Status Active PolicyStat ID 8980846

Effective Date	11/2008
Approved Date	12/2020
Revised Date	12/2020
Next Review	12/2023

Owner	Elan Moreno
Policy Area	VAD & MCS Guidelines
Applicability	Ronald Reagan UCLA Medical Center
Reference Tags	Lippincott

Selection Criteria For MCS – Bridge To Transplantation, MCS 2.0

PURPOSE:

To provide written selection criteria in determining patient suitability for mechanical circulatory support as a bridge to transplantation

POLICY:

A. Implantation of Mechanical Circulatory Support (MCS) Devices as a bridge to transplantation is a treatment option for many forms of end-stage cardiac disease when heart transplantation is an option. Besides improving life expectancy, goals of MCS therapy include returning recipients to functional, productive lives and acceptable quality of life.

B. A selection committee composed of cardiac surgeons, cardiologists, MCS coordinators, psychiatrists, social workers, pulmonologists, infectious disease specialists, dietitians, advance care planning / palliation experts and other involved professionals meets weekly to determine the candidacy of potential MCS recipients.

C. Candidacy for bridge to transplantation is non-discriminatory and is determined without influence or favoritism based on gender, race, ethnicity, national origin, religion, political influence, social or financial status, educational level, or sexual orientation.

D. General Acceptance Criteria

1. Heart Failure Survival Score (HFSS) high-risk category
2. Peak VO2<12 ml/kg/min if on beta blocker therapy and <14 ml/kg/min in not on beta blocker therapy after reaching anaerobic threshold

3. NYHA class III/IV heart failure refractory to maximal medical therapy
4. Severely limiting ischemia not amenable to interventional or surgical revascularization
5. Recurrent symptomatic ventricular arrhythmias refractory to medical, ICD and surgical treatment

E. For absolute and relative contraindications, refer to the following transplant policies:
1. Selection Criteria for Adult Heart Transplantation, RR AHT 240
2. Selection Criteria for Pediatric Heart Transplantation, RR PHT 230

ATTACHMENTS:

Attachment A: Selection Criteria for Adult Heart Transplantation, RR AHT 240
Attachment B: Selection Criteria for Pediatric Heart Transplantation, RR PHT 230
Attachment C:Procedure History
Attachment D:New/Revised Procedure Checklist

REFERENCES:

1. Slaughter MS, Pagani FD, Rogers JG, et al. Clinical management of continuous – flow left ventricular assist devices in advanced heart failure. J Heart Lung Transplant 2010; 29: 4S

REVISION HISTORY (Pre-PolicyStat)

Effective date:	11/08
Review date(s):	1/11, 12/2020
Revised date(s):	1/11, 6/15, 7/17, 08/17, 12/2020

APPROVAL:

Role	Name	Date
Unit Director/ Manager:	Elan Moreno, RN, BSN, CCRN	12/2020
Executive Director:	Laura Yost, Executive Director, Clinical Services	12/2020
Medical Director:	Ali Nsair, MD, Medical Director	12/2020
Surgical Director	Murray Kwon, MD,Surgical Director	12/2020

Attachments

C: Procedure History

D: New Revised Procedure Checklist

Approval Signatures

Step Description	Approver	Date
	Fiona Dunne: Adm Crd Ofcr	12/2020
Department Approval	Elan Moreno: Clin Nurse 4	12/2020

Attachment A

Status **Active** PolicyStat ID **11759901**

Effective Date	03/2018
Approved Date	05/2022
Revised Date	05/2022
Next Review	05/2025

Owner	Stephanie Fraschilla
Policy Area	Transplant Policies
Applicability	Ronald Reagan UCLA Medical Center
Reference Tags	Lippincott

Selection Criteria for Adult Heart Transplantation, RR AHT 240

PURPOSE

To provide written selection criteria in determining patient suitability for placement on the waiting list for heart transplantation in accordance with CFR §482.9, CMS Conditions of Participation.

SCOPE

This policy applies to the Ronald Reagan UCLA Medical Center

POLICY

I. Heart Transplantation is a treatment option for many forms of end-stage cardiac disease. Besides improving life expectancy, goals of heart transplantation include returning recipients to functional, productive lives and acceptable quality of life.

II. A selection committee composed of transplant surgeons, cardiologists, nurse coordinators, psychiatrists, social workers, pulmonologists, infectious disease specialists, pharmacists, dietitians, advance care planning / palliation experts and other involved transplant professionals meets weekly to determine the candidacy of potential heart transplant recipients.

III. Candidacy for heart transplantation is non-discriminatory and is determined without influence or favoritism based on gender, race, ethnicity, national origin, religion, political influence, social or financial status, educational level, or sexual orientation.

IV. Decisions about heart transplant recommendations are based on two complementary goals (in order of priority):

A. Largest possible short and long-term comparative benefits for the individual patient at the time of evaluation

B. Preserving long-term programmatic excellence requires responsible use of scarce resources

V. General Acceptance Criteria:

A. Heart Failure Survival Score (HFSS) high/medium-risk category.

B. Peak VO2<12 ml/kg/min if on beta blocker therapy and <14 ml/kg/min if not on beta blocker therapy after reaching anaerobic threshold.

C. NYHA class III/IV heart failure refractory to maximal medical therapy.

D. Severely limiting ischemia not amenable to interventional or surgical revascularization.

E. Recurrent symptomatic refractory ventricular arrhythmias to medical, ICD and surgical treatment.

F. Presence of durable or temporary mechanical circulatory support.

G. Every condition that elevates the early and long-term postoperative risk for the patient, and therefore reduces the anticipated survival and quality of life benefit from cardiac transplantation, must be considered a risk factor and potential contraindication to transplantation. The objective of the evaluation process is to identify and characterize these risks to allow the selection committee to make an informed decision about a patient's transplant candidacy.

A. **Absolute Contraindications:** The presence of any of these factors generally precludes heart transplantation.

i. Acute sepsis and/or major organ system failure deemed irreversible.

ii. Current or historical non-adherence with medical therapy or follow-up that is perceived to indicate significant risk of non-adherence after transplantation.

iii. Active substance abuse or dependence.

iv. Psychiatric, psychological, or neurologic conditions likely to impose a significant threat to compliance with a complex medical regimen.

v. Active, or recent malignancy that has a significant risk of impacting the post-transplant outcome. The risk profile of the specific malignancy will be considered and any time period needed without evidence of active disease will be based on a case-by-case assessment in consultation with Oncology.

vi. Absence or lack of consistent or reliable social support system; a primary and backup caregiver is required for post-transplant care.

vii. Absence or lack of stable housing, financial or other resources needed for attending medical appointments and maintaining adherence to the post-transplant regimen.

viii. Severe obesity or severe malnourishment.

ix. Severe frailty that is deemed to be not reversible by advanced therapies.

x. Patients who have had a prior cardiac surgery or require a combined organ transplant **and** are unwilling to accept any blood products or factors that may adversely influence procedural outcome.

xi. Infection with highly virulent, resistant or incurable microbes that may significantly impact the post-transplant outcome.

xii. Any other condition or factor not listed above that the selection committee determines may significantly reduce post-transplant survival or quality of life.

B. **Relative Contraindications:** While each of these risk factors, if not severe, may not in isolation preclude transplantation, a combination of these factors may increase the risk of poor post-transplant outcomes to an unacceptable level.

i. Advanced age, especially in combination with poor physiologic reserve. Increasing age is generally associated with comorbid conditions that are absolute or relative contraindications to transplant.

ii. Irreversible pulmonary hypertension.

iii. Significant chronic renal impairment for isolated heart transplant if not a candidate for concomitant kidney transplant.

iv. Significant chronic hepatic impairment for isolated heart transplant if not a candidate for concomitant liver transplant.

v. Significant or advanced systemic disease that would lead to poor outcomes.

vi. Frailty.

vii. Moderate obesity or malnourishment.

viii. Recent pulmonary infarction.

ix. Extensive prior chest surgery or excessively increased surgical risk.

x. Significant risk factors including previous strokes, clot burden and significant calcifications.

xi. Significant symptomatic carotid or peripheral vascular disease.

xii. Advanced lung disease.

xiii. Significant allosensitization.

xiv. Uncorrectable bleeding diathesis.

xv. Poorly controlled diabetes mellitus with end-organ dysfunction.

xvi. Significant or symptomatic osteoporosis or any fracture history causing limitation in movement or chronic pain.

xvii. Treatable psychiatric or neurologic conditions that may impact adherence to post-transplant medical regimen.

xviii. Chronic, significant opioid or benzodiazepine use.

xix. Inhaled cannabis use is contraindicated for placement on the waitlist. Ingested, or topical cannabis use will be evaluated on a case-by-case basis to assess if use may lead to potential adverse outcomes based on the candidate's risk profile.

xx. Inability to make a well-informed decision towards heart transplantation.

xxi. Significantly limited functional status with poor rehabilitation potential.

xxii. Patient choice not to proceed with heart transplant.

xxiii. Lack of clear patient commitment to proceeding with transplant and/or the necessary post-transplant care.

xxiv. Any condition that, in the opinion of the selection committee, may adversely impact the post-transplant outcome.

VI. Medical record documentation will include the selection criteria used to accept or deny the patient for being placed on the waitlist.

REFERENCES

CMS Conditions of Participation (CoPs) § 482.9.

Mehra MR, Canter CE, Hannan MM, Semigran MJ, Uber PA, Baran DA, Danziger-Isakov L, Kirklin JK, Kirk R, Kushwaha SS, Lund LH, Potena L, Ross HJ, Taylor DO, Verschuuren EA, Zuckermann A; International Society for Heart Lung Transplantation (ISHLT) Infectious Diseases Council; International Society for Heart Lung Transplantation (ISHLT) Pediatric Transplantation Council; International Society for Heart Lung Transplantation (ISHLT) Heart Failure and Transplantation Council.The 2016 International Society for Heart Lung Transplantation listing criteria for heart transplantation: A 10-year update. *J Heart Lung Transplant*. 2016 Jan;35(1):1-23. doi: 10.1016/j.healun.2015.10.023. PMID: 26776864.

REVISION HISTORY

Effective Date:	7/10
Review Date:	4/15, 3/18, 1/2020, 10/2020, 11/2021, 3/2022, 5/2022
Revision Date:	5/15, 1/18, 3/18, 1/2020, 10/2020, 11/2021, 3/2022, 5/2022

APPROVAL

Role	Name	Date
Unit Director/Manager	Melissa A. Moore,RN, MHA, CCTC	5/2022
Executive Director	Laura Yost, MSHA	5/2022
Medical Director	Ali Nsair, MD	5/2022
Surgical Director	Abbas Ardehali, MD	5/2022

PROCEDURE HISTORY

Date	Initials	Page	Item and Summary of Changes
11/ 2014	HLB	All	Reviewed and reformatted in accordance with SOP policy.
11/ 2014	HLB	All	Policy title revised. *Patient Selection Criteria* to Selection Criteria Policy for Adult Heart Transplantation
11/ 2014	HLB	1	Purpose statement added.
11/ 2014	HLB	1	Indications revised. *Severe heart disease despite medical therapy; Unacceptable quality of life with disabling symptoms of congestive heart failure, unacceptable risk of cardiac death within the next year, despite limited symptoms of congestive heart failure, and no other reasonable surgical option; the patient must be without any noncardiac condition that would itself shorten life expectancy or increase the risk of death from rejection or from complications of immunosuppression, particularly infection;* General acceptance criteria added.
11/ 2014	HLB	1	Absolute contraindications revised. *Active ulcer disease or gastrointestinal bleeding; severe Diabetes Mellitus with documented end organ damage; Forced expiratory volume in 1 second, forced vital capacity less than 50% predicted; high risk of life threatening noncompliance;*
11/ 2014	HLB	1	**Relative contraindications revised. *Advanced age, patients over 70 may be candidates for alternative transplant program; Renal insufficiency secondary to underlying renal disease, Cr > 2 mg/dl; Cr clearance <50 ml/min unless the patient is a potential candidate for combined heart-kidney transplant; limited pulmonary function or history of chronic bronchitis; hepatic dysfunction with bilirubin > 2.5mg/dl, SGOT > 2x, PT > 14 seconds off warfarin* severe peripheral vascular disease; Pulmonary artery systolic pressure > 60mmHg*, mean transpulmonary gradient > 15 mmHg*; history of alcohol or drug abuse; severe obesity; may need to provide optimal hemodynamics with nitroprusside, dobutamine, or both 72 hours to determine reversibility of organ dysfunction caused by heart failure***
5/ 2015	HLB	2	6.2.5 revised. Added - Underweight (BMI < 18)

5/ 2015	HLB	2	6.2.6 Recent pulmonary infarction renumbered to 6.27
5/ 2015	HLB	2	6.27 Significant symptomatic carotid or peripheral vascular disease renumbered to 6.28
5/ 2015	HLB	2	6.2.8 Advanced lung disease renumbered to 6.2.9
5/ 2015	HLB	2	6.2.9 Significant coagulopathies renumbered to 6.2.10
5/ 2015	HLB	2	6.2.10 Diabetes with end organ damage and/or brittle diabetes renumbered to 6.2.11
5/ 2015	HLB	2	6.2.11 Inability to make a well-informed decision towards heart transplantation renumber to 6.2.12
5/ 2015	HLB	2	6.2.13 added Bed bound patient...
5/ 2015	HLB	1	Add to Policy 2: "pharmacists"
1/ 2018	SF	1	Added 5.6: Mechanical assist device in place
1/ 2018	SF	2	Added: 6.2.14 Patient choice not to proceed with heart transplant
1/ 2018	SF	2	Added: 6.2.15 Excessively increased surgical risk
1/ 2018	SF	3	Added: 6.2.16 Combined risk factors expected to prohibit beneficial outcome for patient
3/ 2018	SF	2	Added to 6.1.6: ; a primary and backup caregiver is required for post-transplant care
3/ 2018	SF	All	Policy renumbered from **HRT 24.0** to **RR AHT 240**
1/ 2020	SF	All	Revisions and additions to Selection Criteria throughout entire document.
10/ 2020	SF		Changed V (G) (A) (x) to read: Patients who have had a prior cardiac surgery or require a combined organ transplant **and** are unwilling to accept any blood products or factors that may adversely influence procedural outcome.
11/ 2021	SF		Added B(x): Significant risk factors including previous strokes, clot burden and significant calcifications.
3/ 2022	SF		Added A(iii)(a), added B(xix), both regarding cannabis use.
5/ 2022	SF		Removed A(iii)(a) and added to B(xix) regarding cannabis use.

Approval Signatures

Step Description	Approver	Date
	Fiona Dunne: Regl And Cmplnc Hc Spec 4	05/2022
Department Approval	Stephanie Fraschilla: Mgr	05/2022

Attachment B

Status **Active** PolicyStat ID **9571986**

Effective Date	03/2018
Approved Date	04/2021
Revised Date	04/2021
Next Review	04/2024

Owner	Stephanie Fraschilla
Policy Area	Transplant Policies
Applicability	Ronald Reagan UCLA Medical Center
Reference Tags	Lippincott

Selection Criteria Policy For Pediatric Heart Transplantation, RR PHT 230

PURPOSE

To provide written selection criteria in determining patient suitability for placement on the waiting list for heart transplantation in accordance with CFR §482.9, CMS Conditions of Participation.

SCOPE

This policy applies to the Ronald Reagan UCLA Medical Center

POLICY

I. Heart Transplantation is a treatment option for many forms of end-stage cardiac disease. Besides improving life expectancy, goals of heart transplantation include returning recipients to functional, productive lives and acceptable quality of life.

II. A selection committee composed of transplant surgeons, cardiologists, nurse coordinators, psychiatrists, social workers, dietitians, child life specialists and other involved transplant professionals meets weekly to determine the candidacy of potential heart transplant recipients.

III. Candidacy for heart transplantation is non-discriminatory and is determined without influence or favoritism based on gender, race, ethnicity, national origin, religion, political influence, social or financial status, educational level, or sexual orientation.

IV. Decisions about heart transplant recommendations are based on two complementary goals:

A. Largest possible short and long-term comparative benefits for the individual patient at the time of evaluation

B. Preserving long-term programmatic excellence requires responsible us of scarce resources

V. General Acceptance Criteria:

A. Severe heart failure (NYHA class III/IV) refractory to maximal medical therapy

B. Unacceptable quality of life due to the disabling symptoms of congestive heart failure

C. Unacceptable risk of cardiac death within the next year despite limited symptoms of congestive heart failure

D. Severely limiting ischemia not amenable to interventional or surgical revascularization

E. Primary cardiac tumors with no evidence of systemic involvement

VI. Every condition that elevates the early and long-term postoperative risk for the patient and therefore reduces the anticipated survival and quality benefit from cardiac transplantation has to be considered a risk factor and potential contraindication. During the evaluation process it needs to be established whether or not this circumstance is of a temporary or permanent nature.

A. Absolute Contraindications

i. Active infection and/or sepsis

ii. Current or documented non-adherence with medical therapy or follow-up that are perceived to increase risk of non-adherence after transplant

iii. Evidence of active drug, tobacco, or alcohol use or abuse

iv. Severe psychiatric, psychological or neurologic condition likely to impose a significant threat to compliance with a complex medical regimen

v. Active, recent or disseminated malignancy

a. In general, freedom from most malignancies for a minimum of 2 years combined with a low predicted risk of occurrence after heart transplantation

b. Time required without evidence of disease is dependent on malignancy type.

vi. Absence or lack of consistent, reliable or cooperative social support system.

vii. Patients who are unable receive blood products under any circumstance.

viii. Recipient and all household contacts are not up-to-date with all CDC-recommended vaccines, including seasonal influenza vaccine.

B. Relative Contraindications

i. Irreversible pulmonary hypertension

ii. Significant chronic renal impairment for isolated heart transplant if not a candidate for concomitant kidney transplant

iii. Significant chronic hepatic impairment for isolated heart transplant if not a candidate for concomitant liver transplant

iv. Significant or advanced systemic disease that would interfere with a successful clinical outcome

v. BMI > 35 and/or ≥ 95th percentile for age

vi. Recent pulmonary infarction

vii. Advanced lung disease

viii. Significant coagulopathies

ix. Diabetes with symptomatic end organ damage

x. Severe allosensitivity

xi. Complex vascular or cardiac anatomy

xii. Patient/family choice not to proceed with heart transplant.

xiii. Lack of clear patient and/or caregiver commitment to proceeding with transplant and/or the necessary post-transplant care.

xiv. Any condition that, in the opinion of the selection committee, may adversely impact the post-transpalnt outcome.

VII. Medical record documentation will include the selection criteria used to accept or deny the patient for being placed on the Waitlist.

ATTACHMENTS

Procedure History

REFERENCES

CMS Conditions of Participation (CoPs) § 482.9

REVISION HISTORY

Effective Date	1/11
Review Date:	12/14, 3/18, 5/19, 10/2020, 4/2021
Revision Date:	1/15, 9/15, 3/18, 5/19, 10/2020, 4/2021

APPROVAL

Role	Name	Date
Unit Director/Manager	Melissa A. Moore RN, CCTC	4/2021
Executive Director	Laura Yost, MSHA	4/2021

Medical Director	Juan Alejos, MD	4/2021
Surgical Director	Reshma Biniwale, MD	4/2021

PROCEDURE HISTORY

Date	Initials	Page	Item and Summary of Changes
1/ 2015	HLB	All	Reviewed and reformatted in accordance with SOP policy.
1/ 2015	HLB	All	Policy title revised. *Patient Selection Criteria* to Selection Criteria for Pediatric Heart Transplantation
1/ 2015	HLB	1	Purpose statement added.
1/ 2015	HLB	1	Procedure revised to Policy. Policy # 1-4, 6-7 added
1/ 2015	HLB	1	Indications revised to General Acceptance Criteria. 5.4 added
1/ 2015	HLB	2	Absolute Contraindications revised: *Any non-cardiac condition that would itself shorten life expectancy or increase the risk of death from rejection or from complications of immunosuppression (particularly infection). This includes, but is not limited to*: *Active sepsis; Systemic neoplastic disorder; High risk of life threatening noncompliance;* 6.1.1 – 6.1.7 added
1/ 2015	HLB	2	Relative Contraindications revised: *Renal insufficiency secondary to underlying renal disease – Requires consultation of pediatric nephrology service and possible consideration for multi-organ transplantation; Severe hepatic dysfunction; Severely elevated pulmonary vascular resistance refractory to pharmacologic intervention; Severe obesity; Gestational age less than 36 weeks or birth weight less than 2 kilograms (thus limiting the use of cardiopulmonary bypass); Psychosocial factors including: Inability of patient and/or caregivers to make a strong, consistent commitment to the patient's post-transplant care regimen (including routine clinic visits); Substance abuse by patient and/or caregiver; Patient with cognitive impairment severe enough to limit comprehension of medical regimen;* 6.2.1 – 6.2.9 added
9/ 2015	HLB	2	6.1.4 Revised. Severe or *untreatable* psychiatric, psychological or neurologic condition likely to impose a significant threat to compliance with a complex medical regimen
9/ 2015	HLB	2	6.1.6 Revised: Absence or lack of consistent, reliable or "cooperative" (added) social support system.
9/ 2015	HLB	2	6.2.5 Revised: *Class II or III obesity (BMI > 35);* BMI for age added
9/ 2015	HLB	2	Added - 6.2.10 - Severe allosensitivity Added - 6.2.11- Complex vascular or cardiac anatomy
3/ 2018	SF	All	Policy renumbered from PHT 23.0 to RR PHT 230

3/ 2018	SF	3	Wording change for 6.2.5 to: BMI > 35 and/or ≥ 95th percentile for age
5/ 2019	SF		Added (xii) under Relative Contraindications. Removed "Interim" from Reshma Biniwale's title of Surgical Director.
10/ 2020	SF		Moved "Recipient and all household contacts are not up-to-date with all CDC-recommended vaccines, including seasonal influenza vaccine" from relative to absolute contraindication.
4/ 2021	SF		Added items xii--xiv under (B) Relative Contraindications.

Approval Signatures

Step Description	Approver	Date
	Fiona Dunne: Adm Crd Ofcr	04/2021
Department Approval	Stephanie Fraschilla: Mgr	04/2021

Attachment C

Procedure History

Date	Initials	Page	Item and Summary of Changes
6/2015	HLB	All	Reformatted, renumbered according to SOP Policy

Attachment D

New/Revised Procedure Checklist

1. Information Systems changes required:
   [ ] NA _____
   _____
   _____
   _____

2. Procedure added to Training and Competency Evaluation Tool(s)? [ ] Yes [ ] NA

3. Procedure added/replaced in:
   [ ] Master Copy Manual [ ] Operational Copy Manual(s) [ ] Transplant Online [ ] NA

   Other location(s): _____

4. Obsolete SOP(s) removed from service and filed? [ ] Yes [ ] NA

5. Table of Contents, SOP and Forms Master List modified? [ ] Yes [ ] NA

6. Information will be distributed to (check all that apply):
   [ ] Electronic mail
   [ ] Staff in-service/training/rounds
   [ ] Transplant physicians
   [ ] Other sections/departments (if applicable) specify:
   _____
   [ ] Other: _____
   _____
   _____

Signature: _____
Manager/Director Date