

OPTN Policy Notice

Clarification of HCC Downstaging Protocol for Standard Exceptions

Sponsoring Committee:	Liver and Intestinal Organ Transplantation Committee
Policy Affected:	9.5.I.iii Lesions Eligible for Downstaging Protocols
Executive Committee Approved:	August 1, 2019
Effective Date:	August 1, 2019

Problem Statement

On December 12, 2017, the OPTN Executive Committee approved a policy clarification that changed the criteria for lesions that meet the downstaging protocol for a standard hepatocellular carcinoma (HCC) exception.¹ The downstaging protocol creates an automatic exception pathway for HCC candidates who have lesions larger than T2 criteria but are sufficiently treated by local-regional therapy. The clarification introduced a minimum diameter threshold of three centimeters (cm) for each lesion when two or three lesions are present. However, the policy language also stated that the total diameter of all lesions must be less than or equal to eight centimeters. If a candidate has three lesions and all must be greater than three centimeters, the sum of the three lesions would always be at least nine centimeters, making the requirement invalid.

Summary of Changes

The proposal corrects the downstaging protocol so that the lesion size requirements can be appropriately applied to all eligible HCC candidates seeking a MELD or PELD exception. The policy language maintains the original intent of the Committee and matches established clinical criteria by only including lesions that are larger than T2 lesions in the downstaging protocol, but does so in a way that is applicable for the intended HCC candidates.

What Members Need to Do

The proposal does not require members to create any new implementations or submit additional data. The proposal does not change how members will be evaluated for compliance.

¹ OPTN/UNOS Policy Notice, Clarification to Alpha-Fetoprotein (AFP) Levels for Liver Candidate Eligibility for Standardized HCC Exceptions, available at https://optn.transplant.hrsa.gov/media/2345/executive_policynotice_afp_201712.pdf

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

1 **9.5.1.iii Lesions Eligible for Downstaging Protocols²**

2 Candidates are eligible for a standardized MELD or PELD exception if, before completing local-regional
3 therapy, they have lesions that meet one of the following criteria:

- 4 • One lesion greater than 5 cm and less than or equal to 8 cm
- 5 • Two or three lesions that meet all of the following:
 - 6 ○ at least one lesion greater than 3 cm
 - 7 ○ ~~each greater than 3 cm or lesion~~ less than or equal to 5 cm, and
 - 8 ○ a total diameter of all lesions less than or equal to 8 cm
- 9 • Four or five lesions each less than 3 cm, and a total diameter of all lesions less than or equal
10 to 8 cm

11
12 For candidates who meet the downstaging criteria above and then complete local-regional therapy,
13 their residual lesions must subsequently meet the requirements for T2 lesions according to Policy 9.5.1.ii:
14 Eligible Candidates Definition of T2 Lesions to be eligible for a standardized MELD or PELD exception.
15 Downstaging to meet eligibility requirements for T2 lesions must be demonstrated by CT or MRI
16 performed after local-regional therapy. Candidates with lesions that do not initially meet the
17 downstaging protocol inclusion criteria who are later downstaged and then meet eligibility for T2 lesions
18 are not automatically eligible for a standardized MELD or PELD exception and must be referred to the
19 NLRB for consideration of a MELD or PELD exception.

20
21

#

² Policy section numbers in policy notices may not match the numbering in the master Effective Policy document (available at www.optn.transplant.hrsa.gov/governance/policies) due to ongoing and overlapping implementation timelines. Please contact member.questions@unos.org with questions or for additional information.