Adult Heart Lung Candidate Registration

The fields on the Heart/Lung Candidate Registration form contain demographic and basic clinical information about candidates on the national waiting list.

Add new candidate registration

Center: Verify the transplant hospital name.

Organ: Select organ to register.

Candidate Add

Center: Verify the transplant hospital name.

Organ Registration: Verify organ type.

SSN: Enter the candidate's social security number.

Note: SSN cannot:

Contain 00 in the 4th and 5th place (e.g., XXX-00-XXXX is invalid)

Contain 0000 in the last 4 places (e.g., XXX-XX-0000 is invalid)

Begin with 666

Confirm SSN: Re-enter candidate SSN. A green check mark indicates that the data matches.

Age Group: Select age group (adult or pediatric).

Provider Information

Transplant Hospital: Verify the transplant hospital name.

24 Hour Contact Phone Number: Verify the transplant center phone number. This is a **required** field.

Demographic Information

SSN: Enter the candidate's social security number.

Note: SSN cannot:

Contain 00 in the 4th and 5th place (e.g., XXX-00-XXXX is invalid)

Contain 0000 in the last 4 places (e.g., XXX-XX-0000 is invalid)

Begin with 666

Confirm SSN: Re-enter candidate SSN. A green check mark indicates that the data matches.

Last Name: Enter the last name of the candidate. This is a **required** field.

First Name: Enter the first name of the candidate. This is a **required** field.

MI: Enter the candidate's middle initial.

Date of birth: Enter the candidate's date of birth. This is a **required** field.

Confirm date of birth: Re-enter candidate date of birth. A green check mark indicates that the data matches.

Birth sex: Indicate if the patient is Male or Female. Report patient sex (male or female), based on biologic and physiologic traits at birth. This is a **required** field.

Center Patient ID: Enter the candidate's patient identification number that is assigned by your center, if applicable.

State of Permanent Residence: Select the full name of the state where the candidate's home is located.

Permanent Zip Code: Enter the 5-digit or 9-digit U.S. postal zip code for the address where the candidate's home is located. ***Note:*** Make corrections to an incorrect permanent zip code on the Transplant Candidate Registration (TCR) form in TIEDI®. This field cannot be updated from the active list.

Ethnicity: The Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (Office of Management and Budget (OMB) Statistical Policy Directive No. 15) define the minimum standards for collecting and presenting data on race and ethnicity for all Federal reporting. The OPTN collection of ethnicity is aligned to this standard.

OMB defines ethnicity to be whether a person self-identifies as Hispanic origin or not. For this reason, ethnicity is broken out in two categories, (1) Hispanic or Latino or (2) Not Hispanic or Latino. Select one ethnicity category or select 'Ethnicity Not Reported' if the candidate did not self-identify. This field is **required**.

> **Hispanic or Latino** – A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.
>
> **Not Hispanic or Latino**
>
> **Ethnicity Not Reported**

Race: The Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (Office of Management and Budget (OMB) Statistical Policy Directive No. 15) define the minimum standards for collecting and presenting data on race and ethnicity for all Federal reporting. The OPTN collection of race is aligned to this standard. OMB defines race as a person's self-identification with one or more social groups.

An individual can select one or more race categories (1) White, (2) Black or African American, (3) Asian, (4) American Indian or Alaska Native, (5) Native Hawaiian or Other Pacific Islander. Select 'Race Not Reported' if the candidate's race is not reported. This field is **required**.

Note: A person may report multiple races. Persons reporting Hispanic or Latino ethnicity may report themselves as any race category or report no race at all.

Select one or more race sub-categories or origins. Select 'Other Origin' if origin is not listed. Select 'Origin Not Reported' if the origin was not self-identified by the person.

> **White** – A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
>
> > **European Descent**
> >
> > **Arab or Middle Eastern**
> >
> > **North African (non-Black)**
> >
> > **Other Origin**

Origin Not Reported

Black or African American – A person having origins in any of the Black racial groups of Africa.

African American

African (Continental)

West Indian

Haitian

Other Origin

Origin Not Reported

American Indian or Alaska Native – A person having origins in any of the original peoples of North and South America (including Central America) and who maintains tribal affiliation or community attachment.

American Indian

Eskimo

Aleutian

Alaska Indian

Other Origin

Origin Not Reported

Asian – A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

Asian Indian/Indian Sub-Continent

Chinese

Filipino

Japanese

Korean

Vietnamese

Other Origin

Origin Not Reported

Native Hawaiian or Other Pacific Islander – A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

Native Hawaiian

Guamanian or Chamorro

Samoan

Other Origin

Origin Not Reported

Race Not Reported – Select if person did not self-identify a race category or origin.

Clinical Information

ABO: Select the candidate's blood type. This is a **required** field.

Note: A2 is used as shorthand for any blood type A subtype other than A1 (i.e., non-A1, negative for A1). A2B is used as shorthand for any blood type AB subtype other than A1B (i.e., non-A1B, negative for A1B). Policy **requires** at least two (2) separate blood typings prior to listing. Policy also **requires** you to review all known available blood type source documents to verify the candidate's blood type. See OPTN Policies for additional information. Use the search feature to locate specific policy information on ABO Typing.

O
A
B
AB
Z (in Utero Only)

Height: Enter the height of the candidate in the appropriate space, in feet and inches or centimeters. The height must fall between 0 and 7 feet or 1 and 241 centimeters. This is a **required** field.

Date: Enter the date the candidate's height was measured. This is a **required** field.

Weight: Enter the weight of the candidate in the appropriate space, in pounds or kilograms. Weight must be updated every 6 months in order to keep the candidate BMI current. The weight must fall between 0 and 650 pounds or 0 and 295 kilograms. This is a **required** field.

Date: Enter the date the candidate's weight was measured. If the evaluation date has expired, the least beneficial value for height and weight will be used to calculate the candidate's lung composite allocation score. This is a **required** field.

Note: If candidate height or weight values are missing, the lung composite allocation score calculation will use a substituted value of 100 kg/m^2 for the BMI.

BMI (Body Mass Index): The candidate's BMI will display. For candidates 18 years old or younger, at the time of listing, UNet^{SM} will generate and display calculated percentiles based on the 2000 CDC growth charts.

HLA

HLA: Histocompatibility antigens are currently not required when adding candidates for extra renal organs (LI, IN, HR, HL, and LU) to the active list. If histocompatibility antigens are entered, at least one value is required for each antigen (**A**, **B**, **Bw4**, **Bw6**, and **DR**). The order in which the antigens are entered does not affect the matching and screening process.

Click **Confirm HLA** and re-enter HLA information in Confirm HLA section.

Organ Information

Candidate Medical Urgency Status: Indicate the candidate's medical urgency status. If one of the Active statuses is selected, the candidate is eligible to appear on a UNet match run. If **Temporarily inactive** is selected, the candidate is non-eligible to appear on the UNet match run. This is a **required** field.

Select one of the following for adult candidates. Additional justification form fields are required.

Adult Status 1

Adult Status 2

Adult Status 3

Adult Status 4

Adult Status 5

Adult Status 6

Temporarily Inactive

Inactive reason: Select the reason the candidate is inactive.

Inactive Reason Code	Description
1	Candidate cannot be contacted
2	Candidate choice
3	Candidate work-up incomplete
4	Insurance issues
5	Medical non-compliance
6	Inappropriate substance use
7	Temporarily too sick
8	Temporarily too well
9	Weight currently inappropriate for transplant
10	Transplanted - removal pending UNET data correction
11	Inactivation due to VAD implantation and/or VAD complication
12	TX Pending
13	Physician/Surgeon unavailable
14	Candidate for living donor transplant only
15	Administrative: Waiting time/ped-adult adjustment
16	COVID-19 Precaution

Note: The inactive reason **TX'ed - removal pending UNet data correction** is only to be used when a transplant center removed the incorrect candidate from Waitlist due to transplant and is waiting for UNOS to correct the data so that the correct candidate can be removed with the right donor ID. Candidates should not be set to inactive for this reason for more than 5 days.

Heart Diagnosis Code: Indicate the candidate's heart diagnosis code. This is a **required** field.

Lung Diagnosis Code: Indicate the candidate's lung diagnosis code. This is a **required** field.

Indicate reason for change in diagnosis: If the diagnosis code is changed, this field will display and is required. Indicate the reason that the diagnosis needs to be changed.

Note: Only enter actual test and evaluation data in this section. Do not enter estimated values below.

NYHA Functional Classification: If the patient has pulmonary hypertension as a primary diagnosis, select the patient's New York Heart Association (NYHA) classification. The NYHA classification classifies patients in one of four categories based on their limitations during physical activity; the imitations/symptoms are in regards to normal breathing and varying degrees in shortness of breath and/or angina pain.

Class I – No symptoms and no limitation in ordinary physical activity, e.g., shortness of breath when walking, climbing stairs, etc.

Class II – Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.

Class III – Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (20–100 m). Comfortable only at rest.

Class IV – Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.

Eval Date: Enter the date when this information was obtained.

Brain Natriuretic Peptide Test: Enter the candidate's BNP or NT-proBNP lab values in pg/mL.

Definition: BNP (B-type natriuretic peptide) and NT-proBNP (N-terminal pro-BNP) are fragments cleaved from proBNP (pro B-type natriuretic peptide) that is secreted by cardiomyocytes in response to stretch.

Eval Date: Enter the date when this information was obtained.

Pericardial Effusion: If the patient is currently experiencing pericardial effusion as detected on echocardiogram, select **Yes**. If not select **No**.

Definition: Pericardial effusion refers to increased fluid within the pericardial sac which can cause circulatory compromise by compression of the heart; most often caused by inflammation, infection, malignancy, and uremia.

Eval Date: Enter the date when this information was obtained.

Functional Status: Select the applicable status from the drop-down list. Functional status is a way to measure the effects that lung disease may have on a person's ability to perform routine daily tasks. Enter the **Eval Date** when this information was obtained. This field must be updated every 6 months from the time the candidate was added to the Waitlist. If the field is incomplete or has expired, the least beneficial value will be used to calculate the candidate's lung composite allocation score.

Performs activities of daily living with NO assistance

Performs activities of daily living with SOME assistance

Performs activities of daily living with TOTAL assistance

Diabetes: If the candidate has **Diabetes**, select the option to indicate insulin dependency. If the candidate does not have diabetes, select **Not Diabetic**. A patient should *not* be considered as having diabetes based on a diagnosis of gestational diabetes only. Enter the **Eval Date** when this information was obtained.

Treated with insulin

Not treated with insulin

Not diabetic

Assisted Ventilation: Indicate the type of assisted ventilation the candidate requires. If the candidate does not require assisted ventilation, select **No assisted ventilation needed**. These fields must be updated every 6 months from the time the candidate was added to the Waitlist. If the fields are incomplete or the evaluation date has expired, the least beneficial value will be used to calculate the candidate's lung allocation score. Use of average volume-assured pressure support (AVAPS) should be reported as **intermittent mechanical**.

Eval Date: Enter the date when this information was obtained.

Requires Supplemental O_2: If the patient requires supplemental oxygen, indicate when supplemental oxygen is required and what type of oxygen supply system is used (face mask, high flow nasal cannula, nasal cannula, reservoir cannula, BiPAP, CPAP, continuous mechanical – hospitalized, continuous mechanical – not hospitalized, intermittent mechanical – hospitalized, or intermittent mechanical – not hospitalized). A high flow nasal cannula is a device that allows for independent titration of L/min and FiO2. Enter the amount needed in L/min (the value must fall between 0.25 and 100) or in percent (the value must fall between 22 and 100). For the purposes of calculating the patient's composite allocation score, a substituted value of 26.33 will be used for any values entered over 26.33. Use of average volume-assured pressure support (AVAPS) should be reported as intermittent mechanical.

At rest (not moving or exerting oneself)

With exercise

With sleep

Six minute walk distance: Enter the distance the candidate is able to walk in six minutes in feet. The distance walked is a measure of functional status. The normal range is between 0 and 3000, although a value outside of this range may be entered. Enter the **Test Date** when this information was obtained. These fields must be updated every 6 months from the time the candidate was added to the Waitlist. If they are incomplete or expired, the least beneficial value will be used to calculate the candidate's lung composite allocation score.

Massive hemoptysis: If the patient has experienced massive hemoptysis in the last year, enter the number of times experienced.

Definition: Hemoptysis is the coughing up of blood or bloody sputum from the lungs or airway. For adult patients, massive hemoptysis is defined as acute bleeding of ≥240 mL in a 24-hour period or recurrent bleeding of >100 mL each day for more than two days. For pediatric patients, massive hemoptysis is defined as acute bleeding of ≥8 mL/kg at once or recurrent bleeding over several days equaling 8 mL/kg or more.

Eval Date: Enter the date when this information was obtained.

Exacerbations: Enter the number of times within the last year from the date of entry that the patient has experienced an exacerbation.

On continuous intravenous antibiotics for longer than 60 days in the last year: Select checkbox if patient has been on continuous intravenous antibiotics for longer than 60 days in the last year.

Microbiology: If the patient has a history of infection (either within the last year or more than one year ago) with a multi-drug resistant (MDR) organism select the type of organism. MDR is defined as resistance to at least one agent in three or more antimicrobial classes. If the history of infection is not listed below, it does not need to be reported.

Burkholderia cenocepacia (genomovar III)

Burkholderia gladioli

MDR or Pan-R gram negative bacteria

Mycobacterium abscessus

Scedosporium/Pseudallescheria species complex/Lomentospora

Eval Date: Enter the date when this information was obtained.

Most Recent Heart Catheterization Date: Enter the date of the candidate's most recent heart catheterization.

Pulmonary Artery Systolic Pressure: Enter the pulmonary artery systolic pressure in mmHg. The normal range is between 10 and 120, although a value outside of this range may be entered.

Pulmonary Artery Diastolic Pressure: Enter the candidate's pulmonary artery diastolic pressure in mmHg. The expected value range is 5 - 40 mmHg; although the absolute value range is 0 - 110 mm Hg may be entered. **Definition:** The minimum arterial pressure during relaxation and dilatation of the ventricles of the heart when the ventricles fill with blood.

Mean Pulmonary Artery Pressure: Enter the mean pulmonary artery pressure in mmHg. The normal range is between 5 and 80, although a value outside of this range may be entered.

Note: The formula used to obtain Mean Pulmonary Artery Pressure is:

$$\text{Mean Pulmonary Artery Pressure} = ((\text{Systolic Pressure} - \text{Diastolic Pressure})/3) + \text{Diastolic Pressure}$$

Pulmonary Capillary Wedge Mean: Enter the mean pulmonary capillary wedge pressure in mmHg. The normal range is between 5 and 20, although a value outside of this range may be entered.

Cardiac Output (CO): Enter the candidate's cardiac output in L/min. The expected value range is 2 - 8 L/min; although the absolute value range is 0.2 - 15 L/min may be entered. **Definition:** The volume of blood pumped out of the heart. Cardiac output is expressed as volume of blood per unit time or liters per minute. Cardiac output can be calculated using the Fick method (oxygen consumption divided by arteriovenous oxygen difference) or by the thermodilution technique, using a Swan-Ganz catheter.

Cardiac Index (CI): Enter the candidate's cardiac index in L/min/m^2. The absolute value range is 0 - 50 L/min/m^2 may be entered. **Definition:** The amount of blood ejected by the heart in a unit of time divided by the body surface area. It is usually expressed in liters per minute per square meter.

Right Atrial Pressure (RAP): Enter the patient's mean right atrial pressure in mmHg. The mean should be calculated from measurements taken by right heart catheterization within the last year.

Definition: Right atrial pressure refers to blood pressure in the right atrium of the heart.

Pulmonary Vascular Resistance (PVR): Enter the pulmonary vascular resistance in dynes/sec/cm5 or in Wood units (mmHg/L/min).

Central Venous Pressure (CVP): Enter the candidate's central venous pressure in mmHg. The expected value range is 0 - 15 mmHg; although the absolute value range is 0 - 50 mmHg. **Definition:** The venous pressure as measured at the right atrium, done by means of a catheter introduced through the median cubital vein to the superior vena cava with the distal end of the catheter being attached to a manometer.

Hgb/Hct Test Date: Enter the **Test date** in the standard 8-digit MM/DD/YYYY format in the space provided. The date cannot precede the candidate's date of birth.

Hemoglobin (Hgb): Enter the candidate's hemoglobin in g/dL. The expected value range is 7–18 g/dL; although the absolute value range is 5–30 g/dL. **Definition:** The oxygen-carrying molecule in red blood cells.

Hematocrit (Hct): Enter the candidate's hematocrit in %. The expected value range is 25 - 50%; although the absolute value range is 0–75%. **Definition:** The proportion of the blood that consists of packed red blood cells. The hematocrit is expressed as a percentage by volume. The red cells are packed by centrifugation. For example, a hematocrit of 25% means that there are 25 milliliters of red blood cells in 100 milliliters of blood. The red cells make up a quarter of the blood.

Organ Information – Blood Gas Information

Date: Enter the date of the candidate's blood gas test in the standard 8-digit MM/DD/YYYYY format. The date cannot precede the candidate's date of birth.

Time: Enter the time of the candidate's blood gas test.

Blood Gas Test Type: Select the blood gas test type from the drop-down list. UNet will convert a venous or capillary value to estimate an arterial value: a capillary value will equal an arterial value and UNet will subtract 6 mmHg from a venous value to equal and arterial value.

Arterial
Capillary
Venous

pH: Enter the candidate's pH. The expected value range is 7.3–7.5; although the absolute value range is 5–10. **Definition:** A measure of the alkalinity or acidity of arterial blood. CO_2 acts as an acid in the blood and HCO_3 acts as a base in the blood. If the kidneys are not producing enough HCO_3, then the brain will tell the lungs to increase the respiratory rate in an effort to expel more CO_2. Some candidates with chronic lung disease will always have more CO_2 than normal in their blood because the gas exchange units in the lungs are impaired. To compensate for a high CO_2, the body will produce more HCO_3 than normal to try to achieve a balanced pH. If the pH is too high or low, enzymes will stop functioning.

PCO_2: Enter the candidate's partial pressure of carbon dioxide in mmHg. The expected value range is 25–60 mmHg; although the absolute value range is 10–200 mmHg. The normal clinical value of PCO_2 is 40 mmHg. UNet will substitute this normal clinical value in the lung composite allocation score calculation when the value of current PCO_2 is expired. **Definition:** Partial pressure of CO_2 in blood. Indicates adequacy of ventilations.

Supplemental O_2 at time of test?: Select **Yes**, if the candidate's supplemental O_2 at time of test. If it is not, select **No**.

O_2 Amount (L/min or %): The amount in L/min absolute value range is 0.25–26.3. The percent absolute value range is 22–100.

Organ Information – Serum Creatinine

Serum Creatinine: Enter the serum creatinine value. The value must fall between 0.1 to 40 mg/dl. Enter the **Date** and **Time** when this information was obtained. These fields must be updated every 6 months from the time the candidate was added to the Waitlist. If they are incomplete or expired, the policy default value will be used to calculate the candidate's lung composite allocation score.

Organ Information – Total Bilirubin

Total Bilirubin: Enter the total bilirubin value. The value must fall between 0 to 50 mg/dl. Enter the **Date** and **Time** when this information was obtained. These fields must be updated every 6 months from the time the candidate was added to the Waitlist. If they are incomplete or expired, the policy default value will be used to calculate the candidate's lung composite allocation score.

Organ Information – Pulmonary Function Test

Enter the **Date** and **Time** of the pulmonary function test.

Actual Forced Vital Capacity (FVC): Enter the candidate's Actual FVC in liters. This is a lung function test that measures the maximum amount of air you can breathe out after breathing in as deeply as possible. This amount may be lower in patients with lung disease. The normal range is between 0.2 and 10, although a value outside of this range may be entered.

Pre Bronchodilator Actual FEV_1: Enter the candidate's pre-bronchodilator actual Forced Expiratory Volume in 1 second. The expected value range is 0.2–5 liters; although the absolute value range is 0–20 liters may be entered.

Organ Information – Diffusing Capacity of the Lungs for Carbon Monoxide (DLCO) Test

Diffusing Capacity of the Lungs for Carbon Monoxide (DLCO): Enter the value of the diffusing capacity of the lungs for carbon monoxide in mL/min/mmHg, obtained from a pulmonary function test. Do not enter values corrected for hemoglobin or alveolar volume. If the patient cannot perform this test due to their medical status, select checkbox for "Too sick to perform DLCO test?"

Definition: Diffusing capacity of the lungs for carbon monoxide is a measurement to assess the lungs' ability to transfer gas from inspired air to the bloodstream.

Organ Information

Preliminary Crossmatch Required: Select **Yes**, if a preliminary cross-match is required. If it is not, select **No**.

Number of previous Heart/Lung Transplants: Indicate the number of candidate's previous heart/lung transplants. This field is **required**.

Is the candidate listed for a vascularized composite allograft (VCA)?: Select **Yes** or **No**.

Additional Organs

Check any additional organs that the candidate may need. Checking organ(s) within this section will not register the candidate on the checked organ waiting list. You will need to complete a registration and verify the accuracy of donor acceptance criteria for each additional organ checked.

Kidney

Pancreas

Pancreas Islet

Intestine

Heart

Liver

Lung

Donor Characteristics

Minimum acceptable donor age: Enter the minimum donor age that the candidate can accept. The age must fall between 0 and 99 years. This field is **required**.

Maximum acceptable donor age: Enter the maximum donor age that the candidate can accept. The age must fall between 0 and 99 years. The maximum value must only be entered in months if the minimum value is also entered in months (e.g., you are able enter that you will accept donors from 3 months to 3 years in age, but you may NOT enter that you would accept a donor from 1 year to 36 months in age). This field is **required**.

Minimum acceptable donor height: Enter the minimum donor height that the candidate can accept in inches (in) or centimeters (cm). The height must fall between 0 to 305 inches, or 0 to 305 centimeters. The minimum acceptable donor height must be equal to or no more than 12 in. less than the candidate's listing height. This field is **required**.

Maximum acceptable donor height: Enter the maximum donor height that the candidate can accept in inches (in) or centimeters (cm). The height must fall between 0 to 305 inches, or 0 to 305 centimeters. The maximum acceptable donor height must be equal to or no more than 12 in. greater than the candidate's listing height. This field is **required**.

Minimum acceptable donor weight: Enter the minimum donor weight that the candidate can accept. The weight must be a whole number that falls between 0 and 440 pounds, or 0 and 200 kilograms. The minimum acceptable donor weight should be no more than 30 percent (30%) below the candidate's listing weight. To eliminate the possibility of conversion or rounding issues, the match system deducts .5 kg when comparing this value to the donor weight. This field is **required**.

Maximum acceptable donor weight: Enter the maximum donor weight that the candidate can accept. The weight must be a whole number that falls between 0 and 440 pounds, or 0 and 200 kilograms. The maximum acceptable donor weight must be more than the candidate's listing weight, and must be greater than the minimum acceptable donor weight. To eliminate the possibility of conversion or rounding issues, the match system adds .5 kg when comparing this value to the donor weight. This field is **required**.

Donor birth sex requirements: Select whether the matching donor must be **male**, **female**, or **either** birth sex (male or female).

Accept DCD donor: Select **Yes** if the candidate will accept a DCD (Donation after Circulatory Death) donor. If not, select **No**. Donation after Circulatory Death (DCD) describes the organ recovery process that may occur following death by irreversible cessation of circulatory and respiratory functions. A DCD donor may also be called a non-heartbeating, asystolic, or donation after cardiac death donor. This field is **required**.

Medical and Social History

Accept a donor with a history of coronary artery disease?: Select **Yes** if the candidate will accept a donor with a history of coronary artery disease. If not, select **No**.

Accept a donor with cigarette use > 20 pack years ever?: Select **Yes** if the candidate will accept a donor with cigarette use more than 20 pack years ever. If not, select **No**. Donor cigarette use does not include vaping or e-cigarette usage.

Infectious Diseases

Accept a Hepatitis B Core antibody positive donor?: Select **Yes** if the candidate will accept a Hepatitis B core antibody positive donor. If not, select **No**. This field is **required**.

Accept an HBV NAT positive donor?: Select **Yes** if the candidate will accept an HBV NAT positive donor. If not, select **No** This field is **required**.

Accept an HCV antibody positive donor?: Select **Yes** if the candidate will accept an HCV antibody positive donor. If not, select **No**. This field is **required**.

Accept an HCV NAT positive donor?: Select **Yes** if the candidate will accept an HCV NAT positive donor. If not, select **No**. This field is **required**.

Recovery

Maximum miles the organ or recovery team will travel: Enter the maximum miles the candidate's organ or recovery team will travel to obtain an organ. The number must fall between 0 and 9,999 miles. This field is **required**.

The matching system calculates mileage between the donor hospital and the recipient center based on the hospitals' zip codes. This distance is measured in nautical miles (a measure of flight distance), not in statute miles (a measurement of driving distance).

Conversion Table for Nautical and Statute Miles

Nautical Miles	Statute Miles
250	287.7
500	575.4
1000	1150.8
1500	1726.2
2000	2301.6
2500	2876.9

Unacceptable Antigens

Select all A unacceptable antigens: Select the candidate's A unacceptable antigens, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

Select all B unacceptable antigens: Select the candidate's B unacceptable antigens, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

Select BW unacceptable antigen: Select the candidate's BW unacceptable antigen, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

Select all C unacceptable antigens: Select the candidate's C unacceptable antigens, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

Select all DR unacceptable antigens: Select the candidate's DR unacceptable antigens, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

Select all DR 51/52/53 unacceptable antigens: Select the candidate's DR 51, 52 and 53 unacceptable antigens, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

Select all DQB1 unacceptable antigens: Select the candidate's DQB1 unacceptable antigens, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

Select all DQA1 unacceptable antigens: Select the candidate's DQA1 unacceptable antigens, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

Select all DPB1 unacceptable antigens: Select the candidate's DPB1 unacceptable antigens, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

Select all DPB1 unacceptable epitopes: Select the candidate's DPB1 unacceptable epitopes, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

Select all DPA1 unacceptable antigens: Select the candidate's DPA1 unacceptable antigens, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

Risk Stratification Data

The goal of collecting the risk stratification data is to potentially inform future heart allocation policy. The data has no bearing on allocation in terms of where the candidate is placed on a match. Per OPTN Policy, this data must be submitted at time of registering the candidate and each time a status justification form is submitted.

Candidate History

Enter data in all of the fields in this section. If nothing has changed since the last time you provided this data, re-enter the same data if it remains true.

Total number of prior sternotomies: Enter the total number of any prior sternotomies into the space provided. The entry must fall between 0 and 10. Check **Not available** if the information is not accessible. This is a **required** field.

Any prior history of stroke?: If the candidate has ever had a stroke, select **Yes**. If not, select **No**. If unknown, select, **Unknown**. This is a **required** field.

Any prior history of peripheral thromboembolic events?: If the candidate has ever experienced peripheral thromboembolic events, select **Yes**. If not, select **No**. If unknown, select, **Unknown**. This is a **required** field.

Number of hospitalizations for heart failure in last 12 months: (Both observation and inpatient stays are counted as hospitalizations) Enter the number of times the candidate has been hospitalized for heart failure in the last twelve months. The entry must fall between 0 and 50. Check **Not available** if the information is not accessible. This is a **required** field.

Current Therapies

Enter data in all of the fields in this section. If nothing has changed since the last time you provided this data, re-enter the same data if it remains true.

Is the candidate on a diuretic?: If the candidate is currently on a diuretic, select **Yes**. If not, select **No**. If unknown, select, **Unknown**. This is a **required** field.

If yes, enter the cumulative 24-hour dosage values.

Furosemide: Enter the dosage of furosemide in mg. The entry must fall between 1 and 200. If the value exceeds the maximum acceptable limit, enter the maximum acceptable limit. If the value falls below the minimum allowed value, enter the minimum allowed value. Select **IV** (intravenous) or **PO** (per os (by mouth)).

Torsemide: Enter the dosage of torsemide in mg. The entry must fall between 1 and 400. If the value exceeds the maximum acceptable limit, enter the maximum acceptable limit. If the value falls below the minimum allowed value, enter the minimum allowed value. Select **IV** (intravenous) or **PO** (per os (by mouth)).

Bumetanide: Enter the dosage of bumetanide in mg. The entry must fall between 1 and 50. If the value exceeds the maximum acceptable limit, enter the maximum acceptable limit. If the value falls below the minimum allowed value, enter the minimum allowed value. Select **IV** (intravenous) or **PO** (per os (by mouth)).

Chlorothiazide: Enter the dosage of chlorothiazide in mg. The entry must fall between 1 and 200. If the value exceeds the maximum acceptable limit, enter the maximum acceptable limit. If the value falls below the minimum allowed value, enter the minimum allowed value. Select **IV** (intravenous) or **PO** (per os (by mouth)).

Metolazone: Enter the dosage of metolazone in mg. The entry must fall between 1 and 50. If the value exceeds the maximum acceptable limit, enter the maximum acceptable limit. If the value falls below the minimum allowed value, enter the minimum allowed value. Select **IV** (intravenous) or **PO** (per os (by mouth)).

Other diuretic: Enter the name of the diuretic in the space provided and the mg. The entry must fall between 1 and 400. If the value exceeds the maximum acceptable limit, enter the maximum acceptable limit. If the value falls below the minimum allowed value, enter the minimum allowed value. Select **IV** (intravenous) or **PO** (per os (by mouth)).

Is the candidate on vasoactive support?: If the candidate is currently on vasoactive support, **Yes**. If not, select **No**. If unknown, select, **Unknown**. This is a **required** field.

If yes, enter the additional information:

Dobutamine: Enter the dosage of dobutamine in mcg/kg/min. The entry must fall between 0.001 and 999.

Dopamine: Enter the dosage of dopamine in mcg/kg/min. The entry must fall between 0.001 and 999.

Milrinone: Enter the dosage of milrinone in mcg/kg/min. The entry must fall between 0.001 and 999.

Epinephrine: Enter the dosage of epinephrine in mcg/kg/min. The entry must fall between 0.001 and 999.

Norepinephrine: Enter the dosage of norepinephrine in mcg/kg/min. The entry must fall between 0.001 and 999.

Vasopressin: Enter the dosage of vasopressin in units/min. The entry must fall between 0.001 and 999.

Is the candidate on anti-arrhythmics?: If the candidate is currently on anti-arrhythmics, select **Yes**. If not, select **No**. If unknown, select, **Unknown**. This is a **required** field.

Is the candidate on pulmonary vasodilators?: If the candidate is on pulmonary vasodilators, select the from the list of options. One or more options may be selected. If not, select **No**. If unknown, select, **Unknown**. This is a **required** field.

IV
Inhaled
Oral

Is the candidate on dialysis?: If the candidate is currently on dialysis, select **Yes**. If not, select **No**. If unknown, select, **Unknown**. This is a **required** field.

Is the candidate on continuous invasive mechanical ventilation?: If the candidate is currently on continuous invasive mechanical ventilation, select **Yes**. If not, select **No**. If unknown, select, **Unknown**. This is a **required** field.

Most Recent Cardiopulmonary Stress Test

Enter the most recent cardiopulmonary stress test date and the data obtained. If a certain test in this category has not been performed since the last time you reported the data, check “Not Performed” to indicate the same. If no new tests have been performed since the last time the data was reported, click “Not Performed” at the category level to indicate that no new values are available for any of the fields in this category.

Example:

1. The first time that you report this data, you are reporting values obtained from a test performed on 09/15/2018. You have provided data in all of the fields (Peak O2 consumption, RER and VE/VCO2).
2. A new status justification form is being submitted on 09/20/2018.
3. New tests have been performed on 09/18/2018 for Peak O2 Consumption and RER but not for VE/VCO2.
4. On the new form being submitted, enter 09/18/2018 as the Assessment Date and provide the new values obtained for Peak O2 consumption and RER.
5. Since no test was performed for VE/VCO2, click "Not Performed" to indicate that a new test was not performed on 09/18/2018.

Assessment Date: Enter the assessment date the stress test was performed. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field.

Peak O_2 consumption: Enter the peak oxygen (O_2) consumption in ml/kg/min. The entry must fall between 0 and 50. Check **Not performed** if no test was performed. This is a **required** field.

Respiratory exchange ratio (RER): Enter the ratio between the amount of carbon dioxide (CO_2) produced in metabolism and oxygen (O_2) used into the space provided. The entry must fall between 0 and 2. Check **Not performed** if no test was performed. This is a **required** field.

VE/VCO_2: Enter the carbon dioxide output per unit of time into the space provided. The entry must fall between 0 and 200. Check **Not performed** if no test was performed. This is a **required** field.

Most Recent Sensitization Data

Enter the most recent sensitization test date and the data obtained. If a certain test in this category has not been performed since the last time you reported the data, check “Not Performed” to indicate the same. If no new tests have been performed since the last time the data was reported, click “Not Performed” at the category level to indicate that no new values are available for any of the fields in this category. Refer to example in the “Most recent cardiopulmonary stress test” section.

Assessment Date: Enter the assessment date of the most recent sensitization data. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field.

CPRA: Enter the current Calculated Panel Reactive Antibodies (CPRA) percentage into the space provided. The entry must fall between 0 and 100. Check **Not performed** if no test was performed. This is a **required** field. ***Note:*** Please enter the current CPRA value and not the peak CPRA value.

PRA typing method: Select the Panel Reactive Antibodies (PRA) typing method from the list of options. Check **Not performed** if no test was performed. This is a **required** field.

Cytotoxicity testing – extended incubation
Cytotoxicity testing – wash
Cytotoxicity testing – wash and extended incubation
Cytotoxicity testing – AHG (antihuman immunoglobulin)

Flow cytometry with cell targets
Flow cytometry with bead targets
ELISA
Micro array
Other, specify (if chosen, enter the method in **Other specify text** box)

MFI threshold: Enter the mean fluorescence intensity (MFI) threshold into the space provided. The entry must fall between 0 and 50000. If there are different cutoffs for different HLA loci, provide the lowest threshold used for that candidate. Check **Not performed** if no test was performed. This is a **required** field.

Most Recent Hemodynamic Data

Enter the most recent hemodynamic data test date and the data obtained. If a certain test in this category has not been performed since the last time you reported the data, check "Not Performed" to indicate the same. If no new tests have been performed since the last time the data was reported, click "Not Performed" at the category level to indicate that no new values are available for any of the fields in this category. Refer to example in the "Most recent cardiopulmonary stress test" section.

Hemodynamic data obtained using: Select whether the data was obtained using **Invasive pulmonary artery catheter**, **Implanted hemodynamic monitoring**, or **Other**. Select as many as necessary. Check **Not performed** at the category level if no hemodynamic measurements were obtained. This is a **required** field.

Were hemodynamic values obtained while the patient was on inotrope and or device support?: If hemodynamic values were obtained while the candidate was on inotrope and or device support, click the appropriate check boxes. If unknown, select **Not available** to indicate the same.

Systolic blood pressure: Enter the measure of systolic blood pressure in mmHg. The entry must fall between 50 and 200 mmHg. Check **Not performed** if no test was performed. This is a **required** field.

Diastolic blood pressure: Enter the measure of diastolic blood pressure in mmHg. The entry must fall between 20 and 150 mmHg. Check **Not performed** if no test was performed. This is a **required** field.

Resting heart rate (on same date as hemodynamic tests): Enter the resting heart rate in beats per minute (bpm). The entry must fall between 0 and 300. Check **Not performed** if no test was performed. This is a **required** field.

Central venous pressure: Enter the central venous pressure in mmHg. The entry must fall between 0 and 50 mmHg. Check **Not performed** if no test was performed. This is a **required** field.

Pulmonary artery systolic pressure: Enter the pulmonary artery systolic pressure in mmHg. The entry must fall between 0 and 200 mmHg. The pulmonary artery systolic pressure must be greater than mean pulmonary artery pressure. Check **Not performed** if no test was performed. This is a **required** field.

Pulmonary artery diastolic pressure: Enter the pulmonary artery diastolic pressure in mmHg. The entry must fall between 0 and 110 mmHg. Check **Not performed** if no test was performed. This is a **required** field.

Mean pulmonary artery pressure: Enter the mean pulmonary artery pressure in mmHg. The entry must fall between 0 and 150 mmHg. The mean pulmonary artery pressure must be greater than the pulmonary artery diastolic pressure. Check **Not performed** if no test was performed. This is a **required** field.

Value obtained for PCWP or LVEDP?: If a value was obtained for Pulmonary Capillary Wedge Pressure (PCWP) or Left Ventricular End-Diastolic Pressure (LVEDP), select **Yes**. If not, select **No**. If unknown, select, **Unknown**. If yes, select the appropriate option and enter the value in mmHg. The entry must fall between 0 and 100. This is a **required** field.

Cardiac output: Enter the cardiac output in L/min. The entry must fall between 0.2 and 15 L/min. Check **Not performed** if no test was performed. This is a **required** field.

Cardiac index: Enter the cardiac index in L/min/m2. The entry must fall between 0 and 50 L/min/m2. Check **Not performed** if no test was performed. This is a **required** field.

Mixed venous oxygen saturation: Enter the percentage of mixed venous oxygen saturation into the space provided. The entry must fall between 0 and 100. Check **Not performed** if no test was performed. This is a **required** field.

Hemoglobin at time of SvO_2: Enter the measurement of oxygenation saturation from mixed venous blood (SvO2) in the pulmonary artery in g/dL. The entry must fall between 5 and 20 g/dL. Check **Not performed** if no test was performed. This is a **required** field.

Most Recent Data for VAD Patients

If the candidate is supported by a VAD, enter data in this section. If the candidate is not supported by a VAD, check “Not Performed” at the category level.

Enter the most recent data and the corresponding test date in the fields in this category. If a certain test in this category has not been performed since the last time you reported the data, check “Not Performed” to indicate the same. If no new tests have been performed since the last time the data was reported, click “Not Performed” at the category level to indicate that no new values are available for any of the fields in this category. Refer to example in the “Most recent cardiopulmonary stress test” section.

Note: Enter data in this section only if the candidate is currently on a ventricular assist device (VAD). If not, select **Not performed**.

LDH: Enter the Lactic Acid Dehydrogenase (LDH) value in U/L. The entry must fall between 0 and 10000 U/L. Enter the test date. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field.

Plasma free hemoglobin: Enter the plasma free hemoglobin value in mg/dL. The entry must fall between 0 and 200 mg/dL. Enter the test date. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field.

Has the candidate experienced hemoglobinuria?: If the candidate has experienced hemoglobinuria at any point, select **Yes**. If not, select **No**. If unknown, select, **Unknown**. This

is a required field. ***Note:*** If initially listing a candidate, indicate whether the candidate has experienced hemoglobinuria at any time prior to listing. If submitting a justification form, indicate whether the candidate has experienced hemoglobinuria since submission of the last justification form. If urinalysis was not repeated since the submission of the last justification form, select unknown.

Most Recent Heart Failure Severity Data

Enter the most recent heart failure severity data and corresponding test date in the fields in this category. If a certain test in this category has not been performed since the last time you reported the data, check "Not Performed" to indicate the same. If no new tests have been performed since the last time the data was reported, click "Not Performed" at the category level to indicate that no new values are available for any of the fields in this category. Refer to example in the "Most recent cardiopulmonary stress test" section.

Serum sodium: Enter the serum sodium in mEq/L. The entry must fall between 100 and 200. Enter the test date. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field. ***Note:*** Plasma sodium is also considered an acceptable value.

Serum creatinine: Enter the serum creatinine in mg/dL. The entry must fall between 0.01 and 40. Enter the test date. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field. ***Note:*** Plasma creatinine is also considered an acceptable value.

BUN: Enter the Blood Urea Nitrogen (BUN) in mg/dL. The entry must fall between 0 and 300. Enter the test date. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field.

Serum albumin: Enter the serum albumin in g/dL. The entry must fall between 0.5 and 9.9. Enter the test date. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field.

AST: Enter the aspartate transaminase (AST) in U/L. The entry must fall between 0 and 40000. Check **Not performed** if no test was performed. This is a **required** field.

Serum bilirubin: Enter the serum bilirubin in mg/dL. The entry must fall between 0 and 50. Enter the test date. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field.

Arterial lactate: Enter the arterial lactate in mmol/L. The entry must fall between 0 and 50. Enter the test date. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field.

INR: Enter the International normalized ratio (INR) into the space provided. The entry must fall between 0 and 20. Enter the test date. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field.

Brain natriuretic peptide test performed?: Select **Yes**, if a brain natriuretic peptide test was performed. If not, select **No**. If the unknown, select, **Unknown**. This is a **required** field.

If yes, select **BNP** or **NT Pro BNP** and enter the Brain natriuretic peptide in pg/mL into the space provided. The BNP entry must fall between 0 and 20000. The NT Pro BNP entry must fall between 0 and 40000. This is a **required** field.

Justification Form Information

Surgeon/Physician NPI: Enter the NPI of the candidate's surgeon/physician. This is a **required** field.

Surgeon/Physician name: Enter the name of the candidate's surgeon/physician. This is a **required** field.

Hospital telephone number: Enter the transplant hospital telephone number. This is a **required** field.

Justification Form Status 1

Is the candidate currently admitted to the listing transplant hospital? If the candidate is currently admitted to the listing transplant hospital, select **Yes**. If not, select **No**. This is a **required** field.

Report the device that qualifies the candidate for the medical urgency status as the primary device. One additional support device can be reported as the secondary device. If the medical urgency status requires the candidate to be on a BiVAD, then the two VAD devices must be reported separately in the primary device and secondary device fields.

Primary device: Select the candidate's primary device type from the drop-down list of options.

TAH
IABP
VA ECMO
Percutaneous Device
Dischargeable VAD
Non-Dischargeable VAD

Device brand: If non-dischargeable VAD is selected, choose the brand of the device from the drop-down list of options. If you select **Other, Specify** enter the device brand in the **Other specify** field.

Abiomed BVS 5000
Biomedicus
Medos
Thoratec IVAD
Toyobo
Abiomed AB5000
Berlin Heat EXCOR
CentriMag (Thoratec/Levitronix)
Maquet Josta Rotaflow
Terumo DuraHeart
Thoratec PVAD
Ventracor VentrAssist
PediMag (Thoratec/Levitronix)
Other Specify

Device brand: If dischargeable VAD is selected, choose the brand of the device from the drop-down list of options. If you select **Other, Specify** enter the device brand in the **Other specify** field.

HeartMate II
Heartsaver VAD
Jarvik 2000
Evaheart
Heartware HVAD
Worldheart Levacor
HeartMate III
ReliantHeartAssist 5
ReliantHeart aVAD
Other Specify

Date of implant/initiation: Enter the date the device was implanted/date of initiation. Date of implant/date of initiation cannot exceed the current date. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

Time of implant/initiation: Enter the time of implant/time of initiation. Device support begins when the procedure begins to insert or implant the device. The intent of this field is to validate time frame requirements in policy for qualifying criteria (evidence, events, or measurements) that must occur prior to implant or initiation of device support. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Enter the earliest of the following: documented procedure start time, operation start time, surgery start time, or incision time.

Defining support as the procedure start time provides the most consistent and largest acceptable time period for candidates.

Suggested data sources include: anesthesia record, operative report, or circulation record/OR nurses record.

Note: Time of implant is a required field if the candidate is being listed at status 1, criteria 1

Ventricle support: If applicable, select the type of ventricle support from the list of options.

Left
Right
Single

Secondary device: Select the candidate's secondary device type from the list of options.

IABP
VA ECMO
Percutaneous Device
Dischargeable VAD
Non-Dischargeable VAD

Date of implant/initiation: Enter the date the device was implanted. Date of implant/date of initiation cannot exceed the current date. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

Ventricle support: If applicable, select the appropriate ventricle support from the list of options.

Left
Right

To qualify for status 1, the patient must meet one of the following criteria.

1. Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)

Candidate is admitted to the transplant center that registered the candidate on the waitlist and is supported by VA ECMO for cardiogenic shock. Within 7 days prior to support.

Select one of the following:

Hemodynamic measurements were obtained and within 24 hour period:

- Cardiac index was:
  - Less than 1.8 L/min/m^2 if the candidate was not supported by an inotrope or
  - Less than 2.0 L/min/m^2 if the candidate was supported by at least one inotrope
- Pulmonary capillary wedge pressure was greater than 15 mmHg and
- Systolic blood pressure was less than 90 mmHg

Was the candidate on inotropes at the time cardiac index was obtained?: If the candidate was on inotropes at the time cardiac index was obtained, select **Yes**. If not, select **No**. This is a **required** field.

Cardiac index: Enter the candidate's cardiac index in L/min/m^2. The entry must fall between 0 and 1.79 if the candidate was not supported by inotropes and must be less than 2.0 L/min/m^2 if the candidate was supported by inotropes. Enter the **Test Date** of when the cardiac index value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

Pulmonary capillary wedge pressure: Enter the candidate's pulmonary capillary wedge pressure in mmHg. The entry must fall between 16 and 100 mmHg. Enter the **Test Date** of when the PCWP value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

Systolic blood pressure: Enter the candidate's systolic blood pressure in mmHg. The entry must fall between 50 and 89 mmHg. Enter the **Test Date** of when the systolic blood pressure was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

Hemodynamic measurements were not obtained. However, within 24 hours prior to ECMO support:

- CPR was performed on the candidate or
- systolic blood pressure was less than 70 mmHg or
- arterial lactate was greater than 4 mmol/L or
- aspartate transaminase was greater than 1,000 U/L or
- alanine transaminase was greater than 1,000 U/L.

Enter a qualifying value for at least one of the following:

Date of administration of CPR: Enter the date of administration of CPR. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. Enter the time that CPR was administered. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Systolic blood pressure: Enter the candidate's systolic blood pressure in mmHg. The entry must fall between 50 and 69 mmHg. Enter the **Test Date** of when the systolic blood pressure was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Arterial lactate: Enter the candidate's arterial lactate in mmol/L. The entry must fall between greater than 4 and 50 mmol/L. Enter the **Test Date** of when the arterial lactate value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Aspartate transaminase: Enter the candidate's aspartate transaminase in U/L. The entry must fall between 1001 and 40000 U/L. Enter the **Test Date** of when the aspartate transaminase value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Alanine transaminase: Enter the candidate's alanine transaminase in U/L. The entry must fall between 1001 and 40000 U/L. Enter the **Test Date** of when the alanine transaminase value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

2. **Non-dischargeable, surgically implanted, non-endovascular biventricular support device**

   Candidate is admitted to the transplant center that registered the candidate on the waitlist, is supported by a surgically implanted, non-endovascular biventricular support device, and must remain hospitalized because the device is not FDA-approved for out of hospital use.

3. **Mechanical circulatory support device (MCSD) with life threatening ventricular arrhythmia**

   Candidate is admitted to the transplant center that registered the candidate on the waitlist, is supported by an MCSD, and is experiencing recurrent or sustained ventricular tachycardia or ventricular fibrillation. Select at least one of the following:

   - Placement of a biventricular mechanical circulatory support device for the treatment of sustained ventricular arrhythmias.
   - The patient was not considered a candidate for other treatment alternatives, such as ablation, by an electrophysiologist, and has experienced 3 or more episodes of ventricular fibrillation or ventricular tachycardia separated by at least an hour, over the previous 7 days that both:
     - Occurred in the setting of normal serum magnesium and potassium levels
     - Required electrical cardioversion despite receiving continuous intravenous antiarrhythmic therapies

4. **Exception for status 1**
   Candidate does not meet any of the criteria above but is admitted to the transplant hospital that registered the candidate on the waiting list and has an urgency and potential for benefit comparable to that of other candidates at this status. A clinical narrative must be provided to support the candidate's eligibility at this status.

   A transplant program may assign a candidate who does not meet any of the above status 1 criteria to status 1 by requesting an exception. The candidate must be admitted to the transplant hospital that registered the candidate on the waiting list, and the program must explain why it considers the candidate to have an urgency and potential for benefit comparable to other status 1 candidates using acceptable medical criteria. The review board will retrospectively review exception requests. If the review board denies an exception request, then within one day of receiving notification of the denial, the candidate's transplant program must either appeal to the review board or assign the candidate to the status for which the candidate qualifies.

   Clinical Narrative: Enter a clinical narrative which supports the eligibility of the candidate for an exceptional case. ***Note:*** A maximum of 5000 characters is accepted.

Justification Form Status 2

Is the candidate currently admitted to the listing transplant hospital?: If the candidate is currently admitted to the listing transplant hospital, select **Yes**. If not, select **No**. This is a **required** field.

Report the device that qualifies the candidate for the medical urgency status as the primary device. One additional support device can be reported as the secondary device. If the medical urgency status requires the candidate to be on a BiVAD, then the two VAD devices must be reported separately in the primary device and secondary device fields.

Primary device: Select the candidate's primary device type from the drop-down list of options.

TAH
IABP
VA ECMO
Percutaneous Device
Dischargeable VAD
Non-Dischargeable VAD

Device brand: If non-dischargeable VAD is selected, choose the brand of the device from the drop-down list of options. If you select **Other, Specify** enter the device brand in the **Other specify** field.

Abiomed BVS 5000
Biomedicus
Medos
Thoratec IVAD
Toyobo
Abiomed AB5000
Berlin Heat EXCOR
CentriMag (Thoratec/Levitronix)
Maquet Josta Rotaflow
Terumo DuraHeart

Thoratec PVAD
Ventracor VentrAssist
PediMag (Thoratec/Levitronix)
Other Specify

Device brand: If dischargeable VAD is selected, choose the brand of the device from the drop-down list of options. If you select **Other, Specify** enter the device brand in the **Other specify** field.

HeartMate II
Heartsaver VAD
Jarvik 2000
Evaheart
Heartware HVAD
Worldheart Levacor
HeartMate III
ReliantHeartAssist 5
ReliantHeart aVAD
Other Specify

Date of implant/initiation: Enter the date the device was implanted/date of initiation. Date of implant/date of initiation cannot exceed the current date. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

Time of implant/initiation: Enter the time of implant/time of initiation. Device support begins when the procedure begins to insert or implant the device. The intent of this field is to validate time frame requirements in policy for qualifying criteria (evidence, events, or measurements) that must occur prior to implant or initiation of device support. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Enter the earliest of the following: documented procedure start time, operation start time, surgery start time, or incision time.

Defining support as the procedure start time provides the most consistent and largest acceptable time period for candidates.

Suggested data sources include: anesthesia record, operative report, or circulation record/OR nurses record.

Ventricle support: If applicable, select the type of ventricle support from the list of options.

Left
Right
Single

Secondary device: Select the candidate's primary device type from the list of options.

IABP
VA ECMO
Percutaneous Device
Dischargeable VAD
Non-Dischargeable VAD

Date of implant/initiation: Enter the date the device was implanted/date of initiation. Date of implant/Date of initiation cannot exceed the current date. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

Ventricle support: If applicable, select the appropriate ventricle support from the list of options.

Left
Right

To qualify for status 2, the patient must meet one of the following criteria.

1. **Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD)**

   Candidate is admitted to the transplant center that registered the candidate on the waiting list, is supported by a surgically implanted, non-endovascular LVAD, and must remain hospitalized because the device is not FDA approved for out of hospital use.

2. **Total artificial heart (TAH), BiVAD, right ventricular assist device (RVAD), or ventricular assist device (VAD) for single ventricle patients**

   Candidate is supported by a TAH, BiVAD, RVAD, or VAD for single ventricle patients.

3. **Mechanical circulatory support device (MCSD) with malfunction**

   Candidate is admitted to the transplant center that registered the candidate on the Waitlist[SM] and is supported by an MCSD that is experiencing device malfunction as evidenced by all of the following.

   - Malfunction of at least one of the components of the MCSD
   - The malfunction cannot be fixed without an entire device replacement
   - The malfunction is currently causing inadequate circulatory support or places the candidate in imminent risk of device stoppage

4. **Percutaneous endovascular mechanical circulatory support device**

   Candidate is admitted to the transplant center that registered the candidate on Waitlist[SM] and is supported by a percutaneous endovascular mechanical circulatory support device for cardiogenic shock. **Within 7 days prior to support:**

   Select one of the following:

   Hemodynamic measurements were obtained and within 24 hour period

   - Cardiac index was:
     - Less than 1.8 L/min/m^2 if the candidate was not supported by an inotrope or
     - Less than 2.0 L/min/m^2 if the candidate was supported by an inotrope
   - Pulmonary capillary wedge pressure was greater than 15 mmHg and
   - Systolic blood pressure was less than 90 mmHg

   Was the candidate on inotropes at the time cardiac index was obtained?: If the candidate was on inotropes at the time cardiac index was obtained, select **Yes**. If not, select **No**. This is a **required** field.

   Cardiac index: Enter the candidate's cardiac index in L/min/m^2. The entry must fall between 0 and 1.79 L/min/m^2 if the candidate was not supported by inotropes and must be less than 2.0 L/min/m^2 if the candidate was supported by inotropes. Enter the **Test Date** of when the cardiac index value were obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

   Pulmonary capillary wedge pressure: Enter the candidate's pulmonary capillary wedge pressure in mmHg. The entry must fall between 16 and 100

mmHg. Enter the **Test Date** of when the PCWP value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

Systolic blood pressure: Enter the candidate's systolic blood pressure in mmHg. The entry must fall between 50 and 89 mmHg. Enter the **Test Date** of when the systolic blood pressure was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

Hemodynamic measurements were not obtained. However, within 24 hours prior to percutaneous endovascular mechanical support. Enter a qualifying value for at least one of the following:

Date of administration of CPR: Enter the date of administration of CPR. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. Enter the time that CPR was administered. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Systolic blood pressure: Enter the candidate's systolic blood pressure in mmHg. The entry must fall between 50 and 69 mmHg. Enter the **Test Date** of when the systolic blood pressure was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Arterial lactate: Enter the candidate's arterial lactate in mmol/L. The entry must fall between greater than 4 and 50 mmol/L. Enter the **Test Date** of when the arterial lactate value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time should be in military format.

Aspartate transaminase: Enter the candidate's aspartate transaminase in U/L. The entry must fall between 1001 and 40000 U/L. Enter the **Test Date** of when the aspartate transaminase value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Alanine transaminase: Enter the candidate's alanine transaminase in U/L. The entry must fall between 1001 and 40000 U/L. Enter the **Test Date** of when the alanine transaminase value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available.Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

5. Intra-aortic balloon pump

Candidate is admitted to the transplant center that registered the candidate on Waitlist[SM] and is supported by IABP for cardiogenic shock. **Within 7 days prior to support:**

Select one of the following:

Hemodynamic measurements were obtained and within 24 hour period:

- Cardiac index was:
  - Less than 1.8 L/min/m^2 if the candidate was not supported by an inotrope or
  - Less than 2.0 L/min/m^2 if the candidate was supported by an inotrope
- Pulmonary capillary wedge pressure was greater than 15 mmHg and
- Systolic blood pressure was less than 90 mmHg

Was the candidate on inotropes at the time cardiac index was obtained?: If the candidate was on inotropes at the time cardiac index was obtained, select **Yes**. If not, select **No**. This is a **required** field.

Cardiac index: Enter the candidate's cardiac index in L/min/m^2. The entry must fall between 0 and 1.79 L/min/m^2 if the candidate was not supported by inotropes and must be less than 2.0 L/min/m^2 if the candidate was supported by inotropes. Enter the **Test Date** of when the cardiac index value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

Pulmonary capillary wedge pressure: Enter the candidate's pulmonary capillary wedge pressure in mmHg. The entry must fall between 16 and 100 mmHg. Enter the **Test Date** of when the PCWP value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

Systolic blood pressure: Enter the candidate's systolic blood pressure in mmHg. The entry must fall between 50 and 89 mmHg. Enter the **Test Date** of when the systolic blood pressure was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

Hemodynamic measurements were not obtained. However, within 24 hours prior to IABP support. Enter a qualifying value for at least one of the following:

Date of administration of CPR: Enter the date of administration of CPR. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. Enter the time that CPR was administered. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Systolic blood pressure: Enter the candidate's systolic blood pressure in mmHg. The entry must fall between 50 and 69 mmHg. Enter the **Test Date** of when the systolic blood pressure was obtained. The date must be in the

following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Arterial lactate: Enter the candidate's arterial lactate in mmol/L. The entry must fall between greater than 4 and 50 mmol/L. Enter the **Test Date** of when the arterial lactate value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time should be in military format.

Aspartate transaminase: Enter the candidate's aspartate transaminase in U/L. The entry must fall between 1001 and 40000 U/L. Enter the **Test Date** of when the aspartate transaminase value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Alanine transaminase: Enter the candidate's alanine transaminase in U/L. The entry must fall between 1001 and 40000 U/L. Enter the **Test Date** of when the alanine transaminase value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

6. Ventricular tachycardia (VT) or ventricular fibrillation (VF)

Candidate is admitted to the transplant center that registered the candidate on Waitlist[SM] and is not considered a candidate for other treatment alternatives, such as ablation, by an electrophysiologist, and is experiencing recurrent or sustained VT or VF with at least three episodes separated by at least one hour within a period of 14 days. The VT or VF must have occurred in the setting of normal serum magnesium and potassium levels and required electrical cardioversion despite receiving antiarrhythmic therapies. ***Note:*** Anti-tachycardia pacing (ATP) qualifies as electrical cardioversion, in a hospitalized candidate experiencing VT on anti-arrhythmic medication.

7. Exception for status 2

Candidate does not meet any of the criteria above but is admitted to the transplant hospital that registered the candidate on the waiting list and has an urgency and potential for benefit comparable to that of other candidates at this status. A clinical narrative must be provided to support the candidate's eligibility at this status.

A transplant program may assign a candidate who does not meet any of the above status 2 criteria to status 2 by requesting an exception. The candidate must be admitted to the transplant hospital that registered the candidate on the waiting list, and the program must explain why it considers the candidate to have an urgency and potential for benefit comparable to other status 2 candidates using acceptable medical criteria. The review board will retrospectively review exception requests. If the review board denies an exception request, then within one day of receiving notification of the denial, the candidate's transplant program must either appeal to the review board or assign the candidate to the status for which the candidate qualifies.

Clinical Narrative: Enter a clinical narrative which supports the eligibility of the candidate for an exceptional case. ***Note:*** A maximum of 5000 characters is accepted.

This exception request is specifically related to a device recall: Check the checkbox if this exception request is specifically related to a device recall.

Clinical Narrative: Provide a clinical narrative to support the candidate's eligibility at this status.

Justification Form Status 3

Is the candidate currently admitted to the listing transplant hospital?: If the candidate is currently admitted to the listing transplant hospital, select **Yes**. If not, select **No**. This is a **required** field.

Report the device that qualifies the candidate for the medical urgency status as the primary device. One additional support device can be reported as the secondary device. If the medical urgency status requires the candidate to be on a BiVAD, then the two VAD devices must be reported separately in the primary device and secondary device fields.

Primary device: Select the candidate's primary device type from the drop-down list of options.

TAH
IABP
VA ECMO
Percutaneous Device
Dischargeable VAD
Non-Dischargeable VAD

Device brand: If non-dischargeable VAD is selected, choose the brand of the device from the drop-down list of options. If you select **Other, Specify** enter the device brand in the **Other specify** field.

Abiomed BVS 5000
Biomedicus
Medos
Thoratec IVAD
Toyobo
Abiomed AB5000
Berlin Heat EXCOR
CentriMag (Thoratec/Levitronix)
Maquet Josta Rotaflow
Terumo DuraHeart
Thoratec PVAD
Ventracor VentrAssist
PediMag (Thoratec/Levitronix)
Other Specify

Device brand: If dischargeable VAD is selected, choose the brand of the device from the drop-down list of options. If you select **Other, Specify** enter the device brand in the **Other specify** field.

HeartMate II
Heartsaver VAD
Jarvik 2000
Evaheart
Heartware HVAD
Worldheart Levacor

HeartMate III
ReliantHeartAssist 5
ReliantHeart aVAD
Other Specify

Date of implant/initiation: Enter the date the device was implanted/Date of initiation. Date of implant/Date of initiation cannot exceed the current date. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

Time of implant/initiation: Enter the time of implant/time of initiation. D Device support begins when the procedure begins to insert or implant the device. The intent of this field is to validate timeframe requirements in policy for qualifying criteria (evidence, events, or measurements) that must occur prior to implant or initiation of device support. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Enter the earliest of the following: documented procedure start time, operation start time, surgery start time, or incision time.

Defining support as the procedure start time provides the most consistent and largest acceptable time period for candidates.

Suggested data sources include: anesthesia record, operative report, or circulation record/OR nurses record.

Ventricle support: If applicable, select the type of ventricle support from the list of options.

Left
Right
Single

Secondary device: Select the candidate's primary device type from the list of options.

IABP
VA ECMO
Percutaneous Device
Dischargeable VAD
Non-Dischargeable VAD

Date of implant/initiation: Enter the date the device was implanted/date of initiation. Date of implant/date of initiation cannot exceed the current date. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

Ventricle support: If applicable, select the appropriate ventricle support from the list of options.

Left
Right

To qualify for status 3, the candidate must meet one of the following criteria.

1. **Dischargeable left ventricular assist device (LVAD) for discretionary 30 days**
   Candidate is supported by a dischargeable LVAD. The 30 days do not have to be consecutive. If the candidate undergoes a procedure to receive another replacement dischargeable LVAD, then the candidate qualifies for a new term of 30 days. When a candidate receives a replacement device, the 30 day period begins again, and the candidate cannot use any time remaining from the previous period.
2. **Multiple inotropes or a single high dose inotrope and hemodynamic monitoring**
   Candidate is admitted to the transplant hospital that registered the candidate on the waiting list. Within 7 days prior to inotrope administration or while on inotropes, all of the following are true.

A. Select one of the following:

- Candidate has an invasive pulmonary artery catheter
- Candidate has daily hemodynamic monitoring to measure cardiac output and left ventricular filling pressures

B. Candidate is supported by either:

- A continuous infusion of at least one high dose intravenous inotrope:
  - Dobutamine greater than or equal to 7.5 mcg/kg/min
  - Milrinone greater than or equal to 0.50 mcg/kg/min
  - Epinephrine greater than or equal to 0.02 mcg/kg/min
- A continuous infusion of at least two intravenous inotropes:
  - Dobutamine greater than or equal to 3mcg/kg/min
  - Milrinone greater than or equal to 0.25 mcg/kg/min
  - Epinephrine greater than or equal to 0.01 mcg/kg/min
  - Dopamine greater than or equal to 3 mcg/kg/min

C. The candidate is in cardiogenic shock as evidenced by all the following values obtained within one 24 hour period

- Cardiac index was:
  - Less than 1.8 L/min/m^2 if the candidate was not on inotropic or mechanical support within 7 days prior to inotrope administration or
  - Less than 2.2 L/min/m^2 if the candidate was on inotropic or mechanical support
- Pulmonary capillary wedge pressure greater than 15 mmHg
- Systolic blood pressure less than 90 mmHg

Was the candidate on inotropic or mechanical support at the time cardiac index was obtained?: If the candidate was on inotropic or mechanical support at the time of cardiac arrest, select **Yes**. If not, select **No**. This is a **required** field.

Cardiac index: Enter the candidate's cardiac index in L/min/m^2. The entry must fall between 0 and 1.79 L/min/m^2 if the candidate was not on inotropic or mechanical support and must be less than 2.2 L/min/m^2 if the candidate was on inotropic or mechanical support. Enter the **Test Date** of when the cardiac index value was obtained. The date must be in the following

format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

Pulmonary capillary wedge pressure: Enter the candidate's pulmonary capillary wedge pressure in mmHg. The entry must fall between 16 and 100 mmHg. Enter the **Test Date** of when the PCWP value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

Systolic blood pressure: Enter the candidate's systolic blood pressure in mmHg. The entry must fall between 50 and 89 mmHg. Enter the **Test Date** of when the systolic blood pressure was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

3. **Mechanical circulatory support device (MCSD) with hemolysis**
   Candidate is supported by an MCSD that is not experiencing device malfunction, but is experiencing hemolysis, as evidenced by both of the following:
   - **A. Two separate samples collected within 48 hours of each other confirming markers of active hemolysis as evidenced by at least two of the following:**
     - Blood lactate dehydrogenase (LDH) at least 2.5 times the upper limit of normal at the laboratory reference range
     - Plasma free hemoglobin greater than 20 mg/dL
     - Hemoglobinuria
   - **B. Documentation is available of at least one attempt to treat the condition using an intravenous anticoagulant, intravenous anti-platelet agent, or thrombolytic, with persistent or recurrent hemolysis.**
4. **Mechanical circulatory support device (MCSD) with pump thrombosis**
   Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by MCSD, and the transplant program has identified a suspected pump thrombosis in either an implanted LVAD or a dischargeable paracorporeal device and both of the following criteria are met:
   The candidate has one of the following conditions:
   - **A.** Transient Ischemic Attack (TIA) lasting less than 24 hours or Reversible Ischemic Neurologic Deficit (RIND) lasting less than 72 hours (as observed by symptoms such as, but not limited to unilateral facial weakness, vision problems, and/or slurred speech),

Cerebrovascular Accident (CVA), or peripheral thromboembolic event in the absence of intracardiac thrombus or significant carotid artery disease

B. A condition that requires inotropic support and presence of leftsided heart failure not explained by structural heart disease such as Aortic Insufficiency (AI) as demonstrated by

- Pulmonary Capillary Wedge Pressure (PCWP) greater than 15, and
- Mean Arterial Pressure (MAP) less than 90

C. Abnormal pump parameters, such as significant and persistent increase in pump power and low flow despite good blood pressure control

D. Visually detected thrombus in a paracorporeal ventricular device (VAD)

AND The candidate is supported by one of the following treatments in the hospital:

- Intravenous anticoagulation (e.g., heparin)
- Intravenous thrombolytics (e.g., tPA)
- Intravenous antiplatelet therapy (e.g., eptifibatide or tirofiban)

5. Mechanical circulatory support device (MCSD) with right heart failure
Candidate is supported by an MCSD and has at least moderate right ventricular malfunction in the absence of the left ventricular assist device (LVAD) malfunction and meets the following qualifying requirements:

A. Has been treated with at least one of the following therapies for at least 14 consecutive days and requires ongoing treatment with at least one of the following therapies:

- **Dobutamine:** Enter the dosage of dobutamine in mcg/kg/min. The entry must fall between 5 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.
- **Dopamine:** Enter the dosage of dopamine in mcg/kg/min. The entry must fall between 4 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.
- **Epinephrine:** Enter the dosage of epinephrine in mcg/kg/min. The entry must fall between 0.05 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.
- **Milrinone:** Enter the dosage of milrinone in mcg/kg/min. The entry must fall between 0.35 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date

must be in the following format: MM/DD/YYYY. A calendar link is available.

- **Inhaled nitric oxide:** Select checkbox, if applicable. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.
- **Intravenous prostacyclin:** Select checkbox, if applicable. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

B. Within 7 days prior to initiation of any of the therapies above, all of the following are true within one 24 hour period:

- Pulmonary capillary wedge pressure less than 20 mmHg
- Central venous pressure greater than 18 mmHg

Pulmonary capillary wedge pressure: Enter the candidate's pulmonary capillary wedge pressure in mmHg. The entry must fall between 0 and 19 mmHg. Enter the **Test Date** of when the PCWP value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Central venous pressure: Enter the candidate's central venous pressure in mmHg. The entry must fall between 19 and 50 mmHg. Enter the **Test Date** of when the CVP value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

6. Mechanical circulatory support device (MCSD) with device infection
Candidate is supported by an MCSD, is experiencing a pump-related local or systemic infection and has one of the following symptoms or continues to require IV antibiotics:

A. Erythema and pain along the driveline with either leukocytosis or a 50 percent increase in white blood cell count from the last recorded white blood cell count, and either:

- Positive bacterial or fungal cultures from the driveline exit site within the last 14 days
- A culture positive fluid collection between the exit site and the device

B. Debridement of the driveline with positive cultures from sites between the exit site and the device requiring IV antibiotics

C. Recurrent debridement

D. Positive culture of material from the pump pocket of an implanted device

E. Bacteremia treated with antibiotics

F. Recurrent bacteremia that recurs from the same organism within four weeks following antibiotic treatment to which the bacteria is susceptible

7. **Mechanical circulatory support device (MCSD) with mucosal bleeding**
Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and meets all of the following qualifying requirements:

   A. Is supported by an MCSD

   B. Has been hospitalized for mucosal bleeding at least two times within the past six months, excluding the candidate's hospitalization for implantation of the MCSD

   C. The candidate has received blood transfusions of at least two units of packed red blood cells per hospitalization during at least two hospitalizations for mucosal bleeding

   D. The candidate's international normalized ratio (INR) was less than 3.0 at the time of at least one of the bleeds

   E. The candidate's hematocrit upon admission is less than or equal to 0.20 or decreased by 20 percent or more relative to the last measured value at any time during the bleeding episode

   Number of hospitalizations for mucosal bleeding within the past six months: Select **2** or **3 or more**.
   Note: Hospitalizations must exclude candidate's hospitalization for implantation of the MCSD.

8. **Mechanical circulatory support device (MCSD) with aortic insufficiency (AI)**
Candidate is supported by an MCSD and is not exhibiting evidence of device malfunction, but is experiencing AI and meets all of the following requirements:

   A. At least moderate AI by any imaging modality in the setting of the mean arterial pressure (MAP) less than or equal to 80 mmHg

   B. Pulmonary capillary wedge pressure greater than 20 mmHg

   C. New York Heart Association (NYHA) Class III-IV symptoms

9. **Veno-arterial extracorporeal membrane oxygenation (VA ECMO) after 7 days**
Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by VA ECMO, and the transplant hospital has already assigned the candidate to status 1 under the VA ECMO criteria for 7 days.
Note: The system will not allow this selection unless the prerequisites have been met.

10. **Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD) after 14 days**
Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by a non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD), and the transplant hospital has already assigned the candidate to status 2 under the non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD)criteria for 14 days.

Note: The system will not allow this selection unless the prerequisites have been met.

11. **Percutaneous endovascular circulatory support device after 14 days**
    Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by a percutaneous endovascular circulatory support device, and the transplant hospital has already assigned the candidate to status 2 under the percutaneous endovascular circulatory support device criteria for 14 days.
    Note: The system will not allow this selection unless the prerequisites have been met.
12. **Intra-aortic balloon pump after 14 days**
    Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by an intra-aortic balloon pump, and has already assigned the candidate to status 2 under the intra-aortic balloon pump criteria for 14 days.
    Note: The system will not allow this selection unless the prerequisites have been met.
13. **Mechanical Circulatory Support Device (MCSD) with life threatening ventricular arrhythmia after 7 days**
    Candidate is admitted to the transplant hospital that registered the candidate on the waitlist, has already been assigned to status 1 under Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia for 7 days criteria for 7 days, and is supported by:
    Select at least one of the following:
    - **A.** Placement of a biventricular mechanical circulatory support device for the treatment of sustained ventricular arrhythmias.
    - **B.** Receiving continuous intravenous antiarrhythmic therapy.
14. **Exception for status 3**
    Candidate does not meet any of the criteria above but is admitted to the transplant hospital that registered the candidate on the waiting list and has an urgency and potential for benefit comparable to that of other candidates at this status. A clinical narrative must be provided to support the candidate's eligibility at this status.
    A transplant program may assign a candidate who does not meet any of the above status 3 criteria to status 3 by requesting an exception. The candidate must be admitted to the transplant hospital that registered the candidate on the waiting list, and the program must explain why it considers the candidate to have an urgency and potential for benefit comparable to other status 3 candidates using acceptable medical criteria. The review board will retrospectively review exception requests. If the review board denies an exception request, then within one day of receiving notification of the denial, the candidate's transplant program must either appeal to the review board or assign the candidate to the status for which the candidate qualifies.

This exception request is specifically related to a device recall: Check the checkbox if this exception request is specifically related to a device recall.

Clinical Narrative: Enter a clinical narrative which supports the eligibility of the candidate for an exceptional case. ***Note:*** A maximum of 5000 characters is accepted.

Justification Form Status 4

Is the candidate currently admitted to the listing transplant hospital? If the candidate is currently admitted to the listing transplant hospital, select **Yes**. If not, select **No**. This is a **required** field.

Report the device that qualifies the candidate for the medical urgency status as the primary device. One additional support device can be reported as the secondary device. If the medical urgency status requires the candidate to be on a BiVAD, then the two VAD devices must be reported separately in the primary device and secondary device fields.

Primary device: Select the candidate's primary device type from the drop-down list of options.

TAH
IABP
VA ECMO
Percutaneous Device
Dischargeable VAD
Non-Dischargeable VAD

Device brand: If non-dischargeable VAD is selected, choose the brand of the device from the drop-down list of options. If you select **Other, Specify** enter the device brand in the **Other specify** field.

Abiomed BVS 5000
Biomedicus
Medos
Thoratec IVAD
Toyobo
Abiomed AB5000
Berlin Heat EXCOR
CentriMag (Thoratec/Levitronix)
Maquet Josta Rotaflow
Terumo DuraHeart
Thoratec PVAD
Ventracor VentrAssist
PediMag (Thoratec/Levitronix)
Other Specify

Device brand: If dischargeable VAD is selected, choose the brand of the device from the drop-down list of options. If you select **Other, Specify** enter the device brand in the **Other specify** field.

HeartMate II
Heartsaver VAD
Jarvik 2000
Evaheart
Heartware HVAD
Worldheart Levacor
HeartMate III
ReliantHeartAssist 5
ReliantHeart aVAD
Other Specify

Date of implant/initiation: Enter the date the device was implanted/date of initiation. Date of implant/date of initiation cannot exceed the current date. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

Time of implant/initiation: Enter the time of the implant/time of initiation. Device support begins when the procedure begins to insert or implant the device. The intent of this field is to validate timeframe requirements in policy for qualifying criteria (evidence, events, or measurements) that must occur prior to implant or initiation of device support. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Enter the earliest of the following: documented procedure start time, operation start time, surgery start time, or incision time.

Defining support as the procedure start time provides the most consistent and largest acceptable time period for candidates.

Suggested data sources include: anesthesia record, operative report, or circulation record/OR nurses record.

Ventricle support: If applicable, select the type of ventricle support from the list of options.

Left
Right
Single

Secondary device: Select the candidate's primary device type from the list of options.

IABP
VA ECMO
Percutaneous Device
Dischargeable VAD
Non-Dischargeable VAD

Date of implant/initiation: Enter the date the device was implanted/date of initiation. Date of implant/Date of initiation cannot exceed the current date. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

Ventricle support: If applicable, select the appropriate ventricle support from the list of options.

Left
Right

To qualify for status 4, the candidate must meet one of the following criteria.

1. **Dischargeable left ventricular assist device (LVAD) without discretionary 30 days**

   Candidate is supported by a dischargeable LVAD.

2. **Inotropes without hemodynamic monitoring**

   Candidate is supported by a continuous infusion of a positive inotropic agent.

   A. Requires treatment with at least one of the following intravenous inotropes:

   Dobutamine: Enter the dosage of dobutamine in mcg/kg/min. The entry must fall between 3 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

   Milrinone: Enter the dosage of milrinone in mcg/kg/min. The entry must fall between 0.25 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

Epinephrine: Enter the dosage of epinephrine in mcg/kg/min. The entry must fall between 0.01 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

Dopamine: Enter the dosage of dopamine in mcg/kg/min. The entry must fall between 3 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

B. Meets the following qualifying requirements:

Cardiac index: Enter the candidate's cardiac index in L/min/m^2. The entry must fall between 0 and 2.19 within 7 days prior to inotropic administration or while on inotrope infusion. Enter the **Test Date** of when the cardiac index value were obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. ***Note:*** The test date for cardiac index must be within 7 days prior to, or anytime after, the date of initiation of one of the inotropes.

Pulmonary capillary wedge pressure: Enter the candidate's pulmonary capillary wedge pressure in mmHg. The entry must fall between 16 and 100. Enter the **Test Date** of when the PCWP value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

3. Congenital heart disease

Candidate is diagnosed with a hemodynamically significant congenital heart disease. Check all that apply.

Atrial Isomerism/Heterotaxy

Atrioventricular Septal Defect

Congenitally Corrected Transposition (L-TGA)

Double Outlet Right Ventricle

Ebstein's Anomaly

Hypoplastic Left Heart Syndrome

Other left Heart Valvar/Structural Hypoplasia

Pulmonary Atresia with Intact Ventricular Septum

Single Ventricle

Tetralogy of Fallot

Transposition of the Great Arteries

Truncus Arteriosus

Ventricular Septal Defect(s)

Other

4. Ischemic heart disease with intractable angina

Candidate is diagnosed with ischemic heart disease and has intractable angina with all of the following:

- Coronary artery disease
- Canadian cardiovascular society grade IV angina pectoris that cannot be treated by a combination of medical therapy, and percutaneous or surgical revascularization
- Myocardial ischemia shown by imaging

5. Amyloidosis, or hypertrophic or restrictive cardiomyopathy

A. Candidate is diagnosed with at least one of the following:

- Amyloidosis
- Hypertrophic cardiomyopathy
- Restrictive cardiomyopathy

B. Candidate meets at least one of the following requirements:

Canadian Cardiovascular Society Grade IV angina pectoris that cannot be controlled by medical therapy

New York Heart Association (NYHA) Class III-IV symptoms with either:

- Cardiac index less than 2.2 L/min/m^2
- Left or right atrial pressure, left or right ventricular end-diastolic pressure, or pulmonary capillary wedge pressure greater than 20 mmHg

Ventricular tachycardia lasting at least 30 seconds

Ventricular fibrillation

Ventricular arrhythmia requiring electrical cardioversion

Sudden cardiac death

6. Retransplant

Candidate has had a previous heart transplant and there is evidence of International Society of Heart and Lung Transplantation (ISHLT) coronary allograft vasculopathy (CAV) grade 2-3, or New York Heart Association (NYHA) Class III-IV heart failure symptoms. ***Note:*** Previous heart transplants include non-US transplants.

7. Exception for status 4

Candidate does not meet any of the criteria above, but has an urgency and potential for benefit comparable to that of other candidates at this status. Provide a clinical narrative below to support the candidate's eligibility at this status.

A transplant program may assign a candidate who does not meet any of the above status 4 criteria to status 4 by requesting an exception. The program must explain why it considers the candidate to have an urgency and potential for benefit comparable to other status 4 candidates using acceptable medical criteria. The review board will retrospectively review exception requests. If the review board denies an exception request, then within one day of receiving notification of the denial, the candidate's transplant program must either appeal to the review board or assign the candidate to the status for which the candidate qualifies.

Clinical Narrative: Enter a clinical narrative which supports the eligibility of the candidate for an exceptional case. ***Note:*** A maximum of 5000 characters is accepted.

Verify ABO

Select the candidate's ABO. Policy **requires** at least two (2) separate blood typings prior to listing. Policy also **requires** you to review all known available blood type source documents to verify the candidate's blood type.