Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil
Bealach amach 5 an M50, An Bóthar Thuaidh, Fionnghlas
Baile Átha Cliath 11, D11 XKF3
Guthán: (01) 864 7100 Facs: (01) 834 3589

Health Service Executive, Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: (01) 864 7100 Fax: (01) 834 3589

3rd August 2023

Circular 025/23

Medicinal Cannabis Access Programme (MCAP) – Update to List of Products

Dear Pharmacist,

I refer to Circulars 025/21 and 018/22 in relation to the Medicinal Cannabis Access Programme (MCAP). I am writing to update you on an additional product which is now reimbursed under this programme for approved patients.

Althea CBD12: THC 10 (50mls) was added to the list of products available under the programme effective 1st August 2023.

The Medicinal Cannabis Access Programme is to provide access for patients with the following medical conditions only which have failed to respond to standard treatments:

- spasticity associated with multiple sclerosis resistant to all standard therapies and interventions
- intractable nausea and vomiting associated with chemotherapy, despite the use of standard anti-emetic regimes
- severe, refractory epilepsy that has failed to respond to standard anticonvulsant medications

In line with Ministerial policy pertaining to the Medicinal Cannabis Access Programme in Ireland, the specified controlled drugs listed below that are in Schedule 1 of the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) (Amendment) Regulations 2023 have been assigned administrative codes by PCRS.

The Consultant Neurologist / Oncologist must make an application to register the patient on the Cannabis for Medical Use Register. The HSE Cannabis for Medical Use Register Application form (enclosed) must be completed by the prescribing medical consultant and the patient/parent/guardian.

Persons added to the register will be issued with a Cannabis for Medical Use Registration (CMUR) number from PCRS and this CMUR number will be provided to the prescribing consultant on the Cannabis for Medical Use Prescription Form which must be used for prescribing these products. These products cannot legally be prescribed on any other prescription form. The prescription form will include the CMUR number for the approved patient.

Reimbursement of the listed products prescribed by medical consultants and supplied through community pharmacies for a specified therapeutic indication as outlined in Schedule 2 of the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019 (as amended), will be on an individual named patient basis aligned to the patient's eligibility under the Community Drug Schemes.

To claim reimbursement, the top copy of the Unified Claim Form (UCF) is submitted for each dispensing with a copy of the Cannabis for Medical Use Prescription Form using form number format. The UCF will need to include patient name, Community Drug Scheme eligibility details (e.g. LTI number), administrative codes, name and quantities of products dispensed and dates of dispensing. Claims submitted for patients who are not approved will not be paid.

These claims are submitted manually, similar to claims submitted for the Opioid Substitution Treatment Scheme. A separate bundle containing copies of the Cannabis for Medical Use Prescription Forms with UCFs attached, and the summary of claims certificate must be forwarded to the HSE no later than 14 days after the last day of the month in which the supply was completed.

Claims are submitted in the normal manner and should be posted to:
Health Service Executive (HSE)
Primary Care Reimbursement Service (PCRS), P.O. Box 6422, Finglas, Dublin 11

List of MCAP Products as of 1st August 2023

Administrative Code	Product Description	Pack Size	Reimbursement Price
46121	CannEpil™ Oral Solution (100mg/ml CBD, 5mg/ml THC in MCT oil)	50ml	€467.64
46120	CannEpil™ Oral Solution (100mg/ml CBD, 5mg/ml THC in MCT oil)	30ml	€280.80
46122	Tilray® THC10:CBD10 Oral Solution (10mg/ml CBD, 10mg/ml THC)	25ml	€185.00
46123	Oleo Bedrobinol® dried flower THC 13.5% w/w (THC 135 mg/g)	5 gram	€84.67
46125	Oleo Bedrocan® dried flower THC 22% w/w (THC 220 mg/g)	5 gram	€84.67
46127	*Oleo Panacea Inhaler	1	€76.00
46128	Althea CBD12:THC10	50ml	€327.89

**Only 1 device permitted every 24 months.*

Yours faithfully,

Shaun Flanagan
Primary Care Reimbursement Service

FOR OFFICIAL USE ONLY	
CMUR Number Assigned	

HSE
Primary Care Reimbursement Service (PCRS)
Cannabis for Medical Use Register (CMUR) Application Form

Before completing this form please read text below:

This form relates to the prescription cannabis products listed in Schedule 1 of the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019) (as amended) and as specified in Section 3 of Part 1 below (each a "Cannabis Product")

1. **All fields are mandatory.**
2. Please complete all sections clearly. **Part 1** must be completed by the prescribing medical consultant. **Part 2** must be completed by the patient/parent/guardian. This form must be completed and provided to the HSE for addition of a person to the Cannabis for Medical Use Register and on each occasion where there is a change to the prescription described herein.
3. Any supporting documentation including published clinical evidence can be submitted with this application form.
4. The prescribing medical consultant must, before completing this form, provide the patient/parent/guardian with the risks and benefits of the preparation they intend to prescribe, give the patient/parent/guardian the opportunity to understand the risks and benefits of the preparation and answer any questions the patient/parent/ guardian may have.
5. **Data Protection Notice:** Personal data collected by the HSE is used for the purpose of providing a health service. It is collected, stored, processed and disclosed to other bodies in accordance with the laws relating to proper treatment of personal data and in accordance with the HSE PCRS Privacy Statement.

Please scan and email the competed, signed form (Part 1 and 2) to: PCRS.ExemptMed@hse.ie.

Alternatively post form to:
Pharmacy Function,
Primary Care Reimbursement Service (PCRS),
Exit 5, M50,
North Road,
Finglas,
Dublin 11,
D11 XKF3.

Please Note: By completing this application form you wish for your patient to be added to the 'Cannabis for Medical Use Register' and assigned a 'CMUR number'. A practitioner shall not issue a prescription for a specified controlled drug other than to a person whose name has been entered in the Cannabis for Medical Use Register and who has received a CMUR number from the HSE. Prescriptions for a Cannabis product under Schedule 1 of the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019) (as amended) must be written on the Cannabis for Medical Use Prescription Form issued by the HSE.

Primary Care Reimbursement Service
Cannabis for Medical Use Register Application Form

This application must be completed in full for consideration by the HSE

Part 1 - TO BE COMPLETED BY THE CONSULTANT NEUROLOGIST / ONCOLOGIST ONLY

Section 1: Patient Details

Forename	**Surname**
DOB	d d m m y y
Address	
Period of time under my care	Years / Months
Diagnosis	

Section 2: Prescribing Consultant

Name	**MCRN**
Institution	
Speciality	

Section 3: Cannabis Product *(As per Schedule 1 of the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019)*

Product Name	**Strength**
Manufacturer	
Dosage	
Intended period of treatment	

Specified Medical Condition: tick to confirm

Severe epilepsy where the severity and frequency of seizures are significantly impacting on quality of life and that has failed to respond to 5 or more standard antiepileptic treatments.	☐
Dravet or Lennox-Gastaut syndrome.	☐
Intractable nausea and vomiting associated with chemotherapy, despite the use of standard anti-emetic regimes.	☐
Spasticity associated with multiple sclerosis resistant to all standard therapies and interventions.	☐

1. **Seizure frequency (seizures per month) OR nausea/vomiting frequency OR description of spasticity (mild/medium/severe)**

Before treatment with cannabis product

2. **No. of hospital admissions in a 12 month period:**

Before treatment with cannabis product

3. **Treatment for Specified Medical Condition:**

Current treatments prescribed for seizure control, nausea/vomiting or spasticity:

a)	
b)	
c)	
d)	
e)	
f)	

Exhausted treatments prescribed for seizure control, nausea/vomiting or spasticity:

a)	
b)	
c)	
d)	
e)	
f)	

4. **Please outline the unmet clinical need for the cannabis product that is the subject to this application**

Section 4: Consultant confirmation and declaration

Please Tick to Confirm

1. I confirm that I am a medical consultant for the purposes of the Misuse of Drugs (Prescription and Control and Supply of Cannabis for Medical Use) Regulations 2019 (as amended). ☐

2. I confirm that the patient's name is to be entered on the Cannabis for Medical Use Register and assigned a CMUR number from the HSE on the basis of the information which is set out in this form. ☐

3. I confirm that I am responsible for the clinical governance, including the ongoing supervision, of the treatment which is the subject to this application. ☐

4. I confirm that I am prescribing the Cannabis Product specified above for the specified medical condition outlined at Section 3 of Part 1 above. ☐

5. I confirm that I will assist the HSE in their conduct of audits to provide assurance that the Cannabis Product is being prescribed in line with the Clinical Guidelines published on the Department of Health website. ☐

6. I confirm that the patient is aware that an application is being made to the HSE on their behalf and that audits may occur during which their personal data will be reviewed. ☐

7. I confirm that the information provided in this form is correct. ☐

8. I am aware that the prescribed Cannabis Product is not an authorised medicinal product and therefore is not subject to the same rigorous safety, quality and efficacy standards that are in place for medicines, nor are the producers subject to the same responsibilities as marketing authorisation holders for authorised medicines. ☐

9. The risks, benefits and alternatives of the use of the Cannabis Product and cannabis-based products in general have been discussed in detail with my patient and/or their parent/guardian. ☐

10. I have obtained informed consent from the patient/parent/guardian to this treatment and have explained the risks and benefits of the preparation I intend to prescribe prior to obtaining their consent. ☐

11. I confirm that I have read and understand the Clinical Guidance on Cannabis for Medical Use published by the Department of Health. ☐

12. I agree that, as the prescriber of the Cannabis Product, I am responsible for the prescription of the Cannabis Product and for managing the patient including monitoring the effects of the treatment with the Cannabis Product over time. I acknowledge and agree that the fact that a product is a specified controlled drug is not an endorsement of the safety, quality or efficacy of the specified controlled drug and the Minister for Health shall have no liability in respect of the use of a specified controlled drug by a person issued with a prescription under the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019 (as amended)). ☐

Signature

Date

d	d	m	m	y	y	y	y

Part 2 – TO BE COMPLETED BY THE PATIENT / PARENT / GUARDIAN

This section has been completed by:
(Tick one that applies)

Patient	
Parent	
Guardian	

Section 1: Patient Details																																
Forename														**Surname**																			
DOB	d	d	m	m	y	y								**PPSN**																		
Community Drug Scheme	GMS		DPS		LTI		**Number**																									
Address																																

Section 2: Patient / Parent / Guardian Declaration

- I confirm that the information provided in this form is correct.
- I am aware that the Cannabis Product is not an authorised medicinal product and therefore is not subject to the same rigorous safety, quality and efficacy standards that are in place for medicines, nor are the producers subject to the same responsibilities as marketing authorisation holders for authorised medicines.
- The risks, benefits and alternatives of the use of the Cannabis Product and cannabis-based products in general has/have been discussed in detail with me by the prescribing medical consultant.
- I am aware that use of the Cannabis Product that is the subject to this application is an experimental approach to treatment.
- I have provided informed consent to this experimental treatment.
- I understand that the personal data which I provide in this form, together with other personal data held by my medical consultant will be used in order for my medical consultant to seek approval on

my behalf and that audits of my medical consultant may occur during which my personal data will be reviewed.

- I am aware that the medical consultant, as the prescriber of the Cannabis Product, is responsible for my prescription of the Cannabis Product and managing my treatment and monitoring the effects of same over time.
- I am aware that the fact that a product is a specified controlled drug is not an endorsement of the safety, quality or efficacy of the specified controlled drug and the Minister for Health shall have no liability in respect of the use of a specified controlled drug by a person issued with a prescription under the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019).

Signature:

Name in Block Capitals

First Name:

Second Name:

Date

d	*d*	*m*	*m*	*y*	*y*	*y*	*y*