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Immunotherapy for recurrent or metastatic HNSCC: What are the practical considerations?



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Expert panel



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Agenda

Immune checkpoint inhibitors in the treatment of recurrent/metastatic HNSCC: How do we apply the trial data to clinical practice?

What factors can be used to guide the use of immune checkpoint inhibitors in clinical practice?

How can we identify and manage possible immune-related adverse events in patients with HNSCC?



Immune checkpoint inhibitors in the treatment of recurrent/metastatic HNSCC: How do we apply the trial data to clinical practice?

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Nivolumab P

Licenced indications for immune checkpoint inhibitors to treat unresectable recurrent or metastatic HNSCC

First line¹

- Combination therapy with platinum and 5-FU (all-comers)
- Monotherapy where tumour expresses PD-L1 (CPS ≥1)*

Second line¹

 Monotherapy following disease progression on or after platinum-containing therapy

First line

- Monotherapy or in combination with platinum and 5-FU where tumours express PD-L1 (CPS ≥1)^{2†}
- NICE (UK) recommends monotherapy only (PD-L1 CPS ≥1)³

Second line²

 Monotherapy following disease progression on or after platinum-containing therapy where tumours express PD-L1 (TPS ≥50%)

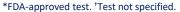
Second line4

 Monotherapy following disease progression on or after platinum-based therapy



Second line5

 Monotherapy following disease progression on or after platinum-based therapy



5-FU, fluorouracil; CPS, combined positive score; HNSCC, head and neck squamous cell carcinoma; NICE, National Institute for Health and Care Excellence;

PD-L1, programmed death-ligand 1; PI, prescribing information; SmPC, summary of product characteristics; TPS, tumour proportion score.

1. Pembrolizumab. Pl. Available at: www.accessdata.fda.gov/drugsatfda_docs/label/2021/125514s096lbl.pdf (accessed 20 December 2021);

2. Pembrolizumab. SmPC. Available at: www.ema.europa.eu/en/documents/product-information/keytruda-epar-product-information en.pdf (accessed 20 December 2021);

3. NICE. TA661. Available at: www.nice.org.uk/guidance/ta661 (accessed 20 December 2021);

4. Nivolumab. Pl. Available at: www.accessdata.fda.gov/drugsatfda_docs/label/2021/125554s091lbl.pdf (accessed 20 December 2021);

5. Nivolumab. SmPC. Available at: www.ema.eu/en/documents/product-information/opdivo-epar-product-information_en.pdf (accessed 20 December 2021).



What factors can be used to guide the use of immune checkpoint inhibitors in clinical practice?

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Variables to be balanced when treating patients with R/M HNSCC¹⁻⁴



Tumour evaluation

- Location •
- Clinical staging
 - T-stage •
 - N-stage •
 - M-stage •
- Platinum-sensitivity/resistance •
- Kinetics of disease progression

Clinical evaluation

- Physiological age
- Performance status (ECOG PS)
- Symptom burden
- Comorbidities
- Cardiopulmonary, renal and hepatic function
- Psychological and social status
- Personal preference

With the exception of platinum-sensitivity/resistance, treatment decision-making factors are continuous variables; they should be considered conjointly, while respecting patient autonomy and local resources¹



Current and emerging biomarkers to support treatment decisions in R/M HNSCC

Current predictive markers^{1,2}

PD-L1 1< CPS ≥1 No ICI | Yes ICI

Test
TPS vs CPS



HPV-status and/or P16

Investigational predictive markers¹



Oral microbiota



Genetic signature (TMB/MSI)



CTC/ctDNA



- Diagnosis
- Monitoring disease progression
- Predicting response to treatment



Potential tools to support the use of novel biomarkers in the clinic:⁴

- Immunogram
- Nomogram

CPS, combined positive score; CTC, circulating tumour cells; ctDNA, circulating tumour DNA; HPV, human papillomavirus; ICI, immune checkpoint inhibitor; MSI, microsatellite instability; PD-L1, programmed death-ligand 1; R/M HNSCC, recurrent/metastatic head and neck squamous cell carcinoma; TMB, tumour mutational burden; TPS, tumour proportion score.

1. Wang H-C. et al. *Int J Mol Sci.* 2020;21:7621; 2. De Keukeleire SJ, et al. *Cancers*, 2021;13:1714; 3. Veigas F, et al. *Cancers*, 2021;13:1018; 4. Blank CU, et al. *Science*, 2016;352:658–60



How can we identify and manage possible immune-related adverse events in patients with HNSCC?

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Overview of potential immune-related adverse events



Fatigue

Common toxicities

Infusion-related reactions

Gastrointestinal:

nausea, diarrhoea, colitis, hepatitis

Skin: rash, pruritus

Musculoskeletal: arthralgia, myalgia

Ophthalmological: dry eye, uveitis

Endocrine: hypo-/hyperthyroidism

Pulmonary: pneumonitis

Renal: tubulointerstitial nephritis, AKI

Rare (life-threatening) toxicities



Skin: pemphigus, pemphigoid, lichenoid rash, SJS/TEN

Endocrine: hypophysitis

Neurological: myasthenia gravis, Guillain–Barré syndrome

Haematological:

thrombocytopenia, haemolytic anaemia

Cardiovascular: myocarditis

Musculoskeletal: myositis

