At-a-Glance

- **Proposal to Clarify Adult Heart Status 1A Exception Language to Enable Consistent Interpretation of Policy and Reflect Current Programming in UNet^{SM}**

- **Affected Policy:** 3.7.3 Adult Candidate Status

- **Thoracic Organ Transplantation Committee**

- In order to reduce confusion about candidate eligibility, this proposal clarifies language about Status 1A requirements in thoracic Policy 3.7.3 (Adult Candidate Status).

  The revised Status 1A-exception language clarifies that clinicians requesting Status 1A-exceptions may only do so for candidates who inpatients at their listing hospital.

  Revised language in criterion (b) clarifies that in UNet^{SM}, clinicians may write in a mechanical circulatory support device complication other than the examples included in policy, and that the OPTN contractor will process such an entry as a request for Status 1A-exception by criterion (b).

  Finally, revised language maintains that a request for Status 1A-excpetion by criterion (b) does not require that the candidate be an inpatient at his or her listing center.

  This proposal will not require programming in UNet^{SM}.

- **Affected Groups**
  Transplant Administrators
  Transplant Physicians and Surgeons
  Transplant Program Directors
  Organ Recipients
  Organ Candidates
  General Public

- **Number of Potential Candidates Affected**
  This policy proposal applies to all adult heart transplant candidates who could be listed as Status 1A-exception or as Status 1A-criterion-b-other.

- **Compliance with OPTN Strategic Goals and Final Rule**
  - Operational Effectiveness (Strategic Goal)
  - "§ 121.8 Allocation of organs. […] (a) Policy development. […] (6) Shall be reviewed periodically and revised as appropriate;" […]

Proposal to Clarify Adult Heart Status 1A Exception Language to Enable Consistent Interpretation of Policy and Reflect Current Programming in UNet[SM]

Affected Policy: 3.7.3 Adult Candidate Status

Thoracic Organ Transplantation Committee

Summary and Goals of the Proposal:

In order to reduce confusion about candidate eligibility, this proposal clarifies language about Status 1A-exception requirements in thoracic Policy 3.7.3 (Adult Candidate Status).

The revised Status 1A-exception language clarifies that clinicians requesting Status 1A-exceptions may only do so for candidates who are inpatients at their listing hospital.

Revised language in criterion (b) clarifies that in UNet[SM], clinicians may write in a mechanical circulatory support device complication other than the examples included in policy, and that the OPTN contractor will process such an entry as a request for Status 1A-exception by criterion (b).

Finally, revised language maintains that a request for Status 1A-exception by criterion (b) does not require that the candidate be an inpatient at his or her listing hospital.

This proposal will not require any programming in UNet[SM]. The clarifications to policy reflect the Thoracic Committee's intent for the exception policy languages, which is already programmed in UNet[SM]. UNet[SM]:

- Allows only inpatient candidates to qualify for the general Status 1A-exception;
- Allows a transplant program to enter an "other" mechanical circulatory support complication;
- Signals the OPTN contractor to prepare manually for distribution to the respective heart regional review board (RRB) a request for Status 1A-exception by criterion (b) due to an entry of an "other" complication; and,
- Allows a transplant center to request Status 1A-exception by criterion (b) for a candidate who may or may not be an inpatient at its listing center.

Background and Significance of the Proposal:

On November 14-15, 2002, the OPTN/UNOS Board of Directors approved the Thoracic Committee's request to remove the letter "e" that labeled the start of the language on general Status 1A-exception (see Appendix). As described in the Appendix, in 2002, the Thoracic Committee opined that transplant centers needed a method for requesting Status 1A exception for candidates who do not meet the criteria for Status 1A, but whose medical urgency warrant such listing. Although the 2002 report did not address a candidate's inpatient status related to Status 1A-exception listing, but as evidenced by programming in UNet[SM] (see "Supporting Evidence" section below), the Thoracic Committee in 2002 likely expected that candidates who do not meet criteria for Status 1A, but whose medical urgency for transplant indicated otherwise, would be admitted to the hospital and monitored closely by clinicians. This same rationale is supported by the present Thoracic Committee.

On November 4, 2009, the Thoracic Committee reviewed a case that involved an adult candidate in need of a heart and a lung. The candidate's transplant program had contacted the OPTN contractor to inquire whether this individual could receive a general Status 1A-exception classification. The transplant program could not complete the exception form in UNet^{SM}, because the candidate was not an inpatient. UNet^{SM} does not allow a center to request a general Status 1A-exception for a candidate if he or she is not an inpatient at the listing center. So, the transplant program asked UNOS staff how best to approach this case as it believed that the candidate was quite ill and befitting of the Status 1A-exception criterion.

The OPTN contractor suggested that the transplant program ask its RRB to conduct a prospective review of the candidate's qualification for the Status 1A-exception classification. Subsequently, the transplant program submitted its request, and the RRB determined that the candidate did indeed qualify for the general Status 1A-exception classification. Once the RRB rendered its decision, the OPTN contractor informed the transplant program of the judgment, but requested that the transplant program not act on this decision until the Thoracic Committee could review and vote on the case. (As it turned out, the case review and the Thoracic Committee meeting occurred within a few days of each other.)

On November 4, the Committee reviewed the general Status 1A-exception policy language and documents related to the aforementioned case. Some Thoracic Committee members found the presentation of the exception language in Policy 3.7.3 unclear on whether or not a candidate should be an inpatient at his or her listing center. The language as it currently stands could be interpreted to mean either that the candidate must be an inpatient or that the candidate may or may not be an inpatient. The Thoracic Committee discussed whether there are situations where candidates could be medically urgent, i.e., qualify for Status 1A-exception, but be outpatients.

Other members argued that a candidate with medical urgency similar to those who qualify for Status 1A by other criteria, and who is not an inpatient, must not receive the Status 1A-exception classification. Historically, the Thoracic Committee determined that inpatient status was required for the majority of criteria to meet the Status 1A classification; hence, the current UNet^{SM} programming. On November, 4, 2009, the Thoracic Committee opined that the way the language is currently written unclear. Thus, this policy modifies the exception language in Policy 3.7.3 to match the Thoracic Committee's judgment on the inpatient requirement for requesting the Status 1A-exception classification. The Thoracic Committee stated that the language should be modified to indicate quite clearly the beginning of the section on general Status 1A-exception.

Some Thoracic Committee members commented that the aforementioned transplant program followed a process as outlined by the OPTN contractor. Since the RRB approved the case, and if the Thoracic Committee was not meeting in the immediate future following that review, the candidate would have received the Status 1A-exception classification. And, the Thoracic Committee may not have received an opportunity to review the case until later. Also, as the candidate was in need of a heart and lung, the transplant program could have considered approaching the lung review board for a higher lung allocation score. After much discussion, a majority of the Thoracic Committee members voted in favor (15-supported; 2-opposed; 1-abstained) to do the following:

a) Deny the general Status 1A-exception for the candidate, i.e., not uphold the RRB's decision;
b) Suggest to the transplant center that it may wish to submit a higher lung allocation score request to the lung review board; and,

c) Revise current the Status 1A-exception language to clarify that candidates must be inpatients in these cases.

The current policy language has been in place since 2002. Therefore, in the interest of transparency, the Thoracic Committee decided that changes to the policy language – albeit changes that match current programming – would require public comment.

On September 2, 2010, the Thoracic Committee voted in favor of the revised policy language: (22-Supported; 0-Opposed; 0-Abstained). The revisions state that the transplant center can:

- Report an "other" mechanical circulatory support complication, which the OPTN contractor will process as a Status 1A-exception request; and
- Request a general Status 1A-exception only for candidates who are inpatients at the listing hospital.

The revisions also include:

- Labeling of Status 1A and 1B exception sections;
- Labeling of sections detailing submission of Status 1A and 1B justification forms;
- Formatting of text in the Status 1A and 1B sections of Policy 3.7.3; and,
- General edits.

Strengths and Intended Consequences:

The proposed modifications will align current programming in UNet^{SM} with the policy language, and enable uniform interpretation of the Status 1A exception policy language, i.e., a transplant center can only request a general Status 1A-exception in UNet^{SM} for a candidate who is an inpatient at his or her listing center. A transplant center can continue to request a Status 1A-exception by criterion (b) for a candidate who may or may not be an inpatient.

Supporting Evidence:

As discussed by the Thoracic Committee at its November, 2009 meeting, and illustrated in the images below, the OPTN contractor programmed UNet^{SM} to match the Thoracic Committee's decision (in 2002 and 2009) that a candidate classified as a general Status 1A-exception must be an inpatient at his or her listing center. Clinicians requesting a Status 1A-exception for candidates who had not been admitted to the listing center were unaware that those candidates were required to be inpatients at the time.

As shown in Figure 1, programming in UNet^{SM} allows a transplant program to enter an "other" complication; but, per policy, hospitalization is not required for a candidate to qualify as Status 1A-exception by criterion b.

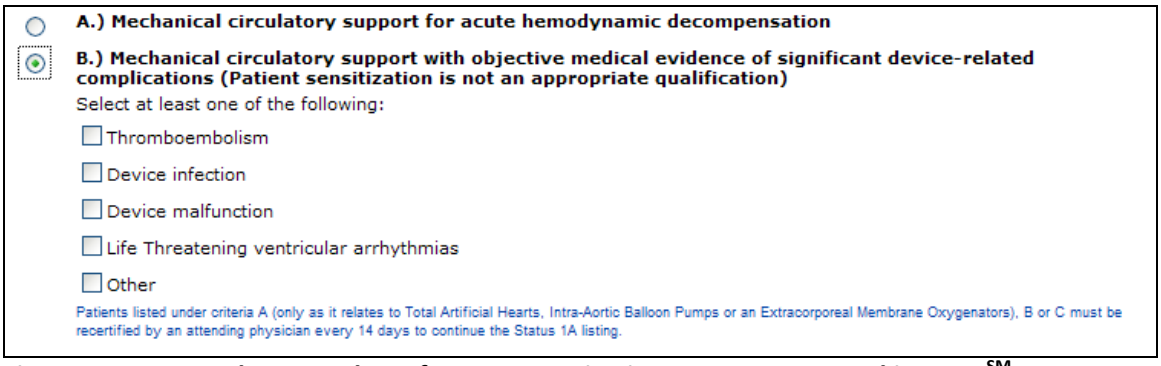


Figure 1: Truncated Screen Shot of Status 1A-Criterion B as Programmed in UNet[SM]

When a clinician checks the "other" box, as shown in Figure 2 below, the clinician must describe the relevant complication in a narrative section of the form. (This narrative must also include information about infection type and the antibiotic prescribed.) Once the clinician submits the Status 1A-criterion (b) justification form, the OPTN contractor staff submits the request, which now is a Status 1A-criterion (b)-exception, to the respective RRB for review. Again, the candidate need not be an inpatient to qualify for Status 1A-exception by criterion (b).

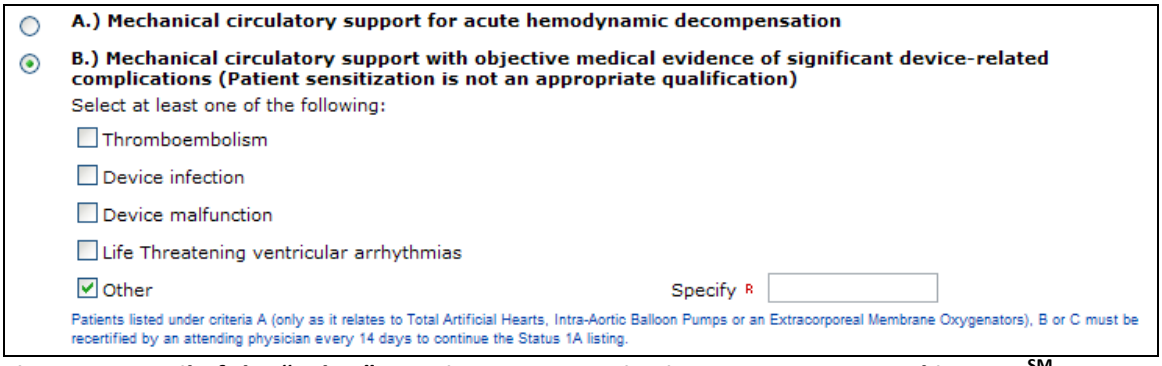
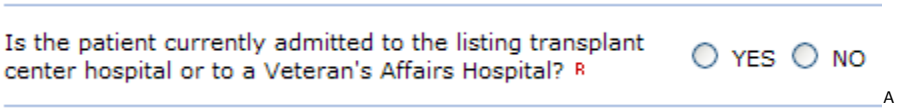


Figure 2: Detail of the "Other" Item in Status 1A Criterion-B as Programmed in UNet[SM]

Unlike the policy for mechanical circulatory support complication, candidates must be inpatients at their listing centers to qualify for Status 1A-exception. As shown in Figure 3 below, the clinician must indicate whether the candidate is an inpatient at the listing center.



[A]

Figure 3: Question about Candidate's Hospitalization Status

If the clinician selects the general Status 1A-Exception pathway for his or her candidate, as shown in Figure 4, the clinician must do so only for a candidate who is an inpatient at the listing center.

[A] The veteran's affairs hospital must be an OPTN member or affiliated with the OPTN member.

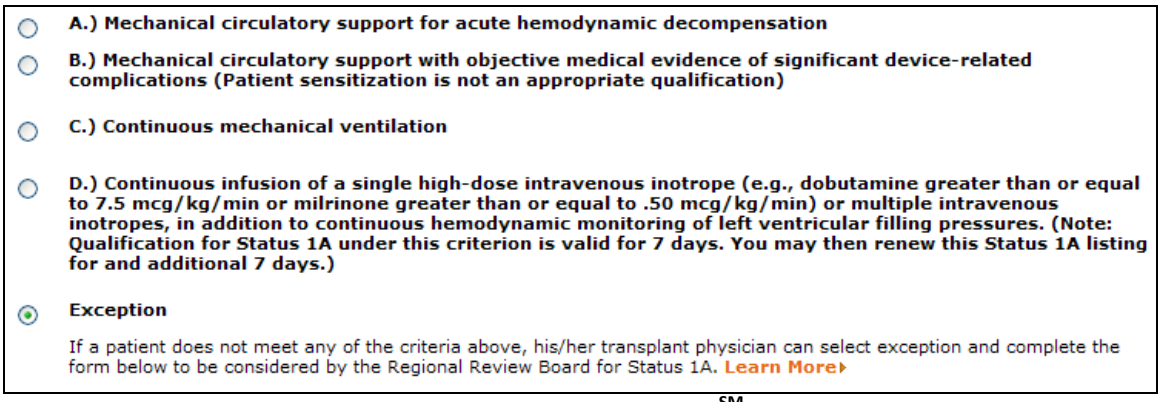
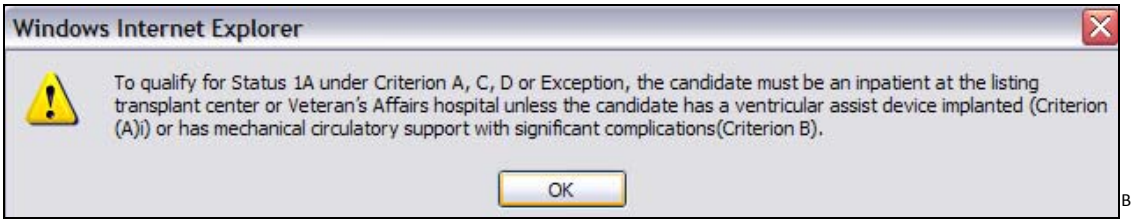


Figure 4: Status 1A Exception Option Programmed in UNet[SM]

If the answer to the question shown in Figure 3 above is "no," then the clinician will receive the error message shown in Figure 5, which states that the candidate must be an inpatient at the listing hospital.



[B]

Figure 5: Error Message Shown in UNet[SM] Candidate Is Not Admitted to the Listing Center

Images of UNet[SM] programming shown above and the ethos of the current Thoracic Committee support the policy language clarifications proposed here.

Adherence to the OPTN Strategic Plan and Final Rule:

The "Operational Effectiveness" construct in the OPTN Strategic Plan supports this proposal. This plan states the following: "The OPTN will identify process and system improvements that best support critical network functions, and work to disseminate them to all members who could benefit."

Clarifying policy to match the intent of the Thoracic Committee and how UNet[SM] currently functions will eliminate varying interpretations of the Status 1A-exception policy with respect to hospitalization, and promote consistent application of the Status 1A-exception policy.

The following construct in the OPTN Final Rule supports this proposal.

> […]
> "121.8 Allocation of organs.
> (a) Policy development. […]
> (6) Shall be reviewed periodically and revised as appropriate;"
> […]

[B] The Veteran's Affairs hospital must be an OPTN member or affiliated with the OPTN member.

The Thoracic Committee's discussion of the Status 1A-exception language resulted in the need for this policy modification.

Plan for Evaluating the Proposed Policy:

The Thoracic Committee will continue to monitor the number of heart transplant candidates listed as Status 1A listings.

Additional Data Collection:

The proposed policy modification will not require data collection in UNet[SM].

Expected Implementation Plan:

UNOS will implement this policy 60 days after its approval by the Board of Directors, as the proposed changes do not require any programming in UNet[SM].

Communication and Education Plan:

Communication Activities			
Type of Communication	**Audiences**	**Deliver Method**	**Timeframe**
Policy Notice	• Transplant Administrators • Transplant Physicians/Surgeons • Transplant Program Directors • Organ Recipients • Organ Candidates • General Public	Email	Submitted 30 days after approval by the Board of Directors

Monitoring and Evaluation:

Site surveyors will continue to review justification forms during site surveys. This proposal will not alter the manual process of the heart review board staff.

Policy Proposal:

3.7.3 Adult Candidate Status. Each candidate awaiting heart transplantation is assigned a status code which corresponds to how medically urgent it is that the candidate receive a transplant. Medical urgency is assigned to a heart transplant candidate who is greater than or equal to 18 years of age at the time of listing as follows:

Status	Definition
1A	A candidate listed as Status 1A is admitted to the listing transplant center hospital (with the exception for 1A (a)(i), and 1A (b) candidates) and has at least one of the following devices or therapies in place:

(a) Mechanical circulatory support for acute hemodynamic decompensation that includes at least one of the following:

(i) left and/or right ventricular assist device implanted Candidates listed under this criterion, may be listed for 30 days at any point after being implanted as Status 1A once the treating physician determines that they are clinically stable. Admittance to the listing transplant center hospital is not required.

(ii) total artificial heart;

(iii) intra-aortic balloon pump; or

(iv) extracorporeal membrane oxygenator (ECMO).

Qualification for Status 1A under criterion 1A(a)(ii), (iii) or (iv) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

(b) Mechanical circulatory support with objective medical evidence of significant device-related complications, such as thromboembolism, device infection, mechanical failure ~~and/~~or life-threatening ventricular arrhythmias. A transplant center can report a complication not listed here. The report of an "other" complication will result in a review by the respective heart regional review board. (Candidate sensitization is not an appropriate device-related complication for qualification as Status 1A under this criterion. The applicability of sensitization to thoracic organ allocation is specified by Policy 3.7.1.1 (Exception for Sensitized Candidates).)

¶

Admittance to the listing center transplant hospital is not required. Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

(c) Continuous Mechanical ventilation. Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

(d) Continuous infusion of a single high-dose intravenous inotrope ~~(e.g., dobutamine >/= 7.5 mcg/kg/min, or milrinone >/= .50 mcg/kg/min),~~ or multiple intravenous inotropes, in addition to continuous hemodynamic monitoring of left ventricular filling pressures~~;~~.

¶

Qualification for Status 1A under this criterion is valid for 7 days and may be renewed for an additional 7 days for each occurrence of a Status 1A listing under this criterion for the same candidate. The OPTN contractor shall maintain in the heart status justification form in UNet^{SM} a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.

Status 1A-Exception

A candidate who does not meet ~~the~~ criteria (a), (b), (c), or (d)~~for Status 1A~~ may nevertheless be ~~assigned to such~~ classified as ~~s~~Status 1A upon application by his~~/~~ or her transplant physician~~(s)~~ and justification to the applicable Regional Review Board that the candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit comparable to that of other

candidates in this status as defined above. The justification must be for a candidate admitted to his or her listing transplant center hospital and must include a rationale for incorporating the exceptional case as part of the status criteria. The justification must be reviewed and approved by the Regional Review Board. Timing of the review of these cases, whether prospective or retrospective, will be left to the discretion of each Regional Review Board. A report of the decision of the Regional Review Board and the basis for it shall be forwarded ~~to~~ for review by the Thoracic Organ Transplantation Committee to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria. A candidate's listing under this exceptional provision is valid for 14 days.

Any further extension of the Status 1A listing under this criterion requires prospective review and approval by a majority of the Regional Review Board Members. If Regional Review Board approval is not given, the candidate's transplant physician may list the candidate as Status 1A, subject to automatic referral to the Thoracic Organ Transplantation Committee.

Submission of Status 1A Justification Form

~~For all adult candidates listed as Status 1A, a~~A completed Heart Status 1A Justification Form must be ~~received by~~ submitted to ~~on~~ UNet^{SM} in order to list a candidate as Status 1A, or extend ~~their~~ his or her listing as Status 1A in accordance with the criteria listed above ~~in Policy 3.7.3~~. ~~Candidates listed as Status 1A will automatically revert back to Status 1B unless they are re-listed on UNet^{SM} by an attending physician within the time frames described in the definitions of status 1A(a) (d) above.~~ When a candidate's time at Status 1A expires, the candidate will automatically be classified as Status 1B unless the attending physician recertifies the candidate's qualification for a Status 1A criterion. Note: This automatic status downgrade will not require submission of a Status 1B Justification Form.

1B A candidate listed as Status 1B has at least one of the following devices or therapies in place:

(aa) left and/or right ventricular assist device implanted; or

(bb) continuous infusion of intravenous inotropes.

Status 1B-Exception

A candidate who does not meet the criteria for Status 1B may nevertheless be assigned to such status upon application by his~~/~~ or her transplant physician~~(s)~~ and justification to the applicable Regional Review Board that the candidate is considered, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other candidates in this status as defined above. The justification must include a rationale for incorporating the exceptional case as part of the status criteria. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria.

Submission of Status 1B Justification Form

~~For all adult candidates listed as Status 1B, a~~A completed Heart Status 1B Justification Form must be ~~received~~ submitted ~~on~~ to UNet^{SM} in order to list a candidate ~~within one working day of a candidate's listing~~ as Status 1B.

[There are no further changes to Policy 3.7.3.]