Molina Clinical Policy
Pre-Transplant and Transplant Evaluations
Policy No. 459

Last Approval: 06/11/2025
Next Review Due By: June 2026

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 (HSCT) being requested. This evaluation is intended to assess a patient's status prior to being listed on a transplant list or being considered for HSCT. This documentation should include a recent 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.

Once a patient is deemed appropriate and ready to be considered for a solid organ transplant or HSCT, additional testing, both general and specific to the transplant type, is required. The **transplant evaluation** is an assessment of the patient's status while awaiting transplant. 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 listing include ALL the following:

1. A comprehensive history and physical examination has been completed within the past 12 months and includes ALL the following:

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 use disorder (including daily significant cannabis 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 current substance use disorder, as evidenced by clinical evaluation and a negative drug or alcohol screen
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. Documentation submitted by the provider includes a current list of 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, if not currently on dialysis
    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 must include ALL the following if applicable:

1. ALL the above pre-transplant evaluation 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
        i. For kidney transplant requests, a standard compliance report is required
    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

5. Chest x-ray

6. Cardiac evaluation 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. Documentation of current performance status which may include the use of various performance status scoring scales (e.g., Karnofsky Performance Status, Eastern Cooperative Oncology Group Performance Status Scale, and Lanksy-Play Performance Scale)

10. Documentation that laboratory studies have been completed and reviewed, including:
    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 the following must be met:
            1. CD4 count > 200 cells/mm-3 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. Drug and/or alcohol screen if Member has a recent or clinically relevant history of substance use disorder
    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 indicated (e.g., history of prostate cancer or previously elevated prostate specific antigen), with complete workup and treatment of abnormal results as indicated

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/m2
    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 (≥ 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

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 (≥ 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 **American Heart Association (AHA)**, in a scientific statement about the emerging evidence on coronary heart disease screening in kidney and liver transplant candidates, note that coronary heart disease screening in asymptomatic patients has not been demonstrated to improve outcomes but remains common in practice. However, cardiovascular disease is a leading cause of morbidity and mortality in kidney transplantation and liver transplantation candidates and recipients. Multiple clinical guidelines, such as those from the American College of Cardiology, the American Society of Transplantation, and the American Association for the Study of Liver Diseases, advocate for screening based on risk factors (age, comorbidities, family history, smoking history) rather than universal testing. The specific risk factors considered and recommended screening methods vary among organizations (Cheng et al. 2022).

For kidney transplantation, the AHA recommends that all patients without known coronary heart disease undergo a 12-lead electrocardiogram and a resting transthoracic echocardiogram, except for a very low-risk subgroup (age < 40, no diabetes, no smoking, no peripheral arterial disease or cerebrovascular accident, not on dialysis). For liver transplantation, all patients without known coronary heart disease should have a cardiac physical examination, electrocardiogram, and resting transthoracic echocardiogram, with further testing guided by risk stratification. In liver transplantation patients who are at high risk for significant coronary heart disease (diabetes, nonalcoholic steatohepatitis, or ≥ 2 other coronary heart disease risk factors), anatomic coronary imaging is recommended. In general, the purpose of pretransplant screening is to identify patients with severe coronary heart disease who have a prohibitive perioperative risk, to initiate and optimize guideline-directed medical therapy when appropriate, and to perform coronary revascularization when clinically indicated (Cheng et al. 2022).

The **American Society of Transplantation (AST)**, in a multidisciplinary consensus workgroup, developed recommendations for substance use screening and drug testing in transplant population. Workgroup members included psychiatrists, psychologists, pharmacists, social workers, and laboratory medicine specialists from major academic institutions in geographically disparate regions of the United States. The workgroup also included members from states that have legalized recreational marijuana and medical marijuana, and states for which neither were approved. The workgroup reviewed literature and expert experience across domains including substance use

disorders, use of controlled substances, ethical and legal considerations, financial and insurance implications, and laboratory testing methods (Jowsey-Gregoire et al. 2022).

Substance use disorders are defined in the Diagnostic and Statistical Manual 5 edition (DSM-5) as substances that, when used in excess, cause activation of the brain reward system involved in memories and reinforcing behaviors related to pleasure. Substances could include alcohol, cannabis, hallucinogens, inhalants, opioids, sedatives, hypnotics, anxiolytics, stimulants, tobacco, or other substances. Substance use, even when it doesn't meet diagnostic criteria for substance use disorder, may present risks to transplant recipients due to the potential impacts on morbidity, adherence, and graft outcomes. For example, post-transplant cigarette smoking is associated with a greater risk of developing new onset cardiovascular disease, non-skin malignancies, and shorter survival time (Jowsey-Gregoire et al. 2022).

Furthermore, transplant patients are frequently exposed to prescribed opioids, and outcomes for those receiving opioids, particularly liver and kidney recipients, can be poor, with increased risks of morbidity and mortality. Associated complications include ventricular arrhythmia, cardiac arrest, hypotension, accidents, drug dependence, non-adherence, and decreased graft survival. Patients with the highest opioid use pre-transplant had a 46% increased risk of death, and a 28% risk of graft failure after transplantation. Besides opioids, other substances are associated with well-known health risks, such as alcohol associated liver disease from alcohol use, cardiotoxicity from stimulants, risk of hepatitis in intravenous drug users, and exposure to fungal contaminants and interactions with immunosuppressants in marijuana users. While the legalization of marijuana for recreational or medial use in several states has changed the pre-transplant assessment, there is lack of consensus on how to best address recreational use versus patterns suggestive of substance use disorder. Post-transplant complications reported from marijuana use include membranous glomerulonephritis, ventricular tachycardia, tacrolimus toxicity, drug interactions with immunosuppressants and aspergillosis infections (Jowsey-Gregoire et al. 2022).

The AST workgroup recommends that transplant patients be informed of drug testing and be screened for substances prior to transplant to ensure optimal care. Clinicians should conduct ongoing testing if warranted by clinical history. While use of certain substances may not result in exclusion from transplantation, awareness of the patient's practices and possible risk from substances is necessary to allow transplant teams to screen for substance use disorders and to ensure the patient is able to manage and minimize risks post-transplant. The authors also note that substance use legal statutes vary from region to region with some areas specifically outlawing the withholding of medical treatment in patients that use substances. Clinicians need to be aware of regulations within their institution as well as within their state or region to appropriately engage in screening. Overall, drug testing needs to be conducted in association with careful clinical evaluations, to occur routinely for transplant candidates and randomly, and upon suspicion for identified high-risk patients who will need ongoing monitoring over years following listing and transplantation (Jowsey-Gregoire et al. 2022).

The **American Society of Addiction Medicine (ASAM)** published a consensus statement outlining the appropriate use of drug testing in clinical addiction medicine. The authors note that drug testing is a biological tool that, when used correctly, can provide valuable information about recent substance use and assist with the identification, diagnosis, treatment, and monitoring of addiction. Drug testing results should not be the sole determinant in making care decisions, and should be interpreted alongside patient self-report, treatment history, psychosocial assessment, and physical examination. Urine is recognized as the most well-established biological matrix for presumptive detection of substance use in clinical settings. In the context of addiction medicine, the consensus supports at least monthly drug testing once a patient is stable in treatment and recommends more frequent testing at the beginning of treatment. Random unannounced testing is preferred over scheduled testing. Frequency of testing should be individualized based on patient acuity, level of care, and the detection capabilities of the tests used. The ASAM recommends using drug testing as a therapeutic tool, particularly to monitor adherence and abstinence in treatment, and to improve patient outcomes (Jarvis et al. 2017).

The **National Marrow Donor Program (NMDP)** provides evidence-based pre- and post-HSCT guidelines to patients and providers, including: *Consultation Guidelines and Outcomes; Engraftment; Disease-Specific HCT Indications and Outcomes Data; HCT Guidelines for Consultation Timing; Patient Eligibility for HCT; Post-Transplant Care; and Treatment Before Transplant* (NMDP 2023; NMDP 2024; [1-5]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 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" (NMDP 2023).

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 allogenic 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."

The **United States Preventive Services Task Force (USPSTF)** is an independent panel of experts in primary care and prevention that systematically reviews the evidence of effectiveness for clinical preventive services and develops recommendations on services with proven benefits and minimal harms. The USPSTF recommends the following:

- Biennial screening mammography for women aged 40 to 74 years (USPSTF 2024)
- Screening for cervical cancer every 3 years in women aged 21 to 29 years and screening every 3 to 5 years for women aged 30 to 65 ([1]USPSTF 2018)
- Screening for colorectal cancer in adults aged 45 to 49 years, with high certainty the net benefit is moderate or moderate certainty the net benefit is moderate to substantial. The USPSTF recommends screening for colorectal cancer in all adults aged 50 to 75 years, with high certainty the net benefit is substantial (USPSTF 2021).
- For men aged 55 to 69 years, the decision to undergo periodic prostate-specific antigen (PSA) screening for prostate cancer should be an individual one. Screening offers a small potential benefit of reducing the chance of death from prostate cancer in some men. However, many men will experience potential harms of screening, including false-positive results that require additional testing and possible prostate biopsy; overdiagnosis and overtreatment; and treatment complications, such as incontinence and erectile dysfunction ([2]USPSTF 2018)

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

06/11/2025	Policy revised. For pre-transplant evaluation, specified history and physical within past 12 months, and drug and alcohol screen if indicated. For transplant evaluation, removed participating centers of excellence criteria waive. Editing wording on multiple criteria for clarity and clinical efficiency.
10/09/2024	Coverage criteria edited to remove requirement of a specific formal performance status scale.
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.

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

This policy contains prior authorization requirements.