POLICY AND PROCEDURE MANUAL

Policy Title: Kidney Transplant	**Policy Number: F.21**
Primary Department: Medical Management **Affiliated Department(s): N/A**	**NCQA Standard: N/A** **URAC Standard: N/A**
Last Revision Date: 03/08/2019 **Revision Dates: 04/2013; 05/2014; 04/2015; 03/2016; 03/2017; 02/2018; 10/2018; 03/08/2019** **Effective Date: 08/08/2012**	**Next Review Date: 03/31/2020** **Review Dates: 07/13/2012; 06/28/2013; 06/27/2014; 06/26/2015; 03/25/2016; 03/31/2017; 03/28/2018; 12/19/2018; 03/20/2019**
Applicable Lines of Business: ☐MeridianCare ☒MeridianHealth ☐MeridianComplete ☒MeridianChoice	
Applicable States: ☐All ☒MI ☒IL ☐OH ☐_____ ☐_____	
Applicable Programs: ☒All ☐Other _____	
Policy is to be published: Internally Only ☐ Internally & Externally ☒	

If the request is for a Medicare or MMP member this is not the appropriate policy

Definitions:

Xenotransplantation	Transplantation of living cells, tissues or organs from one species to another
Chronic Kidney Disease (CKD)	CKD 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 CKD and treated by kidney transplantation are (i) type 1 & 2 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) in-center hemodialysis; (ii) home renal replacement modalities; or (iii) 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:

Criteria for Coverage:

For multi organ transplant, patient must meet criteria for each organ.

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 one of the aforementioned renal replacement modalities; *or*
2. Member has chronic kidney disease with anticipated deterioration to end stage renal disease, where member is seeking precertification for deceased donor 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.

Required Documentation:

In addition to a standard medical work-up, the evaluation of all transplant candidates should include:

1. Serologies:
    a. Cytomegalovirus (CMV)
    b. Epstein Barr Virus (EBV)
    c. Varicella zoster virus (VZV)
    d. Hepatitis C virus (HCV)
    e. Hepatitis B virus (HBV)
    f. Syphilis
    g. Tuberculosis (TB)
2. Creatinine clearance
3. Evaluation of parathyroid status
4. Coagulation profile
5. Pap smear
6. ABO and histocompatibility typing
7. Urologic evaluation (including a voiding cystourethrogram in selected patients to assess outlet obstruction and reflux)
8. Gastro-intestinal evaluation (as warranted by history of ulcer, diverticulitis, or other symptoms)
9. Psychosocial evaluation
10. Dental exam and evaluation

Absolute Contraindications:

All candidates for transplant **should be free of:**

1. Systemic oruncontrolled infection including sepsis:
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
3. Significant uncorrectable life-limiting medical conditions other than those treated by kidney transplant.
    a. Severe end stage organ damage including:
        i. Diabetes with end organ damage,
        ii. Normal serum transaminases and total bilirubin as liver screens,
        iii. Irreversible severe pulmonary disease, with FEV1<1 L or FVC <50%.
4. The 2005 Canadian Transplant guidelines suggest that patients with the following clinical features should not be candidates for kidney transplantation:
    a. Home oxygen therapy requirement
    b. Uncontrolled asthma
    c. Severe cor pulmonale
    d. Severe chronic obstructive pulmonary disease/pulmonary fibrosis/restrictive disease. This is defined by:
        i. Best FEV1 <25% predictive value

[1] (Ward, Slutsker, Buehler, Jaffe, Berkelman, & Curran, 1992)

ii. PO2 room air <60 mmHg with exercise desaturation SaO2 <90%
iii. >4 lower respiratory tract infections in the last 12 months; and/or
iv. Moderate disease with progression.

e. All patients must discontinue smoking since it increases the risk of allograft loss and patient death

5. Absence of cardiovascular, coronary artery disease or severe MI (Must submit documentation of ECHO, Stress test or catheterization if necessary)
6. 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)
7. No genitourinary disease by history and physical exam or if necessary U/S of abdomen/pelvis, cystoscopy with retrogrades and pyelogram, renal CT scan, and VCUG.
8. No GI disease or documentation of GI clearance with consult notes or EGD/colonoscopies if necessary
9. Irreversible, severe brain damage
10. Emotional instability, significant depression or other psychiatric illness that cannot be controlled that would impact the 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 and the inability to adhere to transplant program requirements
12. Non remediated non-compliance
13. Inability to give informed consent, unless there is an authorized guardian
14. Limited irreversible rehabilitative potential
15. Post -transplant lymphoproliferative disease, unless no active disease is demonstrated by PET scan, CT scan or MRI.
16. No active sickle cell disease

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. Severe systemic amyloidosis
4. Life threatening extra-renal congenital abnormalities
5. Ongoing alcohol or drug abuse
6. 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
7. Untreated coagulation disorder
8. Currently pregnant
9. CVA or TIA within the past 6 months;
10. 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
11. Other organ system failure that is irreversible and not attributed to kidney disease.

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.

Xenotransplantation is not covered due to the lack of studies showing the efficacy and/or safety of the procedure.

Member Assessment of Compliance with Plan of Care (applicable for ages 10 and above):

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

1. Alcohol screen- abstinence for the past 6 months prior to actual transplant approval, if member history includes use of alcohol. If no history exists then 1 negative alcohol screen must be submitted for members with no history of past alcohol use
2. Drug screen-abstinence for the past 6 months prior to actual transplant approval if history exists of drug use. If no history exists then 1 negative drug screen must be submitted for members with no history of positive drug screen.
3. Nicotine screening- abstinence for the past 6 months prior to actual transplant approval if history of smoking. If no history exists then 1 negative cotinine level must be submitted

Refusal or failure to undergo monthly testing for those members with a history of alcohol, tobacco, and/or drug use will be interpreted as a positive test result.

Six month abstinence period may be shortened in cases where patient's condition is sufficiently advanced that mortality is reasonably expected before the full abstinence period can be completed. Patients granted a waiver of the six month abstinence period require documentation of participation in a formal outpatient treatment program, when practical, as well as serial blood or urine testing no less frequently than monthly. A positive test result at any time prior to the procurement phase will result in denial.

Line of Business Applicability:
This policy applies to Michigan Medicaid, Illinois Medicaid, and Individual plans.

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), or the Illinois Medicaid Fee Schedule (located at: http://www.illinois.gov/hfs/MedicalProviders/MedicaidReimbursement/Pages/default.aspx). 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), or the Illinois Medicaid Provider Manual (located at: http://www.illinois.gov/hfs/MedicalProviders/Handbooks/Pages/default.aspx the applicable Medicaid Provider Manual will govern.

For **Individual** members, consult the individual insurance policy. If there is a discrepancy between this policy and the individual insurance policy document, the guidelines in the individual insurance policy will govern.

State specific special instructions:

None: ☒
MI:
IL:
OH:

References:

1. Bertram L. Kasiske, Charles B. Cangro, Sundaram Hariharan, et. al. The Evaluation of Renal Transplant Candidates: Clinical Practice Guidelines. American Journal of Transplantation 2001; Suppl. 1: Vol. 2:5-95

2. Eason, JD, et al. Proceedings of consensus conference on simultaneous liver/kidney transplantation. American Journal of Transplantation 2008; 8:2243-2251
3. K/DOQI Clinical Practice Guidelines on Chronic Kidney Disease: Work Group and Evidence Review Team Membership. *American Journal of Kidney Diseases,* Vol. 39, No 2, Suppl. 1 (February), 2002:pp S11-S12)
4. Ravaioli M, et al. Liver transplantation for hepatocellular carcinoma: results of down-staging in patients initially outside the Milan selection criteria. Am J Transplant 2008 Dec; 8(12): 2547-57
5. Revised Surveillance Case Definitions for HIV Infection Among Adults, Adolescents, and Children Aged <18 Months and for HIV Infection and AIDS Among Children Aged 18 Months to <13 Years — United States, 2008. Centers for Disease Control and Prevention. 2008.
6. Michigan Department of Health and Human Services (MDHHS) Medicaid Provider Manual. Practitioner, Section 12.6(Version Date: January 1, 2017)
7. Khatri P, Sarwal MM. Using gene arrays in diagnosis of rejection. Curr Opin Organ Transplant. 2009;14(1):34-39.
8. Hartono C, Muthukumar T, Suthanthiran M. Noninvasive diagnosis of acute rejection of renal allografts. Curr Opin Organ Transplant. 2010;15(1):35-41.
9. Mihovilovic K, Kardum-Skelin I, Ljubanovic D, et al. Urine Immunocytology as a noninvasive diagnostic tool for acute kidney rejection: A single center experience. Coll Antropol. 2010;34(1):63-67.

State Bulletins				
CMS National/Local Coverage Determination (NCD/LCD)				
Medicare Managed Care Manual:				
Medicaid CFR:				
State Administrative Codes:				
Contract Requirements:				
Related Policies:				
Related Desk Level Procedures/ Job Aids/Template Letters:				
Related Algorithms/Flowcharts/ Attachments				