



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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Subject **Kidney Transplantation**

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INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

Coverage Policy

CIGNA covers kidney transplantation for end-stage renal disease (ESRD) as medically necessary when EITHER of the following criteria is met:

- glomerular filtration rate (GFR) of < 23 mL/min/1.73m²
- GFR ≥ 23 but < 29 mL/min/1.73m² with evidence of uremia, including ANY of the following:
 - anemia of chronic disease
 - nausea, vomiting or anorexia
 - pericarditis or uremic serositis
 - uremic encephalopathy
 - metabolic acidosis (HCO₃ < 15 meq/l)
 - persistent hyperkalemia (K⁺ > 6.0 meq/l)
 - pulmonary edema or congestive heart failure refractory to diuretics
 - incapacitating peripheral edema refractory to diuretics
 - peripheral or autonomic neuropathy
 - uncontrollable hypertension
 - requiring dialysis or meeting criteria for dialysis
 - pediatric only: growth failure as compared to children of same age and gender (weight is < 3rd to 5th percentile, height is > 2 standard deviations below mean; or weight crosses two major percentiles downward, utilizing 90th, 75th, 50th, 10th and 5th)

CIGNA does not cover kidney transplantation for patients with ANY of the following contraindications to transplant surgery because it is considered not medically necessary (this list may not be all-inclusive):

- malignancy that is expected to significantly limit future survival
- persistent, recurrent or unsuccessfully treated major or systemic extra-renal infections
- systemic illness or comorbidities that would be expected to substantially negatively impact the successful completion and/or outcome of transplant surgery
- a pattern of demonstrated patient noncompliance which would place a transplanted organ at serious risk of failure
- human immunodeficiency virus (HIV) disease unless ALL of the following are noted:
 - CD4 count greater than 200 cells/mm³
 - HIV-1 ribonucleic acid (RNA) undetectable
 - stable anti-retroviral therapy for more than three months
 - 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)

General Background

End-stage renal disease (ESRD), or end-stage kidney disease, is a common, worldwide health problem. It occurs when the kidneys are no longer able to function at a level that is necessary for day-to-day life. ESRD almost always follows chronic kidney failure, which may exist for 10–20 years or more before progression to ESRD. The most common cause of ESRD in the U.S. is diabetes mellitus. Other diseases that may lead to ESRD include hypertension, polycystic kidneys, nephrosclerosis, chronic pyelonephritis, glomerulonephritis, kidney stones, renal cell carcinoma and Wilm's tumor.

Glomerular filtration rate (GFR) is considered the best measure of kidney function. While the lower limit of normal GFR varies with age, a GFR level below 60 mL per minute per 1.73m² represents loss of one half or more of the adult level of normal kidney function. A GFR of <30 mL/min/1.73 m² is considered to be abnormal in all ages other than neonates. Kidney failure, (i.e., chronic kidney disease [CKD] stage 5) is defined as either a GFR below 15 mL per minute per 1.73 m² which, in most cases is accompanied by signs and symptoms of uremia, or a need to start kidney replacement therapy (dialysis or transplantation) for the treatment of complications of decreased GFR (Johnson, et al. 2004; Levey, et al. 2003). Authors recommend patients be referred to a nephrologist for renal replacement therapy when the GFR is <30 mL/min/1.73 m² (i.e., stage 4) (Eknoyan and Levin, 2002; Bolton, 2003). Patients with advanced CKD (Kidney Disease Outcomes Quality Initiative [K/DOQI™] CKD Stages 4 and 5) have a high propensity for progression to ESRD in a relatively short period of time with well-known multiple comorbid conditions and poor outcomes (Bolton, 2003).

The two primary treatments for ESRD are dialysis and transplant. Kidney transplantation is the grafting of a kidney from either a living or cadaveric donor. Both pediatric and adult kidney transplant recipients have increased survival compared to patients who remain on dialysis. Kidney transplant is the only treatment for ESRD that allows a lifestyle free from dialysis. The transplant procedure can be performed by way of an open surgical approach or laparoscopically. The use of laparoscopic nephrectomy has reduced the length of hospital stay, pain, and recovery time for donors while having no effect on the quality of the donation.

Kidney transplantation should be timed to occur as close as possible to when the recipient would be expected to require dialysis; however, transplantation should be delayed in patients who may regain kidney function (e.g., malignant hypertension, severe, acute tubular necrosis).

Preemptive Transplantation

Some patients who are nearing ESRD can receive a transplant prior to initiating dialysis. Transplantation performed prior to the need for dialysis is called preemptive transplantation; it confers a survival advantage to the recipient and is more common for recipients of living-donor kidneys. Preemptive kidney transplant has been shown to provide better outcomes compared to transplant after any period of time on dialysis; however, because

of the shortage of donors, preemptive transplantation may not be possible, and therefore the potential recipient should be prepared for dialysis as well as kidney transplantation.

Living-Donor Kidney

Living-donor kidneys have become more common and, although there is potential donor morbidity associated with the procedure, most transplant centers regard living donor as the preferred donation modality.

Living donors can be related or unrelated to the recipient. For the donor, there is some risk in living with one kidney because the remaining kidney compensates to do the work of both kidneys; some evidence has shown a slightly higher risk of high blood pressure and proteinuria. As a result, extensive screening is conducted prior to donation (Boudville, et al., 2006; Steiner, 2004). For the recipient, the results of kidney transplants from living donors are better than those from cadaver donors, with an approximate 5-20% difference in graft survival at five years. Living kidney donation eliminates the recipient's need for waiting time on a national waiting list, are often more successful, and can add psychological benefits to both donor and recipient. Nonetheless, the benefit to the recipient of a live-donor organ must outweigh the risks to the donor.

Cadaveric (Deceased)-Donor Kidney

In the absence of a living donor, many transplanted kidneys come from deceased (i.e., cadaver) organ donors. The average wait time for a cadaver-donor kidney may range from two to six years depending on blood type, cross-matching, and various other factors. The wait time is increasing for all blood groups, and the number of new registrants added to the wait list is also increasing, adding to the wait time. The increased utilization of cadaver-donor compared to living-donor kidney, may be related to improved collaboration among agencies and facilities to improve best practices.

ABO Mismatched Donor Kidney

In the event that no ABO-identical or minor mismatch donor is available, the use of an ABO mismatched donor may be the best option for some kidney transplantation candidates. In the U.S., the most common procedure has used blood subgroup A2 donors for B or O recipients, as A2 kidneys appear to undergo less damage from anti-A antibody. The treatment protocol may include pretransplant plasmapheresis followed by immunosuppressive medication, anti-CD20 antibody therapy, and/or splenectomy, and postoperative anticoagulant therapy to prevent microthrombus formation in the graft and/or surveillance biopsy to identify subclinical rejection. Recent studies have demonstrated that an ABO mismatched living donor transplant may result in survival rates close to those achieved with compatible grafts, although recipients with high anti-blood group titers before plasmapheresis have been reported to have higher rates of humeral rejection and early graft loss (Shimmura, et al., 2000; Sonnenday, et al., 2004; Stegall, et al., 2004; Kaihara, et al., 2005).

Extended Criteria Donor Kidney

In an effort to address the shortage of kidneys available for transplantation, the kidney allocation algorithm was modified in October 2002 to expedite the distribution of kidneys with less favorable donor characteristics, known as extended criteria donor (ECD) kidneys, to patients who had previously agreed to accept them. ECD kidneys are those from donors over the age of 60 or ages 50–60 with two or all three of the following criteria:

- pre-donation serum creatinine greater than 1.5 mg/dL (milligrams per deciliter)
- stroke as cause of death
- hypertension

Graft and patient survival for ECD kidney recipients are not as good as those for non-ECD kidney recipients, and both of these groups have lower survival than patients who received living-donor kidneys.

Relative Contraindications to Kidney Transplant

Many factors affect the outcome of a solid organ transplant. A fairly rigid selection process is required in order to obtain the best results for each patient. In addition to the absolute contraindications noted in the Coverage Policy section above, relative contraindications to kidney transplantation include but are not limited to:

- potential complications from immunosuppressive medications that are unacceptable to the patient
- active substance abuse within the last six months, including tobacco, alcohol and narcotic/other addictive pain medications

- cerebrovascular disease or accident or progressive neuropathy or myopathy that is not amenable to rehabilitation
- body mass index (BMI) less than 17 or greater than 33
- any active medical process that is currently not optimally treated and/or stable and that is likely to result in end-organ damage or medical emergency without appropriate management, such as active peptic ulcer disease, diverticular disease, active hepatitis, cholecystitis, pancreatitis, diabetes mellitus, hypertension, autoimmune disease, cytopenia
- untreated osteoporosis with a T-score greater than 2.5 standard deviations (SD) from mean or Z-score greater than two SD from mean
- hepatic fibrosis or cirrhosis
- hepatitis C with biopsy-proven, histologic evidence of hepatic disease
- uncorrected abdominal aortic aneurysm greater than four centimeters
- diabetes with end-organ damage, such as neuropathy or retinopathy
- advanced age
- peripheral vascular disease not amenable to surgical or percutaneous therapy as evidenced by:
 - asymptomatic stenosis greater than 75% or symptomatic carotid stenosis of less severity
 - ankle brachial index less than 0.7 or substantial risk of limb loss with diminished perfusion

Additionally, there are other conditions that may affect the outcome of kidney transplantation and require further investigation to ensure the best chance for successful kidney transplantation:

- history of recurrent infection or bladder dysfunction indicates the need for a urological evaluation
- potential for renal malignancy should be screened by use of magnetic resonance imaging (MRI), computed tomography (CT) or renal ultrasound
- reflux nephropathy, history of recurrent infections, nephrolithiasis, heavy proteinuria, hypertension resistant to therapy, or enlarged or symptomatic polycystic kidneys should be evaluated for potential nephrectomy

Retransplantation

In general, retransplantation is considered by some to be a controversial procedure, in part due to ethical concerns over the limited supply of organs. A wide range of donor, recipient and other transplant-related factors can influence graft survival. In the event of renal graft failure, renal replacement therapy consists of either dialysis or retransplantation. Although allograft survival is considered good, it is considerably less compared to the primary transplant (Ahmed, et al., 2008). Candidates awaiting kidney retransplant are often allosensitized and may be less likely to receive a transplant than primary candidates. As a result, some transplant centers have developed ongoing efforts involving desensitization protocols.

Desensitization

Guidelines for histocompatibility testing are provided by United Network for Organ Sharing (UNOS). Individuals that have antibodies against donor human leukocyte antigen (HLA) may experience hyperacute or accelerated acute antibody-mediated rejection. Factors that stimulate antibody production include pregnancy, blood transfusions, vaccinations, certain infections, surgery and prior graft failure from organ transplant (UNOS, 2008). Patients with these antibodies (i.e., sensitized patients) typically wait longer than non-sensitized patients for organ transplant and suffer greater risk of graft loss from rejection. As a result there has been an emphasis on investigation and development of desensitization protocols to prevent antibody-mediated acute rejection. The medical literature indicates that clinical outcomes and desensitization protocols vary among transplant centers and are not commonly utilized, however existing protocols include the combination of plasmapheresis or immunoadsorption to remove donor specific anti-HLA antibodies, and/or intravenous immunoglobulin and rituximab (an anti-CD20 antibody) to downregulate the antibody-mediated immune response (Yoon, et al., 2009). Although desensitization protocols may be considered for deceased donor kidney, protocols are generally attempted with living donation so that antibody response against donor tissue can be monitored—patients proceed to transplant surgery only if antibody levels are low. Authors contend that desensitizing highly sensitive patients improves clinical outcomes (short-term patient and graft survival) however acute antibody-mediated rejection is a barrier in 20-30% of patients and there is no consensus regarding which protocol is ideal (Akalin, 2009).

Summary

Kidney transplantation is an accepted and successful treatment for many individuals with end-stage renal disease. The transplant evaluation should begin when it is clear that the patient is destined to develop ESRD. Patient preparation for transplantation is a time-consuming process, and the patient should understand all of the options for renal replacement. In the event of subsequent renal graft failure, retransplant is often performed.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®* Codes	Description
50300	Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral
50320	Donor nephrectomy (including cold preservation); open, from living donor
50323	Backbench standard preparation of cadaver donor renal allograft prior to transplantation; including dissection and removal of perinephric fat diaphragmatic and retroperitoneal attachments, excision of adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50325	Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50327	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each
50328	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; arterial anastomosis, each
50329	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; ureteral anastomosis, each
50340	Recipient nephrectomy (separate procedure)
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy
50370	Removal of transplanted renal allograft
50547	Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor

HCPCS Codes	Description
S2152	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, and rehabilitative services; and the number of days pre- and post-transplant care in the global definition

ICD-9-CM Diagnosis Codes	Description
585.4	Chronic kidney disease, Stage IV (severe)
585.5	Chronic kidney disease, Stage V
585.6	End stage renal disease

*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	9/15/2007	0146	Kidney Transplantation
Great-West Healthcare	5/16/2006	95.216.04	Transplantation, Kidney

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