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5 November 2021

Circular 025/21

Medical Cannabis Access Programme (MCAP)

Dear Pharmacist,

The purpose of this circular is to update you on the implementation of the Medical Cannabis Access Programme (MCAP).

The purpose of the programme is to facilitate access to acceptable cannabis-based products for medical use that are of a standardised quality and which meet the requirements outlined in S.I. No. 262 of 2019 (Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019) (as amended).

The Medical Cannabis Access Programme is to provide access for patients with the following medical conditions 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 antiemetic regimes
- severe, refractory epilepsy that has failed to respond to standard anticonvulsant medications

The Minister for Health, following consultation with the IPU, has determined that the following fee rates should apply for dispensing under the Medical Cannabis Access Programme (MCAP):

Patient care fee:	€53.37
Standard dispensing fee:	€5.00
M.D.A fee	€5.74

In line with Ministerial policy pertaining to the Medical Cannabis Access Programme in Ireland, the specified controlled drugs CannEpil™ Oral Solution and Tilray® THC10:CBD10 Full Spectrum Oral Solution as listed in Schedule 1 of the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) (Amendment) Regulations 2020 have been assigned administrative codes by the HSE Primacy Care Reimbursement Service.

The administrative codes will facilitate access to CannEpil™ Oral Solution and Tilray® THC10:CBD10 Full Spectrum Oral Solution in accordance with the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019 (as amended).

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 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 the HSE PCRS and this CMUR number will be provided to the prescribing consultant on the Cannabis for Medical Use Prescription Form (please see copy in Appendix A) which must be used for prescribing these products.

Reimbursement of CannEpil™ Oral Solution and Tilray® THC10:CBD10 Full Spectrum Oral Solution, 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 (Medical Card, Long Term Illness Scheme and Drugs Payment Scheme).

Better Health

Pharmacists can check if reimbursement approval is in place for patients by contacting Pharmacy Function on 01 8647100 option 7 or email pharmacy.response@hse.ie. Pharmacies can dispense and claim manually for these products using the administrative codes provided on a unified claim form with a copy of the Cannabis for Medical Use prescription (Copy of Summary of Claims Certificate included in Appendix B). Claims submitted for patients who are not approved will not be paid.

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	€135.00

Please see attached list of frequently asked questions (FAQs)

Yours faithfully,

Shaun Flanagan

Primary Care Eligibility & Reimbursement

Appendix A

Cannabis for Medical Use Prescription Form

CANNABIS FOR MEDICAL USE PRESCRIPTION FORM RedInneammacht na Seirbhise Skänte Bealth Service Executive
FOR USE BY CONSULTANT NEUROLOGIST / ONCOLOGIST ONLY Please complete all sections in BLOCK CAPITALS where appropriate Pharmacy sequence number
PART 1 – HOSPITAL AND PATIENT DETAILS
Hospital Name:
Address Line 1: Telephone No.
Address Line 2: Eiroode:
Patient Name:
Address Line 1:
Address Line 2: Eircode:
Phone Number: □ Date of Birth: □ □ M M Y Y Y Y Gender: F Card Type: GMS DPS LTI HAA Card Number Image: Card Number
(Please tick √ as appropriate)
CMUR NUMBER (LEGAL REQUIREMENT)
Part 2-Prescribed Drugs Details (please specify the product, strength, form, or an add Quantity)
Cannabis Product Strength Form age tal Quantity
SAMPLE FOR INFORMATION TURP JES
SAMPLE FOR INFORMATION TURP JES
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Appendix B

Summary of Claims under Medical Cannabis Access Programme

Medical Cannabis Access I HSE PRIMARY CARE REIMBU UNIT 1 - 10 JS PLAZA, NORTH EXIT 6, M50, NORTH ROAD, FINC	RSEMENT SERVICE H PARK BUSINESS PARK
SUMMARY OF CLAIM MEDICAL CANNABIS ACC	
PHARMACY NUMBER	
MONTH / YEAR	
NUMBER OF FORMS	
PHARMACY NAME ADD	RESS AND STAMP

Frequently Asked Questions Medical Cannabis Access Programme (MCAP)

Q1. Where can I find more information on the Medical Cannabis Access Programme (MCAP)?

The Department of Health published clinical guidance - 'Clinical Guidance on Cannabis for Medical Use' which can be accessed at https://www.gov.ie/en/publication/90ece9-medical-cannabis-access-programme/

Q2. How do patients apply for registration on the Cannabis for Medical Use Register (CMUR)?

The Consultant Neurologist / Oncologist must make an application for registration on the Cannabis for Medical Use Register. The HSE <u>Cannabis for Medical Use Register Application form</u> must be completed by the prescribing medical consultant and the patient/parent/guardian.

Q3. How do community pharmacy contractors check if a patient is registered on the Cannabis for Medical Use Register and if reimbursement approval is in place for patients?

Contact pharmacy function on 01 8647100 option 7 or email (by Healthmail) to pharmacy.response@hse.ie

The CMUR number will be provided to the prescribing consultant on the Cannabis for Medical Use Prescription Form and this CMUR number must be included on the prescription form. There is no requirement for a treatment card listing the CMUR number.

Patients will have to be registered on one of Community Drug Schemes. Patient approval will not be visible on Secure Scheme Checker. Initial approval will be for a maximum of 6 months.

Q4. How much does the patient pay for items dispensed under MCAP?

These products are exempt from prescription charges for approved patients.

Q5. What are the reimbursement arrangements for pharmacists?

The pharmacist will order the drug from the supplier as normal and will be reimbursed the

Reimbursement price plus the fees as outlined in Circular 025/21.

GMS approved patients do not also require a separate GMS prescription from their GP.

All patients or their representative must sign the Unified Claim Form (UCF) to confirm that they have received the items.

The top copy of the 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, administrative codes, name and quantities of products dispensed and dates of dispensing.

These claims are submitted manually, similar to claims submitted for 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 Eligibility & Reimbursement Service (PCERS), P.O. Box 6422, Finglas, Dublin 11

Q6. What are the prescription requirements for the cannabis based products listed in Schedule 1 of the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019 (as amended)?

Persons added to the register will be issued with a Cannabis for Medical Use Registration (CMUR) number from the HSE PCRS and this CMUR number will be provided to the prescribing consultant on the <u>Cannabis for Medical Use Prescription Form</u> (As per legislation, 'a practitioner shall not issue a prescription for a specified controlled drug other than in a format prescribed by the Executive for that purpose')

A prescriber cannot legally issue a prescription for a specified controlled drug (Schedule 1 of the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019)(as amended) to a person who is not registered and entered in the Cannabis for Medical Use Register and does not have an individual CMUR number assigned to them.

Prescription requirements for specified controlled drugs as per Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations.

The specified controlled drugs listed in Schedule 1 of the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations (SI 262 of 2019) and amendment Regulations (SI 505 of 2020) are Schedule 2 (CD2) products as per the Misuse of Drugs Regulations 2017 and amendment legislation (Misuse of drugs (amendment) Regulations 2019 (SI 282 of 2019). This means the cannabis products/preparations listed in the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations are Schedule 2 (CD 2) controlled drugs and prescriptions must meet the requirements of the Misuse of Drugs Acts 1977 to 2016 and the Misuse of Drugs Regulations 2017.

Q7. Where can these products be ordered from?

The supplier of CannEpil™ Oral Solution (100mg/ml CBD, 5mg/ml THC in MCT oil) has confirmed that product can be ordered directly from Georgelle.

The supplier of Tilray® THC10:CBD10 Full Spectrum Oral Solution (10mg/ml CBD, 10mg/ml THC) has yet to confirm the date the product will be available or ordering arrangements.