Application for individual reimbursement of Neurotrophic Tyrosine Receptor Kinase (NTRK) gene fusion therapies entrectinib (Rozlytrek®) or larotrectinib (Vitrakvi®), for the treatment of solid tumours that display an NTRK gene fusion

For MMP Use Only	
Case Reference	*Date Received*

ALL SECTIONS OF THIS FORM MUST BE COMPLETED

Please indicate which treatment this application refers to:	
Entrectinib (Rozlytrek®) ☐	Larotrectinib (Vitrakvi®) ☐
Date of application:	

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: Consultant Details

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

Please refer to the HSE Managed Access Protocol for NTRK gene fusion therapies when completing parts 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, to the Summary of Manufacturer's Product Characteristics (SmPC), and to the eligibility and exclusion criteria detailed in the NCCP national regimen for the relevant NTRK gene fusion therapy, entrectinib or larotrectinib

The patient:	**Yes**	**No**
meets any of the contraindications to treatment as outlined in the relevant SmPC		
meets any of the exclusion criteria for treatment as outlined in the relevant NCCP national regimen		

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

I confirm that the patient meets the performance status as outlined in the eligibility criteria in the NCCP national regimens for the relevant NTRK gene fusion therapy

Yes ☐ **No** ☐

Part 5: Place in Therapy

1. I confirm that the NTRK gene fusion therapy will be prescribed for this patient in accordance with the licensed indication for which it has been approved for reimbursement under the High Tech Arrangement, as outlined in the HSE-Managed Access Protocol for NTRK gene fusion therapies i.e. as monotherapy for the treatment of this patient with a solid tumour that display an NTRK gene fusion
   - who has disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and
   - who has no satisfactory treatment options.

   Yes ☐ **No** ☐

2. I confirm that the NTRK gene fusion therapy 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 entrectinib and 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 entrectinib or 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 an 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 Approved 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.