

Protocol Contains CHECKPOINT INHIBITOR IMMUNOTHERAPY	
Indication	First line treatment of locally advanced or metastatic squamous non-small cell lung cancer with a PD-L1 tumour proportion score of 0-100% NB: Use only in patients with PD-L1 TPS of 50-100% if they require an urgent clinical response (e.g. impending major airway obstruction). NB: The patient must have not received any prior treatment with anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-CTLA-4 NB: Completion of treatment with chemotherapy or chemoradiotherapy or checkpoint inhibitor immunotherapy as part of neoadjuvant /adjuvant/maintenance therapy is allowed as long as therapy was completed at least 6 months prior to the diagnosis of recurrent locally advanced or metastatic disease.
Treatment Intent	Palliative
Frequency and number of cycles	Pembrolizumab subcutaneous with carboplatin & paclitaxel repeated every 21 days for a maximum of 4 cycles Followed by, in the absence of disease progression, Pembrolizumab monotherapy 790mg SC repeated every 42 days* to continue for a total treatment duration of 2 years, including the initial 4 induction cycles of treatment, or until disease progression or unacceptable toxicity or withdrawal of patient consent, whichever occurs first (use KMCC protocol MULTI-003). *pembrolizumab can be given at a dose of 395mg SC every 21 days if there is a clinical requirement. During monotherapy, the 6 weekly sub-cutaneous pembrolizumab is the preferred schedule. If a patient is unsuitable for sub cutaneous administration of pembrolizumab, the drug may be given intravenously at a dose of 400mg every 42 days or 200mg every 21 days. Patients can switch between SC and IV therapy if the clinical need arises, the switch takes place at the next scheduled dose. A formal medical review MUST occur by the end of the first 6 weeks of treatment to establish whether treatment should continue.
Monitoring Parameters pre-treatment	• Monitoring parameters for induction phase (cycle 1 -4), for maintenance treatment (from cycle 5) follow KMCC SACT protocol MULTI-003 Pembrolizumab protocol. • Virology screening: All new patients referred for systemic anti-cancer treatment should be screened for hepatitis B and C and the result reviewed prior to the start of treatment. Patients not previously tested who are starting a new line of treatment, should also be screened for hepatitis B and C. Further virology screening will be performed following individual risk assessment and clinician discretion. • Pre-treatment cardiac assessment: ○ ECG baseline, then every 6 weeks or as clinically indicated. ○ Check BNP, and Troponin T prior to treatment. • EDTA/DTPA should be used to measure GFR prior to cycle 1, must be ≥ 30ml/min. C+G to estimate CrCl may only be used before CYCLE 1 when there is a delay in obtaining EDTA/DTPA result. • Discuss with consultant if creatinine clearance drops by 25%. • Monitor FBC, U&Es, LFTs LDH, Ca++ and glucose at each cycle. • If neut <1.5 and/or PLT <100 defer treatment by one week and consider dose reduction of paclitaxel and carboplatin on subsequent cycles. Do not reduce pembrolizumab. • Thyroid function must be assessed at baseline then at least every 6 weeks. To avoid delays, use previous results for prescribing purposes.

Protocol No	LUN-043	Kent and Medway SACT Protocol Disclaimer: No responsibility will be accepted for the accuracy of this information when used elsewhere.	
Version	V5	Written by	M. Archer
Supersedes version	V4	Checked by	C. Waters E. Parry
Date	19.05.2026	Authorising consultant (usually NOG Chair)	J. Pang

	• Cortisol monitoring should be undertaken in line with ESMO immunotherapy toxicity guidance available on KMCC website (see link below). Cortisol level should not be taken within 24 hours of the last steroid dose. • Renal Impairment: ○ Carboplatin: stop if CrCl<30ml/min. ○ Paclitaxel: no dose reduction necessary. ○ Pembrolizumab: No specific dose adjustment is necessary in patients with mild to moderate renal impairment. Severe renal impairment (CrCl<30ml/min) d/w consultant. • Hepatic impairment: (prior to treatment, for immune related hepatitis see below) ○ Paclitaxel: If bilirubin < 1.25 x ULN and transaminase < 10 x ULN, dose at full dose. Otherwise consider dose reduction, not recommended in severe hepatic impairment. ○ Pembrolizumab: No dose adjustment is needed for patients with mild or moderate hepatic impairment. Pembrolizumab has not been studied in patients with severe hepatic impairment. • Dose reductions: ○ Paclitaxel: Dose reduce by 20% in the event of grade $\geq$ 2 neuropathy and consider delay until recovery to $\leq$ grade 1. Consider omitting Paclitaxel in event of recurrent grade $\geq$ 3 neuropathy OR recurrent or persistent $\geq$ grade 2 neuropathy following a dose reduction. ○ Dose reduction of carboplatin and paclitaxel should be considered if any other grade 3 or 4 non-haematological toxicity or repeat appearance of grade 2 (except N&V and alopecia). Delay until resolution of toxicity to $\leq$ grade 1. ○ Pembrolizumab: dose reductions are not recommended. Dosing delay or discontinuation may be required based on individual safety and tolerability. ○ Pembrolizumab may be restarted within 12 weeks after last dose, if an adverse reaction remains at Grade $\leq$ 1 and corticosteroid dose has been reduced to $\leq$ 10 mg prednisone or equivalent per day. • Immune-related adverse reactions may appear during or after treatment. The most common immune-related reactions are: pneumonitis, colitis, nephritis, hepatitis, symptomatic hypophysitis, hyperthyroidism, hypothyroidism and type 1 diabetes. The following additional, immune related adverse reactions have been reported in patients receiving pembrolizumab: uveitis, arthritis, myositis, pancreatitis, severe skin reactions, myasthenic syndrome, encephalitis, Guillian-Barre syndrome, optic neuritis, rhabdomyolysis, sarcoidosis, myocarditis, haemolytic anaemia and partial seizures arising in a patient with inflammatory foci in brain parenchyma. See guidelines for management of immune-related adverse reactions following immunotherapy: https://www.kmcc.nhs.uk/medicines-and-prescribing-incorporating-sact-pathways/immunotherapy/ available on KMCC website and the SPC. • Cases of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), some with fatal outcome, have been reported. For signs or symptoms of SJS or TEN, pembrolizumab should be withheld and the patient should be referred to a specialised unit for assessment and treatment. If SJS or TEN is confirmed, pembrolizumab should be permanently discontinued. • Infusion / injection related reactions: If the infusion related reaction can be attributed to a particular agent, treat as follows: ○ Pembrolizumab: Severe infusion / injection related reactions have been reported in patients receiving pembrolizumab. For severe infusion / injection reactions (grade 3-4), treatment should be stopped and pembrolizumab permanently discontinued. Patients with mild or moderate infusion reaction may continue to receive pembrolizumab with close monitoring; premedication with antipyretic and antihistamine may be considered. ○ Paclitaxel: Patients developing hypersensitivity reactions may be re-challenged with full dose Paclitaxel following prophylactic medication (e.g. famotidine 40mg po given 4 hours prior to treatment plus hydrocortisone 100mg iv and chlorphenamine 10mg iv 30 minutes prior to treatment), then give paclitaxel over 3-6 hours (i.e. starting at over 6 hours and gradually increase rate if possible).
--	---

Protocol No	LUN-043	Kent and Medway SACT Protocol Disclaimer: No responsibility will be accepted for the accuracy of this information when used elsewhere.	
Version	V5	Written by	M. Archer
Supersedes version	V4	Checked by	C. Waters E. Parry
Date	19.05.2026	Authorising consultant (usually NOG Chair)	J. Pang

	○ Carboplatin: Mild/moderate reactions (grade 1-2): If symptoms resolve after treatment with hydrocortisone and chlorphenamine, the infusion may be restarted at 50% rate for 30 mins, then, if no further reaction, increase to 100% rate. If symptoms do not resolve after treatment with hydrocortisone and chlorphenamine, do not restart the infusion. At consultant's discretion, patients may be re-challenged at a later date with additional prophylaxis. In the event of further reaction (grade 1-3), stop infusion and consider desensitisation regimen. Severe (grade 3): Do not restart infusion. Consider re-challenge with carboplatin desensitisation regimen. Anaphylaxis (grade 4): Follow anaphylaxis protocol. Discontinue permanently and consider alternative treatment. ● Pembrolizumab Sub cutaneous administration: ○ If SC Injection is being prepared on the ward Trust SOP should be followed. ○ Remove from fridge and allow to reach room temperature for at least 30minutes before administration. ○ Withdraw the required volume either 2.4 mL (395 mg) or 4.8 mL (790 mg) using a sterile syringe and a transfer needle (18-21G recommended), according to the recommended dosage. To avoid needle clogging, change the needle to a 25-30G, 13 mm hypodermic injection needle immediately prior to subcutaneous injection. ○ Inject into the subcutaneous tissue of the thigh or abdomen, avoiding 5cm area around the naval. ○ Rotate injection sites for subsequent injection, selecting a site that is 2.5 cm from the previous injection site. ○ Do not inject into areas where the skin is damaged, sore, bruised, scarred, scaly, or has red patches. ○ During the treatment other medicinal products for subcutaneous administration should be injected at different sites. ● Common Drug Interactions (for comprehensive list refer to BNF/SPC): ○ Pembrolizumab: The use of systemic corticosteroids or immunosuppressants before starting pembrolizumab should be avoided; dexamethasone is permitted as prescribed within this protocol. Systemic corticosteroids or other immunosuppressants can be used after starting pembrolizumab to treat immune-related adverse reactions ○ Vaccines should only be given where the benefit outweighs the risk and after discussion between consultant and patient. ○ Carboplatin: Caution with other nephrotoxic drugs. ● Driving/using machinery: Pembrolizumab may have a minor influence on the ability to drive and use machines. Fatigue has been reported following administration of pembrolizumab. ● Missed dose: If a planned dose of pembrolizumab is missed, it should be administered as soon as possible. The schedule of administration must be adjusted to maintain the appropriate interval between doses. ● Pregnancy and Contraception: Women of childbearing potential should use effective contraception during treatment with pembrolizumab and for at least 4 months after the last dose of pembrolizumab. ● Each patient should be given a copy of the relevant Keytruda[®] patient alert card at each cycle. ● Patients must be advised to contact the oncology team or the 24 hour hot-line immediately if they experience any side effect, as some side effects worsen rapidly. Prompt management of side effects can ensure that the patient continues with treatment. ● Patients must not have symptomatically active brain metastases or leptomeningeal metastases.
References	KMCC protocol LUN-043 V4 SPC accessed online 25.03.2026

NB For funding information, refer to CDF and NICE Drugs Funding List

Protocol No	LUN-043	Kent and Medway SACT Protocol Disclaimer: No responsibility will be accepted for the accuracy of this information when used elsewhere.	
Version	V5	Written by	M. Archer
Supersedes version	V4	Checked by	C. Waters E. Parry
Date	19.05.2026	Authorising consultant (usually NOG Chair)	J. Pang

Cycles 1-4**Repeat every 21 days**

NB Pembrolizumab can be given at a dose of 200mg IV every 21 days if there is a clinical requirement.

Day	Drug	Dose	Route	Infusion / injection Duration	Administration
1	Metoclopramide	20mg	PO		
	PEMBROLIZUMAB	395mg	SC	1 min	Inject into the subcutaneous tissue of the left or right thigh or abdomen, avoiding 5cm area around the naval. Do not inject at other sites of the body. Injection sites should be rotated for successive injections.
Give pre-meds 30 minutes prior to paclitaxel					
	Dexamethasone	16mg*	IV	bolus	
	Chlorphenamine	10mg	IV	bolus	
	Ondansetron	< 75yrs 16mg ≥75yrs 8mg	IV	15 min	In 50ml sodium chloride 0.9% 30 minutes prior to paclitaxel
	PACLITAXEL	200mg/m²	IV	Over 3 hours	Diluted in 500ml sodium chloride 0.9% (non PVC) Via in-line 0.22micron filter Doses <150mg in 250ml 0.9% sodium chloride
	CARBOPLATIN	(AUC 6) Dose = AUC X (GFR + 25) (max 700mg)	IV	30min	500ml glucose 5%
*From 3rd infusion dexamethasone maybe reduced to 12mg IV					
TTO	Drug	Dose	Route	Directions	
Day 1	Dexamethasone	6mg	PO	OD for 3 days starting on day 2.	
	Metoclopramide	10mg	PO	Up to 3 times a day as required. (max. 30mg per day including 20mg pre-chemo dose) Do not take for more than 5 days continuously.	

Protocol No	LUN-043	Kent and Medway SACT Protocol Disclaimer: No responsibility will be accepted for the accuracy of this information when used elsewhere.			
Version	V5	Written by		M. Archer	
Supersedes version	V4	Checked by		C. Waters E. Parry	
Date	19.05.2026	Authorising consultant (usually NOG Chair)		J. Pang	

MAINTENANCE: to continue in the absence of disease progression (use KMCC protocol MULTI-003)
Repeat every 42 days for a maximum of 16 cycles

NB: if there is a clinical requirement pembrolizumab can be given at a dose of:

395mg SC every 21 days or

400mg IV every 42 days or 200mg IV every 21 days

Day	Drug	Dose	Route	Injection Duration	Administration
1	Metoclopramide	20mg	PO		stat
	PEMBROLIZUMAB	790mg	subcutaneous	2 mins	Inject into the subcutaneous tissue of the left or right thigh or abdomen, avoiding 5cm area around the naval. Do not inject at other sites of the body. Injection sites should be rotated for successive injections.
TTO	Drug	Dose	Route	Directions	
Day 1	Metoclopramide	10mg	PO	Up to 3 times a day as required. (max. 30mg per day including 20mg pre-chemo dose) Do not take for more than 5 days continuously.	

Protocol No	LUN-043	Kent and Medway SACT Protocol Disclaimer: No responsibility will be accepted for the accuracy of this information when used elsewhere.			
Version	V5	Written by		M. Archer	
Supersedes version	V4	Checked by		C. Waters E. Parry	
Date	19.05.2026	Authorising consultant (usually NOG Chair)		J. Pang	