

Colorectal Liver Metastases Transplant Exception Application Form

CRLM Patient Review Committee

CRLM Transplant Exception and Approvals Process

The Colorectal Liver Metastases (CRLM) Review Committee provides a multidisciplinary review of requests for approval of exception points for eligible non-resectable CRLM patients who are being listed for a deceased donor liver transplantation. Committee decisions are made based on the information submitted supporting the medical need for the patient listing and increased Na MELD score, as well as a case presentation. Committee members will review the material submitted and vote on the case presented at the monthly scheduled teleconference. The case presentation is led by a physician representative involved in the care of the candidate. The Most Responsible Physician (MRP) may participate in the review meeting for the purposes of presenting the case to the committee; however, they will not be permitted to vote. The only exception to this rule is if the MRP is an identified Review Committee member.

The case presentation provides the physician the opportunity to articulate their request and discuss the patient's case. The presentation will adhere to the application form framework. Please ensure the information in the application form is concise, complete and provides as much detail as needed. Incomplete application forms will result in a delay in the scheduling of the review for the patient's case. The Committee will attempt to review cases within one month of the completed submission of the application form.

Once the Committee has reached a decision, the physician who sent the request will be notified immediately via e-mail. Adjustments to the patient's Na MELD score will be made by TGLN when a patient application is approved by the Committee. Transplant programs will also be notified of the completed review and decision via email. Upon receipt of the decision, the transplant program will need to confirm receipt of the decision form, and verify that the patients listing information has been accurately captured in the Organ Allocation and Transplant System (OATS).

Guidelines for Review of Patients with Non-resectable CRLM

The following guidelines will be used by the Review Committee to help determine if Na MELD exception points should be granted for cases where patients are being considered for deceased donor liver transplantation for non-resectable CRLMs:

Inclusion Criteria

A patient must fulfill the following criteria to be considered for assignment of CRLM transplant exception points:

Inclusion Criteria
Patients' functional and cognitive capacity (i.e. physically and mentally fit for transplant) as per provincial guidelines
Eastern Cooperative Oncology Group (ECOG) score <2 at all times before transplantation*
Proven colon or rectal liver metastases, isolated to the liver
Bilobar and unresectable liver metastases (on consensus), with no major vascular invasion
Time from primary resection to transplant is ≥6 months, with 1 year most favourable
Undergone ≥6 months of systemic chemotherapy; 1 year of treatment most favourable (eg FOLFOX/ FOLFIRI +/-biologic), or agreeable to restart and be maintained on chemotherapy until dropout or transplant; patient's downstaging process will be centre-specific
Stability or regression of liver metastases ≥3 months before screening and until transplant
CEA levels stable or decreasing at all points before transplant
Previous lung resection (provincially established guidelines)
Negative serum pregnancy test (for women of child-bearing potential)
Use of adequate barrier birth control in both men and women during course of disease management
Willing and able to provide informed consent

*Some exceptions, at discretion of the transplant program/physician

Exclusion Criteria

Meeting any of the following criteria will preclude a patient from being assigned a CRLM transplant exception score:

Exclusion Criteria
Progression of liver metastases at any point before transplant
BRAF-V600E primary tumour
CEA levels >100 at final pretransplant assessment
Radiographic large vessel invasion
Previous lung resection (provincially established guidelines)
Previous/concurrent cancer diagnosis (provincially established guidelines)
Pulmonary insufficiency, history of cardiac disease, renal dysfunction (CrCl <50 mL/min)
Debilitating neuropathy (CTCAE >grade 2)
Uncontrolled infection, known history of HIV infection, or chronic hepatitis B and/or hepatitis C infection. However, diagnosis of chronic Hepatitis B or C, is NOT a contraindication for CRLM patients to be wait listed, if their treatment is well-managed (e.g. ongoing use of tenofovir disoproxil)
Substance abuse, psychological, or social conditions that interfere with participation
Known or suspected allergy to any agent given within the condition management
Pregnant or breastfeeding patients

*Some exceptions, at discretion of the transplant program/physician

The CRLM Transplant Exception Application Form can be completed in the following ways:

1. Electronically by entering information directly onto the form and emailing, OR
2. Manually by printing the form, entering the information, and scanning the document into email.

Submit a copy of the electronic or scanned PDF oh-tgln_specialcasecommittee@ontariohealth.ca and cc: Lucy Truong (lucy.truong@ontariohealth.ca).

CRLM Transplant Exception Application Form

CRLM Review Committee

General Information

Patient TGLN Number			
Date of Application Submission			
Name of Transplant Centre			
Responsible Physician Name			
Case Presenter for Review Meeting			
Urgent Decision Required (within 48 hours)			
Contact Email (decision will be sent to this address)			
Contact Phone Number			
Type of Exception Request (fill in all that apply):	30 Exception Points + 8 Points After 30 Days		
	Other Request (if answered 'No' above) (Please specify)		

Patient Information

Background	Age:		Gender:		ABO:		Height:		Weight:	
	Primary Liver Transplant				Date of Previous Transplant(s)					
	Has Living Donation Been Explored?				ECOG Score					
	Previous Lung Resection				Previous or Concurrent Cancer within 5 Years					
	Date of Previous Primary Resection				Date of System Chemotherapy Start					
	CEA Level and Trending Direction									

	Confirmed Colon or Rectal Metastases Isolated to Liver			
	Past Medical History			
Please complete the most recent results and test date				
Assessment		Date	Result	
	Albumin			
	Bilirubin			
	Creatinine			
	INR			
	Sodium (Na)			
	Current Na MELD			
	Please indicate the impression from any pertinent imaging studies, if applicable			
		Date	Result	
	CT Abdomen/Pelvis			
U/S				
Pathology Biopsy Report				
Other Imaging				

Other information of interest

	Number of hospitalizations in past 6 months	
	Number of days spent in critical care in past 6 months	
	Current Medications	

Sponsoring physician requesting medical priority due to the following key factors

Recommendation	<p>Clearly describe the rationale for requesting CRLM Patient Review Committee approval, and information on risk factors if denied</p>
-----------------------	---