Clinical Policy: Transplant Service Documentation Requirements

Reference Number: LA.CP.MP.247 Coding Implications
Date of Last Revision: 12/24 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 all solid organ and stem cell/bone marrow transplant requests.

**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.*

Policy/Criteria

I. It is the policy of Louisiana Healthcare Connections that requests for transplant evaluation following the first visit for human leukocyte antigen (HLA) typing/stem cell collection/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:
   1. Appropriate prior authorization form;
   2. Routine complete history and physical within one year including:
      a. History of present illness, including a list of all current medications;
      b. Past medical history, pertinent family history and social history;
      c. Complete review of systems, physical examination, including height, weight and body mass index (BMI);
      **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:
   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 of kidney transplant requests or six months of other transplant requests, including:
      a. History of present illness, including a list of all current medications;
      b. Past medical history, pertinent family history and social history;

   c. Complete review of systems, physical examination, including height, weight and BMI;
4. Basic labs (complete chemistry panel/liver function tests and complete blood count) within 12 months for kidney transplants or six months for other transplants;
5. Appropriate testing, imaging, and documentation for the requested transplant:
   a. Liver – International normalized ratio (INR), Model for End Stage Liver Disease (MELD) or Pediatric End Stage Liver Disease Model (PELD) score, hepatitis serologies, imaging studies (MRI, CT, ultrasound), and liver biopsy as indicated;
   b. Kidney – Glomular filtration rate (GFR) or creatinine clearance if not on dialysis;
   c. Heart – echocardiogram, right cardiac catheterization results, including pulmonary vascular resistance (PVR) results. NYHA Class and peak VO2 results;
   d. Lung – Pulmonary function tests, imaging (chest x-rays and/or CT scans), and six-minute walk test;
   e. Pancreas – BMI, and history of insulin treatment;
   f. Intestine/Multivisceral - documentation of failed total parenteral nutrition (TPN);
   g. Stem cell – most recent bone marrow biopsy as indicated, most recent Eastern Cooperative Oncology Group (ECOG) score or Karnofsky score and documentation of donor identification for allogeneic transplants;
6. Annual dental evaluation and clearance (transplant clearance from DDS or a panoramic dental x-ray with clearance from MD);
7. Routine health screening exams as per standards of care (e.g., mammogram, Pap, and/or colonoscopy; these particular screenings are not required for autologous stem cell transplant);
8. Appropriate comorbidity testing/clearance, including cardiology;
9. Serum or urine drug screen results (within 90 days of request);
10. Infectious disease screening for solid organ or allogeneic stem cell transplant, all of the following, as applicable:
    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 for kidney transplants and six months for other transplants.

    ** 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 Louisiana Healthcare Connections 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]

Stem Cell/Bone Marrow Transplantation
Autologous hematopoietic cell transplantation (HCT) describes the use of a patient's own cells to rebuild bone marrow following intensive chemotherapy and/or radiation therapy to treat cancer. Treatment outcomes are dependent upon indicated risks and the underlying disease process. Diseases that can be treated include but are not limited to, multiple myeloma, Hodgkin lymphoma, acute myeloid leukemias and amyloidosis. Pretransplant evaluation prior to autologous HCT should include an assessment of comorbid conditions and the status of the underlying cancer. The evaluation should also include a clinical assessment, laboratory studies, and infectious disease screening, as well as cardiac and pulmonary assessments, and a bone marrow and central nervous system evaluation. An assessment of functional status is also recommended using either the Eastern Cooperative Oncology Group (ECOG) scale or Karnofsky Performance Status. Eligibility criteria varies between institutions but should include comorbidities, organ function, functional status, psychosocial status and disease state.[10]

Allogeneic hematopoietic cell transplantation (HCT) describes the use of hematopoietic cells from another healthy person (e.g., sibling, relative, volunteer donor, umbilical cord blood) to treat a variety of hematologic cancers and nonmalignant marrow disorders, including inborn error of metabolism. Variation exists in eligibility requirements across countries and institutions. Diseases that can be treated include, but are not limited to, acute myeloid leukemia (AML), chronic lymphoblastic leukemia (ALL), follicular lymphoma, nonhematologic malignancies, and nonmalignant inherited and acquired marrow disorders. A pretransplant assessment evaluates the extent of disease and severity of comorbidities to determine the appropriateness of the candidate. The assessment includes a detailed history and physical examination, chest x-ray, electrocardiogram, pulmonary function tests, cardiac function study, and laboratory tests, inclusive of an assessment of prior exposure to infectious agents. Although numerous scoring systems are available for estimating mortality risk in patients considering allogenic HCT, the European Group for Blood and Marrow Transplantation (EBMT) risk assessment score for allogeneic transplantation and the Hematopoietic Cell Transplantation - Specific Comorbidity Index (HCT-CI) are most frequently used. Future studies are needed to validate the various scoring systems, however, all scoring systems, including the Karnofsky performance status, can help patients understand mortality risk following allogeneic HCT. Pretransplant counseling is also suggested to support end-of-life advance care planning, fertility preservation, and patient expectations.[11]

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	Effective Date
Rebrand from Corporate policy	2/23	4/18/23	
Annual review. Minor rewording throughout Criteria with no impact on criteria. Criteria I.B.2. and Criteria I.B.3. updated to say "provider" instead of "physician." Criteria I.B.5. updated to include documentation. C-peptide removed from Criteria I.B.5.e. Criteria I.B.5.f. updated to remove "no specific additional testing" and added documentation of failed total parenteral nutrition. Criteria I.B.10.g. updated to say rapid plasma reagin. Background updated with no impact on criteria. References reviewed and updated. Reviewed by internal specialist.	1/24	3/25/24	
Annual review. Background updated with no impact on criteria. References reviewed and updated. Reviewed by internal specialist and external specialist.	12/24	1/27/25	2/27/25

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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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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 LHCC has no control or right of control. Providers are not agents or employees of LHCC.