

## 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.

**Member must meet the medical necessity criteria below for each component of testing 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.

### **For Kidney Transplant Evaluations**

Approval of adult or pediatric pre-transplant evaluation for **Kidney Transplant** include **ALL** the following:

1. A comprehensive history and physical examination including: a current evaluation of the Member's kidney disease [including race-neutral Estimated Glomerular Filtration Rate (eGFR), dialysis history], past medical history, social history including drug/alcohol use and current smoking status, compliance with the prescribed plan of care, current BMI, current medications, any current lab, or imaging results; **AND**
2. Documentation of compliance with dialysis if the Member is on dialysis. This should be provided from the dialysis center. Member description of dialysis compliance is not adequate to satisfy criteria; **AND**
3. Documentation of a hemoglobin A1c within target range for Members with diabetes; **AND**

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### 4. For Members with Significant or Daily Cannabis Use.

- a. Documentation of compliance with a physician prescribed and managed program of abstinence, and a reasonable expectation that the Member will be abstinent from cannabis use during the transplant and immediate post-transplant time-period. Daily cannabis use is an absolute contraindication for both transplant and pre-transplant evaluation unless there is a state mandate applicable for medical cannabis use and transplants, and there is documentation of Member compliance with a physician prescribed plan of care for prescribed cannabis use.
- b. If the Member's cannabis use follows a formal, State-based program for managed medical cannabis, the request should include:
  - Documentation of the Plan of Care for medical cannabis (including the medical decision making that supports the use of medical cannabis); **AND**
  - Transplant Provider agreement with the Plan of Care (including agreement to be accountable for managing the Member's use of medical cannabis).

**AND**

5. **For Members with a BMI >35.** Documentation of compliance with a physician prescribed and managed program of weight loss, and a reasonable expectation that Member can achieve a BMI $\leq$ 35 at the time of transplant.

For Members who do not meet **ALL** the above criteria, office visits with transplant providers (including transplant nephrologist, psychosocial providers, endocrinologist, etc.) will be approved. This will facilitate generating the above, medically necessary documentation.

### For Liver Transplant Evaluations

Approval of adult or pediatric pre-transplant evaluation for **Liver Transplant** include **ALL** the following:

1. A comprehensive history and physical examination including: a current evaluation of the Member's liver disease (including MELD score and imaging evaluation of hepatocellular carcinoma), past medical history, social history including drug/alcohol use and current smoking status, compliance with the prescribed plan of care, current BMI, current medications, any current lab, or imaging results; **AND**
2. Documentation of at least 6 months of abstinence from alcohol use for Members with alcoholic cirrhosis; **AND**
3. Documentation of a hemoglobin A1c within target range for Members with diabetes; **AND**

**AND**

### 4. For Members with Significant or Daily Cannabis Use.

- a. Documentation of compliance with a physician prescribed and managed program of abstinence, and a reasonable expectation that the Member will be abstinent from cannabis use during the transplant and immediate post-transplant time-period. Daily cannabis use is an absolute contraindication for both transplant and pre-transplant evaluation unless there is a state mandate applicable for medical cannabis use and transplants, and there is documentation of Member compliance with a physician prescribed plan of care for prescribed cannabis use.
- b. If the Member's cannabis use follows a formal, State-based program for managed medical cannabis, the request should include:
  - Documentation of the Plan of Care for medical cannabis (including the medical decision making that supports the use of medical cannabis); **AND**
  - Transplant Provider agreement with the Plan of Care (including agreement to be accountable for managing the Member's use of medical cannabis).

**AND**

5. **For Members with a BMI >35.** Documentation of compliance with a physician prescribed and managed program of weight loss, and a reasonable expectation that Member can achieve a BMI $\leq$ 35 at the time of transplant.

For Members who do not meet **ALL** the above criteria, office visits with transplant providers (including transplant hepatologist, psychosocial providers, endocrinologist, etc.) will be approved. This will facilitate generating the above, medically necessary documentation.

### **For Heart Transplant Evaluations**

Approval adult or pediatric pre-transplant evaluation for **Heart Transplant** include **ALL** the following:

1. A comprehensive history and physical examination including: a current evaluation of the Member's kidney disease, past medical history, social history including drug/alcohol use and current smoking status, compliance with the prescribed plan of care, current BMI, current medications, any current lab, or imaging results; **AND**
2. Documentation of adequate compliance with the plan of care; **AND**
3. For adult Members, documentation that the Member's heart disease is NYHA Class III or greater; **AND**
4. Documentation of a hemoglobin A1c within target range for Members with diabetes; **AND**

**AND**

5. **For Members with Significant or Daily Cannabis Use.**

- a. Documentation of compliance with a physician prescribed and managed program of abstinence, and a reasonable expectation that the Member will be abstinent from cannabis use during the transplant and immediate post-transplant time-period. Daily cannabis use is an absolute contraindication for both transplant and pre-transplant evaluation unless there is a state mandate applicable for medical cannabis use and transplants, and there is documentation of Member compliance with a physician prescribed plan of care for prescribed cannabis use.
- b. If the Member's cannabis use follows a formal, State-based program for managed medical cannabis, the request should include:
  - Documentation of the Plan of Care for medical cannabis (including the medical decision making that supports the use of medical cannabis); **AND**
  - Transplant Provider agreement with the Plan of Care (including agreement to be accountable for managing the Member's use of medical cannabis).

**AND**

6. **For Members with a BMI >35.** Documentation of compliance with a physician prescribed and managed program of weight loss, and a reasonable expectation that Member can achieve a BMI  $\leq 35$  at the time of transplant.

For Members who do not meet **ALL** the above criteria, office visits with transplant providers (including transplant cardiologist or cardiac surgery, psychosocial providers, endocrinologist, etc.) will be approved. This will facilitate generating the above, medically necessary documentation.

### **For All Other Transplants**

Approval adult or pediatric pre-transplant evaluation for **All Other Transplants** include **ALL** the following:

1. A comprehensive history and physical examination including complete history of present illness, past medical history, social history including drug/alcohol use and current smoking status, compliance with the prescribed plan of care, current BMI, current medications, any current lab, or imaging results; **AND**
2. Documentation of compliance with the plan of care; **AND**
3. Documentation of a hemoglobin A1c within target range for Members with diabetes; **AND**

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### 4. For Members with Significant or Daily Cannabis Use.

- a. Documentation of compliance with a physician prescribed and managed program of abstinence, and a reasonable expectation that the Member will be abstinent from cannabis use during the transplant and immediate post-transplant time-period. Daily cannabis use is an absolute contraindication for both transplant and pre-transplant evaluation unless there is a state mandate applicable for medical cannabis use and transplants, and there is documentation of Member compliance with a physician prescribed plan of care for prescribed cannabis use.
- b. If the Member's cannabis use follows a formal, State-based program for managed medical cannabis, the request should include:
  - Documentation of the Plan of Care for medical cannabis (including the medical decision making that supports the use of medical cannabis); **AND**
  - Transplant Provider agreement with the Plan of Care (including agreement to be accountable for managing the Member's use of medical cannabis).

### AND

5. **For Members with a BMI >35.** Documentation of compliance with a physician prescribed and managed program of weight loss, and a reasonable expectation that Member can achieve a BMI  $\leq$ 35 at the time of transplant.

For Members who do not meet **ALL** the above criteria, office visits with transplant providers (including transplant nephrologist, 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](#) that govern operation of United Network for Organ Sharing (UNOS) member transplant hospitals, organ procurement organizations, and histocompatibility laboratories in the United States. Organ-specific [guidance](#) is available from OPTN as well as guidance on living donation, vascularized composite allografts, and patient safety. 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 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

4/13/2023	Policy reviewed, no changes to criteria; replaced "marijuana" with "cannabis"; included UNOS and OPTN information.
4/13/2022	Policy reviewed; included marijuana use under absolute contraindications; updated Summary of Medical Evidence and Reference

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	sections.
4/5/2021	Policy reviewed, no changes.
4/23/2020	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.
9/18/2019	Policy reviewed, no changes.
9/13/2018	New policy.

## REFERENCES

### Government Agency

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search: stem cell transplantation and solid organ transplant). Accessed March 13, 2023. <https://www.cms.gov/medicare-coverage-database/search.aspx>.

### National and Specialty Organizations

1. Danziger-Isakov L, Kumar D, AST ID Community of Practice. Vaccination of solid organ transplant candidates and recipients: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019 Sep;33(9):e13563. doi: 10.1111/ctr.13563. PMID: 31002409.
2. National Marrow Donor Program (NMDP), American Society for Blood and Marrow Transplantation (ASBMT). Transplant consultation timing guidelines. Accessed March 13, 2023. <https://bethematchclinical.org/transplant-indications-and-outcomes/referral-timing-guidelines/>.
3. National Marrow Donor Program (NMDP). Patient eligibility for HCT. Accessed March 13, 2023. <https://bethematchclinical.org/transplant-indications-and-outcomes/eligibility/>.
4. Organ Procurement and Transplantation Network (OPTN). Guidance. Accessed April 3, 2023. <https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/>.
5. Organ Procurement and Transplantation Network (OPTN). Policies & bylaws. Accessed April 3, 2023. <https://optn.transplant.hrsa.gov/policies-bylaws/>.
6. Steinman TI, Becker BN, Frost AE, Olthoff KM, Smart FW, American Society of Transplantation Clinical Practice Committee, et al. Guidelines for the referral and management of patients eligible for solid organ transplantation. Transplantation. 2001 May 15;71(9):1189-204. doi: 10.1097/00007890-200105150-00001. PMID: 11397947.
7. United Network for Organ Sharing (UNOS). About UNOS. Accessed April 3, 2023. <https://unos.org/about/>.

### Other Authoritative Publications

1. Alhamad T, Stratta RJ. Pancreas-kidney transplantation in diabetes mellitus: Patient selection and pre-transplantation evaluation. Updated January 19, 2023. Accessed March 13, 2023. <http://www.uptodate.com>.
2. AMR Peer Review. Policy reviewed on January 16, 2020 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the areas of General Surgery and Transplant Surgery.
3. MCG. Criteria for transplantation (multiple subsets). Published 2022. Accessed March 13, 2023. <http://www.mcg.com>.
4. Deeg HJ, Sandmaier B. Determining eligibility for allogeneic hematopoietic cell transplantation. Updated February 21, 2022. Accessed March 13, 2023. <http://www.uptodate.com>.
5. Dove LM, Brown RS. Liver transplantation in adults: Patient selection and pre-transplantation evaluation. Updated March 26, 2021. Accessed March 13, 2023. <http://www.uptodate.com>.
6. Fishman J. Evaluation for infection before solid organ transplantation. Updated February 22, 2022. Accessed March 13, 2023. <http://www.uptodate.com>.
7. Hachem RR. Lung transplantation: General guidelines for recipient selection. Updated January 18, 2023. Accessed March 13, 2023. <http://www.uptodate.com>.
8. Holmberg L, Deeg H, Sandmaier B. Determining eligibility for autologous hematopoietic cell transplantation. Updated March 7, 2022. Accessed March 13, 2023. <http://www.uptodate.com>.
9. Mancini D. Heart transplantation in adults: Indications and contraindications. Updated August 11, 2022. Accessed March 13, 2023. <http://www.uptodate.com>.
10. Rossi AP, Klein CL. Kidney transplantation in adults: Evaluation of the potential kidney transplant recipient. Updated March 2, 2023. Accessed March 13, 2023. <http://www.uptodate.com>.
11. Wingard J. Evaluation for infection before hematopoietic cell transplantation. Updated May 23, 2022. Accessed March 13, 2023. <http://www.uptodate.com>.