



PATIENT REFERRAL GUIDELINES

Liver Transplant

- Liver Transplant: Adult/Pediatric
- Living-Donor Liver Transplant: Adult – Adult
- Organ Transplantation in Members with HIV/AIDS

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

Criteria

For Medicare Members

| Source | Policy |
|--|---|
| CMS Coverage Manuals | None |
| National Coverage Determinations (NCD) | Adult Liver Transplantation (260.1) |
| Local Coverage Determinations (LCD) | None |
| Local Coverage Article | None |

For Non-Medicare Members

Liver transplantation may be considered for patients with end-stage liver diseases who have no prospect for prolonged survival, or whose quality of life is severely impaired. These guidelines for referral for transplant evaluation are not intended as an automatic inclusion or exclusion of a candidate for referral.

1. GENERAL PRINCIPLES

- a. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, then early referral should be made.
- b. Patients with a history of malignancy with a moderate to high risk of recurrence (as determined after consultation with oncologist considering tumor type, response to therapy, and presence or absence of metastatic disease) may be unsuitable candidates for transplantation. Patients with low risk of recurrence may be considered.
- c. Uncontrollable active infection outside of the hepatobiliary tree is a contraindication to liver transplant.
- d. Candidates with a history of substance abuse must be free from alcohol and other substance abuse and have been evaluated by a substance abuse program. The risk of recidivism, which has been documented to negatively impact transplant outcomes, must be addressed and considered to be low. [1.2.3](#) Exceptions may be made on a case-by-case basis.
 - i. For patients with a first alcohol-related / liver decompensating event, whose severity of liver disease suggests they are unlikely to survive to reach 6 months alcohol abstinence, see appendix for the "Kaiser Permanente Protocol: Reduced Duration Alcohol Sobriety Pathway to Liver Transplant Listing" (Appendix I).
- e. Candidates for thoracic organ (heart, lung and heart/lung) transplants must be free from tobacco use for the previous six (6) months. Routine monitoring may be required. Specific programs for abdominal organs (liver, intestines, and kidney) may require abstinence from tobacco products to be actively listed.
- f. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.
- g. Patients must be willing and able to travel within short notice to the KP approved transplant Center of Excellence and, if necessary, return for treatment of complications.
- h. Patients must have a caregiver or caregivers, who are physically and cognitively able to assist the patient with self-care activities and are able to travel within short notice to the KP approved transplant Center of Excellence.

- i. The presence of significant irreversible neurologic dysfunction, active psychological and/or psychiatric conditions, and/or other social behaviors that prevent adherence with a complex medical regimen, are considered contraindications for referral for transplant.
- j. Evidence of such non-adherence may be failure to keep appointments, failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required for maintenance on the waiting list.
- k. Whenever transplant is considered as an option and discussed with the patient and/or family, consultation with Advanced Life Care Planning/Palliative Care resources is strongly recommended.

2. INDICATIONS FOR LIVER TRANSPLANT

- a. Acute Fulminant Hepatic Failure. Refer patient as soon as diagnosis is made.
 - i. Progressive Coagulopathy
 - ii. Hepatic Encephalopathy
 - iii. Progressive Hyperbilirubinemia
- b. Chronic Liver Disease – referral is generally not advised until there is a MELD or PELD score of 15, with exceptions for the indications listed below: There is evidence that there is no survival benefit for patients transplanted with a MELD score <15. ⁴
 - i. Hepatocellular Carcinoma
 1. Patients who meet Milan/UCSF criteria for hepatocellular carcinoma may be referred to transplant centers for transplant evaluation.
 2. Patients with hepatoblastoma who exceed Milan/UCSF criteria may be considered as liver transplant candidates on a case by case basis. ⁵
 3. Pediatric patients with nonmetastatic and unresectable hepatoblastoma (PRETEXT IV and complex pretext III) should be referred for LT evaluation at the time of diagnosis or no later than after 2 rounds of chemotherapy.
 4. Pediatric patients with hepatoblastoma and pulmonary metastases can be considered for liver transplant if, following chemotherapy, a chest CT is clear of metastases or, if a tumor is identified, the pulmonary wedge resection reveal the margins are free of the tumor (AASLD/NASPGHAN guidelines 2014)
 - ii. Intractable Encephalopathy
 - iii. Intractable Ascites/ hepatic hydrothorax
 - iv. Intractable Variceal Bleeding
 - v. Cholestatic Liver Disease:
 1. Intractable Pruritis
 2. Recurrent Cholangitis
 3. Intractable Bone Disease
 - vi. Progressive Hepatopulmonary Syndrome
 - vii. Hepatorenal Syndrome
 - viii. Additional indications for liver transplant for the pediatric population: Urea cycle defects, organic acidemia and other metabolic disorder

3. CONTRAINDICATIONS FOR LIVER TRANSPLANT

- a. Advanced cardiopulmonary disease or any other life limiting disorder not corrected by liver transplantation. All patients should be evaluated for coronary artery disease (CAD) and occult cardiomyopathy. Hepatopulmonary syndrome and hepatorenal syndrome are not contraindications as they are correctable by transplantation.
- b. Patient whose HCC exceeds Milan criteria or whose alpha fetoprotein (AFP) level is greater than 1000 ng/ml should not be referred for transplant until they have been down staged successfully to within Milan criteria and/or an AFP level of less than 500 ng/ml. Exceptions may be made on a case by case basis for hepatoblastoma. ^{6,7}
- c. Absolute contraindication of liver transplant in pediatric patients - Severe multisystem mitochondrial disease

4. RELATIVE CONTRAINDICATIONS FOR LIVER TRANSPLANT

- a. Pulmonary hypertension with pulmonary artery systolic pressure 50 mmHg or mean >35 mmHg (despite optimal medical management).
- b. Renal failure (excluding hepatorenal syndrome)
- c. Active infection outside the hepatobiliary system
- d. Advanced malnutrition
- e. Severe diabetic complications
- f. Inability to control HbA1C <8
- g. Massive obesity
- h. Multiple abdominal surgeries

- i. Significant irreversible neurologic dysfunction.
- j. Highly selected patients with only intra-ductal cholangiocarcinoma may be considered for transplant on a case-by-case basis, at a transplant center with an established cholangiocarcinoma program. [8.9](#)

5. MULTIPLE ORGAN TRANSPLANTS INCLUDING LIVER

Liver transplantation combined with another organ transplant is indicated in special circumstances in pediatric and adult patients. Examples include, but are not limited to, liver/kidney, liver/lung and liver/heart. These combined organ transplants require case by case evaluation.

6. SPECIAL CONSIDERATIONS FOR LIVING DONOR LIVER TRANSPLANT

In addition to the current KP cadaveric donor patient referral guidelines for adults, the following should be considered when presented with a potential living donor liver transplant.

- a. No recipient should be considered for living donor liver transplant if in status 1 fulminant liver failure.
- b. Patients with MELD < 15 but with complications of liver disease that are uncorrectable and not reflected in the MELD score may be considered for living donor liver transplantation on a case by case basis after consultation with a hepatologist.
- c. Recipients with hepatocellular carcinoma (HCC) should meet the same guidelines as listed for cadaveric donor patient referral guidelines.
- d. Living donor liver transplant is not contraindicated for pediatric patients with acute liver failure if patient is a candidate for liver transplant.

7. ADDITIONAL INFORMATION ON LIVER TRANSPLANTATION

For additional information about UNOS policies on organ allocation and candidate criteria, please visit https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_09

APPENDIX I:

Reduced Duration Alcohol Sobriety Pathway to Liver Transplant Listing - Kaiser Permanente Protocol

(For Northern California, please consult the "[Reduced Duration Alcohol Sobriety Pathway to Liver Transplant Listing Kaiser Permanente Northern California Protocol](#)", available on the Clinical Library under Northern California)

BACKGROUND / PURPOSE:

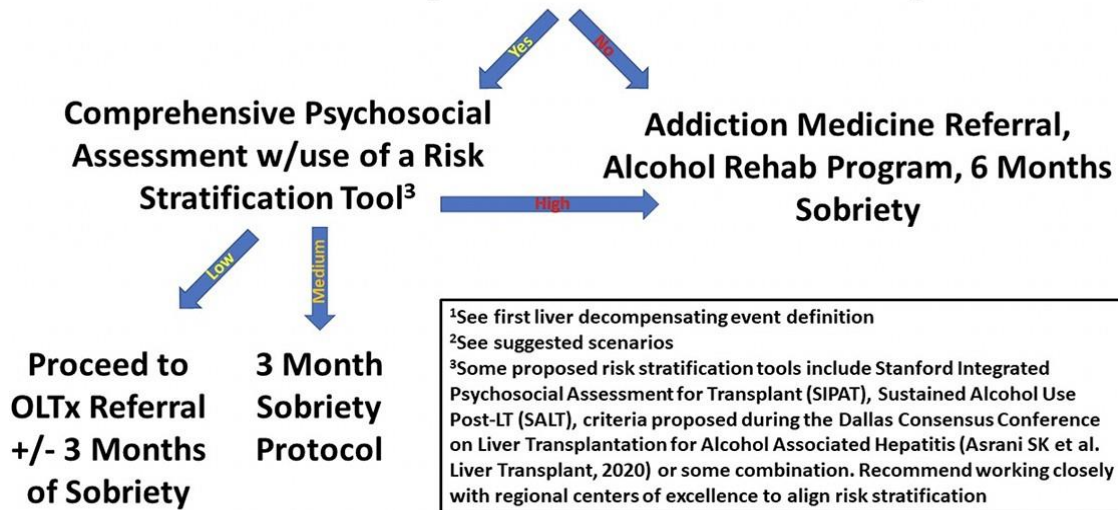
- There is data suggesting that the currently utilized 6-month alcohol sobriety rule needed for liver transplant listing may not be the best predictor of relapse on a liver transplant list or post-transplant
- Some liver transplant programs in the United States and Europe accept a reduced duration alcohol sobriety pathway to liver transplant listing
- This protocol is designed to evaluate and qualify Kaiser Permanente patients for liver transplant listing who have not reached 6-months of alcohol sobriety

WHO THIS PATHWAY APPLIES TO:

- This protocol applies to patients with a first alcohol-related / liver decompensating event (as defined below) and whose severity of liver disease suggests they are unlikely to survive to reach 6 months alcohol abstinence (see suggested scenarios below)
- Patient must be without incapacitating hepatic encephalopathy and/or cannot be intubated when evaluated by addiction medicine and supporting gastroenterology and hepatology physician
 - Family/family friends or significant others will not be used as sole historians in the event the candidate is incapacitated with hepatic encephalopathy and/or intubated
- This protocol does not apply to patients who are not presenting with a first liver-decompensating event or who have already reached 6 months alcohol abstinence. Standard criteria for liver transplant listing should be applied to those patients.

Protocol Flow Diagram:

First Alcohol-Related / Liver Decompensating Event¹ & Unlikely to Survive to 6 Months Sobriety²



DEFINITION OF FIRST ALCOHOL-RELATED / LIVER DECOMPENSATION

To help define a potential first alcohol-related / liver decompensating event, try to answer this question: When faced with the knowledge that their alcohol use was linked to a negative effect on their legal status or medical health, did the candidate stop drinking? If no, then the candidate's presentation with severe alcoholic hepatitis or acute on chronic liver failure is not considered their first decompensating event, as it demonstrated poor insight and decision-making. These criteria represent relatively easy to find information within the medical chart that represent exclusion criteria.

- Exclusion of patients with history of hospital admission due to the following complication of alcohol abuse within *the last 2 years*:
 - Alcohol-related hepatitis
 - Alcohol-related pancreatitis
 - Alcohol-related cardiomyopathy
 - Alcohol withdrawal (including delirium tremens and/or seizures)
 - Alcohol psychosis
- Exclusion of patients with history of an emergency room visit due to the following complication of alcohol abuse within *the last 2 years*:
 - Alcohol-related hepatitis
 - Alcohol-related pancreatitis
 - Alcohol-related cardiomyopathy
 - Alcohol withdrawal (including delirium tremens and/or seizures)
 - Alcohol psychosis
 - Alcohol intoxication with or without a complication (like fall or altercation)
- Exclusion of patients with *more than one* failed alcohol rehabilitation attempt within *the last 2 years*
- Exclusion of patients with any previous diagnosis in problem list of the following complications of alcohol abuse within *the last 2 years*:

- Alcohol-related hepatitis
- Alcohol-related pancreatitis
- Alcohol-related cardiomyopathy
- Severe alcohol use disorder
- Exclusion of patients with any previous diagnosis in problem list of alcohol-related cirrhosis at *any time*.
- Exclusion of patients with active polysubstance abuse (any co-substance except for marijuana and/or nicotine) within *the last 2 years*.

UNLIKELY TO SURVIVE TO REACH 6 MONTHS ALCOHOL ABSTINENCE

No comprehensive definition of patients with severe acute alcohol related hepatitis or alcohol related acute on chronic liver failure can be provided. Ultimately, this assessment is left to patient's treating hepatologist and larger treatment team. Some suggested scenarios include:

- Patient with severe acute alcoholic hepatitis (Maddrey's Discriminant Function >32) who is not a candidate for or has failed medical management (including use of prednisolone with or without N-acetylcysteine infusion with resultant 7-day Lille Score > 0.45)
- Inpatient with persistent MELD score > 30 (see 3-month predicted survival based on MELD score below) Inpatient with dialysis dependent hepatorenal syndrome type 1

3-Month Mortality Based on MELD Scores

The estimated 3-month mortality is based on the MELD score highlighted in yellow above.

| MELD Score | Mortality Probability |
|------------|-----------------------|
| 40 | 71.3% mortality |
| 30-39 | 52.6% mortality |
| 20-29 | 19.6% mortality |
| 10-19 | 6.0% mortality |
| 9 or less | 1.9% mortality |

Footnotes

1. Liver Transplantation 2006, .12:813-820. Alcohol consumption patterns and predictors of use following liver transplantation for alcoholic liver disease.
2. Liver Transplant Surg. 1997, Vol 3, 304 – 310. The natural history of alcoholism and its relationship to liver transplantation.
3. Alcohol abstinence prior to liver transplantation for Alcoholic Liver Disease (G110807), TPMG New Medical Technology
4. American Journal of Transplantation 5 (2) 203-205, February 2005.
5. Hepatoblastoma (HB) is the most common type of liver cancer in children. The gold standard treatment of HB is perioperative chemotherapy followed by complete resection of tumor. Liver transplantation (LT) for children with HB should be considered (even if beyond Milan criteria) if the tumors are nonresectable or show chemotherapy resistance. LT for children with HB should be considered even with very high AFP levels. LT may be considered even if there is a history of pulmonary metastasis (after thoracotomy and resection +/- chemotherapy). Contraindications to LT for HB: Vascular invasion (including tumor clot).
6. The Milan Criteria for liver patients with HCC is 1 tumor: 5 cm or 2 – 3 lesions, none >3 cm and no vascular invasion. Source: NEJM 1996, 334; 693-699.
7. The UCSF/Region 5 Criteria for liver patients with HCC is 1 tumor: 6.5 cm, or 2 – 3 lesions, none >4.5 cm and total tumor diameter ::8 cm, and no vascular invasion. Hepatology, 2001, 33; 1394-1403.

8. Transplantation for Hilar Cholangiocarcinoma. Liver Transplantation, Vol. 10, (10); Supplement II (October) 2004:pp 565-568
9. Goldberg, et. Al. (2014), Hepatology, 60 (5), 1717-1726.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Liver transplantation or hepatic transplantation is the replacement of a diseased liver with a healthy liver from another person (allograft). Liver transplantation is a viable treatment option for end-stage liver disease and acute liver failure.

Medical Technology and Assessment Committee (MTAC)

Living-Donor Liver Transplant – Adult-to-Adult

BACKGROUND

Living donor liver transplantation (LDLT) was developed as an alternative to cadaveric liver transplantations due to the dramatic shortage of available livers. LDLT to pediatric recipients was introduced into clinical practice in 1989 and the procedures are now performed worldwide. Adult-to-adult LDLT was initiated in the United States in the late 1990s. In 1997, one adult-to-adult LDLT was performed at one center in the U.S. and this grew to 266 procedures at 38 centers in 2000 (Brown et al, 2003). Left lateral segmentectomy, which uses approximately 20% of the hepatic mass, is generally used for LDLT to pediatric donors. However, these grafts provide insufficient liver mass for an average sized adult recipient. With adult recipients, a larger portion of the donor's liver must be taken which poses increased risks to the donor. Adult-to-adult liver transplantation involves either a full left or right hepatic lobe. Initially, all adult LDLT used the smaller left hepatic lobe. The hepatic mass was sufficient for some Asian recipients, but not for the average U.S. patient. Currently, adult-to-adult LDLTs in the U.S. use donation of the right hepatic lobe, which represents about 60% of the hepatic mass. Risks to the donor in adult-to-adult LDLT include the possibility that the donor will not be left with sufficient hepatic function, the possibility of biliary complications, risks associated with blood transfusion, risks associated with surgery and unknown, long-term risks associated with major hepatic resection. (American Society of Transplant Surgeons: Ethics Committee, 2000; Renz and Roberts, 2000; Hayashi & Trotter, 2002). There is an ethical debate on adult-to-adult LDLT centering on the question of whether or not it is acceptable for a consenting healthy individual to undergo this surgery and take the risk of complication or death in order to potentially save the life of a loved one. LDLT programs conduct extensive physical and psychological examinations of donors. Related ethical issues are how to select adult recipients of LDLT (i.e. to what extent are they at risk of dying), how successful LDLT is in adult recipients (i.e. increased life expectancy in recipient vs. risk to donor) and how to allocate cadaveric livers.

04/12/2000: MTAC REVIEW

Living-Donor Liver Transplant – Adult-to-Adult

Evidence Conclusion: The limited amount of evidence available is not sufficient to determine the safety and efficacy of LRLT. Case series reports were the best available evidence. The published case studies have small sample sizes and were not rigorously performed (i.e. did not specify inclusion/exclusion criteria or outcome measurement, had variable and relatively short length of follow-up). In addition, the published studies report on different clinical techniques for performing LRLT and these individual techniques have not been systematically evaluated.

Articles: There were no randomized control trials, meta-analyses or cohort studies. Case series for adult-to-adult transplants all had small sample sizes (<50). Several larger case series included both adults and children as recipients and did not present results separately. Evidence tables were created for those with the largest sample sizes: (n=33) Hashikura, Y, Kawasaki, S, Miyagawa, S, Terada, M, Ikegami, T, Miwa, S, Kubota, T, Mita, A. Living-related donor liver transplantation in adults: Experience at Shinshu University Hospital. Transplantation Proceedings 1999; 31: 1953-4; (N=25) Marcos, A, Fisher, RA, Ham, JA, Shiffman, ML, Sanyal, AJ, Luketic, VAC, Sterling, RK, Posner, MP. Right lobe living donor liver transplantation. Transplantation 1999; 68: 798-803. Hashikura, Y, Kawasaki, S, Miyagawa, S, Terada, M, Ikegami, T, Miwa, S, Kubota, T, Mita, A. Living-related donor liver transplantation in adults: Experience at Shinshu University Hospital. Transplantation Proceedings 1999; 31: 1953-4. [See Evidence Table.](#) Marcos, A, Fisher, RA, Ham, JA, Shiffman, ML, Sanyal, AJ, Luketic, VAC, Sterling, RK, Posner, MP. Right lobe living donor liver transplantation. Transplantation 1999; 68: 798-803. [See Evidence Table.](#)

The use of Adult to Adult Living Related Donor Liver Transplant treatment of Liver Failure does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

06/11/2003: MTAC REVIEW

Living-Donor Liver Transplant – Adult-to-Adult

Evidence Conclusion: There is a lack of evidence on the effectiveness of adult-to-adult living-donor liver transplantation compared to cadaveric whole or split-liver transplantation and one small study (Liu) that addresses the effectiveness of LDLT compared to remaining on a wait list for cadaveric transplantation. Liu found a higher survival rate with right lobe LDLT than no transplantation among patients with acute liver failure; however, findings do not necessarily generalize to patients with other indications for transplantation.

The remaining studies are case series. One-year recipient survival rates were 72% in the case series of 308 adults from Japan (Todo) in which 71% of the operations were left-lobe transplantations and 85% for 50 right-lobe operations in the U.S. (Miller). No peri-operative donor mortality was reported in the recent case series articles. Brown identified one donor death among 449 right-lobe adult-to-adult living-donor transplantations performed in the U.S. between 1997 and 2000. Brown's survey found a 14.5% donor complication rate including 6% experiencing biliary leakage and 4.5% needing re-operation. A limitation of the case series data and the Brown survey data is variability in the eligibility criteria and interventions across centers and within centers over time. There are no quality long-term data on outcomes among recipients or donors.

Articles: The search yielded 206 articles, many of which were reviews, opinion pieces or dealt with technical aspects of the procedure. There were no randomized controlled trials. The next preference was given to non-randomized comparative trials. There was one study that compared patients with acute liver failure who did and did not opt for LDLT; this study was reviewed. The remaining studies were case series. Other articles selected were the largest case series (conducted in Japan), the largest case series in the United States and a survey of transplantation programs focusing on donor outcomes. The following four articles were critically appraised: Liu CL, Fan ST, Lo CM et al. Right-lobe live donor liver transplantation improves survival of patients with acute liver failure. *Br J Surg* 2002; 89: 317-322. [See Evidence Table.](#) Todo S, Furukawa H, BonJin M et al. Living donor liver transplantation in adults: Outcome in Japan. *Liver Transplantation* 2000; 6 (Suppl 2): S66-S72. [See Evidence Table.](#) Miller CM, Gondolesi CE, Florman S. et al. One hundred nine living donor liver transplants in adults and children: A single-center experience. *Ann Surg* 2001; 234: 301-012. Brown RS, Russo MW, Lai M. et al. A survey of liver transplantation from living adult donors in the United States. *N Engl J Med* 2003; 348: 818-825. [See Evidence Table.](#)

The use of Adult to Adult Living Related Donor Liver Transplant treatment of Liver Failure does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

Kidney Transplantation in the treatment of HIV+

BACKGROUND

HIV infected patients are at risk for end-stage renal disease caused by HIV-related disease such as HIV-associated nephropathy and hepatitis C infection. HIV-positive patients co-infected with hepatitis B or hepatitis C are also at risk of progression of liver disease (Roland & Stock; Fishman). Until recently, HIV-positive patients have been excluded from organ transplantation programs. A primary reason for this exclusion has been the belief that patients in an immuno-compromised state would be adversely affected by the immunosuppression required for transplantation. Several changes have occurred that have caused some transplant centers to question the exclusion based on HIV infection. Highly active anti-retroviral therapy (HAART) became available in the mid to late 1990s. HAART can prolong survival in HIV-positive patients, thereby increasing the number of patients with stable HIV infection who progress to end-stage organ failure. In addition, there have been improvements in immunosuppressive drug regimens and surgical techniques associated with transplantation. This review will evaluate the evidence published to date on the safety and efficacy of organ transplantation among HIV-positive patients in the HAART era. Kidney transplantation in HIV positive patients was previously reviewed by MTAC in December 2001. At that time, the evidence consisted of several case series with five or fewer HIV-positive patients and the item failed MTAC evaluation criteria. Other types of organ transplantation (liver, lung, heart) have not been reviewed by MTAC.

12/12/2001: MTAC REVIEW

Kidney Transplantation in the treatment of HIV+

Evidence Conclusion: There is insufficient published evidence on which to base a conclusion about the effect of kidney transplant in HIV-positive patients on health outcomes. Although recent changes in the prognosis of HIV-positive individuals suggest that some may benefit from kidney transplant, there are no direct empirical data to support this claim.

Articles: The search yielded 64 articles, many of which dealt with other related procedures or populations or were review articles or opinion pieces. No articles with empirical data were included in the search. Three older case series were identified in the reference list of the Gow review article. Each of these case series included 5 or fewer HIV-positive patients receiving kidney transplants. None of the articles was suitable for critical appraisal.

The use of Kidney Transplantation in the treatment of HIV+ patients with renal failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

08/11/2004: MTAC REVIEW

Heart, Lung, Kidney, & Liver Transplantation in the treatment of HIV+

Evidence Conclusion: There were two primary issues addressed in this review: 1) evidence on the safety and effectiveness of organ transplantation for HIV-positive individuals and; 2) evidence on whether survival among HIV-positive individuals who receive organ transplants is lower than among HIV-negative individuals. There is no published evidence on the safety and effectiveness of lung transplantation in HIV-positive individuals and only two case reports of heart transplants. There were no articles comparing transplantation to another intervention in HIV-positive patients with end-stage liver or kidney disease. The best published evidence on kidney and liver transplants in HIV-positive individuals is from cohort studies conducted in the HAART era. Abbott did a retrospective study comparing outcomes in HIV-positive and HIV-negative individuals, all of whom were identified in a national database of kidney transplants. Ragni compared survival in a prospective series of HIV-positive patients and a retrospective analysis of selected HIV-negative patients from the UNOS Scientific Registry for Liver Transplantation. In both studies, three-year survival rates did not differ significantly in the HIV-positive and HIV-negative groups. Limitations of both studies include: The relatively small sample sizes of HIV-positive patients, 24 in the Ragni study and 47 in the Abbott study. The HIV-positive and HIV-negative groups may have differed in ways that affected outcomes (despite statistical adjustment for confounding in the Abbott study). The authors commented that clinicians may have selected the healthiest HIV-positive patients for transplantation which might increase the likelihood of a successful outcome compared with the HIV-negative patients. The Abbott study was retrospective and the Ragni study included a prospective group of HIV-positive patients but did a retrospective analysis of the HIV-negative control group. Prospective designs are preferred. A prospective, multi-center uncontrolled study to evaluate the safety and efficacy of kidney and liver transplants performed in HIV-positive patients is currently in its early phases. The study is being coordinated by UCSF. The investigators anticipate enrolling up to 275 transplant recipients and following them for 2-5 years.

Articles: The search yielded 217 articles. Most were opinion pieces, on technical aspects of transplantation in HIV-positive patients and articles on related clinical topics. Empirical studies on specific types of organ transplantation were as follows: Lung There were no studies with empirical data. Heart There were two case reports, each reporting on a single case. The articles were ineligible for critical appraisal. Kidney and Liver There was one study on kidney transplants (Abbott et al., 2004) and one study on liver transplants (Ragni et al., 2003) that compared outcomes in HIV-positive patients to outcomes in HIV-negative patients. Data from HIV-negative patients were taken from national transplantation databases in both studies. These two studies were critically appraised. The largest published series from UCSF included 14 patients, 10 received kidney transplants and 3 received liver transplants (Stock et al. 2003). Newer reports with additional patients have been presented at conferences and discussed in review articles, but the data have not been published in empirical articles. The case series was not critically appraised due to the small sample and availability of comparative studies. There was also a retrospective cohort study evaluating data on kidney transplants from 1987-1997; this study was not critically appraised because it primarily included cases from the pre-HAART era.

The studies reviewed were Abbott KC, Swanson SJ, Agodoa LYC et al. Human immunodeficiency virus infection and kidney transplantation in the era of highly active antiretroviral therapy and modern immunosuppression. *J Am Soc Nephrol* 2004; 15: 1633-1639. See [Evidence Table](#). Ragni MV, Belle SH, Im K et al. Survival of human immunodeficiency virus-infected liver transplant recipients. *J of Infect Dis* 2003; 188: 1412-1420. See [Evidence Table](#).

The use of Heart Transplantation in the treatment of HIV+ patients with heart failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

The use of Lung Transplantation in the treatment of HIV+ patients with lung failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

The use of Kidney Transplantation in the treatment of HIV+ patients with renal failure evidence is not sufficient to determine whether HIV infection should or should not be an exclusion for kidney transplantation.

The use of Liver Transplantation in the treatment of HIV+ patients with renal failure the evidence is not sufficient to determine whether HIV infection should or should not be an exclusion for liver transplantation.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT® or HCPC Codes | Description |
|--------------------|--|
| 47135 | Liver allotransplantation, orthotopic, partial or whole, from cadaver or living donor, any age |
| 47140 | Donor hepatectomy (including cold preservation), from living donor; left lateral segment only (segments II and III) |
| 47141 | Donor hepatectomy (including cold preservation), from living donor; total left lobectomy (segments II, III and IV) |
| 47142 | Donor hepatectomy (including cold preservation), from living donor; total right lobectomy (segments V, VI, VII and VIII) |
| 47146 | Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; venous anastomosis, each |
| 47147 | Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; arterial anastomosis, each |

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

| Date Created | Date Reviewed | Date Last Revised |
|--------------|--|-------------------|
| 05/1996 | 07/06/2010 ^{MDCRPC} , 05/03/2011 ^{MDCRPC} , 08/02/2011 ^{MDCRPC} , 03/06/2012 ^{MDCRPC} , 01/08/2013 ^{MDCRPC} , 11/05/2013 ^{MPC} , 02/04/2014 ^{MPC} , 09/02/2014 ^{MPC} , 10/07/2014 ^{MPC} , 07/07/2015 ^{MPC} , 05/03/2016 ^{MPC} , 03/07/2017 ^{MPC} , 01/09/2018 ^{MPC} , 12/04/2018 ^{MPC} , 12/03/2019 ^{MPC} , 12/01/2020 ^{MPC} , 12/07/2021 ^{MPC} , 12/06/2022 ^{MPC} , 12/09/2023 ^{MPC} | 01/10/2022 |

^{MDCRPC} Medical Director Clinical Review and Policy Committee

^{MPC} Medical Policy Committee

| Revision History | Description |
|------------------|---|
| 10/06/2015 | Merged Living Donor Related criteria to Liver Transplant criteria |
| 11/03/2015 | Merged Organ Transplantation for HIV+ Patients for Liver and Kidney |
| 03/05/2019 | MPC approved to adopt KP National Criteria for Liver Transplant |
| 09/03/2019 | MPC approved to change General Principles 1.3 to <i>Uncontrollable infection is a contraindication to transplant</i> as recommended by KP National Transplant Services. |
| 03/03/2020 | MPC approved proposed changes from KP National Transplant Services |
| 04/06/2021 | MPC approved proposed changes from KP National Transplant Services. Requires 60-day notice, effective date September 1, 2021. |
| 01/10/2022 | MPC approved proposed changes from KP National Transplant Services. 60-day notice is not required. |