Application for individual reimbursement of Larotrectinib (Vitrakvi®) for the treatment of solid tumours that display a Neurotrophic Tyrosine Receptor Kinase (NTRK) gene fusion

For MMP Use Only	
Case Reference	*Date Received*

Date of Application:	Nominated Community Pharmacy: (Name & address – *leave blank if uncertain)*

Part 1: Patient Details

Name of patient:				
Date of birth:				
Address:				
GMS / DPS / PPS Number: (Please tick and insert number)	GMS	DPS	PPSN	Number:

Part 2: Prescriber Details

Name of prescribing consultant:	
Medical Council number:	
Contact Details:	Hospital:
	Address:
	Telephone:
	Email:

Please refer to the HSE-Managed Access Protocol for Larotrectinib when completing part 3, 4 and 5 of this application form

Part 3: Patient Diagnosis

Section 1: Confirmed diagnosis of locally-advanced, metastatic or unresectable solid tumour

Please indicate whether the patient meets the following criteria (*please tick which apply and complete requested detail*)

1. Patient has a histological diagnosis of a malignant solid tumour **Yes** ☐ **No** ☐

If **yes**, please provide:

A. the site of origin of the patient's cancer (if sarcoma, please indicate sarcoma; if unknown primary, please indicate as such), and

B. the specific histological type (e.g. for breast cancer: ductal carcinoma, lobular carcinoma, secretory carcinoma etc; for lung cancer: squamous non-small cell lung cancer, non-squamous non-small cell lung cancer; for sarcoma: fibrosarcoma, osteosarcoma, gastrointestinal stromal tumour etc.).

2. The patient has a solid tumour that:	**Yes**	**No**
is locally advanced		
is metastatic		
would require surgical resection likely to result in severe morbidity		

If **yes to any of the above**, please provide information:

- to demonstrate that the solid tumour is locally advanced or metastatic, or
- on the type of surgical resection which would otherwise have been needed and resulted in severe morbidity.

Section 2: Confirmed NTRK gene fusion

3. Patient has a confirmed NTRK 1, 2 or 3 gene fusion in the tumour, without a known acquired resistance mutation, determined by a ribonucleic acid (RNA)-based next generation sequencing (NGS) test **Yes** ☐ **No** ☐

If **yes**, please indicate NTRK gene fusion (*please tick one*)

NTRK 1 ☐ NTRK 2 ☐ NTRK 3 ☐

Please attach a copy of the RNA-based NGS test **Enclosed** ☐

Part 4: Patient Clinical History/Status

Please indicate the current status of the patient in relation to the following clinical parameters (*please tick which apply and complete requested detail overleaf*)

Refer to section 2.4 of the Managed Access Protocol - Patient clinical history/status and to the eligibility and exclusion criteria detailed in the NCCP national regimens for larotrectinib

The patient:	**Yes**	**No**
has symptomatic or unstable brain metastases		
has clinically significant active cardiovascular disease		
is currently in receipt of treatment with a strong or moderate cytochrome P450 3A4/P-glycoprotein inducer and is unable to discontinue treatment prior to initiation of larotrectinib		
has active uncontrolled systemic bacterial, fungal or viral infection		
is pregnant or lactating		
has received prior treatment with any NTRK inhibitor		
has hypersensitivity to larotrectinib or any of the excipients in Vitrakvi®.		

If **yes** has been answered in the above table, please provide relevant information in the box provided overleaf:

Please confirm that the patient meets the performance status as outlined in the eligibility criteria in the NCCP national regimens for larotrectinib:

Yes ☐ **No** ☐

Part 5: Place in Therapy

1. I confirm that larotrectinib is being prescribed for this patient in accordance with the licensed indication for which it has been approved for reimbursement under the High Tech Arrangement, i.e. as monotherapy for the treatment of adult and paediatric patients with solid tumours that display a NTRK gene fusion

- who have disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and
- who have no satisfactory treatment options.

Yes ☐ **No** ☐

2. I confirm that larotrectinib will be prescribed and administered as monotherapy for the treatment of the solid tumour that displays a NTRK gene fusion in this patient.

Yes ☐ **No** ☐

Reimbursement of larotrectinib on the High Tech Arrangement is supported for patients who have no satisfactory treatment options, in line with its licensed indication.

For reimbursement approval, please provide information to demonstrate that reimbursement of larotrectinib is being sought at the appropriate place in therapy as per section 2.5 of the Managed Access Protocol, i.e. all available systemic anti-cancer therapy (SACT) for the tumour site have been previously trialled and exhausted, and surgery and/or radiation would lead to substantial morbidity**.**

For previous SACT trialled, please provide information on duration of treatment(s), including start and stop dates and reason for cessation. Information can be provided in the relevant sections on pages 6 and 7.

Copies of prescriptions, and relevant sections of patient notes and/or clinic letters should be attached to validate treatments.

SACT Regimen 1:

Name of regimen/medicine(s)	
Duration of treatment (include start and stop dates)	
Reason for treatment cessation	

SACT Regimen 2:

Name of regimen/medicine(s)	
Duration of treatment (include start and stop dates)	
Reason for treatment cessation	

SACT Regimen 3:

Name of regimen/medicine(s)	
Duration of treatment (include start and stop dates)	
Reason for treatment cessation	

Please outline below details of other treatments to date for the solid tumour that displays a NTRK gene fusion.

Additional space for supporting information

Completed forms should be returned by:

Email (using secure email, e.g. HSE email or healthmail) to mmp@hse.ie

Please note that the MMP will always acknowledge receipt of each application.

Authorisation of Request

Signature of **Prescribing Consultant**	
Institution	

Data Protection Notice

- The information on this form will be used by the Health Service Executive (HSE) to assess the suitability of the items listed to be provided under Section 20 of the Health (Pricing and Supply of Medical Goods) Act 2013.
- Details of prescription items dispensed to the named person may be notified to the HSE by the dispensing pharmacist to ensure that the names person receives the items required.
- The named person may access information relating to themselves only, on prescription claims processed in their name by the HSE.
- We may share information with the Department of Health, healthcare practitioners and other healthcare bodies.
- We may also disclose information to other parties if the law requires us to do so.
- The PCRS privacy statement can be located at www.pcrs.ie.