

## ANAL CARCINOMA TREATMENT REGIMENS

**Clinical Trials:** The National Comprehensive Cancer Network (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<sup>®</sup> 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<sup>®</sup> is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment. The NCCN 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.

### Localized Cancer<sup>1</sup>

**Note:** All recommendations are category 2A unless otherwise indicated.

| REGIMEN  | DOSING   |
|--|--|
| <b>5-fluorouracil (5-FU) + mitomycin + radiotherapy<sup>2,3a</sup></b> | <p><b>Days 1–4 and 29–32:</b> 5-FU 1,000mg/m<sup>2</sup>/day continuous infusion</p> <p><b>Days 1 and 29:</b> Mitomycin 10mg/m<sup>2</sup> IV bolus (maximum 20mg per course), <b>plus</b> Concurrent radiotherapy.</p> <p><b>OR</b></p> <p><b>Days 1–4 and 29–32:</b> 5-FU 1,000mg/m<sup>2</sup>/day continuous IV infusion</p> <p><b>Day 1:</b> Mitomycin 12mg/m<sup>2</sup> (capped at 20mg), <b>plus</b> Concurrent radiotherapy.</p>  |
| <b>Capecitabine + mitomycin + radiotherapy<sup>4,5</sup></b>           | <p>Capecitabine 825mg/m<sup>2</sup> orally twice daily, Monday–Friday, on each day that radiotherapy is given, throughout the duration of radiotherapy (typically 28 treatment days), <b>plus</b></p> <p><b>Days 1 and 29:</b> Mitomycin 10mg/m<sup>2</sup> IV bolus, <b>plus</b> Concurrent radiotherapy.</p> <p><b>OR</b></p> <p><b>Days 1–5:</b> Capecitabine 825mg/m<sup>2</sup> orally twice daily weekly for 6 weeks, <b>plus</b></p> <p><b>Day 1:</b> Mitomycin 12mg/m<sup>2</sup> IV bolus, <b>plus</b> Concurrent radiotherapy.</p> |
| <b>5-FU + cisplatin<sup>6</sup> (category 2B)</b>                      | <p><b>Days 1–5:</b> 5-FU 1,000mg/m<sup>2</sup>/day continuous IV infusion</p> <p><b>Day 2:</b> Cisplatin 100mg/m<sup>2</sup> IV</p> <p>Repeat cycle every 4 weeks, <b>plus</b></p> <p>Concurrent radiotherapy.</p>   |

### Metastatic Cancer<sup>1</sup>

|                                     |  |
|-------------------------------------|--|
| <b>5-FU + cisplatin<sup>6</sup></b> | <p><b>Days 1–5:</b> 5-FU 1,000mg/m<sup>2</sup>/day continuous infusion</p> <p><b>Day 2:</b> Cisplatin 100mg/m<sup>2</sup> IV over 1 hour.</p> <p>Repeat cycle every 4 weeks.</p> |
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**NOTE:** Patients with anal cancer as the first manifestation of HIV may be treated with the same regimen as non-HIV patients. Patients with active HIV/AIDS-related complications or a history of complications (eg, malignancies, opportunistic infections) may not tolerate full-dose therapy or may not tolerate mitomycin and require dosage adjustment or treatment without mitomycin.

<sup>a</sup> For radiotherapy dosing, please see NCCN Anal Carcinoma Guidelines v 2.2017 “Principles of radiation therapy.”

### References

- Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology™. Anal Carcinoma. v 2.2017. Available at: [http://www.nccn.org/professionals/physician\\_gls/pdf/anal.pdf](http://www.nccn.org/professionals/physician_gls/pdf/anal.pdf). Accessed June 1, 2017.
- Ajani JA, Winter KA, Gunderson LL, et al. Fluorouracil, mitomycin, and radiotherapy vs fluorouracil, cisplatin, and radiotherapy for carcinoma of the anal canal: a randomized controlled trial. *JAMA*. 2008;299(16):1914–1921.
- James RD, Glynne-Jones R, Meadows HM, et al. Mitomycin or cisplatin chemoradiation with or without maintenance chemotherapy for treatment of squamous-cell carcinoma of the anus (ACT II): a randomised, phase 3, open-label, 2×2 factorial trial. *Lancet Oncol*. 2013;14(6):516–524.
- Goodman KA, Rothenstein D, Cambridge L, et al. Capecitabine plus mitomycin in patients undergoing definitive chemoradiation for anal squamous cell carcinoma. *Int J Radiat Oncol Biol Phys*. 2014;90(1):S32–S33.
- Thind G, Johal B, Follwell M, Kennecke HF. Chemoradiation with capecitabine and mitomycin-C for stage I-III anal squamous cell carcinoma. *Radiation Oncology*. 2014;9:124.
- Favre C, Rougier P, Ducreux M, et al. 5-fluorouracil and cisplatin combination chemotherapy for metastatic squamous-cell anal cancer. *Bull Cancer*. 1999;86(10):861–865.

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