

# ASCO® Guidelines

Immunotherapy and Biomarker Testing in Recurrent and Metastatic Head and Neck Cancers: ASCO Guideline				
Clinical Question	Recommendation	Type	Evidence Quality	Strength
What biomarkers are recommended for selecting HNSCC patients for anti- PD-1 immune-checkpoint inhibitor therapy?	1.1. PD-L1 immunohistochemistry testing should be performed in patients with recurrent or metastatic HNSCC.	EB	H	S
	1.2. PD-L1 CPS $\geq$ 1 should be interpreted as positive and correlates with a clinical benefit to PD-1 inhibitors.	EB	H	S
	1.3. TMB testing may be performed in patients with recurrent or metastatic HNSCC when CPS is not available or in patients with rare tumors.	EB	H	S
	1.4. TMB $\geq$ 10 should be interpreted as high and correlates with a clinical benefit to PD-1 inhibitors.	EB	H	S
What is the optimal first-line treatment regimen for recurrent or metastatic HNSCC patients based on PD-L1 status?	2.1. Pembrolizumab monotherapy or pembrolizumab, platinum, and 5-FU should be offered as first-line treatment for patients with recurrent or metastatic HNSCC with a CPS $\geq$ 1.	EB	H	S
	2.2. Pembrolizumab, platinum, and 5-FU may be offered as first-line treatment for patients with recurrent or metastatic HNSCC with a CPS $<$ 1.	EB	M	S
What is the effect of immunotherapy compared to other systemic treatments in platinum-refractory recurrent or metastatic HNSCC?	3.1. Pembrolizumab or nivolumab should be offered to patients with platinum-refractory recurrent or metastatic HNSCC, regardless of CPS status.	EB	H	S
What is the role of immunotherapy for patients with recurrent or metastatic NPC?	4.1. Toripalimab, camrelizumab or tislelizumab, with gemcitabine and cisplatin, should be offered as first-line treatment for patients with recurrent or metastatic nasopharyngeal cancer.	EB	H	S
	<i>Qualifying statement: Pembrolizumab or nivolumab may be offered with gemcitabine and cisplatin if the immune checkpoint inhibitors in Recommendation 4.1 are unavailable.</i>			
	4.2. PD-1 inhibitors may be offered to patients with recurrent or metastatic nasopharyngeal cancer who have progressed following platinum-based therapy.	IC	L	W

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What is the effect of radiation therapy in combination with anti-PD-(L)1 immunotherapy compared to immunotherapy alone for the treatment of locoregionally recurrent or oligometastatic HNSCC?	<b>5.1.</b> For patients with oligometastatic HNSCC, radiation therapy is safe to give concurrently with immunotherapy for the purpose of palliation or local control, but should not be given to enhance response to immunotherapy outside of a clinical trial.	EB	M	W
What is the role of immunotherapy for rare head and neck cancers?	<b>6.1.</b> Pembrolizumab may be offered to patients with TMB-high recurrent or metastatic rare head and neck cancers.	EB	M	W
	<b>6.2.</b> Pembrolizumab may be offered to patients with PD-L1 positive recurrent or metastatic salivary gland cancer.	EB	M	W

**Abbreviations.** EB, evidence based; CPS, combined positive score; H, high; HNSCC, head and neck squamous cell carcinoma; IC, informal consensus; L, low; M, moderate; NPC, nasopharyngeal carcinoma; PD-1, programmed cell death protein 1; PD-L1, programmed death-ligand 1; S, strong; TMB, tumor mutational burden; W, weak