

Indication	For the treatment of recurrent or metastatic squamous, adenocarcinoma, or adenosquamous cervical cancer that has progressed after one or two lines of systemic treatment.
Treatment Intent	Palliative
Frequency and number of cycles	Repeat every 21 days. Continue until disease progression, unacceptable toxicity or patient's choice to stop treatment. Given the potentially necessary frequency and duration of treatment breaks during treatment with tisotumab vedotin, this indication is exempt from NHS England's treatment break policy. If there is disease progression during a treatment break treatment with tisotumab vedotin must be discontinued.
Monitoring Parameters	• 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. • Ophthalmological examination: ○ Prior to the first infusion and as clinically indicated, patients should be referred for a full eye examination (including visual acuity and slit lamp exam). ○ Prior to each infusion, the patient's eyes should be inspected, including control of normal eye movement, and asked about any ocular signs or symptoms. ○ Patients should be instructed to promptly report any new or worsening ocular signs or symptoms and referred to an eye care professional if warranted. • Haematological monitoring and parameters: • FBC, U&Es and LFTs at baseline and at each cycle. • If Neuts <1 and PLTs <100 delay one week and consider GCSF consultant decision. • Hepatic impairment: No dose adjustment is required in mild impairment (total bilirubin of > 1 to 1.5 × ULN and any AST, or total bilirubin ≤ ULN and AST > ULN). However, as the exposure is expected to increase in mild impairment, use with caution. Tisotumab vedotin has not been studied in patients with moderate or severe hepatic impairment. • Renal impairment: No dose adjustment is required in mild or moderate (CrCl 30-90mL/min) impairment. Tisotumab vedotin has not been studied in severe or end-stage renal disease (CrCL < 30mL/min), use with caution. • Management of adverse reactions and dose adjustments: • Eye care: see also ophthalmic examination above. ○ Eye drops must be prescribed and given to the patient at new patient chat. On the day of treatment, the patient should confirm they have administered the prescribed eye drops. ○ Cold packs should be applied prior to the start of the infusion, during the infusion and for 30minutes after completion. Change cold packs as needed throughout infusion to ensure eye area remains cold. ○ Patients should be advised to avoid wearing contact lenses for the entire duration of therapy unless advised by their eye care professional. • Peripheral neuropathy, has been reported in patients treated with tisotumab vedotin. Patients experiencing new or worsening peripheral neuropathy may require dose interruption, dose reduction, or permanent discontinuation. • Severe Cutaneous Adverse Reactions (SCARs): Tisotumab vedotin can induce severe skin reactions such as Stevens-Johnson syndrome. Patients should be monitored for signs and symptoms of SCARs and informed to seek urgent medical advice should any symptoms occur. Treatment should be interrupted immediately if symptoms occur and if confirmed grade 3 or 4 reaction tisotumab vedotin should be permanently discontinued.

Protocol No	GYN-054	Kent and Medway SACT Protocol Disclaimer: No responsibility will be accepted for the accuracy of this information when used elsewhere.	
Version	V1	Written by	M. Archer
Supersedes version	New protocol	Checked by	C. Waters O. Adebayo
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	• Dose Modification: If a dose reduction is required the first dose reduction should be to 1.3mg/kg (up to a maximum dose of 130mg), second dose reduction to 0.9mg/kg (up to a maximum dose of 90mg). If a dose of 0.9mg/kg cannot be tolerated tisotumab vedotin should be discontinued. See table 1 for dose modification guidance. • Common drug interactions (for comprehensive list refer to BNF/SPC): • No formal drug-drug interaction studies have been conducted. Patients should be closely monitored for adverse reactions when tisotumab vedotin is given concomitantly with strong CYP3A4 inhibitors (e.g., boceprevir, clarithromycin, cobicistat, indinavir, itraconazole, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole). • Missed dose: if a dose is missed it should be administered as soon as possible and the administration schedule adjusted to maintain the appropriate interval between doses. • Pregnancy and contraception: Women of reproductive potential should be advised to use effective contraception during treatment and for 2 months after the last dose. Males with female partners of reproductive potential should be advised to use effective contraception during treatment and for at least 4 months after the last dose. • Driving and machinery: Patients should be advised to use caution when driving or operating machines due to the potential of ocular reactions and risk of peripheral neuropathy.
References	CDF list V1.399 accessed online 22.05.2026 SPC accessed online 26.05.2026

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

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Table 1 Recommended dose modifications for adverse reaction

Adverse reaction	Severity*	Occurrence	Dose modification
Keratitis	Grade 1	Any	Withhold dose until clinically stable, then resume treatment at the same dose.
	Grade 2	First occurrence	Withhold dose until Grade ≤ 1 , then resume treatment at the next lower dose level.
		Second occurrence	Withhold dose until Grade ≤ 1 , then resume treatment at the next lower dose level. If no resolution to Grade ≤ 1 , permanently discontinue.
		Third occurrence	Permanently discontinue.
	Grade 3 or 4	Any	Permanently discontinue.
Conjunctival ulceration	Grade 1 or 2	First occurrence	Withhold dose until clinically stable, then resume treatment at the next lower dose level.
		Second occurrence or more	Withhold dose until clinically stable, then resume treatment at the next lower dose level. If no stabilisation or improvement, permanently discontinue.
	Grade 3 or 4	Any	Permanently discontinue.
Conjunctival or corneal scarring or symblepharon	Any grade	Any	Permanently discontinue.
Conjunctivitis and other ocular reactions	Grade 1	Any	Withhold dose until clinically stable, then resume treatment at the same dose.
	Grade 2	First occurrence	Withhold dose until Grade ≤ 1 , then resume treatment at the same dose.
		Second occurrence	Withhold dose until Grade ≤ 1 , then resume treatment at the next lower dose level. If no resolution to Grade ≤ 1 , permanently discontinue.
		Third occurrence	Permanently discontinue.
	Grade 3 or 4	Any	Permanently discontinue.
Peripheral neuropathy	Grade 2 or 3	Any (initial or worsening of pre-existing condition)	Withhold dose until Grade ≤ 1 , then resume treatment at the next lower dose level.
	Grade 4	Any	Permanently discontinue.
Severe cutaneous adverse reactions (including Stevens-Johnson syndrome (SJS))	Suspected (any grade)	Any	Immediately withhold dose and consult a specialist to confirm the diagnosis.
	Confirmed Grade 3 or 4	Any	Permanently discontinue.

* Toxicity was graded per National Cancer Institute Common Terminology Criteria for Adverse Events Version 5.0 (NCI-CTCAE v5.0) where Grade 1 is mild, Grade 2 is moderate, Grade 3 is severe, and Grade 4 is life-threatening

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Repeat every 21 days

Day	Drug	Dose	Route	Infusion Duration	Administration
1	Confirm with the patient that the steroid and vasoconstrictor eye drops have been administered. Apply cold packs fully over the eyes following administration of the vasoconstrictor eye drops, leave on during infusion and until 30 minutes after infusion. Change cold packs as needed throughout infusion to ensure eye area remains cold.				
	Metoclopramide	10mg	IV		
	TISOTUMAB VEDOTIN	2mg/kg Maximum dose 200mg	IV	30 minutes	50-100ml glucose 5% via in-line 0.2micron filter. Final concentration should be between 0.7 mg/mL to 2.4 mg/mL
TTO	Drug	Dose	Route	Directions	
Day 1	Dexamethasone preservative free eye drops	0.1%	Eye drop	1 drop in each eye 3 times daily starting 1 day prior to each infusion and continue for 3 days after each infusion.	
	Phenylephrine hydrochloride preservative free eye drops	2.5%	Eye drops	3 drops in to each eye immediately prior to each infusion.	
	Hypromellose preservative free eye drops (or equivalent lubricating eye drop in line with trust formulary.)	0.3%	Eye drops	1 drop in both eyes every 2-3 hours throughout the day. Continue for 30 days after the last dose of tisotumab vedotin.	
	Loperamide	2mg-4mg	PO	Take two capsules (4mg) after first loose stool, then one capsule (2mg) after each loose stool when required. (Maximum 16mg per day). Dispense on Cycle 1 only, then only if required.	
	Metoclopramide	10mg	PO	10mg up to three times a day PRN. Do not take for more than 5 days continuously.	
				Dispense on Cycle 1 only, then only if required	

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