### HCC-F, 1 of 2

**External request:** Submissions from Bristol-Myers Squibb Company (1/18/19 and 10/2/19) to consider adding nivolumab monotherapy as a first-line treatment option in patients with advanced hepatocellular carcinoma not amenable to curative resection.

Based on a review of data, the panel consensus supported the inclusion of nivolumab monotherapy as a first-line “useful in certain circumstances” treatment option for the following patients with hepatocellular carcinoma who are not eligible for tyrosine kinase inhibitors (TKIs) or other anti-angiogenic agents:
- have unresectable disease and are not a transplant candidate
- are inoperable by performance status or comorbidity, or have local disease or local disease with minimal extrahepatic disease only
- have metastatic disease or extensive liver tumor burden

This is a category 2B recommendation. (See submission for references)

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### HCC-F, 1 of 2

**Internal request:** Comment to reassess the inclusion of nivolumab as a subsequent line treatment option for patients with advanced HCC and progressive disease (Child-Pugh Class A or B7) who have not been previously treated with a checkpoint inhibitor.

Based on a review of data, the panel consensus supported the continued inclusion of nivolumab as a subsequent line treatment option for patients with advanced HCC and progressive disease who have not been previously treated with a checkpoint inhibitor.

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### BIL-C, 1 of 3

**Internal requests:**
- Comments to reassess the inclusion of the following regimens as neoadjuvant treatment options for patients with locoregionally advanced gallbladder cancer (big mass invading liver and/or nodal disease, including cystic duct node positive) or resectable disease with jaundice:
  - 5-fluorouracil + cisplatin
  - Capecitabine + cisplatin
  - Gemcitabine + oxaliplatin

Based on a review of data, the panel consensus was that all of these regimens have limited clinical use as neoadjuvant treatment options for patients with locoregionally advanced gallbladder cancer or resectable disease with jaundice, and the category for each of these regimens was changed from a category 2A to a category 2B recommendation.

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| Comment to include gemcitabine + cisplatin + albumin-bound paclitaxel as a neoadjuvant treatment option for patients with locoregionally advanced gallbladder cancer (big mass invading liver and/or nodal disease, including cystic duct node positive) or resectable disease with jaundice | Based on a review of data, the panel consensus supported the addition of gemcitabine + cisplatin + albumin-bound paclitaxel as a neoadjuvant treatment option for patients with locoregionally advanced gallbladder cancer or resectable disease with jaundice.  
- This is a category 2B recommendation. | 9 | 5 | 4 | 10 |
| Comments to reassess the inclusion of the following regimens as adjuvant treatment options for patients with resected biliary tract cancers:  
- 5-fluorouracil + cisplatin  
- Capecitabine + cisplatin | Based on a review of data, the panel consensus was that both of these regimens have limited clinical use as adjuvant treatment options for patients with resected biliary tract cancers, and the category for both of these regimens was changed from a category 2A to a category 3 recommendation. | 6 | 9 | 3 | 10 |
| Comment to consider capecitabine as a category 1 preferred adjuvant treatment option for patients with resected biliary tract cancers, based on results of the phase III BILCAP trial. | Based on the review of the data in the noted reference, the panel consensus was that capecitabine is supported by high-level evidence and the category was changed from a category 2A to a category 1 preferred recommendation.  
| **BIL-C, 2 of 3**  
Internal requests:  
- Comment to consider the inclusion of gemcitabine + cisplatin + albumin-bound paclitaxel as a primary treatment option for patients with unresectable or metastatic biliary tract cancers. |  
- Based on the review of the data in the noted reference, the panel consensus supported the addition of gemcitabine + cisplatin + albumin-bound paclitaxel as an "other recommended" primary treatment option for patients with unresectable or metastatic biliary tract cancers.  
  ○ This is a category 2B recommendation.  
- Comment to consider the inclusion of FOLFOX as a preferred subsequent therapy option for patients with unresectable or metastatic biliary tract cancer with progressive disease.

- Comment to consider the inclusion of FOLFIRI as a subsequent-line treatment option for patients with unresectable or metastatic biliary tract cancer with progressive disease.

- Comment to consider the inclusion of regorafenib as a subsequent-line treatment option for patients with unresectable or metastatic biliary tract cancer with progressive disease.

External request:

- Submission from Bayer Health Care (12/19/18) to consider adding regorafenib as a single agent for patients with advanced metastatic biliary tract cancer.

- Based on the review of the data in the noted reference, the panel consensus supported the addition of FOLFOX as a subsequent therapy option for patients with biliary tract cancers and disease progression.
  - This is a category 2A preferred recommendation.

Lamarca A, Palmer DH, Wasan HS, et al. ABC-06 | A randomised phase III, multi-centre, open-label study of active symptom control (ASC) alone or ASC with oxaliplatin / 5-FU chemotherapy (ASC+mFOLFOX) for patients (pts) with locally advanced / metastatic biliary tract cancers (ABC) previously-treated with cisplatin/gemcitabine (CisGem) chemotherapy.

- Based on a review of the data, the panel consensus supported the addition of FOLFOX as an “other recommended” subsequent therapy option for patients with biliary tract cancers and disease progression.
  - This is a category 2B recommendation.

- Based on a review of the data in the noted reference, the panel consensus supported the addition of regorafenib as an “other recommended” subsequent therapy option for patients with biliary tract cancers and disease progression.
  - This is a category 2B recommendation.