Society of Interventional Oncology

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NCCN Guidelines Panel: Hepatobiliary Cancer

We thank the panel for adopting the 2020 SIO Hepatobiliary Task Force recommendations.

On behalf of the Society of Interventional Oncology, we respectfully request the NCCN Guidelines Panel for Hepatobiliary Cancer review the enclosed recommendations:

HCC- E (1):

Specific change 2: Consider describing ablative radioembolization as an ablative modality, as is SBRT in plate HCC-F (1).

Rationale: Outcomes have been achieved with high dose radioembolization that are comparable to other ablative modalities (https://pubmed.ncbi.nlm.nih.gov/32749512/).

Specific change 3: Consider mentioning phase 2 randomized evidence in support of superior time to progression in favor of radioembolization over chemoembolization for the treatment of HCC in the TARE discussion (MS-24). (https://pubmed.ncbi.nlm.nih.gov/27575820/).

Rationale: Radioembolization may be associated with fewer treatments for patients with hepatocellular carcinoma unamenable to resection or thermal ablation when compared to chemoembolization.

Specific Change 4: Per the LEGACY study, consider mentioning in the TARE discussion (MS-24) that selective radioembolization can be safely performed with a median treated liver dose of 410.1 Gy when treating less than two hepatic segments in patients with Child Pugh A cirrhosis. The objective response rate in LEGACY was 88.3% (CI: 82.4-92.4) and a ≥ 6 month durability of response was exhibited in 62.2% (CI: 54.1-69.8) of patients. (https://pubmed.ncbi.nlm.nih.gov/33739462/)

Rationale: Ablative dose radioembolization administered to expendable volumes of liver is safe and effective.

INTRA-1:

Specific Change 5: Modification to panel INTRA-1 to include concurrent systemic therapy to arterial directed therapy. Per the MISPHEC open-label multicenter phase II trial, we support the addition of gemcitiabine and cisplatin to radioembolization for the first line treatment of unresectable intrahepatic cholangiocarcinoma in patients without underlying cirrhosis. This trial demonstrated a disease control rate of 98%, 93% response rate per Choi criteria (41% per RECIST), , a median progression free survival of

14 months and overall survival of 22 months. Additionally, there was conversion to resection in 22% of patients in whom a median survival was not met after a median of 46 months. (NCT01912053, published in JAMA Oncology, https://pubmed.ncbi.nlm.nih.gov/31670746/)

Rationale: Patients without cirrhosis can be safely treated with both radioembolization and standard of care systemic therapy for the first line treatment of unresectable intrahepatic cholangiocarcinoma with the potential for conversion to surgical resection.

Thank you for your consideration of these recommendations.

Sincerely,

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