Louis, MO
St. Louis Children’s Hospital*—St. Louis, MO

HEART/LUNG

Barnes-Jewish Hospital*—St. Louis, MO
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St. Louis Children’s Hospital*—St. Louis, MO

INTESTINE

University of Nebraska*-Omaha, NE

Providers may contact the MO HealthNet Division—Transplant Unit at (573) 751-6963 for additional questions concerning the transplant facility listing.

* Medicare-Certified Transplant Facility

13.3 REQUIREMENTS FOR PARTICIPANT PARTICIPATION

In order for MO HealthNet to prior authorize and reimburse a covered transplant the individual must have been determined eligible for MO HealthNet by the Family Support Division (FSD):

• Some participants are determined eligible on a spenddown basis. Refer to Section 1 for information on spenddown.

• Refer to Section 1 for a list of ME codes that identify participants of state only funded Medical Assistance programs who are not eligible for transplant services unless they are under the age of 21 years. Individuals under the age of 21 can receive a transplant under the EPSDT provisions which allow all medically necessary treatment services for both state and federally matched types of assistance. All state only eligible individuals, regardless of age, should apply for a federally matched assistance program. Individuals age 21 and over must be determined eligible for a federally matched assistance program in order to be eligible for authorization of transplant services. Individuals whose type of assistance does not cover transplants should be referred to their local Family Support Division office to request application under a type of assistance that covers transplants. In this instance the MO HealthNet Division Transplant Unit should be advised immediately. The MO HealthNet Division Transplant Unit works with the Family Support Division to expedite the application process.

• Qualified Medicare Beneficiary (QMB) only participants (ME cod 55) are only eligible for coverage of their Medicare premiums, deductibles and coinsurance amounts. MO HealthNet covers the deductible and coinsurance amounts for Medicare covered transplants when billed directly for a Medicare covered transplant. If the QMB participant is in need of a non-Medicare covered transplant, the participant must qualify for MO HealthNet coverage under a federally matched assistance program, in order to receive prior to authorization from MHD for the transplant.
• For the transplant facility or related service providers to be reimbursed by MO HealthNet Division, the transplant patient must be eligible for MO HealthNet assistance on each date of service. A participant must have a valid ID card or eligibility letter to receive MO HealthNet benefits.

Refer to Section 12 regarding Managed Health Care Participants.

13.3.A GENERAL MO HEALTHNET TRANSPLANT ELIGIBILITY

• An eligible participant must be determined to be a suitable transplant candidate:

• The participant must be evaluated according to the facility’s protocol for transplantation, a copy of which must be on file at MHD.

• The transplant evaluation must indicate that the participant is a suitable candidate for the surgery, having met the facility’s patient selection criteria, a copy of which must be on file at MHD.

• In addition to meeting the facility’s patient selection criteria, a bone marrow/stem cell harvest or transplant candidate must be approved by the State Medical Consultant or, when deemed necessary, the Bone Marrow Transplant Advisory Group.

• Each request for coverage is handled on a case-by-case basis:

• A request for prior authorization must be submitted for each participant.

• A request for prior authorization must be submitted for each subsequent transplant for participants previously authorized and transplanted.

• Participants previously authorized but then removed from the waiting list because they failed to continue to meet patient selection criteria, must be re-evaluated and have their requests for transplant coverage prior authorized again in order to be eligible for MO HealthNet transplant coverage.

• A financial agreement (contract) is executed between MHD and the transplant facility for each participant for each authorized transplant:

• The agreement outlines the terms of coverage.

• The agreement is not valid unless signed by an authorized representative of the transplant facility and returned to the MO HealthNet Division.

• The agreement is in effect from the date of the agreement until the participant is transplanted or removed from the transplant list.
• The facility must notify the MO HealthNet Transplant Coordinator if the participant is removed from the list of transplant candidates.
• The participant must be eligible for MO HealthNet on each date service is rendered.

13.4 GUIDELINES AND INFORMATION SPECIFIC TO BONE MARROW/STEM CELL TRANSPLANTS

The following medical guidelines have been established by the MO HealthNet Division as criteria for consideration of requests for coverage of bone marrow/stem cell transplants for MO HealthNet patients.

• Bone marrow/stem cell transplantation is considered an acceptable alternative form of therapy when there is a potential of at least a 20% two year disease free survival after transplant.
• Requests for patients over age 60 years are reviewed on a case-by-case basis.
• The patient should not present evidence of severe cardiac, pulmonary, renal, hepatic, metabolic disease, or poor performance status.

13.4.A DONOR TYPES

The following donor types are currently determined appropriate for bone marrow/stem cell transplants:

Allogeneic (Syngeneic)

• Related Donor: The donor is HLA A, B, and DR genotypically identical; an MLC study is not necessary for sibling donors provided a family study has been completed. A one-antigen mismatch family member is considered appropriate.

• Non-Related Donor: The donor is an unrelated HLA computer matched A and B donor or molecular typing of DR region. Requests for coverage of a matched unrelated donor bone marrow/stem cell transplant are considered on a case-by-case basis:

• Haplo-Identical Donor: Haplo-identical donors are only considered for immunodeficiency syndromes.

• Cord Blood: Requests are reviewed on a case-by-case basis

Autologous
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- Intensive chemo-radiation therapy followed by infusion of the patient’s own marrow or peripheral blood previously harvested and cryopreserved, is considered appropriate for certain malignancies. Peripheral blood stem cell recruitment for autologous transplantation is also considered appropriate for certain conditions. The physician must state that peripheral blood stem cell recruitment is included as part of the treatment plan.

- The requesting physician must, in addition to the diagnosis, treatment and current status of malignancy, document that the bone marrow or stem cell source is free of the disease and, that the facility has the capability of in-vitro marrow purging, if appropriate.

- Because of the changing role of bone marrow/stem cell transplantation in various leukemias, lymphomas, and solid tumors, each request for malignancies not listed in the patient selection criteria is reviewed on a case-by-case basis.

13.4.B DIAGNOSIS CRITERIA

The MO HealthNet Division is aware of the ever changing role of bone marrow/stem cell transplantation, therefore requests for bone marrow/stem cell transplantation for diagnoses not listed in this section are considered on a case-by-case basis. The requesting physician must present the physician's best evidence (journal articles) that bone marrow/stem cell transplant provides the potential of at least a 20% two year disease free survival after transplant.

The following diagnoses criteria are currently considered appropriate for bone marrow/stem cell transplant authorization requests:

**Allogeneic**

For the treatment of leukemia, leukemia in remission or aplastic anemia when it is reasonable and necessary; and

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

Other medical diagnosis will be reviewed on a case by case basis.

**Autologous**

Acute leukemia in remission, lymphoid, myeloid, monocytic, acute erythremia and erythroleukemia and patients who have a high probability of relapse and who have no human leukocyte antigens (HLA)-matched;
Resistant to non-Hodgkins lymphomas or those presenting with poor prognostic features following an initial response;

Recurrent or refractory neuroblastoma; or

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

Multiple myeloma for beneficiaries less than age 78, who have Durie-Salmon stage II or III newly diagnosed or responsive multiple myeloma and adequate cardiac, renal, pulmonary and hepatic functioning.

Multiple rounds of autologous stem cell transplantation (tandem) will only be reviewed on a case by case basis; and

Primary amyloidosis for participants under the age of 64 or any age if they have amyloid deposition in two or fewer organs and cardiac left ventricular ejection fraction (EF) greater than 45 percent.

Other medical diagnosis will be reviewed on a case by case basis.

13.4.C BONE MARROW/STEM CELL RELATED SERVICES

The following unique services are covered for bone marrow/stem cell transplant patients. Services may be billed separately when performed on an outpatient basis. When provided on an inpatient basis, they should be identified as a separate item on the UB-04 claim form. Claims for these specialized services must be billed to

MO HealthNet Division
Pharmacy and Clinical Services Unit—Transplant Program
P.O. Box 6500
Jefferson City, MO 65102-6500.

13.4.C(1) T-Cell Depletion/Marrow Purging

T-Cell depletion or marrow purging of bone marrow/stem cell for transplantation may be billed using procedure codes 38210-38215, in addition to the appropriate blood related revenue code; 39X.

A copy of treatment process record showing the purging process used (chemo or magnetic antibody) and the number of units processed must be sent with the claim.

* These codes are considered outpatient codes only and should be billed appropriately.
13.4.C(2) Processing and Storage of Stem Cells

Procedure codes 38207, 38208, or 38209 may be billed by the facility for the processing and storage/cryopreservation of stem cells that have been harvested, in addition to the appropriate blood related revenue code; 39X.

* These codes are considered outpatient codes only and should be billed appropriately.

13.4.C(3) Stem Cell Recruitment/Harvest

The professional component related to the bone marrow/peripheral stem cell recruitment/harvest may be billed on the CMS-1500 using procedure code 38230, 38205 or 38206.

NOTE: A copy of the peripheral stem cell collection record should be attached to any claims billing peripheral stem cell collection procedures.

13.4.C(4) Stem Cell Harvest Without a Planned Transplant

A stem cell harvest may be requested when there is no immediate plan for transplant. Stem cells must be harvested at a certain stage of the disease. At that stage the patient may not meet MHD patient selection criteria for approval of a transplant. Therefore, the harvest may be approved in order not to lose the window of opportunity for harvesting. The facility/surgeon may request coverage of a stem cell harvest only in cases where a transplant is the treatment of choice should the disease respond to treatment and meet MHD criteria for approval.

13.5 SECOND/THIRD REQUESTS AND MULTIPLE LISTINGS

13.5.A SECOND/THIRD BONE MARROW/STEM CELL TRANSPLANT REQUESTS

Allogeneic

Allogeneic transplant patients who have survived 12 months or more after first transplant and who are in good status but relapse or a patient who has had primary graft failure which is substantiated by documentation can be considered on an individual basis. Other patient selection criteria established for first transplant should then be applied.

Autologous
Criteria for second autologous transplantation is the same as allogeneic transplantation except in the following situations:

- For patients who relapse following autologous transplantation, and have a matched sibling, an allogeneic transplant may be considered.

- When a tandem autologous transplant is the plan of treatment from the onset, approval is given for a maximum authorization amount of $100,000. Any procurement cost (peripheral stem cells harvested and stored) and transplant costs (stem cells infused) associated with the tandem transplant (each inpatient stay) is covered under the single cap amount.

- When a tandem transplant is not the plan, however the plan is to secure additional stem cells post-transplant for future use, the facility may submit a claim for the additional harvest providing a cap amount remains from the transplant.

### 13.5.B SECOND/THIRD ORGAN TRANSPLANT REQUESTS

Organ transplant patients who experience organ failure or rejection may be considered for a second/third transplant. The patient must be reevaluated and found to be a suitable candidate according to the facility’s patient selection criteria. A new authorization must be requested from MHD following the same prior authorization process as for the initial transplant. If graft failure is due to non-compliance with the facility's transplant protocol, documentation addressing the situation must be attached to the new request.

### 13.5.C MULTIPLE FACILITY LISTINGS FOR SOLID ORGANS

A participant may be on multiple waiting lists for solid organs. The multiple waiting lists are defined as concurrent listings with two or more transplant centers that are not associated with the same organ procurement organization or regional OPO. Transplant centers must follow the United Network for Organ Sharing's (UNOS) policy regarding multiple listings.

Once the transplant takes place the facility that did not perform the transplant will be notified that the contract is to be voided.

### 13.6 NON-EXPERIMENTAL/MEDICALLY NECESSARY TRANSPLANT REQUESTS

Non-experimental, medically necessary, organ and bone marrow/stem cell transplants which are not covered by the MO HealthNet Transplant Program may be considered for coverage under the expanded Healthy Children and Youth (HCY) Program for persons under 21 years of age. The need for the transplant must have been identified as the result of an HCY/EPSDT screening and must be
prior authorized by the MO HealthNet Division. Refer to Section 9 for more information on the HCY Program.

Providers may request coverage under the HCY Program for noncovered, non-experimental transplants by completing the transplant prior authorization process.

The maximum allowed amount for any such transplant does not exceed established limitations and is reimbursed in accordance with the limitations and procedures established for covered transplants.

13.7 MEDICARE/MO HEALTHNET TRANSPLANTS

Patients who are eligible for both Medicare and MO HealthNet have services primarily covered by Medicare and secondarily by MO HealthNet. Transplant services covered by Medicare are subject to the limitations or criteria imposed by Medicare.

Medicare patients who do not meet the criteria for coverage under Medicare guidelines but who are eligible for MO HealthNet may be eligible for transplant coverage under MO HealthNet. The provider must contact the MO HealthNet Division to request prior authorization of the transplant.

13.7.A MEDICARE LIMITATIONS

Medicare transplant limitations should be verified to determine Medicare coverage limits prior to the time of transplant. Providers may request a MO HealthNet prior authorization for participants who have Medicare coverage. When an individual is eligible for both Medicare MO HealthNet, a claim must be filed with Medicare first. Providers must know their Medicare carriers policy when billing drugs and services.

13.7.B MEDICARE TRANSPLANT FACILITIES

Kidney, pancreas, heart, limited bone marrow/stem cell, liver, intestinal, and lung transplant coverage is available to persons who have Medicare benefits. If the participant has both Medicare and MO HealthNet coverage, and the transplant is covered by Medicare, the Medicare Program is the first source of payment. In this case, the requirements or restrictions imposed by Medicare apply and MO HealthNet reimbursement is limited to applicable coinsurance and deductible amounts without contract. For transplants not covered by Medicare policy MO HealthNet’s regular transplant policy applies.

Medicare restricts coverage of heart, lung and liver transplants to Medicare-approved facilities. Refer to the Approved Transplant Facility Listing for those facilities that are Medicare approved. Missouri Medicare/MO HealthNet participants should be referred for evaluation to Missouri Medicare approved facilities prior to referral to Medicare approved facilities in other states.
Potential heart, lung and liver transplant patients who have Medicare coverage or who will be eligible for Medicare coverage within 6 months from the date of eminent need for transplant should be referred to one of the approved Medicare transplant facilities for evaluation.

If the Medicare/MO HealthNet participant is too ill to be referred to an approved Medicare transplant facility, MO HealthNet may issue a temporary authorization for transplant services at a non Medicare approved facility until the patient can be stabilized. Refer to Section 14 regarding prior authorization procedures for Medicare/MO HealthNet participants.

13.8 TRANSPLANT PRIOR AUTHORIZATION AND APPROVAL PROCESS

Refer to Section 14 of the Transplant Manual.

13.9 INPATIENT HOSPITAL ADMISSION CERTIFICATION REVIEW

Hospital stays for MO HealthNet eligible participants in facilities located within Missouri or within states which border Missouri are subject to inpatient hospital admission certification review. Transplant prior authorization does not exempt the facility from the admission certification review process.

Approval for inpatient hospital admission should not be confused with the transplant prior authorization. The transplant facility must have prior authorization to perform the transplant and receive ACS approval for admission at the time of the actual transplant. All inpatient admissions for the transplant patient related to the pre-transplant evaluation, the stay for the transplant surgery (which includes pre-transplant days), the stay for the bone marrow/stem cell harvest (autologous marrow patients) and follow-up admissions must be certified in accordance with the criteria established by the MO HealthNet Division. Refer to the MO HealthNet Hospital Manual Section 13 for a complete description of the inpatient hospital admission certification review.

Inpatient services for the bone marrow/stem cell donor (allogeneic/non-related) or the living related kidney or liver donor are considered organ procurement services and are not subject to the admission certification review process.

13.9.A REVIEW AUTHORITY

- ACS must be contacted by physician office staff or hospital staff to provide patient/provider identifying information regarding the patient’s condition and planned services. The patient should be identified as a transplant patient and ACS should be notified that MHD transplant prior authorization has been granted.
• ACS can be contacted to request certification at the toll-free telephone number (in-state or out-of-state), (800) 766-0686, OR by submitting the Mail/Fax Preadmission Certification Request form to (573) 634-4262 OR by mailing the form to:

ACS
3425 W. Truman Blvd.
Jefferson City, MO 65109-5713

13.9.B ACS LETTER OF APPROVAL

After ACS approves an admission they send a letter to both the hospital and the attending physician. It is important to verify the information in the approval letter is complete and accurate. ACS must be contacted to correct any discrepancies or be notified of changes to the patient’s planned services subsequent to the initial request.

ACS contacts the MO HealthNet Division Transplant Unit to provide the transplant unit staff with planned date of admission/date of transplant surgery. The MO HealthNet Division staff records this information in the transplant participant’s file.

13.10 COVERED AND NONCOVERED SERVICES FOR TRANSPLANT

Certain services and procedures are commonly billed for transplant patients. The following covered and noncovered services are identified for provider information. More detailed information is available in this section and other sections of the Transplant Manual, or in the specific MO HealthNet Program Manuals.

13.10.A COVERED SERVICES

The following services are covered for the transplant when there is a signed agreement between the transplant facility and MHD:

• Date of transplant through date of discharge;

• Inpatient donor services for the bone marrow/stem cell harvest, kidney nephrectomy (living donor), liver lobectomy (living donor), or pneumectomy (living donor);

• Outpatient and physician donor (actual donor) services directly related to the bone marrow/stem cell transplant (including cell procurement, labs, etc.)

• Matched donor (actual donor) and nonmtached donor search and testing services must be billed separately;
• Physician's services related to the transplant procurement, including the services of the excision surgeon, the bone marrow/stem cell harvest and other procurement procedures;
• Bone marrow/stem cell cryopreservation;
• Bone marrow/stem cell purging;
• Peripheral stem cell recruitment;
• T-cell depletion.

• Laboratory studies to determine a suitable kidney or bone marrow/stem cell donor; using CPT procedure codes 86812-86822 (related for adults and children, unrelated for children under 21 years of age);

• Physician’s services related to the transplant: the transplant surgeon, co-surgeon, assistant surgeon, infusion surgeon, anesthesiologist, or consulting physician for the transplant participant.

The services identified below are covered services, however when a participant is a member of a MO HealthNet Managed Care plan, the plan is responsible for the services. The health plan may not determine the need for an evaluation or establish criteria of coverage for transplants based on their own internal protocols.

• Dental evaluation and services required to ensure the patient does not have any major cavities and/or infections prior to transplant (under age 21);
• Follow-up services, including evaluations and assessments provided to the successfully transplanted patient;
• Home pulse oximeter following lung transplant (covered through Exceptions Unit; refer to Section 20);
• Human Hyperimmune CMV Globulin (IVG-CMV);
• Inpatient services, including pre-transplant days and follow-up stays;
• Medically necessary services required to assess a patient’s suitability for transplantation are covered, whether or not the patient is ultimately accepted as a candidate;
• Medically necessary inpatient services following the discharge for the transplant stay which are required to manage complications of the transplant including late infection or rejection episodes;
• Physician services, pre-transplant critical care and other post hospital follow-up services; and

• Transportation for the patient who does not have access to free transportation. Refer to Section 22 for more information on Non-Emergency Medical Transportation (NEMT).

13.10.B NONCOVERED SERVICES

The following services are not covered by MO HealthNet:

• Pancreas only transplants, which do not follow a kidney transplant;

• Bone marrow/stem cell transplant services performed as part of a study or protocol for which there is no clear cut evidence that the transplant provides a reasonable chance for cure;

• Services and supplies for which the beneficiary has no legal obligation to pay. For example, MO HealthNet does not reimburse expenses that are waived by the transplant center or for which research funds are available;

• Out-of-hospital living expenses or other non-medical expenses (NOTE: NEMT may assist or cover some out of hospital living expenses. Refer to Section 22 for more information;

• Maintenance services after an individual has been declared deceased are part of the procurement charge billed by the Organ Procurement Agency. Maintenance services may not be billed to MO HealthNet as the cadaveric donor’s own charges when the cadaveric donor is a MO HealthNet participant;

• A beeper/pager for a patient on a waiting list. It is also not a covered service through the MO HealthNet exceptions process;

• The costs associated with the search for a non-related bone marrow/stem cell donor (for a participant 21 years of age or older), except for the laboratory services for the donor who is determined to be a match. (Non-related is considered any relation beyond; parent, sibling, spouse, child (by adoption, marriage or birth), grandparent and grandchild.);

• Psychological battery tests or assessment instrument procedures (BSI, HAP, LES, MBHI, MMSE, SSI, SDMT, TMT, etc.) used to help assess adult patients (age 21 and older) for clinical purposes, as part of the transplant evaluation, when provided to adults by a psychologist; however, they are covered when provided by a psychiatrist;
Nurse Clinician Assistant services for the bone marrow/stem cell harvest or any other type of transplant service—*may not* be billed by a physician or included as part of a revenue code/charges shown on the UB-04 claim form;

Services of a transplant coordinator as part of the facility’s organ procurement costs. They may *not* be included as a pass through charge between the organ procurement agency and transplant facility. The services of the transplant coordinator may *not* be billed by a physician and *cannot* be incorporated into an inpatient revenue code;

Drawing fees (CPT-4 procedure code 36415), whether billed inpatient, outpatient, by a physician or laboratory under any ancillary, as charges, supply, revenue code or “99” (unlisted) CPT procedure code;

“Stat” charges;

Portable x-ray/echography surcharges;

Educational supplies (books, pamphlets, tapes);

Analysis of information data stored in computers (e.g., ECG’s, blood pressure, hematologic data);

Certain services performed in a hospital by specific departments are considered to be part of the hospital’s accommodation rate (room charge) and should *not* be billed separately. Refer to Section 13;

Autopsy/Necropsy (post-mortem examination);

Claim filing fees or preparation of special reports;

Experimental medical procedures and experimental drugs;

Handling charges for specimens referred to an independent laboratory for interpretation;

Charges for incidental surgical procedures performed through the *same* incision;

Occupational Therapy services provided on an outpatient basis for adults;

Non-care and personal comfort items such as telephone, television, newspapers, cots, and the services of a beautician, barber, manicurist, and private duty nurse;

Partial hospitalization or day treatment;

Non-invasive ear or pulse oximetry for oxygen saturation (procedure codes 94760, 94761 and 94762) are *not* covered by MO HealthNet;
• Mark-up for organ procurement, transportation or excision (these charges must provide an invoice to be considered for payment);
• Special dietary items and guest trays; and
• Take home drugs, supplies and equipment (Drugs, supplies, and equipment which meet program limitations can be reimbursed through the Pharmacy or DME Program).
• Services to search or test for non-matched potential donors of transplant participants 21 years of age or older.

13.11 INPATIENT HOSPITAL SERVICES

Pre-transplant inpatient services and follow-up services (inpatient services provided after discharge of the transplant patient) are subject to the limitations of the MO HealthNet Hospital Program which are further described in the MO HealthNet Hospital Manual, Section 13. MO HealthNet Managed Care managed care participants receive pre-transplant inpatient services and follow-up services from the MO HealthNet Managed Care health plan.

13.11.A PARTICIPANT LIABILITY FOR INPATIENT DAYS

Refer to Section 13 of the Hospital Program Manual for further information regarding participant liability for inpatient services.

13.11.B PRE-TRANSPLANT STAY

Fee-for-service patients who are hospitalized prior to the date of transplant are entitled to coverage of inpatient services for the pre-transplant stay (for billing purposes, this is the day(s) prior to the date of transplant) subject to the following benefits and limitations:

• The inpatient stay must be pre-certified by ACS;

and

• Reimbursement of the pre-transplant stay is limited to the facility’s per diem rate and subject to the ACS certification.

Patients who are enrolled in a managed health care plan receive the pre-transplant coverage through the health plan.

13.11.C DATE OF TRANSPLANT
The date of transplant is defined as the day the transplant is performed. This date usually coincides with the date of organ procurement for organ transplants and is the date of marrow infusion for bone marrow/stem cell transplants.

13.11.D TRANSPLANT STAY

Inpatient services from the date of transplant through date of discharge are covered for each day the patient is MO HealthNet eligible. Reimbursement is provided by MO HealthNet for “reasonable charges” up to the maximum allowable for the type of transplant being performed.

Leave of absence from an inpatient facility is not covered by MO HealthNet.

Discharge for transplant participants may also be a significant change in diagnosis prior to actual discharge, but unrelated to the transplant procedure or complications related to the transplant. When using a different date for the transplant stay than the actual discharge date that the patient leaves the hospital, the facility must include medical records showing the change in diagnosis. The facility must contact ACS for certification of days beginning with the date of significant change in diagnosis. Reference Section 13 of the Hospital Manual for further information regarding hospital admission certification.

13.11.D(1) "Reasonable Charges"

Charges must be substantiated by the itemized bill submitted with the claim for the transplant.

The “reasonable charges” must be listed under the appropriate revenue code on the UB-04 claim form.

The claim for the date of transplant through date of discharge may include all “reasonable charges” for:

- Accommodations (services which are charged to every patient for each patient day are to be included in the routine accommodation charge and cannot be billed as ancillary charges);
- Intensive care;
- Coronary care (when appropriate use the heart transplant revenue code);
- Pharmacy (may not include charges for take home drugs or experimental drugs);
- IV therapy;
• Medical/surgical supplies (may not include charges for take home supplies; prosthetic devices; and take home oxygen.) Items of a non-durable nature (syringes, needles, latex gloves, face masks, oxygen tubing, etc.) may be included on the itemized bill if it is the routine practice of the facility to include such items on the itemized bill for non-MO HealthNet patients;

• Oncology;

• Laboratory (may not include charges for renal patient [home]);

• Laboratory—pathological;

• Radiology—diagnostic;

• Radiology—therapeutic;

• Nuclear Medicine;

• CT scan;

• Other imaging services;

• Operating room (OR) services (specific OR revenue codes for the transplant surgery should be used to show charges related to the transplant. General OR revenue codes should be used for all other OR charges occurring during the transplant stay);

• Anesthesia (excluding acupuncture);

• Blood;

• Blood storage and processing;

• Respiratory services;

• Physical, occupational and speech therapy;

• Pulmonary function;

• Cardiology services (heart catheterization, coronary angiography, etc.);

• Recovery room;

• EKG/ECG (electrocardiogram);

• EEG (electroencephalogram);

• Gastro intestinal (endoscopic procedures not performed in an operating room);
• Inpatient renal dialysis;
• Organ acquisition or other donor bank. These charges must be accompanied by an invoice to justify charges and will not be reimbursed above the invoiced charges to the facility. (This includes all services related to organ procurement or bone marrow/stem cell acquisition -- Refer to Section 14); and
• Other diagnostic/therapeutic services.

13.12 PHARMACY SERVICES

Pharmacy services are covered for MO HealthNet participants on a fee-for-service basis.

• Pharmacy services, provided while the MO HealthNet participant is a patient in the hospital, are covered and reimbursement is included in the reimbursement for the inpatient stay (both during the stay for the transplant procedure and during any subsequent admission);
• The provider and patient should be aware that MO HealthNet can make reimbursement only to a participating MO HealthNet pharmacy provider. Out of state hospitals may wish to have the hospital’s pharmacy or a nearby independent pharmacy enroll as a MO HealthNet provider so that patients can have their prescriptions filled upon discharge;

13.13 VENTRICULAR ASSIST DEVICES

A ventricular assist device (VAD) used to assist a damaged or weakened heart is covered when used as a bridge to transplant. The service is covered under the MO HealthNet Hospital Program as part of the per diem and not covered through the Transplant Program. The VAD is not covered as an artificial heart. The device must be used with FDA labeling instructions.

13.14 DENTAL SERVICES

The MO HealthNet Division assures coverage of medically necessary dental services for MO HealthNet transplant candidates. This assurance is given to eliminate any risk-factors posed to the transplant candidate that may result from poor dental health, and that would jeopardize the transplant candidate’s health or impede an opportunity for transplant if the services were not provided.

The dentist providing services for transplant patients must be an enrolled MO HealthNet provider and is reimbursed in accordance with the benefits and limitations outlined in the Dental Manual. Refer to the Dental Manual for dental services for MO HealthNet Managed Care enrollees.

When a transplant patient is not referred to the patient’s own dentist for evaluation, the oral surgeon and/or hospital may bill procedure code 70355 (Orthopantogram) to bill for a full mouth dental survey.

13.15 PHYSICIAN SERVICES

Billed services for a given diagnosis should not exceed the level of service defined for new or established patients. Definitions are described in the introduction section of the Physicians’ Current Procedural Terminology (CPT-4) procedure code book under Definitions and Items of Commonality. Definitions may also be found in the MO HealthNet Physician’s Manual Section 13. Please refer to the definitions when determining the level of service to be billed for each patient.

Refer to the MO HealthNet Physician Manual for a complete listing of benefits and limitations. The following information is provided as a quick reference of services most often provided by transplant surgeons and attending physicians.

13.15.A TRANSPLANT SURGEON

The transplant surgeon’s services should be billed using the appropriate procedure code. The fee is payable either 100% of the maximum allowable amount or the billed amount, if less, for the major surgical procedure (transplant). Routine surgical follow-up care (wound check, etc.) provided by the surgeon is subject to the 30 day post-operative policy.

The transplant surgeon, assistant surgeon or other physician in attendance may bill for critical care or inpatient follow-up care when not related to routine surgical follow-up care.

13.15.B ASSISTANT SURGEON

Only one assistant surgeon is paid for those procedures that warrant an assistant. Refer to Section 13 of the Physician's Manual for more information.

13.15.C CO-SURGEON’S SERVICES (TWO SURGEONS)

“Co-surgeons” are defined as two primary surgeons working simultaneously performing distinct parts of a total surgical service, during the same operative session. Refer to Section 13 of the Physician Manual for more information.

13.15.C(1) Bone Marrow/Stem Cell Harvest—Co-Surgeon

MO HealthNet allows the reimbursement of a co-surgeon for bone marrow/stem cell harvest when necessary for the purpose of bilateral harvest. Documentation of medical necessity is not required; however, a copy of the operative report must be submitted with the claim form.
13.15.D SURGICAL TEAM (THREE OR MORE SURGEONS)

When a surgical team (three or more surgeons) is used to perform a transplant, each surgeon is reimbursed at the base rate divided by the number of surgeons listed on the operative report for the procedure code divided by the number of surgeons on the team, according to the operative report.

When billing for the surgical team, all surgeons must file separate claims, each using their own individual MO HealthNet provider number. The surgical procedure code with modifier 66 (surgical team) should be shown on each claim. A copy of operative report must be submitted with each claim.

13.15.E TRANSPLANT SURGERY CODES

The transplant procedure and appropriate modifier should be used when billing the services of the surgeon, co-surgeon, assistant surgeon, team surgeons, and anesthesiologist.

Surgeon fees associated with the procurement of an organ harvested for transplant must be submitted with the invoice submitted to the transplant facility by the Organ Procurement Organization (OPO).

When billing for an authorized kidney/pancreas transplant use the appropriate kidney transplant procedure code and the appropriate pancreas transplant procedure code. The pancreas transplant is reimbursed as a second surgery on the same date in accordance with policy for reimbursement of multiple surgeries. The operative report must reflect that a pancreas transplant was performed in addition to the kidney transplant.

On a case by case basis, MO HealthNet may provide reimbursement for isolated pancreas transplant when there has not been a previous kidney transplant.

13.15.F POST-OPERATIVE CARE

Post-operative care includes 30 days of routine follow-up care (wound check, etc.) for those surgical or diagnosis procedures having a MO HealthNet reimbursement amount of $75.00 or more. For counting purposes, the date of transplant surgery is the first day.

- Post-operative care by a physician other than the transplant surgeon is payable if:
  - the diagnosis treated is not related to the surgery.
  - the illness would have required hospitalization in its own right.
  - the surgeon would not be expected to handle the condition.

- When a surgeon provides the surgical procedure and the post-operative care, 100% of the maximum allowable amount for the procedure is allowed.
• When a surgeon performed the surgical procedure(s) only, 80% of the maximum allowable amount for the surgical procedure is allowed.

• When a physician provides post-operative care only, 20% of the maximum allowable amount for the surgical procedure is allowed.

13.15.G CRITICAL CARE

Critical care services provided by the transplant surgeon, assistant surgeon and co-surgeon are not subject to post-op limitation policies.

13.16 OUTPATIENT HOSPITAL SERVICES

13.16.A OUTPATIENT STEM CELL TRANSPLANTS

Although the MO HealthNet Division recognizes stem cell transplants performed on an outpatient basis are a standard treatment method in some facilities, the Division does not currently authorize stem cell transplants that will be performed on an outpatient basis.

The Division does not allow infusion of stem cells for clinical purposes other than those outlined in the Physician Manual, Section 13 (Therapeutic apheresis).

Inpatient admissions for follow-up after a stem cell infusion (apheresis) performed on an outpatient basis are reviewed carefully to assure that a transplant has not occurred. Claims to any provider for unauthorized stem cell transplants and related services may be recouped.

13.17 DONOR LEUKOCYTE INFUSION (DLI)

MO HealthNet does not consider donor leukocyte infusions (DLI) to be traditional transplants. However, a request must be made and approved through the Transplant Program for a DLI to take place.

13.17.A PHYSICIAN CLAIM

The physician performing the DLI uses CPT code 38242 on the date the infusion(s) are performed.

13.17.B OUTPATIENT CLAIM

The facility can perform infusions on an outpatient basis and these claims are not paid through the Transplant Program. The claims must be submitted fee-for-service and paid on the outpatient rate and/or lab fee schedule.
13.17.B(1) DLI Procurement

If additional procurement is necessary for a DLI to take place the facility will request approval for an additional harvest. If approved, the facility will receive a maximum reimbursement of $1,150 for the additional harvest/procurement. The facility should bill the procurement/harvest on a separate outpatient claim to the Transplant Unit, accompanied by an invoice from the procurement organization. If the participant is enrolled in a MO HealthNet Managed Care program the MO HealthNet Managed Care plan is responsible for the reimbursement of all fees in connection with the DLI with the exception of the procurement.