Liver Transplantation for Metastatic Colorectal Cancer Protocol
University of Cincinnati

Inclusion Criteria
Patients can be considered for liver transplantation for metastatic colorectal cancer (mCRC) if the following criteria are met:

**Patient specific factors**
- Good performance status, ECOG 0 or 1
- Meet standard liver transplant inclusion criteria (cardiopulmonary, financial, psychosocial)

**Primary diagnosis**
- Histological diagnosis of colon/rectal adenocarcinoma
- BRAF and KRAS wild type, MSI stable
- At least one year from time of CRC diagnosis to time of listing for liver transplantation

**Treatment of primary CRC**
- Standard surgical resection procedure of primary tumor with adequate resection margins, including circumferential resection margins (CRM) of at least >= 2 mm for rectal primary (R0 resection)
- No evidence of local recurrence by colonoscopy within 12 months of listing

**Evaluation of extrahepatic disease**
- No signs of extrahepatic disease or local recurrence, based on CT/MRI (chest, abdomen and pelvis) and/or PET scan within one month of listing. (*Addition of PET scan at discretion of treating oncologist*).

**Evaluation of hepatic disease and prior systemic/liver directed treatment**
- Received first-line chemotherapy
- Relapse of liver metastases after second liver resection or liver metastases not eligible for curative resection
- No hepatic lesion should be greater than 10 cm before start of chemotherapy
- Must have stability or regression of disease with systemic and/or locoregional therapy

Exclusion Criteria
Patients will not be considered for liver transplantation for metastatic colorectal cancer (mCRC) if the following criteria are met:

**Patient specific factors**
- Weight loss >10% in last 6 months
- Other malignancies
- Known hypersensitivity to rapamycin
• Women who are pregnant or breast feeding
• Patients with hereditary CRC syndromes (FAP or Lynch Syndrome)

**Primary and mCRC specific factors**
• Palliative resection of primary CRC tumor
• Prior extra-hepatic disease
• Local relapse
• Patients who had not received standard pre-operative, peri-operative or post-operative treatment for primary CRC
• Rising CEA level without radiographic evidence of disease progression or new lesion

**Waitlist surveillance**
• CT/MRI (chest, abdomen and pelvis) and/or PET scan with CEA every three months from listing until transplant or one of the following occurs:
  (1) Progression of hepatic disease
  (2) Development of extrahepatic disease

**Transplant**
• Conventional liver transplant operation, with allocation based on candidates native MELD score.
• Only utilize extended criteria liver allografts (elderly (>70), steatotic (>30% macro), split livers, HBV/HCV NAT +, DCD, national shares, or regional open offers) if candidate native MELD < 15. Living donor allografts can be utilized once program established.

**Immunosuppression**
• Standard immunosuppression regimen with conversion to mTOR inhibitor from calcineurin inhibitor at one-month post-transplant.

**Post-transplant surveillance**
• CT/MRI (chest, abdomen and pelvis) with CEA every three months for the first 2 years then every 6 months for up to 10 years.
• Colonoscopy – if advanced adenoma (villous polyp, polyp > 1cm or high-grade dysplasia) on pre-transplant colonoscopy, repeat in one year from last colonoscopy, otherwise repeat in three years from last colonoscopy then every five years.