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STOP-HCV Stratified Medicine for HepC

Stratified Treatment OPtimisation for HCV-1
STOP-HCV-1

PHARMACY MANUAL OF OPERATIONS

v6.0. 26-Sep-2018

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CTA #: **19174/0370/001-0001**
MREC #: **15/EE/0435**

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1. Trial Summary

Summary Information Type	Summary Details
Acronym	STOP-HCV-1
Long Title of Trial	Stratified Treatment Optimisation for HCV-1
Version	7.0
Date	22-Feb-2018
ISRCTN #	ISRCTN37915093
EudraCT #	2015-005004-28
CTA #	19174/0370/001-0001
MREC #	15/EE/0435
Study Design	An open-label randomised controlled trial (RCT) testing biomarker-stratified short-course first-line and re-treatment direct-acting antiviral (DAA) oral treatment regimens to cure mild chronic Hepatitis C (HCV) disease.
Type of Patients to be Studied	Adults (≥18 years) infected with HCV genotype 1a/1b or 4 for ≥6 months, with detectable plasma HCV RNA and mild liver disease (Fibroscan score F0-F1 or biopsy proven minimal fibrosis), HCV viral load <10 million IU/ml, no previous DAA exposure (previous pegylated-interferon/ribavirin allowed) and not pregnant. Patients co-infected with HIV are eligible if HIV viral load has been <50 copies/ml for >24 weeks on anti-HIV drugs.
Setting	NHS
Interventions to be Compared	The main intervention to be compared is varying (intervention) 4-7 weeks vs fixed (control) 8 weeks combination first-line DAA treatment, with or without ribavirin, in an open-label partial factorial design. • Varying intervention duration will be stratified by baseline HCV RNA on a sliding scale, with duration determined by estimated time for HCV RNA to decline to reduce levels to ~1 copy in the whole body at end of treatment. • As soon as viral failure is detected at any time post-randomisation (first-line failure), patients will stop first-line treatment (if still receiving it) and be immediately retreated with 12 weeks of a different regimen. • Ribavirin will be dosed twice daily, adjusted for weight Current first-line combination regimens are those licenced for use

Summary Information Type	Summary Details
	against Hepatitis C, namely: (i) a fixed dose combination of DAA active against genotype 1a/1b and 4; the Abbvie combination ombitasvir/paritaprevir/ritonavir (12.5mg/75mg/50mg) co-formulated film-coated tablets once daily (total daily dosage: 25/150/100mg) plus for genotype 1a/1b one dasabuvir 250 mg tablet twice daily (total daily dosage: 500mg) (using "ombitasvir/paritaprevir/(dasabuvir)/ritonavir" to denote the combination regimen) (ii) a fixed dose combination of 2 novel DAA active against all genotypes; the Abbvie combination glecaprevir/pibrentasvir (100mg/40mg) co-formulated tablets once daily (total daily dosage: 300/120mg) Current retreatment regimens are: (iii) a fixed dose double combination of sofosbuvir/ledipasvir (400mg/90mg) once a day plus ribavirin twice a day
Study Hypotheses	**(i)** HCV-RNA determined short-course (4-7 weeks) first-line will cure similar proportions with chronic, mild HCV disease as a fixed 8 week first-line course once failures have been retreated for 12 weeks (ii) Adjunctive ribavirin improves cure rates with biomarker-stratified short-course and fixed duration DAA first-line regimens that are shorter than the full licensed duration of therapy (iii) Re-treatment with a longer 12 week regimen, given after detecting virological failure on or following first-line treatment, still achieve cures in the majority of the small proportion of patients failing first-line treatment.
Primary Outcome Measure	For the varying duration comparison the primary outcome will be: • Sustained Virological Response (SVR, plasma HCV RNA persistently <LLOQ (lower limit of quantification)) measured 12 weeks after the end of the combined first and any re-treatment phases (SVR12) For the ribavirin comparison the primary outcome will be: • SVR12 after first-line treatment only
Secondary Outcome Measure(s)	• SVR12 after first-line treatment (where not the primary outcome) • SVR12 after the end of the combined first and any re-treatment phases (where not the primary outcome) • SVR24 after the end of the combined first and any re-treatment phases • SVR24 after first-line treatment only ◦ lack of initial virological response

Summary Information Type	Summary Details
	• viral load rebound after becoming undetectable • serious adverse events • grade 3/4 adverse events • grade 3/4 adverse events judged definitely/probably related to interventions • treatment-modifying adverse events (any grade) • grade 3/4 anaemia • emergence of resistance-associated HCV variants • sensitivity/specificity of point–of-care diagnostic for IL28 • costs and cost-effectiveness
Randomisation	Patients will be allocated 1:1 using a factorial design to each of • biomarker-stratified varying vs fixed duration • adjunctive ribavirin or not (this randomisation will be a partial factorial in those receiving a shorter course than the full licensed duration of therapy) Randomisation will be stratified. Randomisation on to STOP-HCV-1 ended on 31-August-2018.
Number of Patients to be Studied	Total planned: 408 Actual: 204
Duration	• Patients are planned to be recruited over 2 years • Each first-line intervention will be administered for 4-8 weeks • Each patient will be followed for 24 weeks post end of first-line treatment: if they fail first-line, they will receive another 12 weeks re-treatment and be followed for a further 24 weeks post end of re-treatment • The overall trial duration is planned for 4 years (including start-up and close-out)
Sponsor	Imperial College London
Funder	Efficacy and Mechanism Evaluation (EME) Programme, an MRC and NIHR partnership (14/02/17)
Trial Manager	Emily Dennis
Chief Investigator	Graham Cooke
MRC CTU at UCL Project Leader	Ann Sarah Walker

Please note: Maviret was added to protocol v6.0 in anticipation of approaching changes within NHS England, where we are expecting Maviret to be made available in the near future and possibly become the recommended first-line treatment option. **Sites should not prescribe Maviret in STOP-HCV-1 until they receive notification from the MRC CTU**

that it is now available and may now be used within the trial. If you would like to use Maviret before you receive notification from us, please do get in contact to discuss this.

2. Trial Schema

Please note: randomisation on to STOP-HCV-1 ended on 31-August-2018.

All participants will be randomised using a partial factorial design to one of each to:

- Open label varying (4-7 weeks) vs fixed duration (8 weeks) first-line treatment
- Open-label adjunctive ribavirin vs no ribavirin

The duration of first-line treatment is determined by the participant's randomised allocation to either varying or fixed duration.

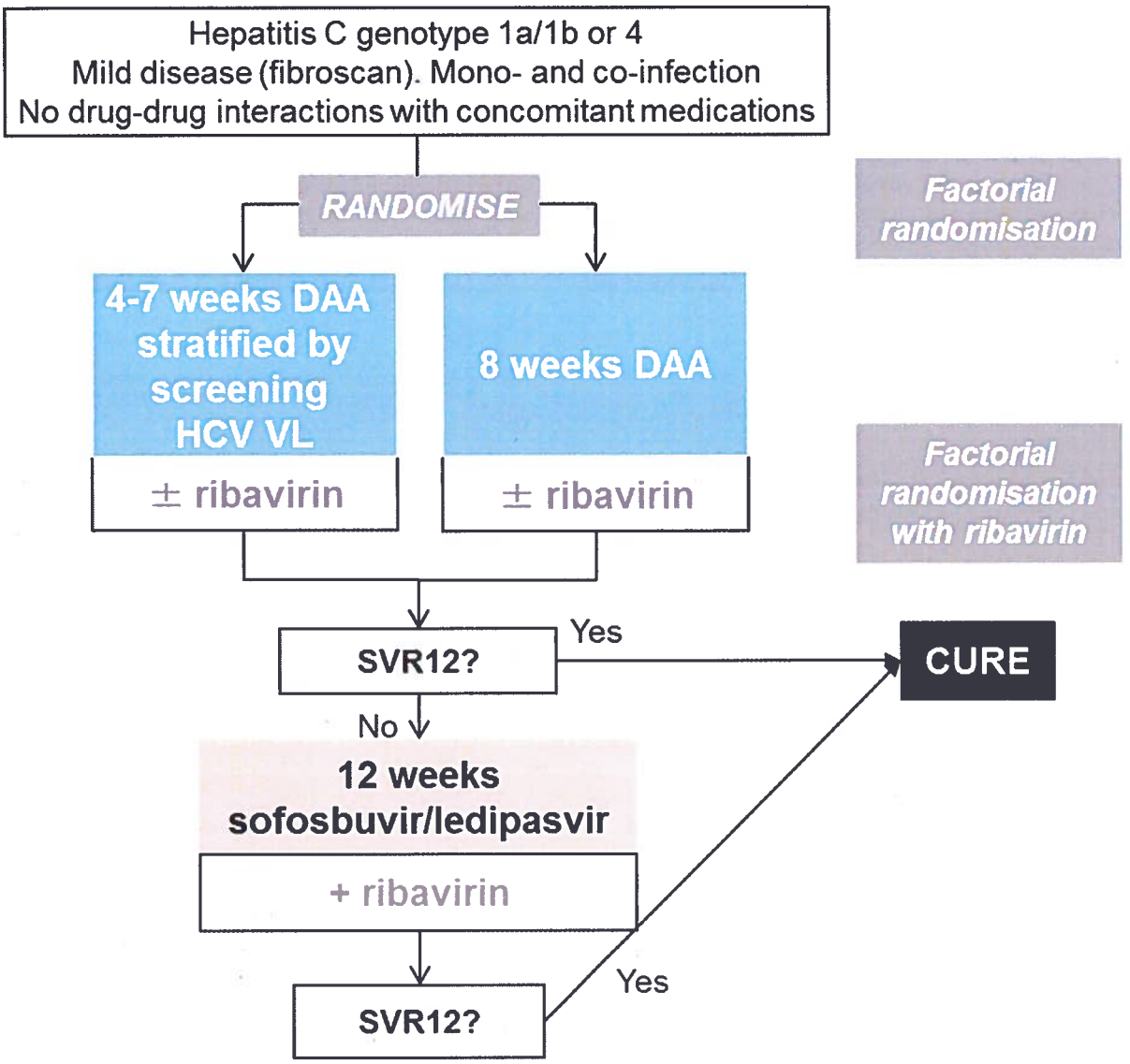
There are 3 possible first-line drug combinations that participants can be treated with in the trial, depending on their genotype and local availability:

- Viekirax (ombitasvir/paritaprevir/ritonavir) and Exviera (dasabuvir) for genotype 1a/1b
- Viekirax (ombitasvir/paritaprevir/ritonavir) for genotype 4
- Maviret (glecaprevir/pibrentasvir) for genotype 1a/1b and 4

With all 3 possible first-line treatments, participants randomised to the **varying duration** arm will also be randomised with or without ribavirin. For participants randomised to the 8 week **fixed duration** arm, those taking Viekirax, with or without Exviera, will also be randomised with or without ribavirin. Participants taking Maviret that are randomised to 8 weeks fixed duration,will not receive ribavirin.

If participants fail first-line treatment they will be offered 12 weeks Harvoni (sofosbuvir/ledipasvir) with Ribavirin.

Figure 1. Trial Flow Diagram



Follow-up: day 3, 7, 14, 28, End of Treatment; then 4-weekly until 12 weeks post end of treatment, then at 24 weeks post end of treatment.

Primary endpoint: **SVR12 (ie cure)**

Secondary endpoints: SVR24; lack of initial virological response; viral load rebound (**relapse**) after becoming undetectable; serious adverse events; grade 3 or 4 adverse events; grade 3 or 4 adverse events judged definitely/probably related to the intervention; treatment-modifying adverse events of any grade; grade 3 or 4 anaemia; emergence of resistance-associated Hepatitis C variants

Note: as above, the ribavirin randomisation will be a partial factorial in those receiving a shorter course than the full licensed duration of therapy.

3. Study Drugs

During screening sites should choose which first-line regimen to treat a patient with depending on genotype and local availability. Sites should treat with the drug that is the local recommended first-line treatment option for the participant's genotype.

Viekirax® (ombitasvir/paritaprevir/ritonavir)

Viekirax is a triple combination of 3 novel DAA's (ombitasvir 12.5mg/paritaprevir 75mg/ritonavir 50mg) manufactured by AbbVie. Taken alone it is used to treat hepatitis C genotype 4; taken with Exviera it is used to treat hepatitis C genotype 1a/1b,

Viekirax is dosed orally once daily:

Morning: 2 tablets of ombitasvir 12.5mg/paritaprevir 75mg/ritonavir 50mg **with food without regard to fat or calorie intake.**
(Total daily dosage: 25/150/100mg)

Exviera® (dasabuvir)

Exviera is dosed orally BID:

Morning: 1 x 250mg tablet of dasabuvir **with food without regard to fat or calorie intake;**
Evening: 1 x 250mg tablet of dasabuvir **with food without regard to fat or calorie intake.**

(Total daily dosage: 500mg)

Maviret® (glecaprevir/pibrentasvir)

Maviret is a fixed dose combination of glecaprevir 100mg and pibrentasvir 40mg. It is a pangenotypic DAA regimen manufactured by AbbVie.

Maviret is dosed orally once daily:

3 tablets of glecaprevir 100mg/pibrentasvir 40mg **with food.**

(Total daily dosage: 300/120mg)

Harvoni® (sofosbuvir/ledipasvir)

Harvoni is a combination of 400mg sofosbuvir and 90mg ledipasvir novel DAA active against hepatitis C genotype 1a/1b and 4 manufactured by Gilead. Harvoni will be only be used in the STOP-HCV-1 trial for participants who fail first line treatment and are subsequently retreated.

Harvoni is dosed orally once daily:

1 tablet of sofosbuvir 400mg/ledipasvir 90mg with or without food.

(Total daily dosage: 400/90mg)

Ribavirin

Ribavirin film-coated tablets (or hard capsules) either contain 200mg or 400mg of ribavirin per tablet. There are many manufacturers of Ribavirin. Any brand of Ribavirin that has Marketing Authorisation within the European Union can be used in the trial.

Ribavirin is dosed orally BID and taken **with food**. The standard dose is weight-based, see table 1.

Table 1. Weight Based Dosing of Ribavirin

Medicinal product used in combination	Weight based daily ribavirin dose	Number of 200mg ribavirin tablets
DAA	body weight <75kg: 1000mg	5 x 200mg (2 morning, 3 evening)
	body weight ≥75kg: 1200mg	6 x 200mg (3 morning, 3 evening)

There are no special storage requirements for any of the drugs.

Missed doses

Viekirax®, Exviera® and Ribavirin

Patients should be instructed that if a dose is missed within 6 hours of the usual dosing time, the missed dose should be taken as soon as possible and then the next dose taken at the usual time. If it is after 6 hours then the missed dose should not be taken and the next dose should be taken at the usual time.

If vomiting occurs within 6 hours of dosing, an additional dose should be taken. If vomiting occurs more than 6 hours after dosing, no further dose is needed.

A double dose should not be taken.

Any doses missed during the treatment course should be taken at the end of the prescribed course.

Maviret®

If a dose is missed and it is within 18 hours of the usual dosing time, patients should be instructed to take the tablet as soon as possible and then the next dose taken at the usual time. If it is after 18 hours then patients should be instructed to wait and take the next dose at the usual time.

Patients should be instructed that if vomiting occurs within 3 hours of dosing an additional dose of the trial drug should be taken. If vomiting occurs more than 3 hours after dosing, no further dose is needed.

A double dose should not be taken.

Any doses missed during the treatment course should be taken at the end of the prescribed course.

Harvoni®

Patients should be instructed that if a dose is missed within 18 hours of the usual dosing time, the missed dose should be taken as soon as possible and then the next dose taken at the usual time. If it is after 18 hours then the missed dose should not be taken and the next dose should be taken at the usual time.

If vomiting occurs within 5 hours of dosing, an additional dose should be taken. If vomiting occurs more than 5 hours after dosing, no further dose is needed.

A double dose should not be taken.

Any doses missed during the treatment course should be taken at the end of the prescribed course.

4. Drug Supply & Management

NHS England (NHSE) has agreed to fund all study drugs. Sites will need to procure all study drugs through their usual mechanisms. They will then be able to claim reimbursement via the NHS Blueteq system by making patient specific claims.

Blueteq forms

- Sites should ensure participants are registered on Blueteq at screening, using a first-line treatment form (see *Appendix 2*), before any medication is dispensed. This will notify NHSE that the participant is eligible against the study inclusion and exclusion criteria and will register the participant on the trial.
- **Note:** The participant's NHS number, hospital number, GP code and postcode will be required for the Blueteq form.

Question 3: it is suggested that option 1 – "Fixed duration of 8 weeks" is initially selected.

3. I confirm the patient has been randomised to ONE of the following arms: Option 1 - Fixed duration of 8 weeks Option 2 - Variable duration of 4 to 6 weeks ☒	☒ Yes ☒ No

Question 4: it is suggested that option 1 "Treatment with ribavirin" is initially selected.

4. I confirm the patient has been randomised to ONE of the following: Option 1 - Treatment with ribavirin Option 2 - Treatment without ribavirin ☒	☒ Yes ☒ No

- Once the participant has been randomised, the form will then need to be updated with the participant's actual randomisation allocation.
- If a participant fails treatment, they will need to be registered again on Blueteq using the Re-treatment form (see *Appendix 3*) before re-treatment is commenced.

Stock management

- Due to the varying duration arm of the trial there is a requirement for drug packs to be split between participants.
- It is essential for pharmacy to be made aware of upcoming randomisations to ensure adequate stocks are in place.
- It is possible that the time between screening and randomisation may be very short for some participants. Pharmacy should therefore consider having a buffer stock in place. This will depend on local procedures, time taken between order and delivery, and the rate at which the site is randomising.
- Pharmacy should ensure that stock is rotated, with shorter expiry drugs being dispensed before those with longer expiry dates. This is especially important when receiving drug

packs with short expiry dates and for those pharmacies choosing to maintain a buffer stock.

- There should be no wastage of more than 1 pack, ideally this treatment will be dispensed as part of treatment for another patient and subsequently reimbursed by NHSE. If not, NHSE will cover the cost of up to 1 pack of each drug per site.
- Pharmacy should invoice NHS England for the precise number of tablets dispensed; NHS England will match the invoice to the approved patient on Blueteq and reimburse the medication.

5. Study procedures

Clinics will screen and check participants for eligibility. Depending on local Operational Delivery Network (ODN) for Hepatitis requirements, the participant may or may not be discussed at a Multidisciplinary Team meeting (MDT) for approval.

Once approvals (if required) have been received and the participant's eligibility has been confirmed, the patient will be randomised.

Please note: randomisation on to STOP-HCV-1 ended on 31-August-2018. No further patients should be screened, consented or randomised to STOP-HCV-1.

Following randomisation:

- An email confirming randomisation will be sent to the site containing:
    - Participant trial number
    - Enrolment number
    - Individual Visit Schedule (includes the randomisation allocation and first-line treatment to be dispensed).
- Randomisation emails will be sent to the Principal Investigator, Research Nurse and Trial pharmacist. Additional members of staff at the site can be added to the email group if required.
- Upon receipt of the randomisation e-mail a prescription should be written for the participant (see *Appendix 1*).
- The prescription should be signed by an investigator delegated this responsibility on the Signature and Delegation Log.
- Study drug should be dispensed with any treatment information that is usually given.

  Note: It is important to remind the participant that Viekirax®, Exviera®, Maviret® and Ribavirin should be taken with food.
- It is advised that all participants are initially dispensed 28 days of treatment EXCEPT those randomised to 29, 30 or 31 days treatment who should be dispensed their full treatment regime on day 0.
- For participants randomised to 32-49 days treatment, pharmacy should consider setting aside the remaining balance of tablets required to make up their total allocation. The tablets should be labelled with the participant's trial number. This remaining balance should then be dispensed to the participant when they return for their day 28 visit.
- **Note:** Initially prescribing and dispensing 28 days treatment is advised due to the importance of the day 28 visit to the trial; however this decision ultimately remains at the discretion of the clinician.
- It is important to consider the visit window for the day 28 visit is +/- 1 day. It is recommended that the day 28 visit is planned on day 0. If the participant will attend this visit on day 29 then 29 days treatment will need to be dispensed.

Every Monday MRC CTU will run a report listing which participants have a day 28 visit in the following week. If your site has any participants on this list then a report will be sent to you, containing the PID number, expected visit date and number of days treatment to dispense. This will enable those sites unable to put participants remaining tablet allocation aside on the day of initial dispensing to ensure they have adequate stock for the following week.

6. Drug Accountability

- Pharmacy should maintain a record of each registration on Blueteq.
- Sites should record each dispensing episode on the trial accountability logs.
- Sites may keep drug specific accountability logs and/or patient specific accountability logs (see *Appendix 4 and 5*).
- Accountability logs should include the participant's trial number, Blueteq ID and the number of tablets dispensed (see A*ppendix 4*).
- Drug accountability should confirm that participants have been dispensed medication according to their randomised allocation.
- Accountability Logs may also be requested by NHSE when applying for reimbursement, to confirm that the total amount claimed matches the number of tablets dispensed to the participant.

It is essential that participants are registered on Blueteq before you dispense study medication.

7. Pill Returns

- Participants should return any unused pills either directly to pharmacy, or to the trial team (who should then pass on to pharmacy).
- For participants who use a patient diary card the number of pill returns should be recorded on the diary card.
- The number of missed doses will be recorded by the clinic team in the participant's medical notes, and reported to MRC CTU on the Follow-up CRF (Form 12) and, if applicable, the Trial Drug Log (Form 09).
- All pills returned to the site pharmacy should be documented on the Drug Accountability Logs.
- Returned singular pills should be quarantined and destroyed following local procedures.

8. Drug Destruction

- Wastage should be kept to a minimum.
- If drug is procured for a screened participant who is not subsequently randomised, this drug can be re-allocated to a different participant who will be randomised.
- Any drug that has not been dispensed at the end of the trial can be transferred to local pharmacy stock for dispensing to non-study patients.
- NHSE have agreed to reimburse up to 1 pack of each drug remaining at the end of the trial.
- Returned or expired pills should be destroyed as per local procedures; the destruction of pills should be documented on the STOP-HCV-1 Drug Destruction Record (see *Appendix 6*).
- Sites can destroy returned or expired pills at any time. The STOP-HCV-1 Drug Destruction Records will be checked during routine pharmacy monitoring visits. If local procedures require the authorisation by the trial monitor this will occur during pharmacy monitoring visits.

9. Monitoring

MRC CTU will monitor drug accountability at site monitoring visits. Accountability logs will need to be maintained and will be required in the event NHSE request these to verify participants on the trial and the number of pills dispensed to them.

Appendix 1. Prescription Template

Stratified Treatment Optimisation for HCV-1 Trial Prescription

Participant Name:	NHS Blueteq Identification Number:
Participant Trial Number:	Visit Date:
Principal Investigator:	
Any known drug allergies? *Circle* YES or NO, if yes specify:	

Randomised Allocation

Tick one	Tick one
☐ 8 weeks first line	☐ With weight-based ribavirin
☐ Varying first line for ☐ days	☐ Without weight-based ribavirin

NOTE ON PRESCRIBING:
First line day 0: 4 week supply should be prescribed to all participants **EXCEPT:** Those randomised to 29, 30 or 31 days treatment should be prescribed and dispensed their full regime (ie. 29, 30 or 31 days treatment) on day 0.
First line day 28: the precise number of days treatment remaining should be prescribed.
Retreatment week 0, 4, 8: prescribe 4 weeks treatment at each visit.

Visit Identifier
First line Day 0 ☐ First line Day 28 ☐ Retreatment: Week 0 ☐ Week 4 ☐ Week 8 ☐

Please tick	Drug	Route	Dose and frequency	Supply
First Line Treatment Viekirax / Exviera / Maviret / Ribavirin				
☐	**Viekirax** ombitasvir 12.5mg / paritaprevir 75mg / ritonavir 50mg	Oral	Take TWO tablets each MORNING	……days
☐	**Exviera** dasabuvir 250mg	Oral	Take ONE tablet each MORNING and EVENING	……days
☐	**Maviret** glecaprevir 100mg / pibrentasvir 40mg	Oral	Take THREE tablets each MORNING	……days
☐	**Ribavirin** 200mg	Oral	Take TWO tablets/capsules each MORNING and THREE tablets/capsules each EVENING **** Dose if weight <75 kg****	……days
☐	**Ribavirin** 200mg	Oral	Take THREE each MORNING and THREE tablets/capsules each EVENING ****Dose if weight ≥ 75 kg****	……days
Retreatment – Harvoni & Ribavirin				
☐	**Harvoni** sofosbuvir 400mg / ledipasvir 90mg	Oral	Take ONE tablet each MORNING	……days
☐	**Ribavirin** 200mg	Oral	Take TWO tablets/capsules each MORNING and THREE tablets/capsules each EVENING **** Dose if weight <75 kg****	……days
☐	**Ribavirin** 200mg	Oral	Take THREE each MORNING and THREE tablets/capsules each EVENING ****Dose if weight ≥ 75 kg****	……days

Prescriber name		Checked by	
Prescriber signature & date		Collected by	
Dispenser & date dispensed		Date of collection	

Appendix 2. Sample Blueteq Form - First Line Treatment Regimen

NHS England - STOP-HCV-1 Trial - Initial Treatment Funding Application - Ombitasvir/Paritaprevir/ Ritonavir/Dasabuvir for the treatment of genotype 1a/1b hepatitis C virus (HCV)			
Patient NHS No:		Trust:	
Patient Hospital No: ☒		Practice Code:	
Patient's Initials and DoB:		GP Postcode:	
Choose Consultant:	☒		
Consultant Name:	☒ .	Other Contact Details:	☒ .
Notification Email Address: ☒ (@NHS.net account ONLY)			
TickBox			

Please indicate whether patient meets the following criteria:	Please tick
1. I confirm the patient has genotype 1a/1b chronic hepatitis C virus (HCV)	☒ Yes ☒ No
2. I confirm the patient has been registered for the STOP-HCV-1 trial and meets the eligibility criteria.	☒ Yes ☒ No
3. I confirm the patient has been randomised to ONE of the following arms: Option 1 - Fixed duration of 8 weeks Option 2 - Variable duration of 4 to 6 weeks ☒	☒ Yes ☒ No
4. I confirm the patient has been randomised to ONE of the following: Option 1 - Treatment with ribavirin Option 2 - Treatment without ribavirin ☒	☒ Yes ☒ No
5. I confirm the patient's viral load will be measured in line with the trial protocol.	☒ Yes ☒ No
6. I confirm the patient's viral load will be measured and recorded 12 weeks after the end of treatment to determine that sustained viral response (SVR) has been achieved.	☒ Yes ☒ No
7. I confirm the approved dose and frequency of this drug regimen will be used.	☒ Yes ☒ No
8. What is the acquisition cost of the drug including VAT (if applicable)? £ per month **Commissioners will complete if cost not known as this will allow us to ensure budgets are allocated appropriately.**	

Appendix 3. Sample Blueteq Form - Retreatment Regimen

NHS England - STOP-HCV-1-Trial - Funding Application - Sofosbuvir/ledipasvir and ribavirin for retreatment of genotype 1a/1b hepatitis C virus (HCV) following treatment failure.			
Patient NHS No:		Trust:	
Patient Hospital No: ☒		Practice Code:	
Patient's Initials and DoB:		GP Postcode:	
Choose Consultant:	☒		
Consultant Name:	☒	Other Contact Details:	☒
Notification Email Address: ☒ (@NHS.net account ONLY)			
TickBox			

Please indicate whether patient meets the following criteria:	Please tick
1. I confirm the patient has genotype 1a/1b chronic hepatitis C virus (HCV)	☒ Yes ☒ No
2. I confirm the patient has been registered for the STOP-HCV-1 trial and has virological failure following first line treatment.	☒ Yes ☒ No
3. I confirm the patient's viral load will be measured in line with the trial protocol.	☒ Yes ☒ No
4. I confirm the patient's viral load will be measured and recorded 12 weeks after the end of treatment to determine that sustained viral response (SVR) has been achieved.	☒ Yes ☒ No
5. I confirm the approved dose and frequency of this drug regimen will be used.	☒ Yes ☒ No
6. What is the acquisition cost of the drug including VAT (if applicable)? £ per month: ☒ **Commissioners will complete if cost not known as this will allow us to ensure budgets are allocated appropriately.**	

Appendix 4. Example Drug Accountability Log - Exviera

STOP HCV-1 Drug Accountability Log

Dasabuvir 250mg tablets (Exviera®)

Site Name	Site Number	PI

DATE	RECEIVED				DISPENSED							BALANCE	RETURNS			
Date Received/ Dispensed	Batch Number	Expiry Date	Quantity Received (Tablets)	Received By	Patient Trial Number	Patient ID	Number of Days Prescribed	Quantity Dispensed (Dose Units)	Batch Number	Dispensed By	Checked By	Running Balance	Date	Quantity (Tablets)	Counted By

Appendix 5. Example Patient Specific Drug Accountability Log - Exviera

STOP HCV-1 Patient Specific Drug Accountability Log

Dasabuvir 250mg tablets (Exviera®)

Site Name	Site Number	PI	
Patient Initials	**Patient Trial Number**	**Patient Bluteq ID**	**Total Number of Days Randomised**

DISPENSING							RETURNS			
Date Dispensed	Number of Days Prescribed	Quantity Dispensed (Dose Units)	Batch Number	Expiry Date	Dispensed By	Checked By	Date Returned	Quantity (Dose Units)	Initials	Comments

STOP HCV-1 Patient Specific Drug Accountability Log - Exviera
v1.0 12-October-2016

Appendix 6. Example Drug Destruction Record

STOP-HCV
Stratified Medicine for HepC

STOP HCV-1 Drug Destruction Record

Site Name: _____ **Site Number:** _____

Complete this record when drugs returned by participants are destroyed on site. Participant returns and expired drugs are to be destroyed, and the destruction witnessed. The destruction should be recorded on the accountability record.

EXPIRED Drug destroyed			
Drug name	Batch number	Expiry date	Number of bottles

Participant RETURNS Pills/Packs destroyed				
Participant trial number	Drug name	Batch number	No. of pills	No. of bottles

Destroyed by: _____ (signature)

_____ (print name)

on: _____ (date)

Witnessed by: _____ (signature)

_____ (print name)

Comments: _____

_____

_____

STOP HCV-1 Drug Destruction Record Version 1.0 09-Mar-2016