Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

National Hepatitis C Treatment Programme

Clinical Advisory Group

Community Treatment Guidelines 2019

Version 1. July 2019

Version 2. July 2020

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Appendices

1.0 Introduction

Direct Acting Antiviral (DAA) containing regimens for the treatment of chronic hepatitis C infection were approved for use in Ireland in December 2014. To implement the multi-annual treatment plan, the National HCV Treatment Programme (NHCTP) was established in March 2015. The governance structure includes a Programme Advisory Group (PAG) and a Clinical Advisory Group (CAG). Following successful establishment of a hospital based programme it was decided to make hepatitis C treatment available in community settings. These include drug treatment centres, general practices and community pharmacies. In 2017 treatment was successfully expanded to the drug treatment service with on-site dispensing. In 2019 a community prescribing and dispensing pilot programme was initiated. Although the preferred treatment route is through one of the eight hospital based treatment centres community treatment may be preferred if patients find it difficult to attend the hospital based services for logistical, social or psychological reasons. For the present, community treatment will be restricted to low risk patients. Patients with cirrhosis, organ transplantation, HIV and recurrent HCV infection, (see exclusion criteria) should be referred to a hospital treatment center. It is expected that these criteria may change over time.

Doctors and Pharmacists wishing to take part in this programme need to undergone a short training programme and be approved by PCRS. Each doctor wishing to prescribe would need a partner with at least one local Community Pharmacist to ensure treatment can be provided. Training is provided by PCRS (Declan Bradley Declan.Bradley@hse.ie), ICGP (Dr. Des Crowley des.crowley@hse.ie) and hospital pharmacists (see appendices for details).

2.0 National Hepatitis C Treatment Programme Guidelines 2019

The 2018 European Association for the Study of Liver Disease (EASL) guidelines recommend: "*All treatment-naïve and experienced patients with HCV infection, who are willing to be treated and who have no contraindications for treatment, should be treated."* The guidelines further recommend that treatment should be with Interferon-free, ribavirin-free, DAA based regimens. Current EASL 2018 guidelines stratify treatment regimens according to genotype and the presence or absence of cirrhosis. The Clinical Advisory Group (CAG), under the auspices of the National Hepatitis C

Treatment Programme, concurs with international guidelines and adopts the recommendations as best-practice in the Irish setting. It is anticipated that as international guidelines change, the CAG will review national treatment guidelines and adapt as required to suit local conditions. For the community treatment programme it has been decided to use medications which work for all hepatitis C genotypes i.e pangenotypic regimens. Two pangenotypic regimens are available on the Irish market; Sofosbuvir/Velpatasvir (Epclusa®) and Glecaprevir/Pibrentasvir (Maviret®).

The treatment programme is supported by a Clinical Advisory Group (CAG) and a Programme Advisory Group (PAG). All prescribing clinicians are entitled to membership of the CAG, which meets once a month in Dr Steeven's Hospital and via teleconference. The CAG is responsible for approving the clinical guidelines and access to second line therapies. There is a virtual CAG to support the community prescribing program.

The CAG deals with two sets of clinical guidelines. The first is for hospital clinics and opiate substitution clinics with pharmacies on site. The second (this one) is for community prescribing and dispensing. There are different process and procedures for the two programs and community clinicians who are members of CAG need to be aware of that to avoid confusion.

3.0 The Virtual Clinical Advisory Group (vCAG)

The virtual CAG (vCAG) will comprise of hospital HCV pharmacists, HCV specialist nurses and clinicians. Business will be conducted mainly by email. The contact email is nhctp@hse.ie. The vCAG will give advice on individual patient cases, give general advice on treating hepatitis C patients, advise on management of potential drug-drug interactions and any adverse drug reactions experienced. The Hospital HCV pharmacists can be contacted directly for queries regarding drugs, medications, interactions etc (see appendix for contact details). For other queries please contact the virtual CAG at nhctp@hse.ie. Alternatively the hospital based HCV specialist nurses may be able to assist – see appendix for contact details.

4.0 Current criteria for DAA treatment regimens

The NHCTP Clinical Advisory Group and the Programme Advisory Group have recommended strongly that all patients with active hepatitis C infection should be offered treatment. Active alcohol or substance abuse are not a barrier to treatment providing the prescribing clinician forms the view

that the patient is capable of adhering to the treatment regimen. The number of investigations and treatment visits has been kept to the minimum to maximise adherence. Clinicians are free to see the patients more often or to arrange additional tests, if they feel these are warranted. The NHCTP Programme Advisory Group adopted a "Treatment as Prevention strategy" (TasP) with a view to preventing significant liver disease and reducing the chances of transmission.

The community program is planned on the basis of weekly dispensing. If daily dispensing is considered essential the prescribing clinician can apply to PCRS for exceptional approval. Applications would be considered on a case by case basis.

5.0 Preparation for DAA treatment

Access to DAA treatment regimens through the National HCV Treatment Programme requires the following assessments to be made and reported prior to commencing therapy:

1. Registration to the National HCV Treatment Registry. (see registration document: appendix)
2. Baseline HCV-RNA assessment within 6 months of start date of treatment. HCV genotype and viral quantitation are desirable but not mandatory.
3. Baseline laboratory parameters FBC, U/E, creatinine, LFTS (including ALT, **AST**, bilirubin and albumin) and INR
4. Hepatitis B and HIV serology. There have been rare cases of HBV re-activation following DAA treatment. So baseline HBV markers are advised.
5. Evaluation of liver staging
    a. Fibroscan* –kPa, IQR, success rate **or**
    b. Serum markers of fibrosis e.g APRI or FIB-4. If APRI> 0.5 and/or FIB4>1.45 patient should be referred for Fibroscan
6. Assessment for potential drug-drug interactions by HCV specialist pharmacist (see appendix)

* Fibroscan can be performed by visiting Hepatitis C specialist nurse from one of the Hospital based HCV treatment centres

6.0 Exclusions for community treatment

- Cirrhosis or Fibroscan > 12

- Co-infection with HIV or Hepatitis B
- Previous treatment with DAAs for hepatitis C (If previously treated with interferon/ribavirin this will need to be discussed with vCAG prior to treatment)
- Pregnancy or lactation
- Less than 18 years of age
- Organ transplant recipient or immuno-compromised (e.g. steroids, azathioprine or TNF inhibitors)
- Renal failure requiring renal replacement therapy
- Major medical co-morbidity
- Significant drug interactions difficult to manage in primary care

6.1 Caution for diabetic patients

Diabetes; Rapid reduction in hepatitis C viral load during initial treatment with direct-acting antiviral therapy for hepatitis C may lead to improvements in glucose metabolism in some patients with diabetes. This could potentially result in symptomatic hypoglycaemia if diabetic treatment (including both insulin preparations and oral hypoglycaemic agents) is continued at the same dose. As improvements in glucose metabolism may arise in the months following treatment, appropriate follow up is required.

7.0 Preferred DAAs for community treatment.

Sofosbuvir/Velpatasvir 400mgs/100mg (Epclusa®)

One tablet daily with or without food. Patient should be advised to take the medication at the same time every day.

Pangenotypic 12 week course

Suitable in all stages of hepatic impairment

Renally excreted (requires creatinine clearance > 30mls/min)

Headache, fatigue and nausea are the most common side effects (> 10% of patients). They tend to be mild to moderate in severity. They are most likely to occur in the first four weeks of treatment.

Itch/Rash/Angioedema (uncommon)

Common Drug interactions with Epclusa® (not exhaustive)

- Antacids/PPIs/H_2receptor antagonists
- Amiodarone
- Digoxin
- Rifampicin and derivatives
- DOACs and warfarin
- Some anti-epileptics
- Some diabetes medications
- Carvedilol
- Diltiazem, verapamil
- Some statins

Glecaprevir/Pibrentasvir 100mgs/40mgs (Maviret®)

Three tablets once daily with or after food. Patient should be advised to take the medication at the same time everyday.

Pangenotypic 8 week course

Not suitable for Child Pugh's stage B and C cirrhosis

Suitable in all stages of renal failure including dialysis

Minimal side effects. Headache and fatigue most common. Also potential for GI symptoms particularly if patients do not take their medication with or after food.

Common drug interactions with Maviret® (not exhaustive)

- Oestrogen containing contraceptives
- DOACs and warfarin
- High dose PPIs/H_2receptor antagonists
- Rifampicin and derivatives
- Amiodarone, Digoxin
- Erythromycin, Ketoconazole
- Some anti-epileptics
- Aripiprazole, clozapine, paliperidone, quetiapine.

- Carvedilol, diltiazem, verapamil, eplerenone, some anti-hypertensives e.g. ARBs
- GHB
- Some immunosuppressants
- Domperidone
- Some statins
- Opiates especially fentanyl

8.0 Pregnancy

	FBC	LFTs	HCV RNA
Baseline*	X	X	X
Week 1			
Week 2			
Week 4*	x	X	
Week 8			
Week 12 Post EOT	x	x	X

Patients should be counselled to avoid pregnancy during treatment and advised to take appropriate contraceptive measures. Although there is limited information to date, no major adverse effects have been described in pregnant patients exposed to DAAs. The programme should be inform if a patient becomes pregnant while on treatment. The decision whether to continue or stop the medication should be taken by the treating physician in consultation with the patient. The practice in the program to date has been to stop DAAs. The programme is happy to support re-treatment, when appropriate, after delivery.

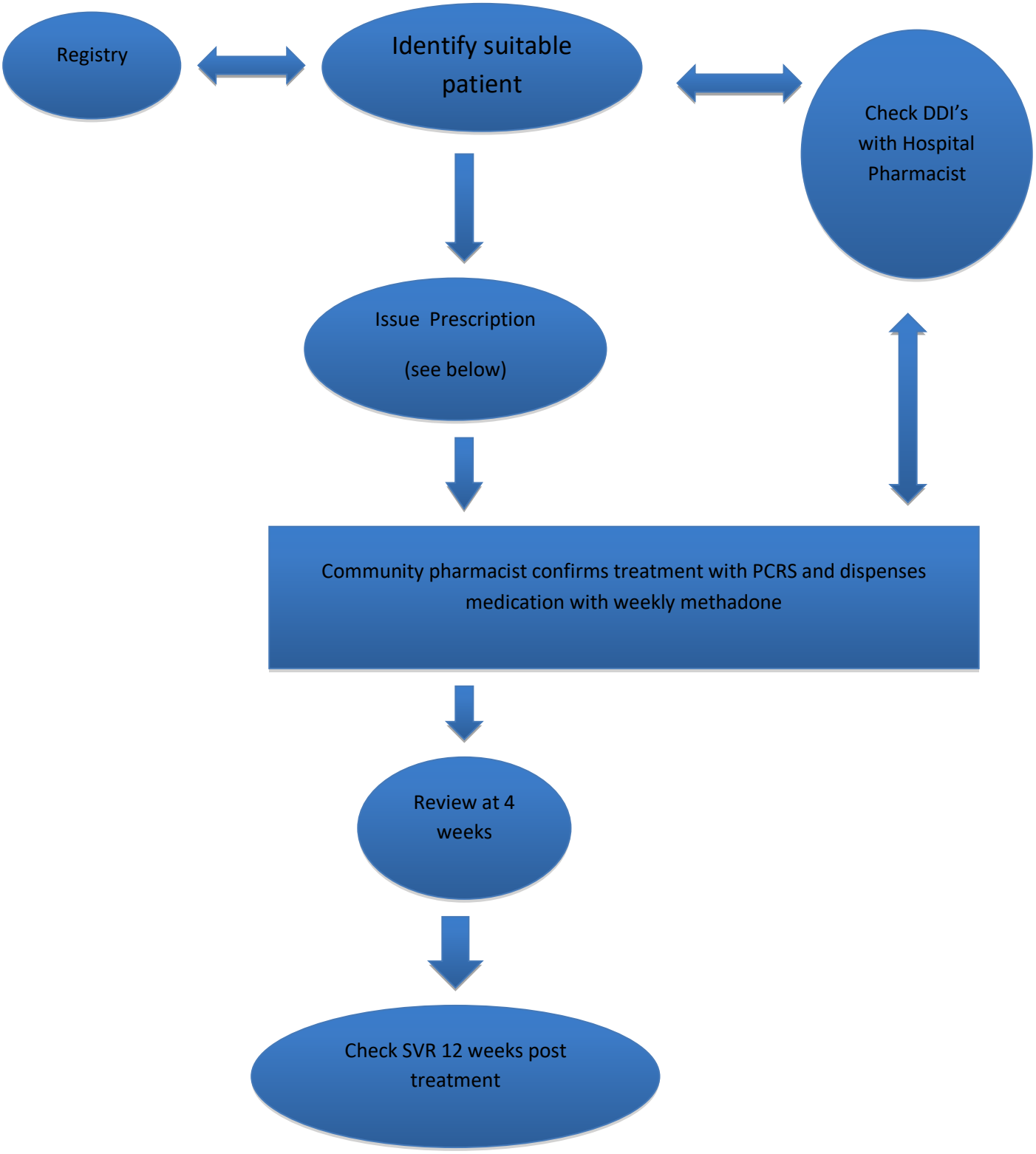
9.0 The General Practitioner:

In order to participate as a GP in the HCV community treatment programme, GPs must be registered to prescribe methadone.

The proposed blood testing schedule and treatment outline are shown below

* HCV PCR RNA within 6 months of start of treatment will be accepted as baseline. Week four bloods may be omitted in low risk patients at the discretion of the treating clinician. This opt-out is designed to facilitate treatment in patients with difficult venous access in the community.

Treatment Process



Visit 1: The GP discusses treatment with the patient, secures consent for inclusion in the treatment registry and forwards the relevant information for the National Hepatitis C Treatment Registry (See appendix). Liver fibrosis is assessed using Fibroscan or APRI score or FIB-4 (see appendix).

The GP forwards details of patient's virology (genotype and viral load), fibrosis measurement and current medications to hospital HCV pharmacist. Hospital pharmacist will advise on potential drug interactions. Providing no patient identifying information is included this can be done by email. If patient identifiable or confidential information is included this communication should be done using a secure and /or encrypted system.

Visit 2: Prescription to PCRS for the whole 8 or 12 week treatment is generated for community pharmacist (with attached advice from hospital based HCV pharmacist).

Visit 3: 4 week on treatment visit to to GP to check compliance, side effects etc. Check FBC, U/E and LFT's (optional if poor venous access).

Visit 4: 12 week post end of treatment visit to GP check PCR. GP reports treatment outcome to the National Hepatitis C Treatment Registry. If HCV PCR negative at 12 weeks this means patient has achieved sustained virological response (SVR) which is believed to equate to viral cure.

GP claims payment of associated fees from PCRS

10.0 The Community Pharmacist

Patients attend their PCRS approved specified pharmacy at intervals dictated by the frequency of their supervised dose of OST (Opioid Substitution Treatment). Pharmacists safely dispense OST and supervise doses as prescribed. Pharmacists operate this OST pathway in accordance with the HSE Clinical Guidelines for Opioid Substitution Treatment. Pharmacists will operate the primary care hepatitis C treatment pathway in line with the NHCTP Clinical Advisory Group Community Treatment Clinical Guidelines. Outlined as follows (and in Appendix).

Pharmacy Care Pathway:

It is proposed that hepatitis C medications will be dispensed weekly at a routine visit to the assigned PCRS pre-approved pharmacy for OST.

- The pharmacy receives the patient prescription from the GP. The pharmacist reviews advice from hospital HCV pharmacist and screens prescription for drug-drug interactions or

contraindications for the appropriate patient. The Virtual Clinical Advisory Group consultation process with a hospital based HCV specialist pharmacist is available for consultation.

- The pharmacist confirms that the patient is registered and approved for treatment with PCRS (via secure mail to cpu@hse.ie). GP and Pharmacist agree a suitable start date for treatment.

- The patient is counselled by the pharmacist prior to initiation of therapy.

- The patient attends for OST at agreed intervals and hepatitis C medication is dispensed weekly and the pharmacist monitors compliance weekly.

- The pharmacist liaises with the prescribing GP, hospital pharmacist and vCAG as appropriate (clinical advice, missed doses, adverse drug reactions etc).

- If a patient does not attend the pharmacy on the day they are scheduled to collect their weekly DAA supply the GP should be contacted as soon as possible. If a patient misses two consecutive daily doses or more than 7 daily doses in total during treatment the GP should be contacted as soon as possible.

- Both GP and pharmacist counsel and support the patient through the treatment pathway.

Pharmacy Administrative Pathway:

The pharmacist confirms that the patient is registered and approved for treatment with PCRS (via secure email to cpu@hse.ie).

Pharmacist orders medication as appropriate (via CPU email also).

Pharmacist claims payment of associated fees from PCRS monthly. Current process outlined in IPU SOP Template Standard Operating Procedure for the Supply of Hepatitis C Treatment in Community Pharmacy

Appendices

General Practitioner: Roles and Responsibilities
Role • Governance of treatment of patient with hepatitis C • Clinical Governance
Responsibilities • Identification of Hepatitis C positive viraemic patients • Baseline Bloods, (including determining Hepatitis C viral load and genotype) • Assessing liver fibrosis via Fibroscan or APRI score • Informing patients of suitability / non-suitability for treatment • Explanation of treatment programme to patients and taking consent for inclusion in HCV treatment registry • Ensuring patient has at least weekly dispensed opioid substitution therapy (OST) • **Inform patient re contraception, need to avoid pregnancy and ask patient to sign form to confirm the understand same** (see appendix) • Reviewing patients existing medication (prescribed and non-prescribed i.e. illicit use) and forwarding details to hospital HCV pharmacist for assessment of potential drug-drug interactions with planned antiviral treatment regimen • Engagement with virtual Clinical Advisory Group when appropriate • Registration of patient with National Hepatitis C Treatment Registry • Planning of treatment start date in conjunction with community pharmacist and patient • Prescribing of appropriate hepatitis C treatment regimen for patient • Ensuring that the prescription is legally and clinically valid and appropriate • Periodic assessment of patient, including compliance and monitoring for possible side effects and potential drug interactions • Liaising with community pharmacist as appropriate • Reporting of clinically significant side effects or adverse outcomes • Reporting of treatment outcome to the NHCTP Registry • Requesting and reviewing of blood tests Referral of patients who are deemed inappropriate for community based treatment to the appropriate hospital-based setting for treatment of hepatitis

Community Pharmacist : Roles and Responsibilities

Role

- Dispensing and Supervision of hepatitis C medications to patient
- Pharmaceutical Governance

Responsibilities

- Explanation of treatment programme to patients
- Ensuring patient has at least weekly dispensed opioid substitution therapy (OST) directly in accordance with OST prescription
- Ensuring patients are advised on appropriate contraceptive methods
- Reviewing patients existing medication (prescribed and non-prescribed i.e. illicit use and OTC medications) for drug-drug interactions with hepatitis C regimen to be dispensed
- Engagement with virtual Clinical Advisory Group when appropriate
- Ensuring patient is registered and approved for treatment with PCRS
- Planning of treatment start date in conjunction with GP and patient
- Ensuring that the prescription received is legally and clinically valid and appropriate
- Sourcing of appropriate treatment regimen for patient (pathway to be confirmed)
- Dispensing of appropriate treatment regimen for patient at weekly intervals ensuring protection of patient confidentiality
- Provision of a patient information leaflet (PIL) to patients at initiation of treatment
- Providing appropriate pharmaceutical counselling to the patient at initiation of treatment
- Weekly compliance assessment of patient, issues to be reported to vCAG and prescriber
- Monitoring of side effects and adverse drug reactions
- Addressing side effects and adverse events related to treatment as appropriate
- Liaising with GP prescriber as appropriate
- Reporting of significant or unexpected side effects and/or adverse outcomes to prescriber in the first instance and to treatment programme, HPRA or drug company if appropriate
- Ensuring good pharmaceutical practice in the stock management of hepatitis C medications
- Liaising with PCRS as appropriate

Virtual Clinical Advisory Group consisting of specialist physicians, hospital pharmacists and nurse practitioners experienced in the treatment of hepatitis C
Role • To provide stewardship and guidance to GPs and pharmacists involved in the community treatment of hepatitis C
Responsibilities • Discussing and providing guidance on individual clinical cases • Advising on the suitability of prescribed therapies • Providing guidance on drug-drug interactions • Advising on clinical queries as they arise • Providing support and expertise to prescribing GPs and dispensing pharmacists • Involvement in provision of education material to GPs and pharmacists as appropriate

Primary care Patient Registration Form

Patient without CIRRHOSIS

Site:	Pt. initials: _____	MRN: _____ DoB: _____	Country of birth: _____ EU passport holder: Yes No	Male Female

Genotype 1a Genotype 1b Genotype 1 Genotype 2 Genotype 3 Genotype 4 Genotype 5 Genotype 6 Genotype 7 Mixed: _____	**Acquisition risk factor** *(circle):* - IVDU - Blood product Anti D (HAA) - Blood product transfusion (Ireland - HAA) - Blood product transfusion (outside Ireland) - Sexual MSM - Sexual heterosexual - Vertical transmission - Tattoos - Country of birth - Unknown - Nosocomial - Dual risk: _____	**Co-morbid conditions** *(circle):* HIV co-infected HBV co-infected Diabetes: T1 T2 **Social:** Current smoker Current alcohol use Current excessive alcohol use Past excessive alcohol use

For IVDU

Currently on methadone Yes No

Currently attending DTC for methadone Yes No Specify DTC: _____

Currently attending pharmacy for methadone Yes No

Treatment naive Yes No

Details of previous HCV treatment *(if applicable):* _____

Liver staging: Only one modality required – fibroscan preferred

Fibroscan results (where available): **Date Fibroscan: _____** **Result:** **_____**kPa	**APRI score:** **AST_____** **Platelets_____** https://www.mdcalc.com/ast-platelet-ratio-index-apri **APRI score: _____**	**FIB-4 score:** **Age: _____** **AST: _____** **ALT:_____** **Plts:_____** https://www.mdcalc.com/fibrosis-4-fib-4-index-liver-fibrosis **FIB-4 score:_____** points

Laboratory data: **Date of sample: _____**

Plts	Alb	γGT

HCV VL _____	**Date of VL:** _____

Re-infection episode: Yes No

Please email this form to HCVregistry@stjames.ie

National Hepatitis C Treatment Programme Registry

Hepatitis C treatment and Hepatitis C Registry

The National Hepatitis C Treatment Program provides highly effective treatment for patients with hepatitis C. This treatment results in cure rates of over 95%. To access treatment your details will be entered into the hepatitis C treatment registry. A treatment order number will then be provided so your doctor and pharmacist can prescribe and dispense the treatment.

It is a requirement to read the following information and sign below to access treatment:

I am aware that pregnancy is not advised while taking any hepatitis C antiviral drugs. I have been advised to take appropriate contraceptive measures for the duration of treatment. Some drugs can be present in semen so male patients should also take appropriate contraceptive measures. If female I have been advised to let my doctor know immediately if I become pregnant.

I confirm that I have read and understand the above information about pregnancy and contraception.

Signed. Date

Witness Date

Hospital HCV Specialist Pharmacist Information Form

Step 1: Patient baseline characteristics

Patient Age	yrs	**Gender**		Patient Weight (Kg)		
Hepatitis C Genotype		**HCV Viral Load**		Treatment Registry Number		Date:
Liver Disease Staging (if available)	Fibroscan: _____kPa	or APRI:		or FIB4:		
Co-morbidities						
Alcohol Intake (weekly)						
Allergy Status						
Baseline Laboratory Markers	Hb		ALT		Bilirubin	
	Na^+		Platelets		Creatinine	
Date of Labs:	Albumin		AST		INR	
Hepatitis B/HIV Markers	Surface antigen	Core Antibody			HIV	
Based on the available information does this patient have cirrhosis? If yes, please complete below questions		Yes No Not determined				

Hospital HCV Specialist Pharmacist Drug Interaction Information Form

Name of patient's community pharmacy:

When obtaining information relating to medication taken by a patient please ensure information on ***all*** potential medication forms is obtained. (Oral medications, topical agents, transdermal patches, inhalers, eye drops, herbal teas etc.).

Please ensure all medications (prescribed and un-prescribed) are captured.

Source	**Medication List**	**Potential for DDI**
Community pharmacy		
Drug treatment clinic		
Hospital Outpatient Clinic		
Healthfood Shop /Supermarket/Gym supplements		
Online		
Illicit		
Other		
Contraception planning for both patient and partner(s) while on Hepatitis C treatment.		

Reference Sources drug interactions

The university of Liverpool hepatitis C drug interaction website is particularly useful and user friendly.

- University of Liverpool Hepatitis C Drug Interaction Charts www.hep-druginteractions.com
- Summary of product characteristics (SPC) www.hpra.ie or www.medicines.ie

National Hepatitis C Treatment Programme Prescription Form and Approval Application to PCRS for supply of Preferred Pangenotypic Regimen of Direct Acting Antiviral (DAA) for Treatment of Hepatitis C in Community Settings

Patient Name:

Patient DOB:

Treatment Card Number: PH

Patient Address:

PPS/Medical Card/HAA/DPS/LTI:
(Please provide one of the above)

Date of Prescription:

Confirmation that patient is enrolled in the HCV registry & outcome data will be provided to the Registry:
Yes ❑ No ❑

HSE Treatment Registry Number:

Date treatment commencing as agreed by patient, GP and Pharmacist:

GP Details

GP Name:

GP Address:

GP Healthmail:

GP GMS Number:

GP Stamp:

Pharmacy Details

Pharmacy Name:

Pharmacy Address:

Pharmacy Healthmail:

Pharmacy GMS Number:

Pharmacy Stamp:

Please Tick Genotype Below:

Genotype 1a ❑	Genotype 1b ❑	Genotype 2 ❑	Genotype 3 ❑	Genotype 4 ❑	Genotype 5 ❑	Genotype 6 ❑	Mixed (specify) ❑

Please Tick Required Regimen Below:

Epclusa® 12 week course ❑

Sofosbuvir 400mg/Velpatasvir 100mg tablets

One tablet, taken orally, once daily with or without food for 12 weeks (84 tablets).
Please Dispense Weekly

Maviret® 8 week course ❑

Glecaprevir 100mg/Pibrentasvir 40mg tablets

Three tablets, taken orally, once daily with food for 8 weeks (168 tablets).
Please Dispense Weekly

Prescribing must be in accordance with the National Hepatitis C Treatment Programme Community Treatment Guidelines
A signed completed copy of this form must be forwarded to PCRS at: cpu@hse.ie for prior authorisation of treatment
Dispensing must be in accordance with the National Hepatitis C Treatment Programme Community Treatment Guidelines

I wish to prescribe the specified DAA regimen for the above patient. I confirm that the information provided in this prescription form is correct.

Prescriber Signature:

Print Name & Medical Council Number:

Record of Dispensing, copy of Prescription and Dispensing Record to be forwarded to PCRS on completion of DAA Therapy

Date Dispensed	Quantity Dispensed	Pharmacist signature

Date Dispensed	Quantity Dispensed	Pharmacist signature

I verify that I have dispensed the items specified hereon
Pharmacist's signature

I verify that I have received the items specified hereon
Signature of patient

Contact Details

1. HCV Specialist Pharmacists + catchment areas

Miriam Coghlan (St. James Hospital) West Dublin, Midlands, Limerick

mcoghlan@stjames.ie

Claire Williamson (St. James Hospital)

CWilliamson@stjames.e

Conor Moran (Mater Hospital) North Dublin, North Leinster, Galway

cmoran@mater.ie

Michael Coughlan (St.Vincent's Hospital) South Dublin, South Leinster, Waterford

michaelcoughlan@svhg.ie

Donal Carroll (St. Luke's Hospital) Kilkenny, Waterford, South-East

donalg.carroll@hse.ie 056 7785328

2. Community Fibroscanning

Enquiries to HCV nurse specialist Aileen Murphy, St Vincent's University Hospital

(01) 221 4323 or liverc@svuh.ie

3. HCV Specialist Nurses

For contacts re clinical queries, fibroscanning in the community etc.

St Vincent's University Hospital

Aileen Murphy (01) 221 4323 or liverc@svuh.ie

Sheila O'Toole and Carol McNulty 01 2214181 or liverc@svuh.ie

Mater university hospital

Jeremy Farrell (ID) jfarrell@mater.ie 087 345 3662

St James's GUIDE

Gillian Farrell (01) 4103821 (has voicemail)

Marian Broderick (01) 4162965 (no voicemail)

4. MDT Teleconferences

The **St Vincent's MDT** teleconference is held on the 2nd Monday of the month at 10.00hrs.

Teleconference guests No is 01 664 8888 – 689126#. GPs intending to call in should email liverc@svuh.ie 5 working days before week as the teleconference will not proceed if there are insufficient cases to discuss.

The **Mater MDT** teleconference is held on the third Thursday of the month room 12:00-12:45. Cases need to be notified to Dr Des Crowley (des.crowley@hse.ie) at least 5 working days before to ensure there are sufficient cases for the MDT to proceed.

5. PCRS

Declan Bradley Declan.Bradley@hse.ie

6. National Hepatitis C Treatment Programme Registry

Caitriona Ni Choitir (St. James Hospital) CniChoitir@stjames.ie

Aisling O'Leary (St. James Hospital) aoleary@STJAMES.IE

7. National Hepatitis C Treatment Programme and Virtual CAG

Eimear Sweeney nhctp@hse.ie

Epclusa® (Sofosbuvir/Velpatasvir)

Patient Information

For full information please read the package leaflets provided with your medicines.

What is your medicine?

Sofosbuvir/velpatasvir (Epclusa®) is an antiviral medicine used to treat hepatitis C. Each tablet contains two antiviral drugs, sofosbuvir 400mg and velpatasvir 100mg.

Who should not take Epclusa®?

Talk to your team before starting this medicine if any of the following apply to you:

- You are allergic to any of the ingredients in the tablet
- You or your partner is pregnant or plan to become pregnant

How do I take Epclusa®?

Take one tablet a day at the same time every day. You can take it with or without food. Swallow the tablet whole as it has a very bitter taste. It is usually taken for 12 weeks.

If you are sick (vomit) less than 3 hours after taking Epclusa®, take another tablet. If you vomit more than 3 hours after taking Epclusa®, you do not need to take an extra tablet.

Always carry a supply of medicine with you. In case you are admitted to hospital unexpectedly or are delayed somewhere, it is important that you have a supply of medicine at all times. As this is a specialist medicine, other hospitals or pharmacies will not be able to supply it to you.

What if I miss a dose?

If you miss a dose and it is within 18 hours of the time you usually take your tablet, take the tablet as soon as possible. If it is more than 18 hours from the time you usually take your tablet, skip the missed tablet.

Take the next dose at the usual time.

What if I take too much?

If you take more medicine than you should, talk to your doctor or go to your nearest emergency department straight away.

What are the side effects?

- Headache
- Feeling tired
- Nausea
- Rash
- Swelling of the face, lips, tongue or throat (uncommon; may affect up to 1 in 100 people)

Do not drive or operate machines if you feel tired while on hepatitis C treatment.

See package leaflets for all of your medicines for full list of side effects

What if I am on medicines already?

Some medicines can affect how Epclusa® works. It is very important to tell your GP about any medicines, supplements, vitamins or herbal products you are using including those not on a prescription. Check with your GP before you start any new medicines while on this treatment, even if it has been prescribed by a doctor.

Medication for stomach ulcers, heartburn or acid reflux

Do not start taking these medicines without checking with your GP or pharmacist.

X Proton pump inhibitors

(Esomeprazole, omeprazole, pantoprazole, lansoprazole)

X Antacids

(Gaviscon, Rennie, Maalox, Milk of Magnesia)

X H2-receptor antagonists

(Ranitidine, cimetidine)

If you are taking an antacid, take it at least 4 hours before or 4 hours after Epclusa®. If you are taking a proton pump inhibitor (used to treat stomach ulcers or reflux) and it needs to continue, it will need to be changed to omeprazole 20mg once a day. In this case take Epclusa® with food and take it 4 hours before the omeprazole.

What if I am taking contraception or need "the morning after pill"?

Tell your doctor if you are using the "pill" or other ways to prevent pregnancy. This is because some medicines for Hepatitis C can stop the "pill" and "morning after pill" from working properly.

Is Epclusa® safe in pregnancy?

Due to limited information, avoid pregnancy while taking Epclusa® and for 12 weeks after finishing treatment.

Your GP is: **Contact no:** **Your Pharmacist is:**	**Your treatment start date is:** _____

Ac

Version number: 1

Written by: Michael Coughlan, Hepatitis C pharmacist

Reviewed by: Miriam Coghlan, Conor Moran and Donal Carroll, Hepatitis C pharmacists

Approved by:

Review date: July 2022

Maviret® (Glecaprevir/Pibrentasvir)

Patient Information

For full information please read the package leaflets provided with your medicines.

What is your medicine?

Glecaprevir/pibrentasvir (also known by the brand name Maviret®) is an antiviral medicine used to treat hepatitis C. Each tablet contains two antiviral drugs, glecaprevir 100mg and pibrentasvir 40mg.

Who should not take Maviret®?

Talk to your team before starting this medicine if any of the following apply to you:

- Allergy to any of the ingredients in the tablet
- If you have advanced cirrhosis (decompensated)
- If you are lactose intolerant

Important warning:

- Tell your doctor if you develop, or you notice worsening, of any of the following symptoms during treatment: Feel sick (nausea), are sick (vomit), lose your appetite, yellowing of skin or eyes or discoloured stools. These could indicate liver inflammation.

How do I take Maviret®?

Take three tablets together once daily at the same time each day. It should be taken with food. Swallow the tablets whole. The treatment is usually taken for 8 weeks.

If you are sick (vomit) less than 3 hours after taking Maviret®), take another dose (3 tablets). If you vomit more than 3 hours after taking Maviret®), you do not need to take an extra dose.

Always carry a supply of medication with you. If you have to be admitted to hospital unexpectedly or are delayed somewhere it is vital that you have a supply of medication at all

times. As this is specialist medication, other hospitals or pharmacies will not be able to supply it to you.

What if I miss a dose?

If you notice the missed dose within 18 hours of the time it is usually taken, take the dose immediately. If it is more than 18 hours, wait and take your next dose at the usual time.

What if I take too much?

If you take more medication than you should, talk to your GP or go to your nearest emergency department straight away.

What are the side effects?

- Headache
- Feeling tired
- Feeling sick
- Diarrhoea
- Itching
- Swelling of the face, lips, tongue, throat, abdomen, arms or legs (uncommon: may affect up to 1 in 100 people)

Do not drive or operate machines if you feel tired while on hepatitis C treatment.

See package leaflets for all of your medicines for full list of side effects.

What if I am on medication already?

Some medications interact with Maviret®. It is very important to tell your GP about any medications, supplements, vitamins or herbal products you are using including those not on a prescription. If you are to start any new medication while on this treatment, even if it has been prescribed by a doctor, contact your GP before you take it to check for interactions.

What if I am taking contraception or need "the morning after pill"?

Tell your doctor if you are using the "pill" or other ways to prevent pregnancy. This is because some medicines for Hepatitis C can stop the "pill" and "morning after pill" from working properly.

Is Maviret® safe in pregnancy?

Tell your doctor if you think you are pregnant or are planning to become pregnant. The risk of taking Maviret® in pregnancy is unknown; therefore, pregnancy must be avoided while on treatment for hepatitis C and for 3 months after treatment has stopped.

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