curative

TITLE:	KIDNEY TRANSPLANT POLICY
POLICY #:	MM-PNP-031
VERSION #:	01
DEPARTMENT:	UTILIZATION REVIEW
ORIGINAL EFFECTIVE DATE:	12/01/2023
CURRENT REVISION DATE:	N/A

1. PURPOSE

To establish medical necessity criteria and requirements for KidneyTransplantation..

2. SCOPE

For use by the Medical UM Department.

3. DEFINITIONS

N/A

4. RESPONSIBILITIES

N/A

5. POLICY

Provides guidelines regarding the medical necessity review of liver transplant requests.

Curative makes every attempt to ensure that people chosen for transplant evaluation are the most suitable for the surgery.

Medically Necessary

Kidney Transplantation

Curative considers kidney transplantation medically necessary for members who meet the transplanting institution's selection criteria. In the absence of an institution's selection criteria, Curative considers kidney transplantation medically necessary when *all* of the following criteria below are met:

- Member has completed an evaluation and been accepted by the kidney transplant committee at the kidney transplantation center.

  Note: Frequently requests for evaluation for transplantation are confused with requests for the transplantation itself. While the transplant evaluation of persons with kidney disease may be indicated, the medical necessity for transplantation itself depends on the results of the evaluation; *and*

- Member meets transplanting institution's protocol eligibility criteria regarding age; *and*
- Absence of malignancy (except for non-melanomatous skin cancers or low-grade prostate cancer) or the malignancy has had curative therapy (e.g., surgical resection of non-invasive squamous cell or basal cell skin cancer) or the estimated risk of recurrence of the malignancy is less than 10% within the next 2 years. For example, renal cell carcinoma treated by nephrectomy with no evidence of metastatic disease 2 years after the nephrectomy, prostate cancer with negative prostate-specific antigen levels after

treatment, surgically treated colon cancer, thyroid cancer with normal thyroglobulin levels after therapy, and others. Women should have a negative Pap smear within the past 3 years and mammography, where indicated, within the past 2 years; *and*

- Absence of systemic infection; *and*
- Absence of symptomatic HIV infection, as defined by *all* of the following:
  - CD4 count greater than 200 cells/mm^3 for more than 6 months; *and*
  - HIV-1 RNA (viral load) undetectable; *and*
  - On stable antiviral therapy for more than 3 months; *and*
  - No other complications from AIDS, such as opportunistic infection (e.g., aspergillus, coccidiomycosis, resistant fungal infections, tuberculosis), Kaposi's sarcoma or other neoplasms; *and*
- Attending physician determines that there is no prohibitive cardiovascular risk; *and*
- Attending physician determines that there is no prohibitive pulmonary risk; *and*
- Attending physician determines that there is no prohibitive hepatic risk; *and*
- Severity of disease:
  - Member is already on hemodialysis or continuous ambulatory peritoneal dialysis (CAPD); *or*
  - Member has chronic renal failure with anticipated deterioration to end stage renal disease, where member is seeking precertification for cadaveric kidney transplantationFootnote1**or*
  - 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; *and*

  Note: 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;

Kidney transplant is not considered medically necessary for persons who do not meet the transplanting institution's protocol selection criteria, or in the absence of a protocol, for persons who have *any* of the following (not an all-inclusive list):

- Active vasculitis; *or*
- Age over 70 years with severe comorbidities; *or*
- Life threatening extra-renal congenital abnormalities; *or*
- Ongoing alcohol or drug abuse; *or*
- 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; *or*
- Untreated coagulation disorder.

Combined Kidney/Pancreas Transplantation

- For persons undergoing kidney transplantation due to diabetic nephropathy, a combined kidney/pancreas transplantation may be considered medically necessary under some circumstances
- Other multi-organ transplants (e.g., kidney/heart, liver/kidney) should be referred to Curative's National Medical Excellence Program for review.

Renal Autotransplantation and Ex-Vivo Bench Surgery

Curative considers autotransplantation and ex-vivo repair medically necessary where repair of the kidney, ureter, renal artery or its branches are not amenable to in-situ reconstruction.

Belatacept (Nulojix)

Curative considers the use of belatacept (Nulojix) medically necessary for the prevention of acute rejection in kidney transplant recipients who are sero-positive for the Epstein Barr virus (EBV).

Curative considers belatacept experimental and investigational for the prophylaxis of organ rejection in other transplanted organs because its effectiveness for the prevention of acute rejection in organ transplant other than kidney has not been established.

Equine Antithymocyte Immunoglobulin

Curative considers equine anti-thymocyte immune globulin (Atgam) medically necessary for the following indications:

- Prophylaxis or treatment of allograft rejection episodes in renal transplantation in combination with conventional therapy; *or*
- Moderate to severe aplastic anemia in persons who are not suitable candidates for bone marrow transplantation.

Curative considers equine antithymocyte immunoglobulin experimental and investigational for all other indications.

Renal Auto-Transplantation

Curative considers renal auto-transplantation medically necessary for the treatment of individuals with loin pain hematuria syndrome who have failed non-surgical therapies including analgesics.

Experimental and Investigational

Curative considers the following experimental and investigational:

- Gene Microarrays for Diagnosis of Rejection

  Curative considers the use of gene microarrays (e.g., the Kidney Microscope Diagnostic System (MMDx-Kidney)) in diagnosis of rejection of kidney transplantation experimental and investigational because of insufficient evidence of their effectiveness.

- **Experimental Markers of Acute Rejection**

Curative considers measurement of cytokines (e.g., cytokine-14, interleukin-1 beta (IL-1β), IL-2, IL-4, IL-6, granulocyte-macrophage colony-stimulating factor (GM-CSF), monocyte chemoattractant protein-1 (MCP-1), and tumor necrosis factor-alpha (TNF-α); not an all-inclusive list) for the diagnosis of acute renal allograft rejection experimental and investigational because the effectiveness of this approach has not been established.

- **Experimental Markers of Rejection Risk**

Curative considers the following experimental and investigational because the effectiveness of this approach has not been established:

  - Clarava as a pre-transplant prognosis test for the risk of early acute rejection in kidney transplant candidates;
  - Human leukocyte antigen-G-14-base-pair-insertion/deletion polymorphism;
  - Interleukin-2-330 T/G promoter;
  - Interleukin-10-1082 (G/A) promoter polymorphisms testing for evaluating the risk of developing kidney graft rejection;
  - Perfusate biomarkers produced during hypothermic machine perfusion for prediction of graft outcomes in kidney transplantation;
  - Pleximark (measurement of donor and third party-induced CD154+T-cytotoxic memory cells) for evaluation of acute cellular rejection following kidney transplantation; and
  - Tuteva as a post-transplant test for acute cellular rejection, including sub-clinical rejection, in kidney transplant recipients.

- **Bisphosphonates**

  Curative considers bisphosphonates experimental and investigational for the treatment of low bone mineral density after kidney transplantation because their effectiveness of this indication has not been established.

- **Pre-Conditioning Therapy**

  Curative considers pre-conditioning therapy (e.g., immune-adsorption or rituximab) in ABO-incompatible kidney transplantation experimental and investigational because the effectiveness of this approach has not been established.

- **Biomarkers of Acute Kidney Injury**

  Curative considers urinary neutrophil gelatinase-associated lipocalin (NGAL) and liver-type fatty acid-binding protein (L-FABP) experimental and investigational as biomarkers of acute kidney injury following kidney transplantation because the effectiveness of this approach has not been established.

- **FASL mRNA**

  Curative considers Fas ligand (FASL) mRNA detection experimental and investigational as a diagnostic marker for acute renal rejection because the effectiveness of this approach has not been established.

- **Urinary Biomarkers (e.g., Chemokines, Extracellular Vesicles, and Monocyte Chemoattractant Protein-1)**

  Curative considers urinary biomarkers (e.g., chemokines including CXCL9 and CXCL10, alone or in combination; extracellular vesicles; monocyte chemoattractant protein-1 (MCP-1/CCL2) experimental and investigational for detection and monitoring of renal graft rejection because the effectiveness of this approach has not been established.

- **Donor-Derived Cell-Free DNA Testing**

  Curative considers donor-derived cell-free DNA testing (e.g., Allosure, Prospera) experimental and investigational for monitoring acute rejection following renal transplantation because the effectiveness of this approach has not been established.

- **Measurement of Angiotensin II Type 1 (AT1) Receptors or AT1 Antibodies for Evaluation of Renal Transplantation Candidates / Recipients**

  Curative considers measurement of angiotensin II type 1 (AT1) receptors or AT1 antibodies experimental and investigational for evaluation of renal transplantation candidates / recipients because the effectiveness of this approach has not been established.

- **Complement Inhibitors (e.g., Eculizumab) for the Treatment of Antibody-Mediated Rejection in Renal Transplantation Recipients**

  Curative considers complement inhibitors (e.g., eculizumab) experimental and investigational for the treatment of antibody-mediated rejection in renal transplantation recipients because their effectiveness for this indication has not been established.

- **Belimumab for the Treatment of Antibody-Mediated Rejection in Renal Transplantation Recipients**

  Curative considers belimumab experimental and investigational for the treatment of antibody-mediated rejection in renal transplantation recipients because its effectiveness for this indication has not been established. See CPB 0818 – Belimumab (Benlysta).

- **Genotyping Donors and Recipients Before Renal Transplantation**

  Curative considers genotyping donors and recipients before renal transplantation experimental and investigational because its effectiveness for this indication has not been established.

- **Recombinant Human Erythropoietin**

  Curative considers recombinant human erythropoietin (e.g., Epogen, Procrit, and Retacrit) experimental and investigational for nephron-protection in persons undergoing kidney transplantation because its effectiveness for this indication has not been established. See also CPB 0195 - Erythropoiesis Stimulating Agents.

- **TruGraf Blood Gene Expression Test**

  Curative considers the TruGraf blood gene expression test experimental and investigational for the management of kidney transplant recipients because its effectiveness has not been established.

- **Plasminogen Activator Evaluation**

Curative considers plasminogen activator evaluation experimental and investigational as part of a hypercoagulable workup prior to kidney transplantation because the effectiveness of this approach has not been established.

- **Evaluation of Urine Immunocytology**

  Curative considers evaluation of urine immunocytology for T cells experimental and investigational for the diagnosis of acute kidney rejection because its role has not been established.

- **Soluble CD30 Level**

  Curative considers measurement of pre-transplantation soluble CD30 level experimental and investigational as a predictor of acute rejection in kidney transplantation because its clinical value has not been established.

- **DNA Methylation**

  Curative considers the use of DNA methylation experimental and investigational as a biomarker of post-transplant complications in kidney transplantation because its clinical value has not been established.

- **Artificial Intelligence/Machine Learning Method for Predicting Graft Survival**

  Curative considers artificial intelligence/machine learning method experimental and investigational for predicting graft survival in kidney transplantation because the effectiveness of this approach has not been established.

6. PROCEDURE

N/A

7. TRAINING REQUIREMENT

- All Medical UM associates are responsible for reading and comprehending this procedure. Employees are also responsible for contacting management or Privacy and Compliance with any questions or concerns regarding the information contained within this procedure.

8. ENFORCEMENT

Violations of this controlled document will cause the imposition of sanctions in accordance with the Curative sanctions-controlled document. This may include verbal/written warning, suspension, up to termination of employment or volunteer, intern, contractor status with Curative. Additional civil, criminal, and equitable remedies may apply.

9. DOCUMENTATION

N/A

10. REFERENCE DOCUMENTS AND MATERIALS

N/A

11. COLLABORATING DEPARTMENTS

- Medical and Pharmacy UM Departments

12. DOCUMENT CONTROL

APPROVED BY:		
(Printed Name)	**(Date)**	**(Signature)**

REVISION HISTORY			
Date	**Author**	**Version**	**Comments**
			Initial Version

APPENDICES

Any applicable attachments, resources or other materials should be included as appendices in this section. Label each appendix as follows:

Appendix A: