Clinical Policy: Transplant Service Documentation Requirements

Reference Number: MC.CP.MP.247 Coding Implications
Date of Last Revision: 12/25 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 evaluation, listing and follow-up visit requests, given the absence of coverage criteria for kidney and lung transplants provided by the Centers for Medicare and Medicaid Services (CMS) and the applicable Medicare Advantage Contractors. This policy is also intended to supplement the criteria in National Coverage Determination (NCD): Adult Liver Transplantation (260.1), NCD: Pediatric Liver Transplantation (260.2), and NCD: Heart Transplants (260.9). The coverage (medical necessity) criteria in NCDs 260.1 and 260.2 do not contain sufficient coverage criteria to consistently determine medical necessity, as they note diagnoses that qualify for adult and pediatric liver transplantation but do not provide detailed criteria regarding clinical documentation required for review of liver transplant evaluation, listing, and follow-up visits. The coverage (medical necessity) criteria in NCD 260.9 notes coverage for place of service for heart transplants but does not provide criteria regarding clinical documentation required for review of heart transplant evaluation, listing, and follow-up visits. Transplant admission requests are subject to separate prior authorization per plan-adopted guidelines.

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 outweigh 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.

- *This policy notes documentation requirements only for solid organ and stem cell transplant requests. Please refer to plan-approved medical necessity criteria for solid organ and stem cell transplant requests.*
- *For criteria applicable to non-Medicare plans, please see CP.MP.247 Transplant Service Documentation Requirements.*

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that requests for transplant candidate evaluations or consultations for stem cell or solid organ transplants 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 the following[10]:
   1. Appropriate prior authorization form;
   2. Complete history and physical within one year including[7,10,11,16].

   ***Note**:*
   - *A complete history and physical includes a history of present illness, including a list of all current medications, past medical history, pertinent family history and social history, a complete review of systems, and physical examination, including height, weight and body mass index (BMI)* [10,11,13];
   - *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 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. 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 documented by one of the following[10,16]:
      a. Transplant clearance from DDS;
      b. Panoramic dental x-ray with clearance from MD;
   7. Routine health screening exams as per standards of care (e.g., breast cancer screening, cervical

cancer screening, and/or colon cancer screening)[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[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 testing within one year unless baseline results are positive;

Note: *If baseline results are positive, a viral load test is required within three months.*

    g. Rapid plasma reagin (RPR) within one year;
    h. Human immunodeficiency virus (HIV) within one year, unless baseline results are positive;

Note: *If baseline results are positive, a CD4 count and viral load test are required within three months.*

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.*
- *Inpatient admissions for transplants require separate authorization from evaluation or listing authorizations.*

C. For post-transplant follow up office visits, all the following:
    1. Appropriate prior authorization form;
    2. Discharge summary or history and physical from the inpatient hospital stay for the transplant admission;

Note: *For authorization requirements for services unrelated to post-transplant follow up office-visits, please check the health plan's prior authorization tool.*

D. Requests for continuity of care authorizations, all 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), more than 48,000 organ transplants were performed in 2024, continuing the annual record setting trend.[4] 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] 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 13 people die each day waiting for an organ transplant.[4] 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 2024, 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
Clarified in description that the policy applies to transplant evaluation and listing requests. Added to the description and in a note after I.B.11 that	03/25	03/25

transplant admissions require separate authorization. Added requirements for post-transplant follow up visits and note in same section regarding other requests.		
Updated policy statement I. regarding transplant evaluations by removing "following the first human leukocyte antigen…"	07/25	07/25
Annual review. Added note to policy description stating "This policy notes documentation requirements only for solid organ and stem cell transplant requests…" Updated verbiage in Criteria I., Criteria I.A.2., and Criteria I.B.4. for clarity. Changed criteria I.A.2.a.-c. into a note. Verbiage updated in Criteria I.B.6. for clarity. Updated verbiage in Criteria I.B.7. to "breast cancer screening", "cervical cancer screening," and "colon cancer screening.". Updated verbiage in Criteria I.B.10., I.B.10.f., and I.B.10.h. for clarity. Background updated with no impact to criteria. References reviewed and updated. Reviewed by internal specialist.	10/25	10/25
Policy description updated to note that the applicable NCDs do not provide sufficient coverage criteria to consistently determine medical necessity.	12/25	

References

1. United Network for Organ Sharing (UNOS). All-time records again set in 2021 for organ transplants, organ donation from deceased donors. https://unos.org/news/2021-all-time- records-organ-transplants-deceased-donor-donation/. Published January 11, 2022. Accessed August 25, 2025.
2. United Network for Organ Sharing (UNOS). UNOS fast facts. https://unos.org/about/fast- facts/. Accessed August 26, 2025.
3. Health Resources & Services Administration (HRSA). Donation and transplantation statistics. March 2024. https://bloodstemcell.hrsa.gov/data/donation-and-transplantation-statistics#:~:text=In%202021%2C%205%2C073%20unrelated%20and,States%20and%20reported%20to%20CIBMTR. Updated Septemeber 2025. Accessed September 11, 2025.
4. Health Resources & Services Administration (HRSA). Organ donation statistics. March 2024. https://www.organdonor.gov/learn/organ-donation-statistics. Updated May 2025. Accessed September 17, 2025.
5. LifeSource Organ, Eye and Tissue Donation. Fast facts: January through March 2023. https://www.life-source.org/latest/fast-facts/. Published April 18, 2023. Accessed September 09, 2025.
6. Chronic Disease Research Group (CDRG). Chronic disease research. Minneapolis, MN: Hennepin Healthcare Research Institute. https://www.cdrg.org/expertise/chronic-disease- research/. Accessed September 05, 2025.
7. Fishman JA. Evaluation for infection before solid organ transplantation. UpToDate. www.uptodate.com. Updated April 15, 2024. Accessed September 05, 2025
8. Watson S. Organ donation and transplant. WebMD. https://www.webmd.com/a-to-z- guides/organ-transplant-donor-information. Updated March 19, 2024. Accessed September 11, 2025.
9. United Network for Organ Sharing (UNOS). UNOS frequently asked questions. https://unos.org/transplant/frequently-asked-questions/. Accessed September 17, 2025.
10. Rossi AP, Cheng XS. Kidney transplantation in adults: evaluation of the potential kidney transplant recipient. UpToDate. www.uptodate.com. Updated September 04, 2025. Accessed September 16, 2025.
11. Hachem RR. Lung transplantation: an overview. UpToDate. www.uptodate.com. Updated May 23, 2024. Accessed September 11, 2025.
12. Organ Procurement and Transplantation Network(OPTN). Organ distribution policies and bylaws. https://optn.transplant.hrsa.gov/policies-bylaws/. Accessed September 17, 2025.
13. Mancini D. Heart transplantation in adults: Indications and contraindications. UpToDate.

www.uptodate.com. Updated October 25, 2024. Accessed September 11, 2025.
14. United Network for Organ Sharing (UNOS). MELD and PELD information for liver transplants. https://unos.org/policy/liver/. Accessed September 17, 2025.
15. United Network for Organ Sharing (UNOS). Guidance on requested deceased donor information. https://optn.transplant.hrsa.gov/media/2528/opo_boardreport_201806_guidance.pdf. Published June 2018. Accessed September 17, 2025.
16. Chadban SJ, Ahn C, Axelrod DA, et al. KDIGO Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation. *Transplantation*. 2020;104(4S1 Suppl 1):S11-S103. doi:10.1097/TP.0000000000003136
17. Leard LE, Holm AM, Valapour M, et al. Consensus document for the selection of lung transplant candidates: An update from the International Society for Heart and Lung Transplantation. *J Heart Lung Transplant*. 2021;40(11):1349-1379. doi:10.1016/j.healun.2021.07.005
18. National coverage determination: adult liver transplantation (260.1). Centers for Medicare and Medicaid Services Web site. http://www.cms.hhs.gov/mcd/search.asp. Published June 21, 2012. Accessed August 30, 2025.
19. National coverage determination: pediatric liver transplantation (260.2). Centers for Medicare and Medicaid Services Web site. http://www.cms.hhs.gov/mcd/search.asp. Published April 12, 1991. Accessed September 17, 2025.
20. National coverage determination: heart transplants (260.9). Centers for Medicare and Medicaid Services Web site. http://www.cms.hhs.gov/mcd/search.asp. Published May 01, 2008. Accessed September 17, 2025.

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.

CLINICAL POLICY
Transplant Service Documentation Requirements

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. 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.