Clinical Policy: Transplant Service Documentation Requirements

Reference Number: MC.CP.MP.247
Date of Last Revision: 10/24

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

The pre-transplant evaluation provides the opportunity to identify conditions that can affect an individual's ability to have a successful transplant. Identifying those who may benefit from a transplant involves many factors; overall health and disease stage are all extremely important considerations in the evaluation process. The pre-transplant evaluation phase includes covered diagnostic tests and consultations performed by a provider that are necessary to assess and evaluate transplant candidacy for acceptance into a transplant program.

The determination of medical necessity for transplant procedures is based on a combination of clinical data and the presence of indicators that would complicate surgery and affect postoperative recovery. The following policy outlines clinical documentation required for review of liver, kidney, heart, and lung transplant requests.

The criteria below are sourced from the Kidney Disease: Improving Global Outcomes (KDIGO) clinical practice guidelines, the International Society for Heart and Lung Transplantation (ISHLT) consensus guidelines, and the United Network for Organ Sharing (UNOS). The guidelines utilized for the below criteria consider the complexity of transplant candidate selection and the various risk factors for poor transplant outcomes. They provide recommendations on the evaluation and management of potential transplant candidates and suitability for transplantation as an effective treatment option to improve quality of life and increase survival. The requirements for the clinical assessments within 12 months of transplant candidate evaluation in the criteria below help to ensure the patient can safely receive an effective transplant based on accurate and current clinical data. Given the rigor of the guidelines on which this policy is based, the benefits of utilizing the below criteria for transplant recipient selection outweighs the risks by ensuring a thorough pre-transplantation evaluation is completed with identification of pertinent conditions or history that can affect the overall success of a liver, kidney, heart, or lung transplant.

Note:

- *For corneal transplant, pancreatic islet cell auto-transplant after pancreatectomy, or parathyroid auto-transplant after thyroidectomy requests, please complete the Health Plan specific prior authorization form located on the Health Plan website.*
- *For criteria applicable to non-Medicare plans, please see CP.MP.247 Transplant Service Documentation Requests.*

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that requests for transplant candidate evaluations following the first visit for human leukocyte antigen (HLA) typing/donor search and transplant consultation or transplant listing at a participating facility are **medically necessary** when all of the following clinical documentation is included:

A. For transplant evaluation requests, all of the following[10]:
   1. Appropriate prior authorization form;
   2. Routine complete history and physical within one year including[7,10,11,16]:
      a. History of present illness, including a list of all current medications[10];
      b. Past medical history, pertinent family history and social history[10];
      c. Complete review of systems, physical examination, including height, weight and body mass index (BMI)[10,11,13];
      **Note: Approved requests for transplant evaluation are effective for six months. After six months have passed, a new authorization is required.*

B. For initial and subsequent transplant listing requests, all of the following[10]:
   1. Appropriate prior authorization form;
   2. Letter of medical necessity from a transplant service provider with signature;
   3. Complete history and physical performed by a transplant service provider within 12 months, including[10,11]:
      a. History of present illness, including a list of all current medications[7,10];
      b. Past medical history, pertinent family history and social history[10];
      c. Complete review of systems, physical examination, including height, weight and BMI[10,11,13];
   4. Basic labs (complete chemistry panel/liver function tests and complete blood count) within 12 months[10,11];
   5. Appropriate testing, imaging, and documentation for the requested transplant[7,10,11,13]:
      a. Liver – International normalized ratio (INR), Model for End Stage Liver Disease (MELD) or Pediatric End Stage Liver Disease Model (PELD) score and liver biopsy as indicated[14,15];
      b. Kidney – Glomerular filtration rate (GFR) or creatinine clearance if not on dialysis[10,16];
      c. Heart – echocardiogram, right cardiac catheterization results, including pulmonary vascular resistance (PVR) results. NYHA Class and peak VO2 results[13];
      d. Lung – Pulmonary function tests, imaging (chest x-rays and/or CT scans), and six-minute walk test[11,17];
   6. Annual dental evaluation and clearance (transplant clearance from DDS or a panoramic dental x-ray with clearance from MD)[10,16];
   7. Routine health screening exams as per standards of care (e.g., mammogram, Pap, and/or colonoscopy)[7,10,16];
   8. Appropriate comorbidity testing/clearance, including cardiology[7,10,11,13,16];
   9. Serum or urine drug screen results (within 90 days of request)[7,10,11,13];
   10. Infectious disease screening for solid organ, all of the following, as applicable[7,10,11,13,16]:
      a. Cytomegalovirus (CMV) and Varicella-zoster virus (VZV) within one year unless baseline IgG antibody positive;
      b. EBV (Epstein Barr virus) within one year, unless baseline IgG antibody positive;
      c. Toxoplasma titer for heart transplant recipients;
      d. Results of annual purified protein derivative (PPD), T-Spot, or QuantiFERON for all solid organ transplants, unless previously positive;
      e. Hepatitis B testing within one year, unless baseline surface antibody positive;

f. Hepatitis C within one year unless baseline positive (viral load required within three months if positive);
g. Rapid plasma reagin (RPR) within one year;
h. Human immunodeficiency virus (HIV) within one year, unless baseline positive (CD4 count and viral load required within three months if positive);

11. Detailed psychosocial evaluation and clearance within 12 months[10,11,13,16].
** Note: Approved requests for transplant listings are effective for 12 months. After 12 months have passed, a new authorization with updated clinical documentation is required.*

C. Requests for continuity of care authorizations must include the following:
1. Documentation of previous insurer coverage, such as if previously covered by state Medicaid fee for service;
2. Documentation of authorization for coverage of transplant evaluation or listings by previous insurer;
3. Copy of United Network for Organ Sharing (UNOS) listing.

II. It is the policy of health plans affiliated with Centene Corporation that authorizations for transplant services at multiple facilities for a single member/enrollee or requests for additional evaluations following transplant listing, or transplant evaluation approval has already been rendered, are considered **medically necessary** for either of the following:
A. Member/enrollee has an episode of illness resulting in a change to transplant eligibility status;
B. Member/enrollee is admitted to a geographically closer facility and is not stable for transfer to the previously approved facility due to declining medical status.

Background

According to the United Network for Organ Sharing (UNOS), 41,354 organ transplants were performed in the United States in 2021, demonstrating an increase of 5.9% over 2020.[1,2] Annual records were set for kidney, liver, and heart transplants with the 40,000-transplant milestone exceeded for the first time. The Health Resources and Services Administration (HRSA) reports that 5,073 unrelated and 4,276 related bone marrow and cord blood transplants were performed in the United States in 2021 and reported to the Center for International Blood and Marrow Transplant Research CIBMTR.[3] UNOS and the HRSA report that there were over 46,000 organ transplants performed in 2023, continuing the annual increase trend.[2,4] The Organ Procurement and Transplantation Network (OPTN) reports that there are more than 105,000 people on the national transplant waiting list with a new name added to the list approximately every nine to ten minutes.[1,2] There are more people in need of transplants than there are donors, and 17 people die each day waiting for an organ transplant. Organ donation from one donor can save eight lives and enhance more than 75 lives.[1,2,4,5]

Solid Organ Transplantation

Chronic diseases, such as cardiovascular, kidney, and liver disease, as well as, cancer, and diabetes are primary causes of morbidity and mortality in the United States.[6] Solid organ transplantation is the treatment of choice for several types of organ failure.[7] Most available organ donations come from deceased donors, but more than 6,000 transplants come from healthy, living donors each year. A series of tests must be completed to ensure the donor and recipient blood and tissue types are compatible.[8] A pretransplant evaluation identifies the risk for post-transplant infections and evaluates exposure history, prior infections, serologic testing for distant exposures, cultures to identify colonization patterns, and administration of vaccines. Active infections, such as HIV, hepatitis B and C, and severe acute respiratory syndrome coronavirus 2

are evaluated near the time of transplantation as well.[7] Additional factors that may be considered during the process are the patient's current medical status, geographical location, and time on the transplant list.[9] Organ transplantation can still occur in the absence of donor and recipient blood and tissue match; however, special treatments are needed to prevent rejection of the organ.[8] Infection and malignancy are two complications that result from the life-long immunosuppression required to maintain allograft function following transplantation. Since established infection is more challenging to treat in the immunocompromised transplant recipient, the pretransplant evaluation is essential to treatment and must be comprehensive.[7]

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed.	02/24	02/24
Annual review. Description updated with no impact on criteria. Background updated with no impact on criteria. References reviewed and updated. Reviewed by external specialist.	10/24	10/24

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

 Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.