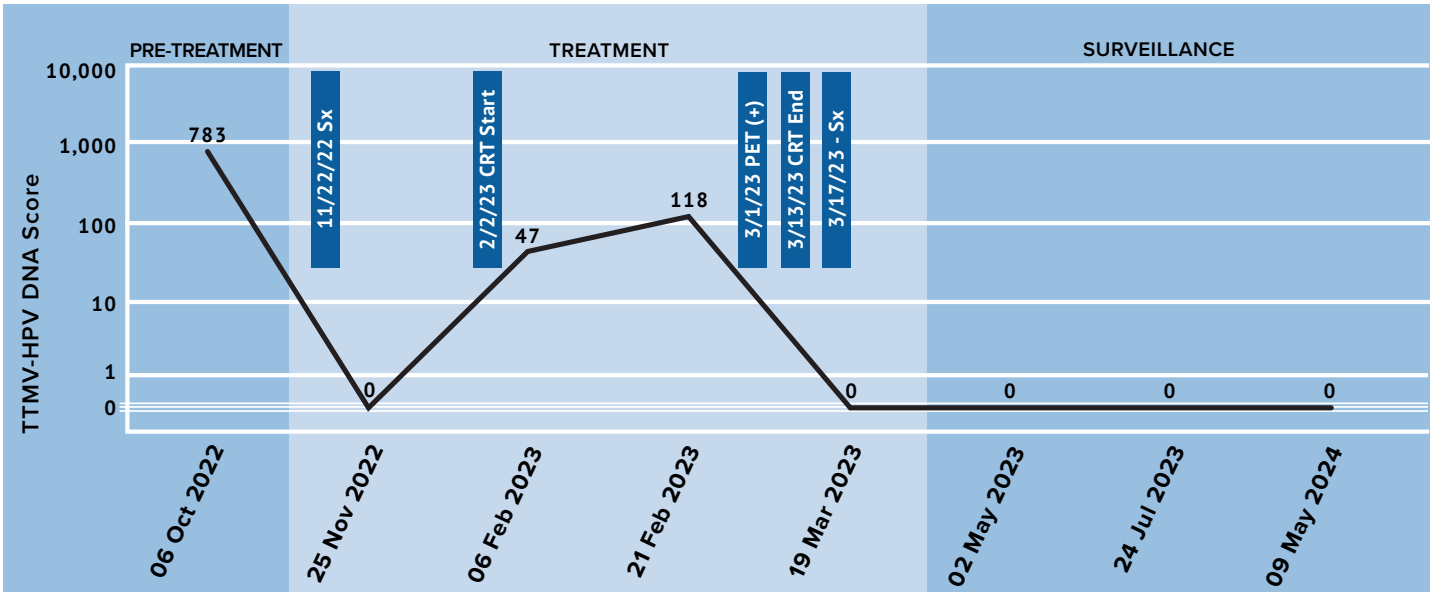
NavDx® Case Study:

NavDx confirms presence of persistent disease enabling earlier intervention

Patient History

A 72-year-old male, former smoker, presented with what was determined to be a right level 2 neck mass. The patient reported he first noticed the mass in Feb 2022.

- Initial FNA right neck LN level 2 = SCC (+), p16 (-) and level 3 = SCC (+), p16 (+), HPV 16 (+)
- T2 N1 M0 SCC of the right base of tongue (BOT), p16 (+), HPV 16 (+) was identified; pretreatment TTMV® Score was 783
- TORS of BOT cancer and bilateral selective neck dissections performed
  - BOT tumor size 2.2 cm, (-) margins, (+) lymphatic invasion, (-) perineural invasion
  - Right neck LN levels 2, 3, and 4 dissection showed 3/16 LNs positive for metastatic tumor, with extranodal extension identified
  - Left neck LN levels 2, 3, and 4 dissection were negative for tumor (0/8)
- Post-surgery, TTMV Score decreased to 0; subsequently, the patient began adjuvant CRT



Optimizing Clinical Care

- Week 1 CRT (~2.5 mos. post-surgery), TTMV Score = 47
- Week 3 CRT (~3mos. post-surgery), TTMV Score = 118
  - Elevated TTMV Score led to a PET-CT scan which detected an interval increase in size and tracer uptake of 2 adjacent left-sided, level 3 tracer avid cervical LN
  - Left neck repeat FNA showed SCC (+)
- Left neck LN level 5 dissection revealed metastatic SCC involving 1/16 lymph nodes
- Following lymph node dissection (Mar 17, 2024), TTMV Score = 0; remaining negative with serial testing for 16 months, a/o May 09, 2024

Summary:

Rising TTMV Scores during chemoradiation therapy triggered a non-routine PET-CT scan and FNA, which confirmed persistent disease. With early detection, the team was able to quickly irradiate the remaining disease, reduce risk of spread and the potential for progression. Following surveillance recommendations, periodic monitoring with NavDx was implemented.

Naveris Inc., Data on File: Case provided by Leslie A. Worona, FNP-BC, OCN with permission

Optimizing HPV+ Cancer Surveillance

About NavDx

NavDx® is the first and only clinically validated circulating tumor tissue modified viral (TTMV®)-HPV DNA blood test that aids in the detection of HPV-driven cancer.[1] Monitoring TTMV-HPV DNA Scores with NavDx at routine surveillance visits has demonstrated unrivaled test performance metrics, assuring earlier detection of patients with residual/recurrent disease.[2-4]

- Distinguish TTMV-HPV DNA from non-cancerous sources of HPV DNA[5]
- **≥97% Specificity** and **≥89% Sensitivity** to more accurately detect true disease status[2,3]
- **≥98% NPV** with no recurrence when TTMV-HPV DNA remained undetectable[2,3]
- **≥95% PPV** for cancer recurrence, when patients had 1 positive test result[2,3]
- **Accurately detect recurrence a median of 4 months earlier** than it would present clinically via PET or CT scan to facilitate earlier initiation of salvage therapy[1]

Testing with NavDx

Clinical practice guidelines and CMS coverage policy for recurrence detection include surveillance at specified intervals:

During Surveillance

- **≥3 months - 2 years post treatment:** every 3 months
- **3-5 years post treatment:** every 6 months
- **6+ years post treatment:** 1 time per year

Pretreatment

- Test with NavDx at least 7 days after any biopsy procedure, and prior to initiating treatment

During Treatment

- During treatment, consider testing with NavDx to assess early response to treatment

Questions?

The Naveris Client Services team is available to help you via email at: contact@naveris.com or phone at (833) 628-3747.

Abbreviations: BOT, base of tongue; CMS, Centers for Medicare and Medicaid Services; CRT, chemoradiation therapy; CT, computed tomography; DNA, deoxyribonucleic acid; ED, Emergency department; ENT, ears, nose throat; FNA, fine needle aspiration; Sx, surgery; HPV, human papillomavirus; LN, lymph node; NED, no evidence of disease, PE, physical exam; PET, positron emission tomography; SCC, squamous cell carcinoma; TORS, transoral robotic surgery; TTMV HPV DNA, tumor-tissue–modified HPV

References: 1. Chera BS, Kumar S, Shen C, et al. Plasma circulating tumor HPV DNA for the surveillance of cancer recurrence in HPV-associated oropharyngeal cancer. J Clin Oncol. 2020;38(10):1050-1058. **2.** Ferrandino RN, Chen S, Kappauf C, et al. Performance of liquid biopsy for diagnosis and surveillance of human papillomavirus-associated oropharyngeal cancer. JAMA Otolaryngol Head Neck Surg. doi: 10.1001 /jamaoto.2023.1937. **3.** Hanna GJ, Roof SA, Jabalee J, et al. Negative predictive value of circulating tumor tissue modified viral (TTMV)-HPV DNA for HPV-driven oropharyngeal cancer surveillance. Clin Cancer Res 2023. doi: 10.1158/ 1078-0432. CCR 23-1478. **4**. Berger BM, Hanna GJ et al; Clin Cancer Res 2022;28(19):4292-4301. **5.** Chera BS, Kumar S, Beaty BT, et al. Rapid clearance profile of plasma circulating tumor HPV type 16 DNA during chemoradiotherapy correlates with disease control in HPV-associated oropharyngeal cancer. Clin Cancer Res. 2019;25(15):4682-4690.

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