Vismodegib Monotherapy

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	HSE approved reimbursement Status*
Treatment of adult patients with symptomatic metastatic basal cell carcinoma (mBCC)	C44	00236a	CDS 01/11/17
Treatment of adult patients with local advanced basal cell carcinoma inappropriate for surgery or radiotherapy.	C44	00236b	CDS 01/11/17

* This applies to post 2012 indications

TREATMENT:

The starting dose of the drugs detailed below may be adjusted downward by the prescribing clinician, using their independent medical judgement, to consider each patients individual clinical circumstances.

Vismodegib is administered once daily until disease progression or unacceptable toxicity develops. Benefit of continued treatment should be regularly assessed, with the optimal duration of therapy varying for each individual patient.

Drug	Dose	Route	Cycle
Vismodegib	150mg daily	PO	Continuous therapy
If a dose is missed, patients should be instructed not to take the missed dose but to resume with the next scheduled dose.			
Take with or without food at the same time each day. Capsule must be swallowed whole with 200mL water. Capsules should NOT be crushed or opened. Vismodegib is commonly available as 150mg capsules.			

ELIGIBILITY:

- Indications as above
- ECOG status 0-2

EXCLUSIONS:

- Pregnancy or breastfeeding.
- Women of childbearing potential who do not comply with the Erivedge® Pregnancy Prevention Programme. (Please see other supportive care section for further details and for precautions to be taken by males)
- Hypersensitivity to vismodegib or any of the excipients.

PRESCRIPTIVE AUTHORITY:

The treatment plan must be initiated by a Consultant Medical Oncologist.

TESTS:

Baseline tests:

- FBC, renal and liver profile.
- Assessment and registration as per Erivedge® Pregnancy Prevention Programme for both male and female patients.

Regular tests:

- FBC, renal and liver profile every 4 weeks.
- Pregnancy test requirements based on the Erivedge® Pregnancy Prevention Programme.

Disease monitoring:

Disease monitoring should be in line with the patient's treatment plan and any other test/s as directed by the supervising Consultant.

DOSE MODIFICATIONS:

- Any dose modification should be discussed with a Consultant.
- No recommended dose reductions for vismodegib.
- Treatment interruptions of up to 4 weeks were allowed based on individual tolerability in clinical trials.

Renal and Hepatic Impairment:

Table 1: Dose modification of vismodegib in renal and hepatic impairment

Renal Impairment		**Hepatic Impairment**
CrCl (mL/min)	**Dose**	No dose adjustment is needed.
30-79	No dose adjustment is needed.	
<30	No need for dose adjustment is expected	
Haemodialysis:	No need for dose adjustment is expected.	
Renal and hepatic dose modifications from Giraud et al 2023		

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL:

- As outlined in NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting - Available on NCCP website

Vismodegib : Minimal to low (**Refer to local policy).**

For information:
Within NCIS regimens, antiemetics have been standardised by Medical Oncologists and Haemato-oncologists and information is available in the following documents:

- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Medical Oncology) – Available on NCCP website
- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Haemato-oncology) – Available on NCCP website

PREMEDICATIONS: Not usually required

OTHER SUPPORTIVE CARE:

- Vismodegib must never be used by women who are pregnant or by women who could become pregnant unless all the conditions of the Erivedge® Pregnancy Prevention Programme are met. These conditions must be fulfilled for all male and female patients.
  For male patients: Vismodegib is present in semen.
  To avoid potential foetal exposure during pregnancy, a male patient must understand that:
  - Vismodegib exposes a teratogenic risk to the unborn child if he engages in unprotected sexual activity with a pregnant woman,
  - He must always use the recommended contraception
  - He will tell his healthcare provider if his female partner becomes pregnant while he is taking vismodegib or during the 2 months after his final dose.

ADVERSE EFFECTS:

- Please refer to the relevant Summary of Product Characteristics (SmPC) for details.

DRUG INTERACTIONS:

- Current SmPC and drug interaction databases should be consulted for information.

COMPANY SUPPORT RESOURCES/Useful Links:

Please note that this is for information only and does not constitute endorsement by the NCCP

https://assets.hpra.ie/products/Human/9762/378c3274-1ec8-4d60-b86d-697004a31fd7.pdf

Erivedge patient counselling guidleines

https://assets.hpra.ie/products/Human/9762/11f27420-f8cd-49fb-aa3a-ae9c868072b8.pdf

Erivedge healthcare professional reminder card

https://assets.hpra.ie/products/Human/9762/688db46e-3fb6-4c00-8fba-f59edd3d8073.pdf

REFERENCES:

1. Sekulic A, Migden MR, Oro AE, et al. Efficacy and safety of vismodegib in advanced basal-cell carcinoma. N Engl J Med 2012;366:2171-9.
2. Giraud E L, Lijster B D, et al. Dose recommendations for anticancer drugs in patients with renal or hepatic impairment: an update. Available at: https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(23)00216-4/fulltext
3. NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting. V6 2025. Available at: https://www.hse.ie/eng/services/list/5/cancer/profinfo/chemoprotocols/nccp-classification-document-for-systemic-anti-cancer-therapy-sact-induced-nausea-and-vomiting.pdf
4. Vismodegib (Erivedge ®) Summary of Product Characteristics Last updated: 20/03/2023. Accessed: February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/erivedge-epar-product-information_en.pdf

Version	Date	Amendment	Approved By
1	12/10/2017		Dr Emer Hanrahan
2	13/02/2020	Updated emetogenic potential and adverse events	Dr Emer Hanrahan
3	29/04/2025	Updated renal and hepatic dose modifications to align with Giraud et al 2023 . Updated regimen in line with NCCP standardisation.	Dr Emer Hanrahan

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.