Xenotransplantation

Transplantation of living cells, tissues or organs from one species to another is not covered due to the lack of studies showing the efficacy and/or safety of the procedure.

Chronic renal failure

CRF is a slowly progressive disease that occurs over a number of years and most often results from any disease that causes gradual destruction of the internal structures of the kidneys. It can range from mild dysfunction to severe kidney failure, termed end stage renal disease (ESRD). The 3 diseases most commonly leading to CRF and treated by kidney transplantation are (i) type 1 diabetes mellitus, (ii) glomerulonephritis, and (iii) hypertensive nephrosclerosis, accounting for about 75% of the total candidate population. Patients with ESRD have 3 options for renal replacement therapy: (i) hemodialysis; (ii) chronic ambulatory peritoneal dialysis; or (iii) transplantation. There are 3 sources of donor kidneys for kidney transplantation: (i) living related donors; (ii) cadaver donors; and (iii) living unrelated donors. Age is never an absolute contraindication for kidney transplantation.

Policy: Kidney transplantation is the treatment of choice for end-stage renal disease. A successful kidney transplant improves the quality of life and reduces the mortality risk for most patients, when compared with maintenance dialysis. There is, however, a shortage of donated organs and a growing wait list for transplantation. Patients are also waiting increasingly longer and there are an increasing number of older patients on the wait list. It is therefore important that potential kidney transplant recipients are carefully evaluated in order to detect and treat coexisting illnesses which may affect survival after transplantation.
Procedure: All candidates for transplant should be free of:

1. Systemic of uncontrolled infection including sepsis. (TB testing negative, CMV titres, EBV titres, VZV titres, and dental exam)

2. 1 Absence of HIV infection, as defined by all of the following:
   a. CD4 count greater than 200 cells/mm³ for more than 6 months; and
   b. HIV-1 RNA (viral load) undetectable; and
   c. On stable anti-viral therapy for more than 3 months; and
   d. No other complications from AIDS, such as opportunistic infection (e.g., aspergillus, coccidiomycosis, resistant fungal infections, tuberculosis), Kaposi’s sarcoma or other neoplasm

   a. Severe end stage organ damage including diabetes with end organ damage, Normal serum transaminases and total bilirubin as liver screens, irreversible severe pulmonary disease, with FEV1<1 L or FVC <50%. The 2005 Canadian Transplant guidelines suggest that patients with the following clinical features should not be candidates for kidney transplantation:
      i. Home oxygen therapy requirement
      ii. Uncontrolled asthma
      iii. Severe cor pulmonale
      iv. Severe chronic obstructive pulmonary disease/pulmonary fibrosis/ restrictive disease.
      This is defined by:
         a. Best FEV1 <25% predictive value
         b. PO2 room air <60 mmHg with exercise desaturation SaO2 <90%
         c. >4 lower respiratory tract infections in the last 12 months; and/or
         d. Moderate disease with progression.
   b. All patients should also discontinue smoking since it increases the risk of allograft loss and patient death

4. Absence of cardiovascular, coronary artery disease or severe MI (Must submit documentation of ECHO, Stress test or catherization if necessary)

5. Active untreated or untreatable malignancy except localized non-melanoma skin cancer (will need to submit the appropriate documentation: PAP smear, mammogram, PSA, Stool OB, and/or colonoscopy)

6. No genitourinary disease by history and physical exam or if necessary U/S of abdomen/pelvis, cysto with retrogrades and pyelo, renal CT scan, and VCUG.

7. No GI disease or documentation of GI clearance with consult notes or EGD/colonoscopies if necessary

8. Irreversible, severe brain damage

9. Active alcoholism and substance abuse, there should be 6 months of documented abstinence through participation in a structured alcohol/substance abuse program with regular meeting attendance and negative random drug testing; Drug testing may be required at the discretion of MHP. Use of marijuana for medical purposes requires documentation from the treating physician and transplant eligibility is subject to the transplanting institution’s criteria.

10. Emotional instability, significant depression or other psychiatric illness that cannot be controlled that would impact on ability to comply with a complex evaluation process, surgical procedure and post-transplant plan of care.

11. Dementia, memory loss or cognitive disability that would impact on ability to comply with transplant requirements (unless there is a representative/guardian/conservator). Lack of psychological support as indicated by either no identified caregiver or an uncommitted caregiver. This includes lack of transportation, inability to adhere to transplant program requirements

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1 (Ward, Slutsker, Buehler, Jaffe, Berkelman, & Curran, 1992)
12. Lack of sufficient financial means to purchase post-transplant medications.
13. Non remediated non-compliance
14. Inability to give informed consent, unless there is an authorized guardian
15. Limited irreversible rehabilitative potential
16. Post-transplant lymphoproliferative disease, unless no active disease is demonstrated by PET scan, CT scan or MRI.
17. No active sickle cell disease if appropriate

In addition, patients must be willing and able to adhere to post-transplant lifestyle restrictions and medical regimen. MHP does not cover re-transplantation when medical assessments indicate that patient non-compliance with treatment recommendations was a significant contributor to transplant failure.

**Kidney Transplants** are eligible for coverage as follows: When the transplanting institution’s selection criteria are met as well as meeting these criteria elaborated within this policy.

1. Member is already on hemodialysis or continuous ambulatory peritoneal dialysis (CAPD); or
2. Member has chronic renal failure with anticipated deterioration to end stage renal disease, where member is seeking precertification for cadaver kidney transplantation**; or
3. Member has end stage renal disease, evidenced by a creatinine clearance below 20 ml/min or development of symptoms of uremia, and member is seeking precertification for a living donor kidney transplantation anemia of chronic disease, n/v or anorexia, pericarditis or uremic serositis, uremic encephalopathy, metabolic acidosis with HCO3 less than 15 meq/l, persistent hyperkalemia with K > 6.0 meq/l, pulmonary edema or CHF refractory to diuretics, uncontrollable hypertension, for pediatric members growth failure as compared to children of the same age and gender weight is less than the 5th percentile and height is greater than 2 STD below mean.

**Laboratory:** In addition to a standard medical work-up, the evaluation of all transplant candidates should include cytomegalovirus (CMV) antibody titer; creatinine clearance; serology for syphilis, and hepatitis B (HBV) and C (HCV) viruses; evaluation of parathyroid status; coagulation profile; Pap smear; ABO and histocompatibility typing; urologic evaluation (including a voiding cystourethrogram in selected patients to assess outlet obstruction and reflux); gastro-intestinal evaluation (as warranted by history of ulcer, diverticulitis, or other symptoms); and psychosocial evaluation.

**given waiting periods for cadaveric donors averaging 1 to 4 years, kidney transplantation is considered medically necessary for persons with severe chronic renal failure with anticipated progression to end stage renal disease. Severe chronic renal failure is defined as a creatinine clearance of less than 30 ml/min.

**Relative inclusion criteria (conditions that will require additional consideration on a case by case basis):**

1. HIV positive persons
2. BMI > 40
3. Unwilling to accept blood transfusion

**Exclusions:** MHP does not find kidney transplantation medically necessary for members who have any of the following (not an inclusive list):

1. Active vasculitis
2. Over age 70 with severe co-morbidities
3. BMI > 40
4. Severe systemic amyloidosis
5. Life threatening extra-renal congenital abnormalities
6. Ongoing alcohol or drug abuse
7. Severe neurological or mental impairment, in persons without adequate social support, such that the person is unable to adhere to the regimen necessary to preserve the transplant
8. Untreated coagulation disorder
9. Currently pregnant
10. CVA or TIA within the past 6 months;
11. Any anatomic anomaly precluding transplant such as Abdominal aortic aneurysms that involve the origin of the renal arteries; or Disease of the major vessels extends beyond the bifurcation of the main renal artery into the segmental branches; or Extensive athermanous aortic disease when an operation on the aorta itself may prove hazardous; or Multiple vessels supplying the affected kidney are involved; or persons who have large aneurysms, arteriovenous fistulas, or malformations of the kidney; or Traumatic arterial injuries
12. Other organ system failure that is irreversible and not attributed to kidney disease.

**Additional Selection Criteria:** Transplant will not be approved if any one of the following indicators of non-compliance are observed or documented:

1. For members with a history of tobacco use, if the member fails or refuses to submit to monthly cotinine testing for the preceding 6 months prior to the transplant and while listed, or refuses to actively and continuously participate in an accepted smoking cessation program.
2. For members with a history of alcohol abuse, member fails or refuses to submit to testing for alcohol use. Absence of documentation showing member has not engaged in alcohol use for at least six months prior to transplant and monthly while listed.
3. For members with a history of illicit drug use, member fails or refuses to submit to testing for illegal drug use. Absence of documentation showing member has not engaged in illegal drug use for at least six months prior to transplant and monthly testing while listed.
4. Tobacco, Alcohol and Drug Addiction: Refusal or failure to participate in available addiction interventions for actively using members must be documented in non-compliance determinations.
5. Documentation of non-impactable social issues that substantially increase the risks of an adverse outcome of the medical therapy or transplant at issue
6. Severely Mentally Ill Adults and Severely Emotionally Disturbed Minors: Non-adherence to psychotropic medications or medical regimen in SMI or SED members for whom core symptoms include lack of insight into illness, must be assessed for adequacy of and engagement with psychosocial resource supports in Care Coordination prior to non-compliance determinations.
7. Developmental or Acquired Cognitive Impairment and Dementia: Psychosocial and guardianship support as well as reversibility of impairment must be assessed and documented prior to non-compliance determinations.

**Xenotransplantation, defined as transplantation of living cells, tissues or organs from one species to another is not covered due to the lack of studies showing the efficacy and/or safety of the procedure.**

**Gene Microarrays for Diagnosis of Rejection:** MHP currently considers the use of gene microarrays in diagnosis of rejection of kidney transplantation experimental and investigational because of insufficient evidence of their effectiveness.
**Evaluation of Urine Immunocytology:** MHP currently considers evaluation of urine Immunocytology for T cells experimental and investigational for the diagnosis of acute kidney rejection because of insufficient evidence of its effectiveness.

**Special Instructions:**

**Medicare/Medicaid/All:** Member must be in compliance with MHP’s Member Compliance Medical Policy (I.07), if any of the stated non-compliance criteria is observed, MHP will not approve the suggested medical procedure. See MHP Policy I.07 Member Compliance Medical Policy for specific criteria.

**Line of Business Applicability:**

For **Medicaid/Medicaid Expansion Plan** members, this policy will apply. Coverage is based on medical necessity criteria being met and the codes being submitted and considered for review being included on either the Michigan Medicaid Fee Schedule (located at: [http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html)), the Illinois Medicaid Fee Schedule (located at: [http://www.illinois.gov/hfs/MedicalProviders/MedicaidReimbursement/Pages/default.aspx](http://www.illinois.gov/hfs/MedicalProviders/MedicaidReimbursement/Pages/default.aspx)), or the Iowa Medicaid Fee Schedule (located at: [http://dhs.iowa.gov/ime/providers/csrp/fee-schedule](http://dhs.iowa.gov/ime/providers/csrp/fee-schedule)). If there is a discrepancy between this policy and either the Michigan Medicaid Provider Manual (located at: [http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html)), the Illinois Medicaid Provider Manual (located at: [http://www.illinois.gov/hfs/MedicalProviders/Handbooks/Pages/default.aspx](http://www.illinois.gov/hfs/MedicalProviders/Handbooks/Pages/default.aspx)), or the Iowa Medicaid Provider Manual (located at: [http://dhs.iowa.gov/policy-manuals/medicaid-provider](http://dhs.iowa.gov/policy-manuals/medicaid-provider)) the applicable Medicaid Provider Manual will govern.

For **Medicare** members, coverage is determined by the Centers for Medicare and Medicaid Services (CMS). If a coverage determination has not been adopted by CMS, this policy applies. Medicare Fee Schedules can be found on the CMS website ([https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FeeScheduleGenInfo/index.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FeeScheduleGenInfo/index.html)).


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**References:**


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<th>State Bulletins</th>
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<tbody>
<tr>
<td>CMS National/Local Coverage</td>
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<td>Determination (NCD/LCD)</td>
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<td>Medicare Managed Care Manual:</td>
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<td>Medicaid CFR:</td>
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<td>State Administrative Codes:</td>
<td>[441] 78.1(20)a(1) p.7 (November 2011) He-W 531.05 Covered Services, Section (b)</td>
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<tr>
<td>Contract Requirements:</td>
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<tr>
<td>Related Policies:</td>
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