

3701-84-20

APPENDIX B**Screening Criteria for Patients Presenting with Significant Histories of Alcohol or Substance Use Disorder****Screening Criteria for Patients Presenting with Significant Histories of Substance Use Disorder****Evaluation Process**

Individuals presenting with histories suggestive of alcohol or substance use disorder shall be evaluated by an interdisciplinary team including at least the following: a chemical dependency specialist (may be a social worker, psychologist, psychiatrist, or chemical dependency counselor), an internist, and a surgeon. The evaluating committee will determine the patient's suitability for transplantation and will make recommendations regarding rehabilitation or counseling prior to listing or as a condition of listing.

Standard Criteria

For patients with a diagnosis of substance use disorder with Mild, Moderate or Severe severity level as defined by the DSM-5 at the time of evaluation, the patient must sign a contract pledging not to use alcohol or any illicit or addictive substances (unless under a doctor's order) in the future and agreeing to unlimited, random drug and/or alcohol screening both while awaiting and following transplantation. All patients must satisfy the following requirements prior to listing:

1. Patients must demonstrate complete abstinence from all addictive substances (unless under a doctor's order) throughout the pre-transplant period and must meet one of the three determining factors:
 - a) Abstinence for more than 6 months prior to listing and confirmed by collateral information;
 - b) At least three months of abstinence prior to listing and three months of current participation in an active recovery program (structured treatment program; and/or documented 12-Step meeting attendance with sponsor selection/contact) AND random toxicology screens prior to listing and confirmed by collateral information; or
 - c) Meets criteria as a medically urgent patient (see following section on: Criteria for Medically Urgent Patients Unable to Meet Condition 1a or 1b).

2. Patients must also have demonstrated to the transplant treatment team:
 - a) Insight into his/her past substance misuse;
 - b) A good understanding of how substance misuse has had an impact on his/her current health; and
 - c) Adequate coping skills for dealing with stressors; or
 - d) Meets criteria as a medically urgent patient (see following section on: Criteria for Medically Urgent Patients Unable to Meet Condition 1a or 1b).

Current and consistent participation in an active recovery program, corroborated by the transplant team could satisfy these requirements. Patients are expected to continue active participation in a recovery program after listing.

3. Additionally, other prognostic factors for abstinence will be taken into consideration, such as:
 - a) The presence of a sober, stable social network which will be available both pre- and post-transplant to offer ongoing support;
 - b) A stable work history; and
 - c) The presence of a family unit which acknowledges the issues posed by substance addiction and will support the patient’s commitment to abstinence.

Even if the patient satisfies all the above standard criteria, the transplant center does not necessarily have to accept the patient as a transplant candidate. The rationale for why the patient should not be a transplant candidate shall be included in the patient’s medical summary or medical record.

Medically Urgent Patients Unable to Meet Conditions 1a or 1b of the Standard Criteria

Medically Urgent Patients [those with a diagnosis of alcohol or substance use disorder who have not been abstinent for at least 6 months and are too ill (as defined below) to actively work a recovery program for 3 months], may qualify for listing if they demonstrate insight, are committed to maintaining sobriety and agree to actively work a recovery program for at least three months after transplant.

Liver	For those with a MELD score > 22 (calculated or eligible for exception) the following will apply:
Heart	For those who are status 1a the following will apply: For those who are status 1b and are hospitalized, on inotropes, and unable to have VAD placement, the following will apply:
Lung	For those with a calculated LAS score > 50 (candidates with a calculated LAS<50 will be reviewed on a case-by-case basis) the following will apply:
Intestine	For those who are Status 1 the following will apply:

Low Risk

Patients who are low risk for recidivism as defined as having at least one, but not more than three (1-3) OSOTC Substance Relapse Risk Factors as confirmed by the treatment team are eligible for listing with at least 1 month of confirmed abstinence, DSM-5 severity level of mild or moderate, a signed contract and commitment to begin a rehabilitation program pre-transplant if patient’s health will permit, and to continue to actively working the recovery program post-transplant.

Medium Risk

Patients who are medium risk for recidivism as defined as having at least four, but not more than five (4-5) OSOTC Substance Relapse Risk Factors as confirmed by the treatment team are eligible for listing with at least 3 months of confirmed abstinence, a signed contract and commitment to begin a rehabilitation program pre-transplant if the patient’s health permits, and to continue actively working the recovery program post-transplant.

High Risk

Patients who are high risk for recidivism as defined as having six or more (6+) OSOTC Substance Relapse Factors as confirmed by the treatment team are eligible for review based on the recommendation of the treatment team only if they meet the criteria as specified in section 1b of the standard criteria.

OSOTC Substance Relapse Risk Factors (Check <u>all</u> that apply)		
Low Risk Eligible with 1-3 Risk Factors; 1 month of abstinence <u>and</u> DSM-5 mild or moderate level	Medium Risk Eligible with 4-5 Risk Factors; <u>and</u> 3 months of abstinence	High Risk Eligible with 6 or more Risk Factors; 3 months of abstinence <u>and</u> 3 months of treatment
1. <input type="checkbox"/> Has not been abstinent for more than 3 months (outside a controlled environment) 2. <input type="checkbox"/> Has not participated in at least 1 month (3 meetings a week for 4 weeks=12) of an active recovery program (structured treatment program and/or documented 12 step meeting attendance with sponsor selection contact) 3. <input type="checkbox"/> Has not participated in at least 3 months (3 meetings a week for 12 weeks=36) of an active recovery program (structured treatment program and/or documented 12 step meeting attendance with sponsor selection contact) 4. <input type="checkbox"/> Does not have an adequate sober, stable social network to support the patient’s commitment to abstinence both pre and post- transplant 5. <input type="checkbox"/> Does not have insight into his/her past misuse/abuse 6. <input type="checkbox"/> Persistent desire or unsuccessful efforts to cut down or control use 7. <input type="checkbox"/> Continued to use substance despite being told the use is affecting his/her health 8. <input type="checkbox"/> Has a psychiatric disorder and does not have adequate coping skills for dealing with stressors 9. <input type="checkbox"/> History of problems at work, school or home due to substance use 10. <input type="checkbox"/> Has had two or more failures with a structured rehabilitation program 11. <input type="checkbox"/> Has failed random toxicology screens during medical evaluation for transplant 12. <input type="checkbox"/> Meets criteria for multiple substance use disorders 13. <input type="checkbox"/> History of driving under the influence or other legal consequences of substance use		
Total: <input type="checkbox"/> Low Risk (1-3) <input type="checkbox"/> Medium Risk (4-5) <input type="checkbox"/> High Risk (6+)		

For all patients who do not actively work a recovery program for 3 months pre-transplant, each transplant program agrees to closely monitor post-transplant compliance with ongoing active participation in a recovery program. Failure to follow treatment recommendations will be reported to the OSOTC for future use in modifying the CD criteria.

Even if the patient satisfies all of the above medically urgent criteria, the transplant center does not necessarily have to accept the patient as a transplant candidate. The rationale for why the patient should not be a transplant candidate shall be included in the patient's medically summary or medical record.

Chemical Disorder Committee Evaluation

Individuals presenting with substance use disorder and are deemed medically urgent shall be evaluated by a multi-institutional team of chemical dependency specialists (may be a social worker, psychologist, psychiatrist, or chemical dependency counselor) from each Consortium program, and an ethicist, Ohio Department of Health representative, lawyer or other layperson not directly affiliated with a transplant program. The CD representatives from the Consortium programs shall review the patient's medical history and forward their advisory recommendations to the organ specific Patient Selection Committee. This review process will be conducted before or simultaneously with the medical review. The organ specific Patient Selection Committee will take the recommendations of the CD Committee under consideration as they determine whether the patient is appropriate to list for transplantation.

In so far as it reasonably practical, based on first person and/or collateral resources, medically urgent criteria patients will be evaluated regarding:

- a) Insight into his/her past substance misuse/abuse;
- b) A good understanding of how substance misuse has had an impact on his/her current health;
- c) Adequate coping skills for dealing with stressors; and
- d) Has begun participation in an active recovery program (structured treatment program and/or documented 12 step meeting attendance with sponsor selection contact);

Additionally, other prognostic factors for abstinence will be taken into consideration, such as:

- a) The presence of a sober, stable social network which will be available both pre and post-transplant to offer ongoing support;
- b) A stable work history; and
- c) The presence of a family unit which acknowledges the issues posed by substance addiction and will support the patient's commitment to abstinence.

Medically Urgent CD Patient Listing Prior to OSOTC Review

Should it be necessary to list a medically urgent CD candidate with UNOS prior to the review by the CD Committee or the organ specific Patient Selection Committee, the transplant center must submit the patient's clinical summary with chemical use disorder history to the OSOTC online review system simultaneous with UNOS listing. A patient, who is listed and transplanted prior to the completion of the OSOTC review, may not receive an approval letter and risk loss of reimbursement.

Exception

If a patient is unable to actively participate in a recovery program as determined by the medical team and does not fulfill the definition of medical urgency, but the referring team determines that

the patient should be an acceptable candidate for transplantation, a conference call with the Chemical Disorder (CD) Committee to facilitate a full and complete assessment of the patient's situation will be required. The CD representatives from the Consortium programs along with the medical specialists shall review the patient's medical history and forward their advisory recommendations to the organ specific Patient Selection Committee. This review process will be conducted before or simultaneously with the medical review. The organ specific Patient Selection Committee will take the recommendations of the CD Committee under consideration as they determine whether the patient is appropriate to list for transplantation.

Patient Non-Compliance

If evidence arises that the patient has failed to maintain complete abstinence during the evaluation process or after listing, the patient is immediately made inactive or removed from the list. The evaluating team will reconsider the patient and recommend appropriate chemical dependency treatment. The evaluating team will have the discretion to reevaluate the patient or refer the patient on to another center for reevaluation. To be listed at a program in Ohio the patient must requalify for listing by demonstrating 3 months of active participation in a recovery program and 3-6 months confirmed abstinence. Confirmation of the patient's participation in an ongoing recovery program must be presented to the Consortium and will require a conference call with the CD Committee prior to re-listing or reactivating the patient on the waiting list.

Patients who have a second relapse while awaiting a transplant will not be eligible for relisting. Failure to submit to random blood or urine screening is considered to be evidence of a relapse.

Patients who are non-compliant with following treatment recommendations will not be eligible for transplant.