

GALLBLADDER CARCINOMA AND INTRAHEPATIC CHOLANGIOCARCINOMA TREATMENT REGIMENS

Clinical Trials: The NCCN recommends cancer patient participation in clinical trials as the gold standard for treatment.

Cancer therapy selection, dosing, administration, and the management of related adverse events can be a complex process that should be handled by an experienced healthcare team. Clinicians must choose and verify treatment options based on the individual patient; drug dose modifications and supportive care interventions should be administered accordingly. The cancer treatment regimens below may include both U.S. Food and Drug Administration-approved and unapproved indications/regimens. These regimens are only provided to supplement the latest treatment strategies.

These Guidelines are a work in progress that may be refined as often as new significant data becomes available. The NCCN Guidelines® are a consensus statement of its authors regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult any NCCN Guidelines® is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment. The National Comprehensive Cancer Network makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.

Primary Treatment of Unresectable Disease^a

All recommendations are Category 2A unless otherwise indicated.

REGIMEN	DOSING
Gemcitabine + cisplatin (Category 1)²	Days 1 and 8: Cisplatin 25mg/m ² IV (1-hour infusion) followed by gemcitabine 1,000mg/m ² IV (0.5-hour infusion). Repeat every 21 days initially for 4 cycles then re-evaluate and continue for an additional 4 cycles if warranted.
Fluoropyridimine-based or gemcitabine-based chemotherapy regimen^{3b}	The collected clinical experience and a comprehensive meta-analysis imply that gemcitabine and gemcitabine-based platinum regimens are slightly advantageous compared with fluoropyridimine regimens.
Fluoropyridimine chemoradiation⁴	There are limited clinical trial data to define a standard regimen or definitive benefit.

Primary Treatment of Metastatic Disease¹

General Treatment Note: Order of the treatment options below does not indicate preference. The choice of treatment modalities may depend on extent/location of disease and institutional capabilities.¹

Gemcitabine + cisplatin²	Days 1 and 8: Cisplatin 25mg/m ² IV (1-hour infusion) followed by gemcitabine 1,000mg/m ² IV (0.5-hour infusion). Repeat every 21 days initially for 4 cycles then re-evaluate and continue for an additional 4 cycles if warranted.
Fluoropyridimine-based or gemcitabine-based chemotherapy regimen^{3b}	The collected clinical experience and a comprehensive meta-analysis imply that gemcitabine and gemcitabine-based platinum regimens are slightly advantageous compared with fluoropyridimine regimens.
Fluoropyridimine chemoradiation⁴	There are limited clinical trial data to define a standard regimen or definitive benefit.
Locoregional therapy (Category 2B)^{1c}	Locoregional therapy should be considered in those patients not candidates for surgical curative treatments, or as part of a strategy to bridge patients for other curative therapies. These are broadly categorized into ablation and arterially directed therapies. See the NCCN Clinical Practice Guidelines on Hepatobiliary Cancers for more detailed information.

^a General treatment note: clinical trial participation is encouraged first and foremost.¹

^b There are phase 2 trials that support the following combinations: gemcitabine/oxaliplatin, gemcitabine/capecitabine, capecitabine/cisplatin, capecitabine/oxaliplatin, 5-FU/oxaliplatin, 5-FU/cisplatin, and the single agents gemcitabine, capecitabine, and 5-FU; however, the recent phase 3 study showing longer survival with gemcitabine and cisplatin than with gemcitabine alone has set a new standard for this disease.

^c Locoregional therapy is for the primary treatment of unresectable and metastatic intrahepatic cholangiocarcinoma only.

References

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology™. Hepatobiliary Cancers. v 1.2016. Available at: http://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed June 7, 2016.
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3. Hezel AF, Zhu AX. Systemic therapy for biliary tract cancers. *Oncologist*. 2008;13:415-423.
4. Macdonald OK, Crane CH. Palliative and postoperative radiotherapy in biliary tract cancer. *Surg Oncol Clin N Am*. 2002 Oct;11(4):941-954.

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