

Indication	Vismodegib for the treatment of: Gorlin syndrome with non-locally advanced, non-metastatic multiple (≥ 6) BCCs clinically evident lesions at the point of decision to treat of which 3 are at least 5mm and Non-locally advanced, non-metastatic multiple BCC (≥ 6) clinically evident lesions at the point of decision to treat of which 3 are at least 5mm AND are appropriate for surgery. NB: Patients must be appropriate for surgery i.e. surgically eligible tumours. NB: Trust policy regarding the use of unlicensed treatments must be followed as this is an unlicensed dosing schedule and indication for vismodegib.
Treatment Intent	Palliative
Frequency and number of cycles	Vismodegib Intermittent schedule 150mg daily for 12 weeks, followed by 8 weeks off treatment. Continue until disease progression or unacceptable toxicity or patient choice to stop treatment.
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. • Monitor FBC, LFT's and U&E's prior to each cycle. If neuts <1.0 and/or PLT <100 d/w consultant. • Women of child bearing potential must have a negative pregnancy test, conducted by a health care provider <u>within 7 days before starting treatment</u> and have a negative pregnancy test monthly during treatment, even if the patient becomes amenorrhoeic (see pregnancy/contraception section below). • Hepatic impairment: no dose adjustment required. • Renal impairment: no dose adjustment required in mild and moderate renal impairment. Limited data in severe impairment (CrCl <30ml/min), patients should be monitored closely for adverse reactions. • Management of adverse reactions and dose adjustments: ○ Dose adjustments are not recommended. ○ Severe cutaneous adverse reactions (SCARs) including cases of Stevens-Johnson syndrome/Toxic epidermal necrolysis (SJS/TEN), Drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalised exanthematous pustulosis (AGEP), have been reported during treatment with vismodegib, if the patient develops any of these reactions' treatment with vismodegib must be discontinued and not restarted at any time. • Common drug interactions (for comprehensive list refer to BNF/SPC): ○ Avoid concomitant treatment with potent CYP inducers (e.g. rifampicin, phenytoin, carbamazepine). ○ Concomitant use with St John's wort is contraindicated. ○ Vismodegib has the potential to act as an inhibitor of breast cancer resistance protein (BCRP) and may give rise to increased exposure of medicinal products transported by this protein, such as rosuvastatin, topotecan, and sulfasalazine. Concomitant administration should be performed with caution and a dose adjustment may be necessary. ○ Vismodegib is an inhibitor of OATP1B1. Vismodegib may increase the exposure to substrates of OATP1B1, e.g. bosentan, ezetimibe, glibenclamide, repaglinide, valsartan

Protocol No	SKI-005	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 V3 V4 & V5 H. Paddock V2 V3, V4 & V5 minor change pharmacist approval only
Date	19.08.2026	Authorising consultant (usually NOG Chair)	J. Turner V2

	and statins. In particular, caution should be exercised if vismodegib is administered in combination with any statin. • Missed dose: If a dose is missed the patient should not take an additional dose and take at the dose at the next scheduled time. • Pregnancy/contraception: • Vismodegib must not be used during pregnancy and female and male patients should be counselled as described below. ○ Counselling for female patients: ○ Patients should be counselled about the adverse use of vismodegib in pregnancy AND, if a woman of child-bearing potential, be advised to use two forms of contraception (including one highly effective method and one barrier) during vismodegib therapy and for 24 months after the final dose, AND a negative medically supervised pregnancy test should be performed within the past seven days before treatment. ○ Counselling for male patients: ○ Patients should be counselled about the adverse use of vismodegib in relation to pregnancy and be advised to always use a condom (with spermicide if available), during vismodegib therapy and for 2 months after the final dose. Male patients should be advised not to donate semen while taking vismodegib and for 2 months after the final dose. • Patients must comply with the “Erivedge® Pregnancy Prevention Programme” materials. • Blood donation: Patients should not donate blood while taking vismodegib and for 24 months after the final dose. • Vismodegib capsules contain lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. • For oral self-administration: refer to local Trust policy on oral anti-cancer medicines and supply Patient Information Leaflet and Macmillan information sheet.
References	SPC accessed online 12.08.2026 KMCC proforma SKI-005 V4

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

Intermittent schedule of vismodegib given for 12 weeks, followed by 8 weeks off treatment.

TTO	Drug	Dose	Route	Directions
Day 1	VISMODEGIB	150mg	PO	OD for 12 weeks followed by an 8-week break. Swallow whole with water with or without food. Do not open capsules. Available as 150mg capsule
	Metoclopramide	10mg	PO	Up to TDS PRN Do not take for more than 5 days continuously.
	Loperamide	2-4mg	PO	Take 4mg (2 capsules) initially, then 2mg (1 capsule) after each loose stool when required. Maximum 16mg (8 capsules) a day. Dispense 30 capsules on cycle 1 then only if required.

Protocol No	SKI-005	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 V3 V4 & V5 H. Paddock V2 V3, V4 & V5 minor change pharmacist approval only
Date	19.08.2026	Authorising consultant (usually NOG Chair)	J. Turner V2