HEPATOCELLULAR CARCINOMA 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.

Unresectable Hepatocellular Carcinoma (not candidates for transplant)[1]

REGIMEN	DOSING
Sorafenib[2,3]	Sorafenib 400mg orally twice daily without food for Child-Pugh Class A (category 1) or Child-Pugh Class B.
Chemotherapy and radiotherapy	Only in the context of a clinical trial.*

Advanced Metastatic Hepatocellular Carcinoma[1]

Sorafenib	Sorafenib 400mg orally twice daily without food.

General treatment notes:

- Sorafenib is the standard of care for unresectable and metastatic hepatocellular carcinoma in patients with Child-Pugh score A (NCCN category 1) recommendation or Child-Pugh score B.[1-2]
- Treatment should continue until the patient is no longer clinically benefiting from therapy or until unacceptable toxicity occurs.
- Treatment interruption and/or dose reduction may be needed to manage suspected adverse drug reactions.
- Available safety data are limited for Child-Pugh Class B or Class C patients and dosing is uncertain.
- Use with extreme caution in patients with elevated bilirubin levels. The impact of sorafenib on patients potentially eligible for transplant is unknown.[4]

* There are limited data supporting the use of systemic chemotherapy and/or radiotherapy, and their use in the context of a clinical trial is preferred.

References

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology™. Hepatobiliary. v 2.2014. Available at: http://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed April 5, 2014.
2. Cheng AL, Kang YK, Chen Z, et al. Efficacy and safety of sorafenib in patients in the Asia-Pacific region with advanced hepatocellular carcinoma: a phase III randomised, double-blind, placebo-controlled trial. *Lancet Oncol*. 2009;10:25–34.
3. Nexavar [prescribing information]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; 2013.
4. Miller AA, Murry DJ, Owzar K, et al. Phase I and pharmacokinetic study of sorafenib in patients with hepatic or renal dysfunction: CALGB 60301. *J Clin Oncol.* 2009;27:1800-1805.

(Revised 4/2014)