LIVER TRANSPLANTATION

Policy Number: 2013M0046A  Effective Date: February 1, 2014

Table of Contents:  

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
<th>Cross Reference Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>POLICY DESCRIPTION</td>
<td>2</td>
<td>Not Available</td>
</tr>
<tr>
<td>COVERAGE RATIONALE/CLINICAL CONSIDERATIONS</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>BACKGROUND</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>REGULATORY STATUS</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>CLINICAL EVIDENCE</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>APPLICABLE CODES</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>REFERENCES</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>POLICY HISTORY/REVISION INFORMATION</td>
<td>17</td>
<td></td>
</tr>
</tbody>
</table>

INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”

RELATED MEDICAL PRODUCTS:  Not Applicable.

SEARCH TERMS:  Liver allotransplantation; orthotopic, living donor, transplant center, hepatic artery thrombosis, rejection, immunosuppression, hepatocellular carcinoma, cirrhosis, hemochromatosis, chemoembolization, liver disease
POLICY DESCRIPTION:

This policy describes the use of liver transplantation, the act of surgically removing the diseased liver of a patient and replacing it with a healthy liver graft from a donor. The engrafted liver may be all or part of a liver removed from a brain-dead donor or a portion of a liver from a healthy living donor. Liver transplantation may be a lifesaving procedure for patients with chronic end-stage liver disease and acute liver failure (ALF) when there are no alternative treatment options. Prolonged survival and improved quality of life are the major goals of liver transplantation. The success of liver transplantation is directly related to the severity of illness; when patients are critically ill prior to transplant, the outcome is likely to be worse than for patients who are not as ill. The challenge for the transplant team is to choose their candidates wisely to optimize the scarce supply of donor organs and to transplant early enough in the patient’s illness to assure a good chance for recovery.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

Liver transplantation is considered MEDICALLY NECESSARY for individuals with ANY of the following indications:

1. End-stage liver failure (life expectancy < 12 – 24 months and who have developed life-threatening complications).
2. Hepatocellular carcinoma (HCC) within Milan Criteria and no contraindications. Milan Criteria (Mazzaferro):
   - Not a candidate for subtotal hepatic resection
   - Tumor is HCC stage II (T2, one nodule 2.0 - 5.0 cm; two or three nodules, all ≤ 3.0 cm)
   - No macrovascular involvement
   - No identifiable extra-hepatic spread of tumor to surrounding lymph nodes, lungs, abdominal organs or bone.
3. Hepatoblastoma which is confined to the liver (children).
4. Inborn errors of metabolism/metabolic disease with intact hepatic synthetic function, but not limited to: primary hyperoxaluria, familial homozygous hypercholesterolemia, familial amyloidosis, urea cycle disorder or organic acidemia (pediatric), citrullinemia, alpha-1 antitrypsin deficiency, Crigler-Najjar syndrome, Glycogen storage diseases types I and IV, hemochromatosis, metabolic respiratory chain deficiencies.
5. Unresectable hilar cholangiocarcinoma: The patient is under the appropriate protocol at a center with an approved living donor liver transplant program, OR a program in a region where the United Network for Organ Sharing (UNOS) regional review board (RRB) will award Model for End-Stage Liver Disease (MELD) exception points to patients who qualify under the requesting program’s treatment protocol.
6. Hepatopulmonary syndrome.
7. Neuroendocrine/gastroenteropancreatic (GEP) tumors with ALL of the following:
   - Unresectable liver metastasis,
   - Prior complete resection of the primary GEP,
   - Absence of extrahepatic metastasis,
   - Failure to respond to medical and/or interventional treatment,
• Severe hypoglycemia, poorly controlled hyperglycemia, cardiac distress, respiratory distress or other symptoms directly attributable to aberrant GEP tumor production of life-threatening hormones such as insulin, catecholamines, or histamine.

8. Retransplantation, as medically necessary, for individuals considered to have a significant chance of success and who still meet eligibility criteria for primary transplantation for ANY of the following indications:
   • Primary non-function graft failure
   • Hepatic artery and/or portal vein thrombosis
   • Severe rejection
   • Recurrence of the disease which prompted the initial liver transplantation.

Xenotransplantation of solid organ is considered INVESTIGATIONAL AND/OR EXPERIMENTAL.

Note: These recommendations are consistent with the 2005 American Association for the Study of Liver Disease (AASLD) Clinical Practice Guidelines (Murray and Carithers).

Clinical Considerations:
- Liver transplantation may be a lifesaving procedure for patients with chronic end-stage liver disease and acute liver failure (ALF) when there are no alternative treatment options.
- Prolonged survival and improved quality of life are the major goals of liver transplantation.
- Because liver transplantation has a 10% to 15% mortality rate during the first year, only patients who have a projected survival of less than 2 years because of their chronic liver disease should be considered for transplantation.
- Post transplant survival rates have continued to improve with 1-year, 5-year, and 10-year patient survival rates (for all indications) exceeding 85%, 76%, and 61% (Scientific Registry of Transplant Recipients (SRTR) data base).
- Best outcomes are achieved when there is “adherence to objective, evidence-based indications and contraindications for liver transplantation”.
- A Model for End-Stage Liver Disease (MELD) score ≥ 15 or a Child-Turcotte-Pugh (CTP) score of 7 or more correlates with improved one year survival following transplant compared to survival without transplant. Patients with MELD scores < 15 will have an increased risk of death within one year with liver transplant than without.
- Because complete evaluation for transplantation can take weeks to months and patients must wait for variable periods of time before receiving a deceased donor organ, timing referral before the patient’s anticipated mortality exceeds that of the estimated postoperative survival is important.

The American Association for the Study of Liver Disease (AASLD) recommends the following timing for referral for transplant evaluation (Murray and Carithers):
- Patients with cirrhosis should be referred when they develop evidence of hepatic dysfunction (CTP > 7 and MELD > 10) or when they experience their first major complication (ascites, variceal bleeding, or hepatic encephalopathy)
- Children with chronic liver disease should be referred when they deviate from normal growth curves or develop evidence of hepatic dysfunction or portal hypertension
- Patients with type I hepatorenal syndrome should have an expedited referral for liver
transplantation

- Patients may be placed on the UNOS waiting list for liver transplantation without meeting the above criteria. However, priority status is currently defined by the MELD score for adult recipients and the Pediatric End-Stage Liver Disease (PELD) score for pediatric recipients. Definitions and calculators for the MELD and PELD scores can be found on the Organ Procurement and Transplantation Network (OPTN) website at: http://optn.transplant.hrsa.gov/resources/allocationcalculators.asp

- Generally, patients with MELD scores < 15 should not be listed or transplanted unless one or more of the following indications are present:
  - Adults with hepatocellular carcinoma (HCC) who meet Milan criteria (Mazzaferro) will be awarded MELD exception points
    - Currently, MELD exception points are not awarded for cholangiocarcinoma
    - Tumors can be downstaged with hepatic artery chemoembolization (HACE) with or without radiofrequency ablation (RFA)
  - Other conditions in adults where MELD exception points will be awarded are:
    - Hepatopulmonary syndrome
    - Primary oxaluria
    - Familial Amyloidosis
    - Combined liver/intestine transplant
  - Children with any of the following conditions will be awarded PELD exception points:
    - Hepatoblastoma
    - Urea cycle disorders and organic acidemia
    - Combined liver/intestine transplant

- Patients with primary oxalosis with ESRD should be considered for combined liver/kidney transplant (Eason et al).

- Chronic smokers, patients over the age of 50, and those with a clinical or family history of heart disease or diabetes should undergo evaluation for coronary artery disease.

- All patients undergoing evaluation for potential liver transplantation should undergo screening for pulmonary hypertension.

- Patient or guardian is able to give informed consent. Patient/guardian and family/social support system are able to comply with the treatment regimen and the necessary follow-up. Inadequate funding to pay for immunosuppressive medications post-transplant are addressed and resolved.

**Contraindications:**

- Ongoing alcohol abuse and substance abuse.
- Active extrahepatic malignancy that is expected to significantly limit future survival.
- Persistent, recurrent or unsuccessfully treated major or systemic infections.
- Systemic illness or comorbidities that would be expected to substantially and negatively impact the successful completion and/or outcome of transplant surgery, such as, but not limited to:
  - Severe end stage organ damage including: Severe diabetes mellitus with end organ damage, irreversible severe pulmonary disease, with FEV1 <1 L or FVC <50%, irreversible severe hepatic disease, irreversible severe renal disease
Encephalopathy with evidence of irreversible brain damage
- Limited cognitive ability (memory loss, dementia, etc.).
- A pattern of demonstrated noncompliance which would place a transplanted organ at serious risk of failure.
- Human immunodeficiency virus (HIV) disease unless all of the following are noted:
  - Cluster determinant (CD)4 count >100 cells/mm³,
  - HIV-1 ribonucleic acid (RNA) undetectable,
  - Stable antiretroviral therapy for more than three months, and
  - Absence of serious complications associated with HIV disease (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; or resistant fungal infections; or Kaposi’s sarcoma or other neoplasm).
- Known intrahepatic or central cholangiocarcinoma.
- Inadequately treated malignancies outside of the liver with substantial likelihood of recurrence.
- Donor with:
  - Ongoing alcohol abuse
  - Active malignancy, with the exception of non-melanotic skin cancer
  - Persistent, recurrent or unsuccessfully treated infections, including hepatitis A, B or C or HIV
  - Active systemic illness or serious comorbidities that would be expected to substantially negatively impact the successful completion and/or outcome of transplant surgery
  - Active systemic illness that is likely to negatively affect survival.

BACKGROUND:

Transplantation for progressive liver disease that will ultimately lead to a fatal outcome, or end-stage liver disease, is currently accepted as a practical and established medical therapy. This therapy could theoretically be used for every patient with terminal liver disease. Technical and pharmaceutical advances have made liver transplantation available to patients who might not have previously qualified, such as those diagnosed with hepatitis or hepatocellular carcinoma. The question is no longer whether to perform this complex surgery but how to identify the best candidates.

Life cannot be sustained without the metabolic function of the liver. Due to the complexity of the liver’s function, it is not possible to treat liver dysfunction with mechanical assistance for extended periods of time. In cases of irreversible liver disease, the only possibility of avoiding patient death is to replace the liver by a transplant. Retransplantation currently is the only means of preventing patient death after graft failure; it is necessary in 15% to 20% of transplanted patients (Trotter et al., 2002).

Progressive liver disease that will eventually result in death in either the short or long term is referred to as end-stage liver disease. It is caused by a variety of conditions that lead to a disruption of normal architecture and malfunction of the liver. The most common causes of liver dysfunction for adults include:

- Infection (acute or chronic hepatitis)
- Toxic effects (alcohol, medications)
- Disorders of metabolism (Wilson’s disease, hemochromatosis)
- Tumors (primary or metastatic)
Liver transplantation was first performed in 1963. Success was limited until the introduction and approval by the Food and Drug Administration (FDA) of cyclosporine as an immunosuppressant. In the late 1980s, the introduction of the University of Wisconsin cold preservation system allowed physicians approximately 24 hours to conduct the transplant, as opposed to the previous 6 to 8 hours that had been the standard. These developments in transplantation technology allowed for significantly improved success rates from the earlier studies. Since the liver contains a large number of blood vessels, liver transplantation is the most difficult organ transplant procedure. Despite its complexity, liver transplantation is a practical and established therapy for life-threatening liver disease. With a limited supply of donor organs available for transplantation, the most critical challenge today is to choose transplant candidates judiciously to ensure long-term survival of both patient and graft (Trotter et al., 2002).

The major problem in liver transplantation remains the severe shortage of donor livers. The national list of patients awaiting transplantation for all organs is maintained by the United Network for Organ Sharing (UNOS). The number of potential recipients has outpaced the quantity of available livers almost since the inception of liver transplantation. The waiting time for some prospective recipients can exceed 2 years. The liver shortage for pediatric patients is most severe; at some centers, the waiting list mortality rate is 25%, with 5-year survival for transplant patients approaching 70% (Sterling and Fisher, 2001). In 1980, 184 transplants were performed in the United States; by 1999, 14,710 patients waited for liver transplants, and the waiting time had increased from 65 days in 1991 to 514 days in 1998 (Dodson, 1993; Wood et al., 1994; Trotter et al., 2002). In 2000, 10,893 patients were added to the waiting list for liver transplantation, 7799 transplant surgeries were performed, and 1661 patients died while waiting for a liver transplant (UNOS, 2002). With transplantation, the 3-month, 1-year, 3-year, and 5-year survival rates in 2000 were 91.4%, 87.0%, 80.9%, and 75.1%, respectively (UNOS, 2002a).

In February 2002, UNOS began using the Model for End-Stage Liver Disease (MELD) scoring system as the basis for the allocation of livers to adult recipients. The most seriously ill patients remain classified as Status I, but patients in other status designations will be affected by this change. The MELD score is arrived at through a calculation based on the patient’s serum creatinine value, bilirubin and international normalized ratio (INR). The time spent on the waiting list is used as a “tie-breaker” in case there are two patients with identical scores. A separate evaluation based on the tumor size is used for patients with hepatocellular carcinoma. Patients with severe hepatopulmonary syndrome may be reevaluated by their regional organ distribution board and assigned a different MELD score. Patients with familial amyloidosis or other patients whose physicians believe that their MELD scores do not accurately reflect the severity of their condition may have their scores changed after review by the regional allocation board (UNOS, 2002b).

Since the number of patients awaiting liver transplantation continues to outpace the quantity of available donors, physicians have developed new techniques to adapt existing livers to patient need in order to alleviate the organ shortfall; these techniques include reduced-size liver transplantation, split liver transplantation, and living donor liver transplantation, hepatocyte transplantation and xenotransplantation (Pappas et al., 1995; Steinman et al., 2001; Sterling and Fisher, 2001).

**Cadaveric (Deceased) Donor Transplantation**

A major factor in patient survival following transplantation is the degree of hepatic decompensation and associated debility at the time of transplantation. The Model for End Stage Liver Disease (MELD) scoring model is used for individuals who are ≥12 years and is based on a statistical formula that predicts the probability of death within three months of listing. Similar to the MELD system, the Pediatric End-Stage
Liver Disease (PELD) scoring model is used for a child <12 years. Donor organs are allocated to transplant candidates designated as having the greatest mortality risk (i.e., status 1A or 1B) followed in descending order as determined by the number of MELD/PELD score points. Exceptions to this policy, which result in the assignment of additional MELD/PELD points and therefore a higher priority for allocation of donor organs, can be requested of a United Network for Organ Sharing (UNOS) regional review board by the transplantsing physician and/or facility for individuals with certain diagnoses, such as unresectable hilar cholangiocarcinoma (CCA).

Outcomes of liver transplantation have markedly improved due to effective immunosuppression, improved surgical preservation techniques, and enhanced strategies to treat postoperative complications. Both patient and graft survival rates are calculated to determine overall survival. Based on primary liver transplants performed between 1997 and 2004, one- and five-year patient survival rates for cadaveric (deceased) donor recipients were 87.7% and 74.3%, respectively, with one- and five-year graft survival rates of 83.3% and 67.3%, respectively (OPTN, 1997-2004).

**Living-Donor Transplantation**

Living-donor liver transplantation was introduced as an alternative to deceased donor transplantation in response to the shortage of available cadaveric donor organs and is used for both adults and children. The graft from a living donor is more commonly from a relative of the recipient.

The success of this type of transplantation is based on the ability of the liver to regenerate in both the donor and the recipient. The graft must be of adequate size in order to function in the recipient (Emond, 2001). The risks and benefits of using a living-donor graft must be considered as there are surgical risks to both the recipient and the donor. Benefits to the recipient include a reduced chance of mortality related to waiting for a cadaveric-donor organ, a reduced likelihood of primary non-function of the graft, and a potential decrease in the chance of graft rejection and the need for immunosuppression (OPTN, 2012).

**REGULATORY STATUS:**

1. **U.S. FOOD AND DRUG ADMINISTRATION (FDA):**

   Medical procedures such as liver transplantation are not subject to FDA regulations.

   Cyclosporine, azathioprine, polyclonal antithymocyte globulin, muromonab-CD3 (monoclonal antibodies), and tacrolimus (FK506) are all immunosuppressive agents approved by the FDA for use with organ transplantation; however, not all are approved specifically for liver transplantation. Cyclosporine (Sandimmune®, Sandoz, Basel, Switzerland) is approved for the prevention of organ rejection in kidney, liver, and heart allogenic transplantations. Polyclonal antithymocyte globulin (ATGAM®, Novartis, East Hampton, NJ) is indicated to prevent rejection in renal allografts only. 
   Muromonab-CD3 (ORTHOCLINE OKT®3, Ortho Biotech, Raritan, NJ) has approval for the treatment of acute allograft rejection in renal transplant patients and for treatment of steroid-resistant acute allograft rejection in heart and liver transplant patients. Formerly known as FK506, tacrolimus (PROGRAF™, Fujisawa USA, Deerfield, IL) is indicated to prevent organ rejection in patients receiving allogenic liver transplants. Sirolimus (Rapamune®, Wyeth-Ayerst, Madison, NJ) is approved for the treatment of graft rejection in renal transplant patients, but its safety and efficacy has not been established in liver transplant patients. In addition, sirolimus and tacrolimus, when used together in
clinical trials for liver transplant patients, were associated with an increased rate of hepatic artery thrombosis, infection, and graft rejection (FDA, 2002; PDR, 2002).

Prednisone and methylprednisolone, each manufactured under a variety of names by different manufacturers, are corticosteroids approved for numerous indications, although neither is specifically approved for use in organ transplantation. Approved indications include: endocrine disorders, rheumatic disorders, collagen diseases, dermatologic diseases, allergic states, ophthalmic diseases, respiratory diseases, hematologic disorders, neoplastic diseases, edematous states, and gastrointestinal disorders (FDA, 2002; PDR, 2002).

While heparin sodium is not specifically approved for use in organ transplantation, its approved uses relate to surgical procedures. Its approved indications include: prevention of clotting in arterial and heart surgery, prevention of postoperative deep venous thrombosis and pulmonary embolism in patients undergoing abdominothoracic surgery or patients who for other reasons are at risk for developing thromboembolic disease, anticoagulant therapy, and maintenance of patency of indwelling venipuncture devices used for intermittent injection or infusion therapy (FDA, 2002; PDR, 2002).

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):

A. Adult Liver Transplantation Overview (NCD 260.1)

Liver transplantation, which is in situ replacement of a patient’s liver with a donor liver, in certain circumstances, may be an accepted treatment for patients with end stage liver disease due to a variety of causes. The procedure is used in selected patients as a treatment for malignancies, including primary liver tumors and certain metastatic tumors, which are typically rare but lethal with very limited treatment options.

Effective July 15, 1996, adult liver transplantation, when performed on beneficiaries with end-stage liver disease other than hepatitis B or malignancies, is covered under Medicare when performed in a facility which is approved by the Centers for Medicare & Medicaid Services (CMS) as meeting institutional coverage criteria.

Effective December 10, 1999, adult liver transplantation when performed on beneficiaries with end-stage liver disease other than malignancies is covered under Medicare when performed in a facility which is approved by CMS as meeting institutional coverage criteria.

September 1, 2001, Medicare covers adult liver transplantation for hepatocellular carcinoma when the following conditions are met:

- The patient is not a candidate for subtotal liver resection,
- The patient’s tumor(s) is less than or equal to 5 cm in diameter,
- There is no macrovascular involvement,
- There is no identifiable extrahepatic spread of tumor to surrounding lymph nodes, lungs, abdominal organs or bone, and
- The transplant is furnished in a facility that is approved by CMS as meeting institutional coverage criteria for liver transplants (see 65 FR 15006).

Reimbursement Guidelines

Effective for claims with dates of service June 21, 2012 and later, contractors may, at their
discretion determine coverage of adult liver transplantation for the following malignancies:

- Extrahepatic unresectable cholangiocarcinoma (CCA),
- Liver metastases due to a neuroendocrine tumor (NET), and
- Hemangioendothelioma (HAE).

Follow-up care or re-transplantation required as a result of a covered liver transplant is covered, provided such services are otherwise reasonable and necessary. Follow-up care is also covered for patients who have been discharged from a hospital after receiving non-covered liver transplant. Coverage for follow-up care is for items and services that are reasonable and necessary as determined by Medicare guidelines.

B. **Pediatric Liver Transplantation Overview (NCD 260.2)**

Effective for services performed on or after February 9, 1984, liver transplantation is covered for children (under age 18) with extrahepatic biliary atresia or any other form of end stage liver disease, except that coverage is not provided for children with a malignancy extending beyond the margins of the liver or those with persistent viremia.

**Reimbursement Guidelines**

Liver transplantation is covered for Medicare beneficiaries when performed in a pediatric hospital that performs pediatric liver transplants if the hospital submits an application which CMS approves documenting that:

- The hospital's pediatric liver transplant program is operated jointly by the hospital and another facility that has been found by CMS to meet the institutional coverage criteria in the "Federal Register" notice of April 12, 1991;
- The unified program shares the same transplant surgeons and quality assurance program (including oversight committee, patient protocol, and patient selection criteria); and
- The hospital is able to provide the specialized facilities, services, and personnel that are required by pediatric liver transplant patients.

C. **Credentialing and Licensing:** The Centers for Medicare & Medicaid Services (CMS) requires that a transplant facility must demonstrate experience and success with clinical organ transplants. The facility staff must have performed a specified volume of transplants for each organ type (12 or more adult heart or liver transplants or 10 or more lung transplants) for covered conditions in each of the two preceding 12-month periods. No specification is made relative to the number of pediatric procedures performed. Additionally, the facility must demonstrate a minimum actuarial 1-year and 2-year survival rate. Heart transplant hospitals must demonstrate actuarial survival rates of 73% for 1 year and 65% for 2 years. Liver facilities must demonstrate a 1-year actuarial survival rate of 77% and a 2-year actuarial survival rate of 60% for adult patients. Lung transplant facilities must demonstrate a 1-year actuarial survival rate of 69% and a 2-year actuarial survival rate of 62% (CMS, 2002).

On March 23, 2007, Medicare issued a final rule setting forth requirements that transplant centers must meet to participate in the Medicare program that moves Medicare covered transplant programs toward an outcome-focused system (CMS, 2007). The rule became effective on June 28, 2007. Transplant organ programs were defined as a component within a transplant hospital that provides transplantation of a particular type of organ. All organ transplant programs must be
located in a hospital that has a Medicare provider agreement. In addition to meeting the transplant Conditions of Participation, the transplant program must also comply with the hospital Conditions of Participation (CMS, 2009).

3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):
MHCP coverage for organ and tissue transplant procedures is limited to those procedures covered by the Medicare program or approved by the DHS consulting contractor.

Transplant coverage includes: preoperative evaluation, recipient and donor surgery, follow-up care for the recipient and live donor, and retrieval of organs, tissues. All transplant related services are billed under the recipient’s ID number.

CLINICAL EVIDENCE:

SUMMARY:
Liver transplantation is a complex surgical procedure involving the replacement of the recipient liver with a liver from a deceased (e.g., cadaveric) or living-donor. The primary indications for liver transplantation in adults include a life-threatening complication of chronic liver disease, a decompensation of previously stable liver disease, or the severe impairment of quality of life related to liver disease. In the absence of contraindications, liver transplantation and retransplantation are considered appropriate treatment options for selected adults and children.

The reviewed studies provided evidence that there has been continuous improvement in the management of end-stage liver disease with liver transplantation, with advancements in surgical technique, improved preoperative and postoperative management of patients, more effective immunosuppressive regimens, and less toxic antiviral therapies, and less toxic immunosuppressive regimens. However, patients are spending more time on the waiting list due to the increased relative shortage of donors, and patient selection criteria are expanding. Although UNOS criteria for prioritization of transplant candidates have been developed to include all potential patients and allow for the distribution of organs to patients who are most able to benefit from them, the shortage of appropriate organs for transplantation has resulted in the current UNOS system for organ allocation. Allocation of donor organs will remain problematic until the donor liver supply can meet demands either through more successful recruiting of organ donors or alleviation of supply problems through techniques such as split liver transplantation and living-donor liver transplantation.

APPLICABLE CODES:
The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2152</td>
<td>Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor (s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency,</td>
</tr>
</tbody>
</table>
and Rehabilitative services, and the number of days of pre- and post-transplant care in the global definition.

<table>
<thead>
<tr>
<th>ICD-9 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>47133</td>
<td>Donor hepatectomy (including cold preservation), from cadaver donor</td>
</tr>
<tr>
<td>47135</td>
<td>Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age</td>
</tr>
<tr>
<td>47136</td>
<td>Liver allotransplantation; heterotopic, partial or whole, from cadaver or living donor, any age</td>
</tr>
<tr>
<td>47140</td>
<td>Donor hepatectomy (including cold preservation), from living donor; left lateral segment only (segments II and III)</td>
</tr>
<tr>
<td>47141</td>
<td>Donor hepatectomy (including cold preservation), from living donor; total left lobectomy (segments II, III and IV)</td>
</tr>
<tr>
<td>47142</td>
<td>Donor hepatectomy (including cold preservation), from living donor; total right lobectomy (segments V, VI, VII and VIII)</td>
</tr>
<tr>
<td>47143</td>
<td>Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; without trisegment or lobe split</td>
</tr>
<tr>
<td>47144</td>
<td>Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with trisegment split of whole liver graft into two partial liver grafts (e.g., left lateral segment (segments II and III) and right trisegment (segments I and IV through VIII))</td>
</tr>
<tr>
<td>47145</td>
<td>Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with lobe split of whole liver graft into two partial liver grafts (e.g., left lobe (segments II, III, and IV) and right lobe (segments I and V-VIII))</td>
</tr>
<tr>
<td>47146</td>
<td>Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; venous anastomosis, each</td>
</tr>
<tr>
<td>47147</td>
<td>Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; arterial anastomosis, each</td>
</tr>
</tbody>
</table>

CPT® is a registered trademark of the American Medical Association.

REFERENCES:


41. Hayes, Winifred S. Search and Summary. Liver Transplantation, Pediatric. Reviewed July 31, 2007. Available at:
65. National Cancer Institute. Childhood liver cancer treatment (PDQ©) [b]. Updated 2013 March 29. Available at URL...


POLICY HISTORY:

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/19/2013</td>
<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Council (QIACC).</td>
</tr>
<tr>
<td>01/01/2014</td>
<td>Published to UCare.org</td>
</tr>
</tbody>
</table>