

HEAD AND NECK CANCER TREATMENT REGIMENS (Part 1 of 5)

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.

Squamous Cell Cancers*

Primary Systemic Therapy + Concurrent Radiotherapy¹

REGIMEN	DOSING
Cisplatin (preferred)^{2,3}	Days 1, 22 and 43: Cisplatin 100mg/m ² IV + concurrent radiotherapy 2Gy/day to a total of 70Gy.
Cetuximab⁴	Day 1: Cetuximab 400mg/m ² loading dose over 2 hours, 1 week before radiotherapy, plus Day 7: Begin radiotherapy with 7 weekly infusions of cetuximab 250mg/m ² .
Carboplatin + infusional 5-FU^{5,6}	Days 1–4: 5-FU 600mg/m ² /day as continuous IV infusion + carboplatin 70mg/m ² /day IV bolus. Repeat every 3 weeks for 3 cycles (given concurrently with radiotherapy).
5-FU + hydroxyurea⁷	Day 1: Hydroxyurea 1,000mg PO every 12 hours (11 doses/cycle) and 5-FU 400mg/m ² /day continuous IV infusion, plus radiotherapy: 70Gy, delivered in 35 fractions; 1 fraction delivered daily Monday–Friday. Concurrent radiotherapy and chemotherapy every other week for total treatment duration of 13 weeks.
Cisplatin + paclitaxel⁷	Day 1: Paclitaxel 30mg/m ² IV (begin on Monday), plus Day 2: Cisplatin 20mg/m ² IV (every Tuesday). Repeat cycle every week for 7 cycles, plus radiotherapy: 70Gy, delivered in 35 fractions; 1 fraction delivered daily Monday–Friday.
Cisplatin + infusional 5-FU⁸	Day 1: Cisplatin 60mg/m ² over 15 minutes; plus Days 1–5: 5-FU 800mg/m ² by continuous infusion; plus Days 1–5: Radiotherapy: 2Gy repeated every other week for 7 cycles.
Carboplatin/paclitaxel⁹	Day 1: Paclitaxel 40–45mg/m ² /week and carboplatin 100mg/m ² /week; prior to radiotherapy: 70.2Gy at 1.8Gy/fraction/day for 5 days/week.
Weekly cisplatin^{10,11}	Day 1–28: Cisplatin 40mg/mg ² IV over 30 minutes weekly; plus Days 1–38: Radiotherapy (5 fractions/week): 1.8Gy single dose (up to total dose of 50.4Gy); plus Days 22–38: Boost radiotherapy: 1.5Gy/day (up to 19.5Gy) in addition to regular dose. Booster doses to be given at least 6-hours after regular dose (total tumor dose of 69.9Gy.) OR Day 1–28: Cisplatin 40mg/mg ² IV weekly; plus Days 1–40: Radiotherapy: five fractions of 1.8Gy/week (up to total dose of 54Gy); plus Days 25–40: Boost radiotherapy: 1.5Gy/day (up to 19.5Gy) in addition to regular dose. Booster doses to be given at least 6-hours after regular dose.

Primary Chemotherapy With Postoperative Chemoradiation¹

Cisplatin^{12–15} **Days 1, 22 and 43:** Cisplatin 100mg/m² IV + radiotherapy.

Induction Chemotherapy¹/Sequential chemotherapy¹⁴

Docetaxel + cisplatin + 5-FU^{16–18} **Day 1:** Docetaxel 75mg/m² IV + cisplatin 75mg/m² IV, **plus**
Days 1–5: 5-FU 750mg/m² continuous IV infusion.
Repeat every 3 weeks for 4 cycles.

Paclitaxel + cisplatin+ infusional 5-FU¹⁹ **Day 1:** Paclitaxel 175mg/m² over 3 hours
Day 2: Cisplatin 100mg/m²; **plus**
Day 2–6: 5-FU 500mg/m² continuous infusion
Repeat every 3 weeks for 3 cycles.⁵

continued

HEAD AND NECK CANCER TREATMENT REGIMENS (Part 2 of 5)

Nasopharynx Cancer

Chemoradiation Followed by Adjuvant Chemotherapy¹

REGIMEN	DOSING
Cisplatin + radiotherapy + cisplatin + 5-FU²⁰⁻²²	<p>Cycles 1-3 Day 1: Cisplatin 100mg/m² IV; plus radiotherapy. Repeat cycle every 3 weeks; followed by</p> <p>Cycles 4-6 Days 1-4: Cisplatin 80mg/m²/day + 5-FU 1,000mg/m²/day IV over 96 hours. Repeat cycle every 4 weeks for 3 cycles.</p>
Carboplatin + radiotherapy + carboplatin + 5-FU²³	<p>Cycles 1-3 Day 1: Carboplatin AUC 6 IV; plus radiotherapy: 200cGy/fraction w/ five daily fractions/week (to a total dose of 6600-7000cGy). Repeat every 3 weeks for 3 cycles; followed by</p> <p>Cycles 4-6 Days 1-4: Carboplatin AUC 5 IV + 5-FU 1,000mg/m²/day IV over 96 hours. Repeat cycle every 3 weeks.</p>

Induction Chemotherapy¹ / Sequential Chemotherapy¹

Docetaxel + cisplatin + 5-FU²⁴	<p>Day 1: Docetaxel 70mg/m² IV over 1 hour and cisplatin 75mg/m² IV over 3 hours; followed by</p> <p>Days 1-4: 5-FU 1,000mg/m² IV over 96 hours. Repeat every week for 3 cycles; followed by Cisplatin 100mg/m²; plus radiotherapy: 5 daily fractions of 1.8 or 2Gy/day (total dose of 68.4Gy) Repeat every 3 weeks.</p>
Cisplatin + 5-FU^{17,25}	<p>Day 1: Cisplatin 100mg/m²/day IV. Days 1-4: 5-FU 1,000mg/m²/day continuous IV infusion. Repeat cycle every 3 weeks for a minimum of 6 cycles.</p>

Cisplatin + epirubicin + paclitaxel This regimen was included in the NCCN guidelines but no reference was provided to indicate appropriate dosage.

Principles of Systemic Therapy¹

- The choice of chemotherapy should be individualized based on patient characteristics (performance status, goals of therapy).
- Unless otherwise specified, regimens listed below can be used for either nasopharyngeal or non-nasopharyngeal cancer.

Combination Therapy for Recurrent, Unresectable, or Metastatic Disease (Incurable)¹

Cisplatin or carboplatin + 5-FU + cetuximab²⁶ (non-nasopharyngeal)	<p>Day 1: Cisplatin 100mg/m² IV or carboplatin AUC=5mg/mL/min 1 hour IV infusion, plus</p> <p>Day 1: Cetuximab 400mg/m² IV over 2 hours (initial dose), followed by 250mg/m² IV over 1 hour once weekly. Days 1-4: 5-FU 1,000mg/m²/day. Repeat cycle every 3 weeks for a maximum of 6 cycles.</p>
Carboplatin + docetaxel²⁷	<p>Day 1: Docetaxel 65mg/m² IV over 1 hour; followed immediately by carboplatin AUC=6 IV. Repeat cycle every 3 weeks.</p>
Cisplatin + paclitaxel²⁵	<p>Day 1: Cisplatin 75mg/m²/day IV + paclitaxel 175mg/m² IV over 3 hours. Repeat cycle every 3 weeks for a minimum of 6 cycles.</p>
Cisplatin + cetuximab²⁸ (for non-nasopharyngeal disease)	<p>Day 1: Cetuximab 400mg/m² IV for one cycle, then cetuximab 250mg/m² IV for subsequent cycles. Repeat once weekly, plus</p> <p>Day 1: Cisplatin 100mg/m² IV. Repeat every 4 weeks</p>
Cisplatin + 5-FU^{25,29}	<p>Day 1: Cisplatin 100mg/m²/day IV. Days 1-4: 5-FU 1,000mg/m²/day continuous IV infusion. Repeat cycle every 3 weeks for a minimum of 6 cycles.</p>
Carboplatin + cetuximab³⁰	<p>Day 1: Cetuximab initial dose of 400mg/m² IV over 2 hours; followed by weekly doses of cetuximab 250mg/m² IV over 1 hour; followed by carboplatin AUC=5 IV. Repeat every 3 weeks for a maximum of 8 cycles.</p>

continued

HEAD AND NECK CANCER TREATMENT REGIMENS (Part 3 of 5)

Nasopharynx Cancer (continued)

Combination Therapy for Recurrent, Unresectable, or Metastatic Disease (incurable)¹ (continued)

REGIMEN	DOSING
Gemcitabine + vinorelbine³¹	Day 1 and 8: Vinorelbine 25mg/m ² IV; followed by gemcitabine 1,000mg/m ² IV over 30 minutes. Repeat every 3 weeks.

Single Agents for Recurrent, Unresectable, or Metastatic Disease (incurable)¹

Cisplatin^{28,32}	Day 1: Cisplatin 100mg/m ² IV over 15-20 minutes. Repeat every 3-4 weeks.
Carboplatin³³	Day 1: 25mg/m ² daily followed by radiotherapy: 5 daily fractions of 1.8 or 2Gy.
Paclitaxel³⁴	Day 1: Paclitaxel 80mg/m ² IV over 1 hour. Repeat every 6 weeks.
Docetaxel^{35,36}	Day 1: Docetaxel 40-100mg/m ² IV over 1 hour. Repeat every 3 weeks.
5-FU³²	Days 1-4: 5-FU 1,000mg/m ² IV over 24 hours. Repeat every 3 weeks.
Methotrexate^{29,37}	Day 1: Methotrexate 40mg/m ² IV weekly.
Cetuximab³⁸ (non-nasopharyngeal)	Day 1: Cetuximab 400mg/m ² over 2 hours as a loading dose (including a 20mg test dose); followed by cetuximab 250mg/m ² IV over 1 hour weekly. Repeat at least every 6 weeks.
Ifosfamide³⁹	Days 1-3: Ifosfamide 3g/m ² IV daily; plus mesna 600mg/m ² PO daily. Repeat every 3 weeks.
Bleomycin^{40,41}	Days 1-21: Bleomycin 10mg IV bolus twice weekly on Tuesday and Thursday (60mg/six fractions); followed by radiotherapy: 25Gy split into two courses, with each course given in 10 fractions over 2 weeks, with a 2 week split (total dose of 50Gy/20 fractions). OR Days 1-35: Bleomycin 15mg IM twice a week (total dose 150mg); followed by radiotherapy: 70Gy
Gemcitabine⁴² (nasopharyngeal)	Days 1, 8, 15: Gemcitabine 1,000mg/m ² IV over 30 minutes. Repeat every 4 weeks.
Capecitabine⁴³	Days 1-14: Capecitabine 1,250mg/m ² PO; followed by a 1-week rest period. Repeat every 3 weeks for at least two cycles.
Vinorelbine^{44,45} (non-nasopharyngeal)	Day 1: Vinorelbine 30mg/m ² /week IV (over a short duration, on an out-patient basis)

* Includes lip, oral cavity, oropharynx, hypopharynx, glottic larynx, supraglottic larynx, ethmoid sinus, maxillary sinus, occult primary.

† Induction chemotherapy should only be done in a tertiary setting.

‡ Following induction, agents to be used with concurrent chemoradiation typically include weekly carboplatin or cetuximab.⁴⁶⁻⁴⁸

§ Patients with complete partial response of greater than 80% in primary tumor received additional chemoradiation therapy (i.e., cisplatin 100mg/m² on days 1, 22, and 43 plus 70Gy). Radiotherapy was administered in 35 fractions of 2Gy each over a 7-week period.

|| Following induction, agents to be used with concurrent chemoradiation typically include weekly cisplatin²¹ or carboplatin.⁴⁶

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