Hepatocellular Carcinoma

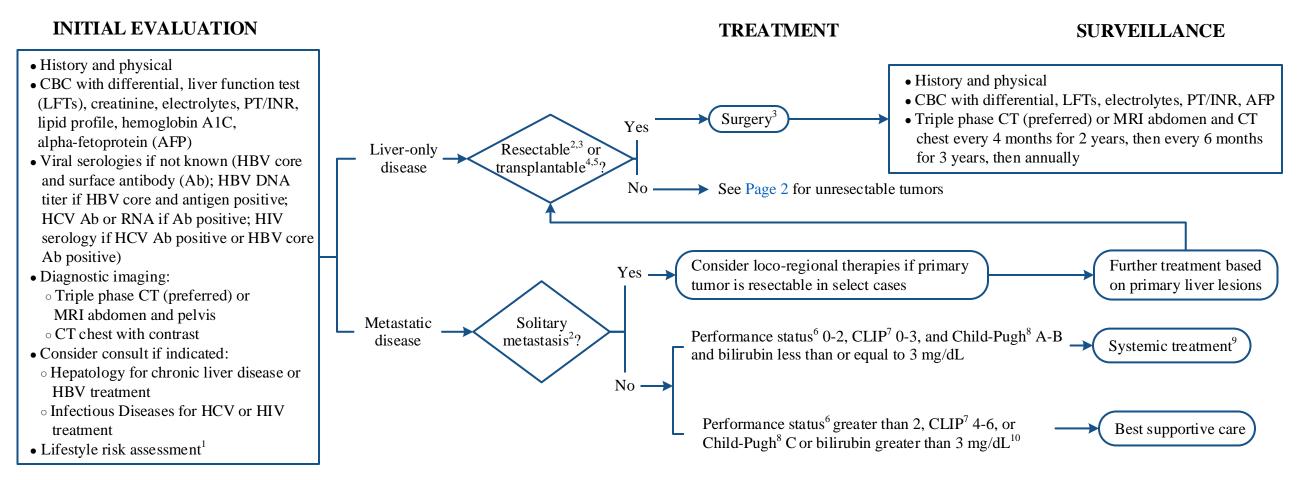
Cancer Center Making Cancer History*

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Note: Consider Clinical Trials as treatment options for eligible patients.



See Physical Activity, Nutrition, and Tobacco Cessation algorithms; ongoing reassessment of lifestyle risks should be a part of routine clinical practice ²Consider MD Anderson approved hepatocellular biomarkers

³Resection is considered for single or multiple tumors (up to 3 tumors). Macroscopic vascular invasion or portal hypertension is not a contraindication to resection. Major and minor resection based on:

• Minor resection: Child-Pugh A, normal liver function tests (bilirubin less than or equal 1.0 mg/dL), absence of ascites, and platelet count greater than 100 K/microliter

• Major resection: Same as minor resection plus either absence of portal hypertension or portal vein embolization (PVE) for a small future liver remnant

⁴ Milan criteria (criteria for eligibility for liver transplantation for patients with hepatocellular carcinoma and cirrhosis) the presence of a tumor 5 cm or less in diameter in patients with single hepatocellular carcinomas; or no more than three tumor nodules, each 3 cm or less in diameter; in patients with multiple tumors, and without macrovascular invasion per imaging studies

⁵ Loco-regional therapies including ablation, transcatheter arterial chemoembolization (TACE), and transarterial radioembolization (TARE) can be offered for bridging/down staging liver transplant patients

⁶ See Appendix A for Eastern Cooperative Oncology Group (ECOG) performance status ⁷See Appendix B for determination of Cancer of Liver Italian Program (CLIP) Investigators score ⁸See Appendix C for Child-Pugh scores ⁹See Appendix D for Systemic Therapy options ¹⁰ Treatment may be considered in select cases with bilirubin 2-3 mg/dL

Department of Clinical Effectiveness V7 Approved by Executive Committee of the Medical Staff 09/15/2020

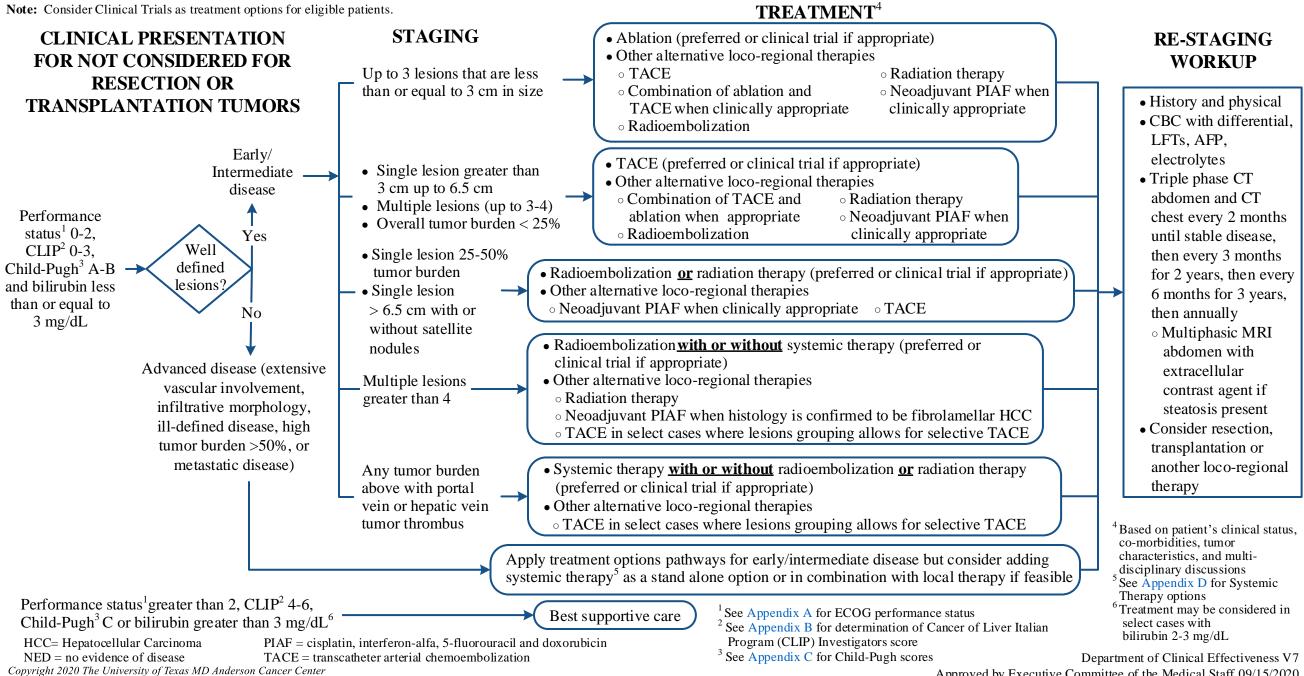
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APPENDIX A: Eastern Cooperative Oncology Group (ECOG) Performance Status Criteria

Grade	Scale
0	Fully active, able to carry on all pre-disease performance without restriction (Karnofsky 90-100)
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, <i>i.e.</i> , light housework, office work (Karnofsky 70-80)
2	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours (Karnofsky 50-60)
3	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours (Karnofsky 30-40)
4	Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair (Karnofsky 10-20)
5	Dead

APPENDIX B: Cancer of Liver Italian Program (CLIP) Scoring System

Variables	0	1	2
Child-Pugh Class	А	В	С
Tumor morphology	Uninodular and extension less than or equal to 50%	Multinodular and extension less than or equal to 50%	Massive or greater than 50%
AFP	Less than 400 ng/dL	Greater than or equal to 400 ng/dL	
Portal vein thrombosis	No	Yes	

AFP = alpha fetoprotein



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APPENDIX C: Child-Pugh Scoring System

Chemical and Biochemical Parameters	Scores (Points) for Increasing Abnormality			
	1	2	3	
Encephalopathy*	None	Grade I - II	Grade III - IV	
Ascites	None	Slight	Moderate	
Albumin	Greater than 3.5 g/dL	2.8-3.5 g/dL	Less than 2.8 g/dL	
Prothrombin time prolonged	1-4 seconds	4 – 6 seconds	Greater than 6 seconds	
Bilirubin	1-2 mg/dL	2-3 mg/dL	Greater than 3 mg/dL	
For primary biliary cirrhosis	1 - 4 mg/dL	4-10 mg/dL	Greater than 10 mg/dL	

*Grades for encephalopathy:

Grade I: Altered mood/confusion Grade II: Inappropriate behavior, impending stupor, somnolence Grade III: Markedly confused, stuporous but arousable

Grade IV: Comatose/unresponsive

Score interpretation

Class A = 5 to 6 points Class B = 7 to 9 points Class C = 10 to 15 points



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APPENDIX D: Systemic Therapy¹

Frontline systemic therapy for patients with advanced HCC and Child-Pugh A	Dose and Schedule
Atezolizumab plus bevacizumab	Atezolizumab 1200 mg IV and bevacizumab 15 mg/kg IV every 3 weeks
Lenvatinib	12 mg PO daily for patients \geq 60 kg and 8 mg for patients $<$ 60 kg
Sorafenib (Child-Pugh A or B)	400 mg PO twice daily
Nivolumab (if patients ineligible or intolerant to other frontline medications, Child-Pugh A or B)	240 mg IV every 2 weeks or 480 mg IV every 4 weeks

Subsequent line systemic therapy for patients with advanced HCC and Child-Pugh A	Dose and Schedule
Cabozantinib (Cabometyx [®])	60 mg PO daily
Nivolumab (Child-Pugh A or B)	240 mg IV every 2 weeks or 480 mg IV every 4 weeks
Ipilimumab plus nivolumab	Ipilimumab 3 mg/kg IV and nivolumab 1 mg/kg IV every 3 weeks for 4 doses, followed by single-agent nivolumab 240 mg every 2 weeks or 480 mg every 4 weeks
Pembrolizumab	200 mg IV every 3 weeks or 400 mg IV every 6 weeks
Ramucirumab (if AFP \ge 400)	8 mg/kg IV every 2 weeks
Regorafenib	160 mg once a day for 21 days on and 7 days off of each 28-day cycle
Sorafenib (Child-Pugh A or B)	400 mg PO twice daily

AFP = alpha fetoprotein

¹MD Anderson will abide by FDA label for starting doses for eligible patients. In some case scenarios, where liver functions are borderline, our clinical discretion leads to starting with variables doses and schedules which is personalized in this setting



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Systemic Therapy

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MDAnderson Hepatocellular Carcinoma

Making Cancer History*

Disclaimer: This algorithm has been developed for MD Anderson using a multidisciplinary approach considering circumstances particular to MD Anderson's specific patient population, services and structure, and clinical information. This is not intended to replace the independent medical or professional judgment of physicians or other health care providers in the context of individual clinical circumstances to determine a patient's care. This algorithm should not be used to treat pregnant women.

DEVELOPMENT CREDITS

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