PEMBROLIZUMAB (Keytruda) with concurrent RT (neoadjuvant then adjuvant)

INDICATION (ICD10) C76

Check the most recent Blueteq eligibility criteria before prescribing. Blueteq registration required. (www.england.nhs.uk/publication/national-cancer-drugs-fund-list/) (PEMB34)

1. Pembrolizumab for SACT treatment naïve resectable, locally advanced, non-metastatic head and neck squamous cell carcinoma of the oral cavity, larynx, hypopharynx, or oropharynx.in adults (HPV-positive oropharyngeal stage III (T4, N0-2, M0) or HPV-negative oropharyngeal, larynx, hypopharynx, or oral cavity stage III or IVA) whose tumours express PD-L1 with a combined positive score of 1 or more. PS 0 or 1.

REGIMEN SC

Cycle 1 (neoadjuvant)

Day 1	PEMBROLIZUMAB	790mg subcutaneous* (4.8ml) over 2 minutes

Cycles 2 to 9 (adjuvant)

Day 1	PEMBROLIZUMAB	790mg subcutaneous* (4.8ml) over 2 minutes

*Into the thigh or abdomen, avoiding the 5cm area around the navel

REGIMEN IV

Cycle 1 (neoadjuvant)

Days 1 and 22	PEMBROLIZUMAB	200mg in 100ml sodium chloride IV infusion over 30 minutes

Cycles 2 to 9 (adjuvant)

Day 1	PEMBROLIZUMAB	400mg in 100ml sodium chloride IV infusion over 30 minutes

CYCLE FREQUENCY AND NUMBER OF CYCLES

Every 42 days for 9 cycles

ADMINISTRATION

Pembrolizumab SC - withdraw the required volume using a transfer needle (18-21G recommended). To avoid needle clogging, change the needle to a 25-30G, 13 mm hypodermic injection needle immediately prior to SC injection.

ANTI-EMETICS

Minimal risk

CONCURRENT MEDICATION REQUIRED

Pembrolizumab	None required

EXTRAVASATION AND TYPE OF LINE / FILTERS

Pembrolizumab IV – neutral
Use low protein binding 0.2 to 5micron in-line or add-on filter

Peripheral line

INVESTIGATIONS

Blood results required before SACT administration
FBC, U&E and LFTs every cycle
Neutrophils x 10^9/L ≥1.5
Platelets x 10^9/L ≥100
Thyroid function* baseline, then every cycle
Random cortisol baseline, then every cycle (or as specified in Trust guideline)
Random glucose every cycle
Hba1c baseline
Baseline weight and every cycle

MAIN TOXICITES AND ADVERSE REACTIONS

Pembrolizumab	Immune related toxicities - pneumonitis, colitis or hepatitis etc Pembrolizumab SC skin reactions at site of administration route

INTERACTIONS WHICH MAY REQUIRE DOSE MODIFICATIONS

(not exhaustive list check SPC/BNF/Stockleys)

Pembrolizumab	-

DOSE MODIFICATIONS

Non-haematological

Pembrolizumab
Immune-related adverse reactions - refer to TV immune-oncology agent immune related adverse event clinical guideline.
If the drug-related toxicity does not resolve to grade 0-1 within 12 weeks after onset of toxicity, discontinuation is recommended.

Hepatic impairment

Pembrolizumab
No dose adjustment is needed

Renal impairment

Pembrolizumab
No dose adjustment is needed

REFERENCES

1. Uppaluri et al; KEYNOTE-689 Investigators. Neoadjuvant and Adjuvant Pembrolizumab in Locally Advanced Head and Neck Cancer. N Engl J Med. 2025 Jul 3;393(1):37-50