CEMIPLIMAB (Libtayo)

INDICATION (ICD10) C43, C53

Check the most recent Blueteq eligibility criteria before prescribing. Blueteq registration required. (www.england.nhs.uk/publication/national-cancer-drugs-fund-list/) (CEM1) (CEM3)

1. Cemiplimab monotherapy for the treatment of adult patients with locally advanced or metastatic **cutaneous** squamous cell carcinoma and is not a candidate for curative surgery or curative radiotherapy or metastatic disease with spread that includes distant metastasis (eg lung, liver, bone etc). Not received prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody. No symptomatically active brain metastases or leptomeningeal metastases. PS 0 or 1. (TA802)
2. Cemiplimab to treat recurrent or metastatic **cervical** cancer that has progressed on or after platinum-based chemotherapy, has a histological diagnosis of recurrent or metastatic squamous, adenocarcinoma, or adenosquamous.cervical cancer, and has exhibited disease progression, either whilst receiving, or after treatment with platinum-containing chemotherapy. Has received either ONE or TWO prior lines of systemic treatment for their recurrent/metastatic cervical cancer but not received prior treatment with an anti PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTL-4) antibody. Has no symptomatically active brain metastases or leptomeningeal metastases. PS 0 or 1.

REGIMEN

Day 1 CEMIPLIMAB 350mg in 100ml sodium chloride IV infusion over 30 minutes

CYCLE FREQUENCY AND NUMBER OF CYCLES

Cutaneous every 21 days until disease progression up to a maximum of 2 years (35 cycles).
Cervical - every 21 days until disease progression up to a maximum of 96 weeks.
A formal medical review as to whether treatment with cemiplimab should continue or not will be scheduled to occur at least by the end of the first 6 weeks of treatment.

ANTI-EMETICS

Low emetic risk

CONCURRENT MEDICATION REQUIRED

None

EXTRAVASATION AND TYPE OF LINE / FILTERS

Cemiplimab - neutral

Use non pyrogenic, 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 per Trust policy)
Random glucose every cycle
Baseline weight and every cycle

MAIN TOXICITES AND ADVERSE REACTIONS

Cemiplimab	Immune related toxicities - pneumonitis, colitis or hepatitis, severe cutaneous adverse reactions etc

INTERACTIONS WHICH MAY REQUIRE DOSE MODIFICATIONS
(not exhaustive list check SPC/BNF/Stockleys)

Cemiplimab	-

DOSE MODIFICATIONS

Non-haematological

Cemiplimab

Immune-related adverse reactions - refer to TV immune-oncology agent immune related adverse event clinical guideline.

Hepatic impairment

Cemiplimab

No dose adjustment is recommended for patients with mild or moderate hepatic impairment.
Cemiplimab has not been studied in patients with severe hepatic impairment.

Renal impairment

Cemiplimab

No dose adjustment of cemiplimab is recommended for patients with renal impairment.
Cemiplimab has not been studied in patients CrCl <21ml/min.

REFERENCES

1. Migden, M et al; NEJM 2018; 379: 341–351
2. SPC