

# Molina Clinical Policy

## Pre-Transplant and Transplant Evaluations:

### Policy No. 459

Initial Approval: 6/12/2024

Next Review Due By: June 2025



## 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.

## OVERVIEW

The **pre-transplant evaluation** consists of documentation that supports a reasonable expectation that the member can meet medical necessity criteria for the organ or hematopoietic stem cell transplant being requested. This documentation should include a recent (in the past 3-6 months) comprehensive history and physical exam, relevant test results based on the type of transplant requested, relevant social determinants of health, documentation of compliance with the prescribed plan of care, and a substance use history including test results if indicated.

Additional testing, both general and specific to the transplant type, is required once the member meets the medical necessity criteria in the pre-transplant evaluation. The additional testing and documentation requirements are considered the **transplant evaluation**. Documentation and/or test results may need to be updated periodically depending upon how long the member remains on the transplant list.

## COVERAGE POLICY

**All transplants require prior authorization from the Corporate Transplant Department. Solid organ transplant requests 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 MCP policies 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.*

**The Pre-Transplant Evaluation is used to establish medical necessity for transplant evaluation. After medical necessity has been established, the Member must complete the components of the transplant evaluation in addition to any organ or hematopoietic stem cell transplant specific requirements found in the relevant MCP.**

### Pre-Transplant Evaluation

*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** 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

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- use) requires documentation of a formal substance use disorder evaluation with clear and unambiguous documentation of **ALL** 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 (**solid organ transplant requests ONLY**). **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
- 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** 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

**Transplant Evaluation**

Components of the transplant evaluation include the following:

1. **ALL** pre-transplant criteria have been met
2. History and physical examination that includes current evaluation of Member's disease necessitating transplant. Refer to organ or hematopoietic stem cell transplant disease-specific policy for additional history and physical exam requirements
3. Psychosocial evaluation and clearance:
  - a. Absence of any history of medical treatment non-compliance
  - b. Member understands surgical risk and post procedure follow-up required
  - c. Adequate family and social support
  - d. Absence of behavioral health disorder by history or psychosocial issues:
    - i. If history of behavioral health disorder, no severe psychosis or personality disorder may be present
    - ii. Mood/anxiety disorder must be excluded, unless actively treated and controlled
4. EKG

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5. Chest x-ray
6. Cardiac clearance in the presence of **ANY** of the following:
  - a. Chronic smokers
  - b. Members > 50 years age
  - c. Those with a clinical or family history of heart disease or diabetes
7. Pulmonary clearance if evidence of pulmonary artery hypertension or chronic pulmonary disease
8. Neurological exam and clearance for transplant including **ONE** of the following:
  - a. Normal neurologic exam
  - b. Non-life limiting neurological impairment that does not preclude transplant and not caused by hematologic malignancy (e.g., diabetic peripheral neuropathy)
  - c. Abnormal neurological exam with positive findings including **ONE** of the following:
    - i. Lumbar puncture normal cytology
    - ii. Lumbar puncture with cytological exam abnormal, however central nervous system disease treated prior to clearance
9. A Performance Status that includes **ONE** of the following:
  - a. Karnofsky score 70-100%
  - b. Eastern Cooperative Oncology Group (ECOG) Grade 0-2
10. Lab studies that include:
  - a. Complete blood count; kidney profile (blood urea nitrogen, creatinine); electrolytes; calcium; phosphorous; albumin; liver function tests; and coagulation profile (prothrombin time, and partial thromboplastin time)\*
  - b. Serologic screening for: Human Immunodeficiency Virus (HIV); Epstein Barr virus; Hepatitis B virus; Hepatitis C virus; cytomegalovirus; rapid plasma reagin and/or fluorescent treponemal antibody:\*
    - i. If HIV positive **ALL** of the following must be met:
      1. CD4 count > 200 cells/mm<sup>3</sup> for > 6 months
      2. Human Immunodeficiency Virus 1 (HIV-1) ribonucleic acid undetectable
      3. On stable anti-retroviral therapy > 3 months
      4. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm)
  - c. Urine drug screen if Member Urine drug screen if Member has a history of and/or current drug abuse
  - d. Hemoglobin A1c ≤ 8 or a 30-day average glucose ≤ 200 prior to transplant for Members with diabetes
11. Colonoscopy (if indicated or if Member is age ≥ 45) with complete workup and treatment of abnormal results as indicated. An initial screening colonoscopy after initial negative screening requires a follow-up colonoscopy every 10 years\*
12. Dental examination or oral exam showing good dentition and oral care or no abnormality on panorex or plan for treatment of problem pre- or post-transplant within the last 12 months
13. For women: Gynecological examination with Pap smear for women ages ≥ 21 to ≤ 65 years of age or if indicated (not indicated in women who have had a total abdominal hysterectomy or a total vaginal hysterectomy) within the last three years with complete workup and treatment of abnormal results as indicated\*
14. For women: Mammogram for women, if indicated or > age 40, with complete workup and treatment of abnormal results as indicated\*
15. For men: Prostate specific antigen, if history of prostate cancer or previously elevated prostate specific antigen with complete workup and treatment of abnormal results as indicated\*

\* Participating Centers of Excellence may waive these criteria.

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### Contraindications for All Transplants

The following are absolute and relative contraindications that apply to ALL transplants (organ and hematopoietic stem cell). Additional organ or disease-specific contraindications may be found in the organ or disease-specific policy.

1. The requesting transplant recipient is free of **ALL** the following absolute contraindications:
  - a. Cardiac, pulmonary, and nervous system disease that cannot be corrected and is a prohibitive risk for surgery
  - b. Malignant neoplasm, aside from which the transplant is indicated and excluding localized skin cancer, with a high risk for reoccurrence, non-curable malignancy
  - c. Systemic and/or uncontrolled infection
  - d. AIDS (CD4 count < 200 cells/mm-3)
  - e. Unwilling or unable to follow post-transplant regimen as documented by history of non-compliance and/or inability to adhere to follow through with medication adherence or office follow up
  - f. Chronic illness, aside from which the transplant is indicated, with one year or less life expectancy
  - g. Severe irreversible extra renal disease
  - h. Limited, irreversible rehabilitation potential
  - i. Active, untreated substance abuse or misuse (including significant and/or daily cannabis use) requires formal substance use disorder evaluation with clear and unambiguous documentation of:
    - 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
  - j. Inadequate social or family support
  - k. Active pregnancy
2. The requesting transplant recipient is carefully evaluated and potentially treated for any of the following relative contraindications:
  - a. Irreversible lung disease, requires consultation and clearance by a Pulmonologist prior to consideration of transplantation
  - b. Current smoker, requires documentation supporting free from smoking for 6 months or meets transplant center criteria
  - c. Active peptic ulcer disease
  - d. Active gastroesophageal reflux disease
  - e. Cerebrovascular accident with long term impairment that is not amendable to rehabilitation or a Member with cerebrovascular accident/transient ischemic attack within past 6 months
  - f. BMI > 35 kg/m<sup>2</sup>
  - g. Chronic liver disease such as Hepatitis B/C/D, or cirrhosis, requires consultation by a gastroenterologist or hepatologist
  - h. Gall bladder disease, requires ultrasound of the gall bladder with treatment prior to transplantation

### Continuation of Therapy for All Transplants

When extension of a previously approved transplant authorization is requested, review using updated clinical information is appropriate.

1. If Molina Healthcare has authorized prior requests for transplantation, **ALL** the following information is required for medical review:
  - a. Presence of no absolute contraindication as listed above
  - b. History and physical within the last 12 months
  - c. Kidney profile within the last 12 months
  - d. Cardiac update if history of cardiac disease within two years ( $\geq$  50 years of age)
  - e. Psychosocial evaluation or update within the last 12 months
  - f. Per initial and updated history and physical, any other clinically indicated tests and/or scans as determined by transplant center physician or Molina Medical Director

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2. If authorized prior requests for transplantation were obtained from another insurer, **ALL** the following information is required for medical review:
  - a. Authorization letter/documentation from previous insurer
  - b. Presence of no absolute contraindication as listed above
  - c. History and physical within the last 12 months
  - d. Cardiac update if history of cardiac disease within two years ( $\geq 50$  years of age)
  - e. Psychosocial evaluation or update within the last 12 months
  - f. Per initial and updated history and physical, any other clinically indicated tests and/or scans as determined by transplant center physician or Molina Medical Director

**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

### National and Specialty Organizations

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.

The **National Marrow Donor Program (NMDP)** has published the following guidance: *Disease-Specific HCT Indications and Outcomes Data; Engraftment; HLA Matching; Patient Eligibility for HCT; Transplant Consultation Timing; and Treatment Before Transplant* (<sup>1-6</sup> NMDP date unknown). The *Patient Eligibility for HCT* guidelines state that “patients under consideration for HCT require a thorough evaluation performed by a transplant physician. A comprehensive pre-transplant evaluation should: determine the patient’s health and performance status, assess the patient’s disease status, guide the informed consent process, and identify any psychosocial issues that would interfere with the transplant procedure/recovery.” The *Patient Eligibility for HCT* guidelines further state that “well-established health and performance status criteria to assess patient eligibility for HCT include age, Karnofsky performance score, left ventricular ejection fraction, pulmonary function test [with forced vital capacity], diffusion capacity (DLCO), kidney function, liver function, and mental health.”

The **American Society for Transplantation and Cellular Therapy (ASTCT)** published *Indications for Hematopoietic Cell Transplantation and Immune Effector Cell Therapy: Guidelines from the American Society for Transplantation and Cellular Therapy* (Kanate et al. 2020) which stipulates the various indications and uses for autologous and allogeneic HSCT and immune effector cell therapy for different disease processes. The guidelines state that “instead of patient age, evaluations such as functional status, patient frailty, HCT-specific comorbidity index score, European Society for Blood and Marrow Transplantation risk score, and pretransplantation assessment of mortality risk score can assist in determining risks of [nonrelapse mortality] and transplant candidacy for individual patients.”

The **National Comprehensive Cancer Network (NCCN)** has several guidelines for the treatment of various types of cancers (NCCN 2024). Each guideline has a list of laboratory tests, imaging, and exams that are “essential” and “useful in selected cases.”

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## 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

**06/12/2024** New policy created by combining MCP 323 with the transplant evaluation found in each transplant MCP. Changes to criteria include clarification of evaluation for history and physical exam, hemoglobin A1c < 8 or 30-day average glucose < 200 prior to transplant, and addition of "aside from which the transplant is indicated" for malignant neoplasm and chronic illness absolute contraindications. IRO Peer Review on June 3, 2024, by a practicing, board-certified physician with specialties in Surgery, Vascular Surgery, and Surgical Critical Care.

## REFERENCES

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5. <sup>1</sup>National Marrow Donor Program (NMDP). Disease-specific HCT indications and outcomes data. Accessed April 29, 2024. <https://bethematchclinical.org>.
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13. van den Boom W, Schroeder RA, Manning MW, Setji TL, Fiestan GO, Dunson DB. Effect of A1C and Glucose on Postoperative Mortality in Noncardiac and Cardiac Surgeries. *Diabetes Care*. 2018 Apr;41(4):782-788. doi: 10.2337/dc17-2232. Epub 2018 Feb 13. PMID: 29440113.