

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

COVERAGE POLICY

All pretransplant evaluations require prior authorization from the Corporate Transplant Department. Requests for solid organ transplant, bone marrow transplant, and chimeric antigen receptor (CAR) T-cell therapy will be reviewed by the Corporate Senior Medical Director or qualified clinical designee. All other transplants will be reviewed by the Corporate Senior Medical Director or covering Medical Director. If the criteria are met using appropriate NCD and/or LCD guidelines, State regulations, and/or Molina Clinical Policies (MCPs) the Corporate Senior Medical Director's designee can approve the requested transplant.

Office visits with participating Providers do NOT require prior authorization. Providers should see the Member in office visits as soon as possible and without delay. Failure to see the Member in office visits may be considered a serious quality of care concern.

Pre-Transplant Evaluation

The information required for approval of a pre-transplant evaluation must document a reasonable expectation that the member can meet medical necessity criteria for the organ transplant being evaluated. This should include a recent (in the past 3-6 months) comprehensive history and physical exam, relative test results, relevant social determinants of health, documentation of compliance, and a substance use history including test results if indicated.

Pre-transplant evaluation may be authorized when the following criteria are met as indicated by the appropriate utilization management hierarchy.

Tests or services that are not standard of care for pre-transplant evaluations should be requested separately. Approval of these tests and services must meet specific medical necessity criteria to be approved.

Approval of adult or pediatric pre-transplant evaluations for transplant include **ALL** of the following:

1. A comprehensive history and physical examination including:
 - a. Past medical history
 - b. Social history including drug/alcohol use and current smoking status. **For Members with Significant or Daily Cannabis Use:** Active, untreated substance abuse or misuse (including daily significant cannabis use) requires documentation of a formal substance use disorder evaluation with clear and unambiguous documentation of **ALL** of the following:
 - i. A reasonable expectation that the member can adequately comply with a complex, post-transplant plan of care
 - ii. The member is free from addiction for at least 6 months
 - c. Compliance with the prescribed plan of care
 - d. Current body mass index. **For Members with a body mass index > 35:** Documentation of compliance with a physician prescribed and managed program of weight loss, and a reasonable expectation that Member can achieve a BMI < 35 at the time of transplant

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- e. Current medications
 - f. Relevant lab and imaging results, including documentation of a hemoglobin A1c within target range for Members with diabetes.
2. The following criteria must be met for pre-transplant evaluation based on the type of transplant requested:
- a. For **kidney transplant** evaluations:
 - i. A current evaluation of the Member's kidney disease including race-neutral Estimated Glomerular Filtration Rate and dialysis history
 - ii. Documentation of compliance with dialysis if the Member is on dialysis. Member description of dialysis compliance is not adequate to satisfy criteria.
 - b. For **liver transplant** evaluations:
 - i. A current evaluation of the Member's liver disease including Model for End-Stage Liver Disease (MELD) or Pediatric End-Stage Liver Disease (PELD) score and imaging evaluation of hepatocellular carcinoma
 - ii. Documentation of abstinence from alcohol use for Members with alcoholic liver disease. For further guidance on abstinence from alcohol use and for Members that are too ill to meet the abstinence requirements, refer to MCP-114 Liver Transplantation (Adult and Pediatric)
 - c. For **heart transplant** evaluations:
 - i. A current evaluation of the Member's heart disease
 - ii. For adult Members, documentation that the Member's heart disease is NYHA Class III or greater.
 - d. For **all other transplant** evaluations, documentation of the complete history of present illness is required.
3. If **ALL** of the above criteria are not met, office visits with transplant providers (including transplant specialists [e.g., hepatologist, nephrologist, cardiologist, cardiac surgery, etc.], psychosocial providers, endocrinologist, etc.) will be approved. This will facilitate generating the above, medically necessary documentation.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

The Organ Procurement and Transplantation Network (OPTN) has published policies and bylaws that govern operation of United Network for Organ Sharing (UNOS) member transplant hospitals, organ procurement organizations, and histocompatibility laboratories in the United States (OPTN 2024). Organ-specific guidance is available from OPTN as well as guidance on living donation, vascularized composite allografts, and patient safety (OPTN date unknown). The focus of UNOS is to manage the national transplant waiting list and match donors to recipients (24 hours a day, 365 days a year). In addition, UNOS manages the database of all organ transplant data in the United States, monitors organ matches to ensure that allocation policies are followed, assists patients and their family members, and educates transplant professionals and the public on various aspects of organ donation.

CODING & BILLING INFORMATION

CPT/HCPCS Codes – N/A

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

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04/10/2024	Policy reviewed, changes to criteria include condensing criteria into one all-inclusive list, inclusion of PELD score in liver transplant criteria, removed requirement of documentation from dialysis center, removed 6-month requirement and added statement referring to liver transplant policy for liver transplantation, and removal of physician prescribed/managed program and state mandate from significant/daily cannabis use criteria. IRO Peer Review on March 27, 2024, by a practicing, board-certified physician with specialties in Surgery, Vascular Surgery, and Surgical Critical Care.
04/13/2023	Policy reviewed, no changes to criteria; replaced "marijuana" with "cannabis"; included UNOS and OPTN information.
04/13/2022	Policy reviewed; included marijuana use under absolute contraindications; updated Summary of Medical Evidence and Reference sections.
04/05/2021	Policy reviewed, no changes.
04/23/2020	Policy reviewed by transplant team and evaluation criteria was outlined based on each type of transplant. Added that daily marijuana use is an absolute contraindication for both transplant and pre-transplant evaluation, unless there is a state mandate applicable for medical marijuana use and transplants, and there is documentation of member compliance with a physician prescribed plan of care for prescribed marijuana use.
09/18/2019	Policy reviewed, no changes.
09/13/2018	New policy.

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search: stem cell transplantation and solid organ transplant). Accessed March 15, 2024. <https://www.cms.gov/medicare-coverage-database/search.aspx>.
2. Melaragno JI, Bowman LJ, Park JM, et al. The clinical conundrum of cannabis: Current practices and recommendations for transplant clinicians: An opinion of the immunology/transplantation PRN of the American College of Clinical Pharmacy. *Transplantation*. 2021 Feb 1;105(2):291-299. doi: 10.1097/TP.0000000000003309. PMID: 32413017.
3. Organ Procurement and Transplantation Network (OPTN). Policies & bylaws. Updated January 10, 2024. Accessed March 15, 2024. <https://optn.transplant.hrsa.gov/policies-bylaws>.
4. Organ Procurement and Transplantation Network (OPTN). Guidance. Accessed March 15, 2024. <https://optn.transplant.hrsa.gov/professionals/by-topic/guidance>.