

HIV/HCV TREATMENT PROTOCOL



Table of Contents

SECTION 1 – INTRODUCTION	3
SECTION 2 – RESOURCES FOR CLINICIANS TREATING HEPATITIS C.....	4
SECTION 3 – INITIAL SCREENING AND EVALUATION PHASE	6
SECTION 4 - MODIFICATIONS TO HIV DRUG REGIMENS PRIOR TO HCV TREATMENT.....	16
SECTION 5 – CHOICE OF HCV TREATMENT REGIMEN PHASE	16
SECTION 6 – HEPATITIS C DRUG ACCESS PHASE	17
SECTION 7 – HEPATITIS C TREATMENT PHASE.....	17
SECTION 8 – HEPATITIS C POST-CURE PHASE.....	18
SECTION 9 – REFERENCES	18
SECTION 10 - APPENDICES	19

SECTION 1 – INTRODUCTION

A successful coinfection program requires staff expertise in key areas. In addition, involved staff need to be organized to function as a coordinated team so that co-infected clients receive a **comprehensive and consistent approach** to evaluation for treatment, management of barriers that may prohibit treatment, support during treatment, and careful monitoring and management of treatment responses and complications. Table B summarizes our proposed model for integrated HIV/HCV care provision.

TABLE B – MODEL FOR INTEGRATED HIV/HCV CARE PROVISION					
Model	Common Setting	Initial evaluation conducted by	HCV treatment and monitoring conducted by	Liver disease staging pre-treatment conducted by	Patient support and education conducted by
Integrated HCV treatment without a designated HCV clinic	RWHAP funded clinic with multiple medical providers involved	Multiple medical providers and team at HIV clinic	Medical provider and team at HIV clinic	Medical provider using lab-based scoring system and/or noninvasive imaging	Dedicated community health workers/patient navigators

In this model, the clinic site provides HCV treatment but not as a designated HCV clinic. Patients receive HCV clinical care and treatment in the setting of their primary HIV care clinic, with services provided by their primary care clinician who may or may not be an infectious disease (ID) specialist. Clinicians who are not ID specialists will acquire HCV treatment expertise via the newly launched AETC HIV/HCV online curricula and will be supported during patient management by an ECHO (Extension of Community Healthcare Outcomes) telementoring program based at UTHSCSA (see Goal 2 below). This will additionally be a resource for experienced clinicians to discuss complex cases. The ECHO model will also address the insurance restriction by some payers of having HCV treatment occur in conjunction with specialist consultation if it is being provided by a non-specialist provider, by offering an inexpensive mechanism for specialist consultation.

The proposed clinic model involves a team approach. The medical provider and team at the HIV clinic are responsible for initial evaluation, introduction of treatment, evaluation of response to therapy, and monitoring for adverse effects of treatment. Expert consultation for HCV with outside providers is also used for patients with significant complications related to the HCV treatment or underlying liver disease. Such consultation may be needed even with providers that are experienced and comfortable in managing HCV.

From diagnosis through treatment, CHWs will provide clients with counselling, navigation, and medication adherence support. The CHW will also serve as the primary contact for interaction with SUD/mental health services partnering organizations. We are not going to explore direct observed therapy for HCV medication adherence in the TACKLE HIV/HCV program. We will use adherence to HIV medication as a proxy for the ability to adhere to daily HCV medication, although additional support via CHWs will be needed for adding HCV medication and lab monitoring to the treatment regimen of PLWH.

This protocol represents the **standardized process of patient flow across the HCV care continuum from screening to linkage to care and curative treatment** developed for the network of RWHAP-funded clinics in the TACKLE HIV/HCV program.

SECTION 2 – RESOURCES FOR CLINICIANS TREATING HEPATITIS C

As these are RWHAP-funded clinics, all providers will already have expertise in managing HIV infection. Providers who require support to treat co-infected patients or peer interaction with complex cases if they have experience treating patients with HCV infection will utilize UT Health San Antonio HIV/HCV ECHO which includes telementoring via case-based learning and a didactic curriculum. An area-wide Community of Practice and Learning (CPL) will be developed for HCV care and treatment providers using the ECHO model to advance the knowledge of existing providers and expand the provider pool by supporting non-specialist providers to participate in care provision for PLWHIV who have HCV infection. The distance-based videoconferencing capability of ECHO in this regard is particularly important in a setting such as South Texas that has shortages of specialist physicians. The ECHO model will be implemented initially at the TACKLE HIV/HCV clinical sites but will be expanded once up and running to invite participation of other providers. The ECHO program will therefore complement the resources below to both advance the knowledge of existing providers and expand the provider pool in South Texas by supporting non-specialist providers with HIV expertise to manage HCV in PLWHIV.

Recommended resources for clinicians who have little or no experience treating HCV infection or who would like to update their knowledge are as follows:

- 1) The HIV/HCV AETC National curriculum online was launched in 2017. It consists of six self-study core competency modules:

- a. Epidemiology
- b. Prevention
- c. Screening, Testing and Diagnosis
- d. HCV Treatment
- e. Recommendations for Subpopulations of HIV/HCV Co-Infected Persons
- f. Addressing Barriers for Co-Infected People of Color

It is available at:

<https://aidsetc.org/hivhcv>

2) Hepatitis C Online – University of Washington consists of six self-study course modules

- a. Screening and Diagnosis of Hepatitis C Infection
- b. Evaluation Staging and Monitoring of Chronic Hepatitis C
- c. Management of Cirrhosis-Related Complications
- d. Evaluation and Preparation for Hepatitis C Treatment
- e. Treatment of Chronic Hepatitis C Infection
- f. Treatment of Special Populations and Special Situations

It is available at:

<https://www.hepatitisc.uw.edu/>

3) Both resources 2) and 3) above are based on the American Association for Study of Liver Disease (AASLD)/Infectious Disease Society of America (IDSA) guidelines: HCV Guidance: Recommendation for Testing, Managing and Treating Hepatitis C which are available at:

<https://www.hcvguidelines.org/>

It should be noted with the above resources that the most up to date information when it comes to HCV treatment is available at the AASLD/IDSA website Resource 3) above. It can take the other two sites some time to update their websites with, for example newly FDA approved HCV drugs or new clinical trial data. Attention should therefore be paid to the latest update date on all these websites.

Given the comprehensiveness and ready availability of the above resources it is not the intention of this HCV/HIV treatment protocol to replicate any of the guidance above. Within this protocol:

- We will highlight our standardized process by which patients will move through the HCV care continuum to access curative treatment.
- We will highlight our standardized process by which all HIV/HCV co-infected patients will be screened for substance use disorder and depression at commencement of treatment and referred to SUD and mental health services as necessary
- We will summarize important treatment data for quick reference by clinicians i.e. frequency of visits, frequency of laboratory tests and choice of tests before during and after HCV treatment
- We will highlight factors that need to be considered pre-treatment in PLWHIV, for example any necessary switches of their antiretroviral treatment regimen

SECTION 3 – INITIAL SCREENING AND EVALUATION PHASE

Screening and Diagnostic Testing for HCV infection

Who to screen: All patients newly diagnosed with HIV infection should be screened for HCV infection. All patients with HIV infection should be screened **annually** for HCV infection

1. Screening is done with an HCV antibody blood test in a laboratory or a rapid test which can be done with a fingerstick blood sample.
2. If the HCV antibody test is reactive (positive), HCV infection must be confirmed with an HCV RNA viral load test. Ideally the HCV viral load test will reflex automatically if the HCV antibody test is positive. Not all labs have the capability for reflex testing but is the most appropriate as it avoids bringing the patient back for a second confirmatory test. We will attempt to establish a reflex from antibody to RNA to genotype process with all HCV Ab testing labs for clinic sites.
3. If the confirmatory HCV RNA viral load test is positive patients diagnosed with HCV infection will be appropriately counselled about their diagnosis and offered a follow-up appointment within 4 weeks for further assessment for treatment

Note that if a patient has previously been HCV antibody positive followed by a negative HCV RNA viral load test (due either to innate clearance of the HCV virus or successful treatment) they must be screened thereafter for HCV infection with an HCV RNA viral load test. Once an HCV antibody test is positive it

remains so for life and can not be used as a screening test in someone who has previously cleared the virus or been treated.

Post Diagnosis counselling and linkage to Community Health Worker (CHW)

All PLWHIV diagnosed with HCV infection will be matched to a CHW who will provide counselling and assist with support through follow-up clinic appointments.

All community health workers will familiarize themselves with the comprehensive Center for Disease Control and Prevention (CDC) document “A Guide to Comprehensive Hepatitis C Counseling and Testing.” This document includes sample conversations about various aspects of HCV counseling.

The document is available for download here:

<https://www.cdc.gov/hepatitis/resources/professionals/pdfs/counselingandtesting.pdf>

A bilingual (English-Spanish) mobile app for HCV counselling with a teach-back feature that has been developed for the TACKLE HIV/HCV program will be used in addition to the above standard post diagnosis counselling.

Pre-treatment diagnostic labs

Refer to laboratory and frequency of visit tables in Appendix A

Liver disease staging

Either the FIB-4 or APRI scoring systems should be used for liver disease staging.

Additionally, all patients with confirmed chronic HCV infection will be staged for liver fibrosis using a Fibroscan machine which is available at all clinic sites.

Screening and vaccination for hepatitis A and hepatitis B

Vaccination for hepatitis A and hepatitis B (HBV) are recommended (1). Non-immune patients will be vaccinated. Insured patients will be vaccinated according to their plan. Uninsured or underinsured patients will be vaccinated under the Texas Department of State Health Services Adult Safety Net program either at their respective clinic, if it is a Safety Net Vaccine provider, or by referral to a local alternative provider if it is not. There is a risk for hepatitis B virus reactivation in those commenced on HCV treatment. PLWHIV who have evidence of HBV infection should be treatment with an antiretroviral drug regimen that includes drugs with activity against HBV preferably tenofovir disoproxil fumarate or tenofovir alafenamide (1).

Screening for Substance use disorder (SUD) and Depression

All current and new untreated patients co-infected with HIV/HCV infection at clinical sites will be screened for SUD and depression. Standardized screening tools and referral pathways to SUD and mental health services have been developed as follows:

Note that it is the clinical decision of the treating provider as to whether SUD or depression is severe enough to necessitate delay in HCV treatment. Active injection drug use alone is not a contraindication to HCV treatment.

Referral Process for HIV/HCV co-infected patients in need of SUD/MH care (from HIV/ HCV treatment clinic to SUD/MH services)

1. Patient with HIV/HCV co-infection comes to clinic for treatment
2. During patient's initial medical appointment or during follow-up appointment, clinic staff (TACKLE CHW or Project coordinator) conducts preliminary screening using **SAMISS** and enters results into patient record/ EMR

➔ **SAMISS Score Key** (Complete SAMISS score key is available at: <https://www.dshs.texas.gov/hivstd/contractor/cm.shtm>)

Question #	Interpretation	Indicate positive screen when
SUD		
1, 2, 3	Looks at alcohol Use	$1 \& 2 \& 3 \geq 5$
4, 5	Looks at substances other than alcohol	$4 \text{ OR } 5 \geq 3$
6, 7	Looks at effects of substance use on daily living	$6 \text{ OR } 7 \geq 1$
Depression		
10, 11	Looks at depression (PHQ-2)	10 or 11 = yes

➔ If screened positive for **SUD**, go to #3

➔ If screened positive for **depression**, go to #5

SUD (e.g. methamphetamine, alcohol, marijuana, cocaine, opioid)

3. If HIV/HCV co-infected patient screens positive for SUD, CHW/Project Coordinator informs medical provider

4. If patient agrees on discussion with medical provider that he/she needs referral for further evaluation for treatment, patient is referred to **external or inhouse SUD services**. Referrals refused by patient should be recorded in patient's medical record.

- **Off-site referral process**

- a) Provider completes referral form (can be filled by project coordinator/CHW and presented to provider for review and signature); give 2 copies to patient (one for patient to keep, one for patient to give to the SUD site), and one copy to file in the patient paper chart record/scan to EMR
- b) TACKLE project coordinator at clinical site to check in EMR or paper chart to ensure release of information documentation is in place, if not obtain signature from patient on release of information form
- c) TACKLE project coordinator at clinical site to contact TACKLE Project Coordinator at Center for Health Care Services (CHCS) to schedule an appointment for the patient
- d) Once appointment confirmed, TACKLE project coordinator at clinical site to record time of appointment on referral form
- e) CHW to instruct the patient on importance of keeping the appointment
- f) Follow up BEFORE appointment: CHW to give patient a call day before the appointment. If time to appointment is more than seven days, call patient one week prior to the appointment in addition to one day before.
- g) Follow up AFTER appointment: CHW to follow up with CHCS TACKLE Project Coordinator one day after the appointment to confirm patient attendance, or CHCS TACKLE Project Coordinator to call HIV clinic within a day after patient appointment to confirm patient attendance.
- h) CHW to assist patients in identifying and overcoming any barriers or challenges to accessing services.

- **On-site referral process**

- a) Provider completes referral form (can be filled by project coordinator/CHW and presented to provider for review and signature); give 2 copies to patient (one for patient to keep, one for patient to give to the SUD department), and one copy to file in the patient paper chart record/scan to EMR
- b) TACKLE project coordinator at clinical site to schedule an appointment for the patient with relevant person in their SUD/mental health department

- c) Once appointment confirmed, record time of appointment on referral form
- d) CHW to Instruct the patient on importance of keeping the appointment
- e) Follow up BEFORE appointment: CHW to give patient a call day before the appointment. If time to appointment is more than seven days, call patient one week prior to the appointment in addition to one day before.
- f) Follow up AFTER appointment: CHW to follow up with relevant person in the SUD/mental health department one day after the appointment to confirm attendance at appointment.
- g) CHW to assist patients in identifying and overcoming any barriers or challenges to accessing services.

Depression

- 5. If patient answered yes to either SAMISS item number 10 or 11, do additional screening using PHQ-9
- 6. if patient gets a score greater than or equal to 10 refer patient to MH services
 - PHQ-9 score key: from Kroenke K, Spitzer RL, Psychiatric Annals 2002;32:509-521

Score	Severity	Proposed Treatment Actions
0-4	None-minimal	None
5-9	Mild	Watchful waiting; repeat PHQ-9 at follow-up
10-14	Moderate	Treatment plan, considering counseling, follow-up and/or pharmacotherapy
15-19	Moderately Severe	Active treatment with pharmacotherapy and/or psychotherapy
20-27	Severe	Immediate initiation of pharmacotherapy and, if severe impairment or poor response to therapy, expedited referral to a mental health specialist for psychotherapy and/or collaborative management

- 7. Depending on depression severity, refer to either external or in-house counseling or psychiatric services:
 - **Off-site referral process** – this will only be to a psychiatrist as all sites have in-house counseling services
 - a) Provider completes referral form to a psychiatrist (can be filled by project coordinator/CHW and presented to provider for review and signature); give 2 copies to patient (one for patient to keep, one for patient to give to the SUD site), and one copy to file in the patient paper chart record/scan to EMR

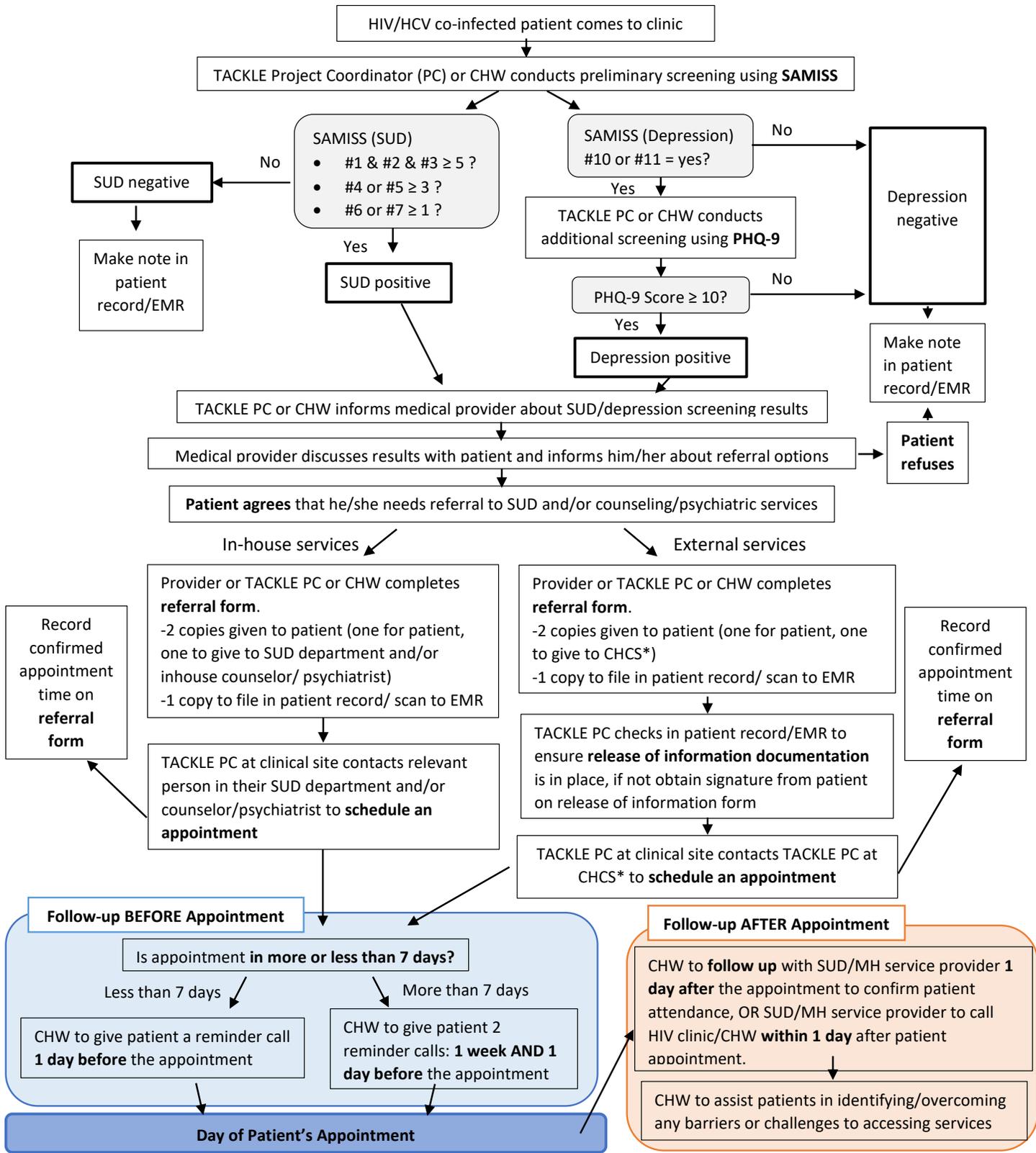
- b) TACKLE project coordinator at clinical site to check in EMR or paper chart to ensure release of information documentation in place, if not obtain signature from patient on release of information form
 - c) TACKLE project coordinator at clinical site to contact TACKLE Project Coordinator at CHCS (or contact person at alternative organization as necessary) to schedule an appointment for the patient with psychiatrist
 - d) Once appointment confirmed, TACKLE project coordinator at clinical site to record time of appointment on referral form
 - e) CHW to instruct the patient on importance of keeping the appointment
 - f) Follow up BEFORE appointment: CHW to give patient a call day before the appointment. If time to appointment is more than seven days, call patient one week prior to the appointment in addition to one day before.
 - g) Follow up AFTER appointment: CHW to follow up with CHCS TACKLE Project Coordinator one day after the appointment to confirm patient attendance, or CHCS TACKLE Project Coordinator to call HIV clinic within a day after patient appointment to confirm patient attendance.
 - h) CHW to assist patients in identifying and overcoming any barriers or challenges to accessing services.
- **On-site referral process** – this will be for both counselling and psychiatry services
 - a) Provider completes referral form to counselling or psychiatry services (can be filled by project coordinator/CHW and presented to provider for review and signature); give 2 copies to patient (one for patient to keep, one for patient to give to the SUD site), and one copy to file in the patient paper chart record/scan to EMR
 - b) TACKLE project coordinator at clinical site to schedule an appointment for the patient with counsellor or psychiatrist
 - c) Once appointment confirmed, record time of appointment on referral form
 - d) CHW to Instruct the patient on importance of keeping the appointment
 - e) Follow up BEFORE appointment: CHW to give patient a call day before the appointment. If time to appointment is more than seven days, call patient one week prior to the appointment in addition to one day before.
 - f) Follow up AFTER appointment: CHW to follow up with relevant person in the SUD/mental health department one day after the appointment to confirm attendance at appointment.

g) CHW to assist patients in identifying and overcoming any barriers or challenges to accessing services.

* Alternative organizations can be contacted for referral to a psychiatrist

*When a psychiatrist is not available: medical provider can reach out to ECHO to submit a depression case presentation form and obtain advice on commencing treatment. If patient's PHQ-9 score is 20-27, an ECHO referral is not appropriate and an assessment to be made by the medical provider to determine if patient is currently in danger of self-harm. If it is determined that this is the case they should be referred immediately to an Emergency Department. If not, they should be referred for intense in-house counselling and support until they are linked to psychiatric care. TACKLE CHW to assist in keeping a close watch on these patients until they are engaged in definitive psychiatric care.

REFERRAL PROCESS FLOW CHART - FROM HIV CLINIC TO SUD/MH SERVICES



*Alternative organizations can be contacted for referral to a psychiatrist

*When a psychiatrist is not available: medical provider can reach out to ECHO to submit a case presentation form and obtain advice on commencing treatment. If patient's PHQ-9 score is 20-27, an ECHO referral is not appropriate and an assessment to be made by the medical provider to determine if patient is currently in danger of self-harm. If it is determined that this is the case, they should be referred immediately to an Emergency Department. If not, they should be referred for intense in-house counselling and support until they are linked to psychiatric care. TACKLE CHW to assist in keeping a close watch on these patients until they are engaged in definitive psychiatric care.

Referral Process for Patients with SUD/MH Disorder in need of HIV/HCV Care (from SUD/MH site to HIV/HCV treatment clinic)

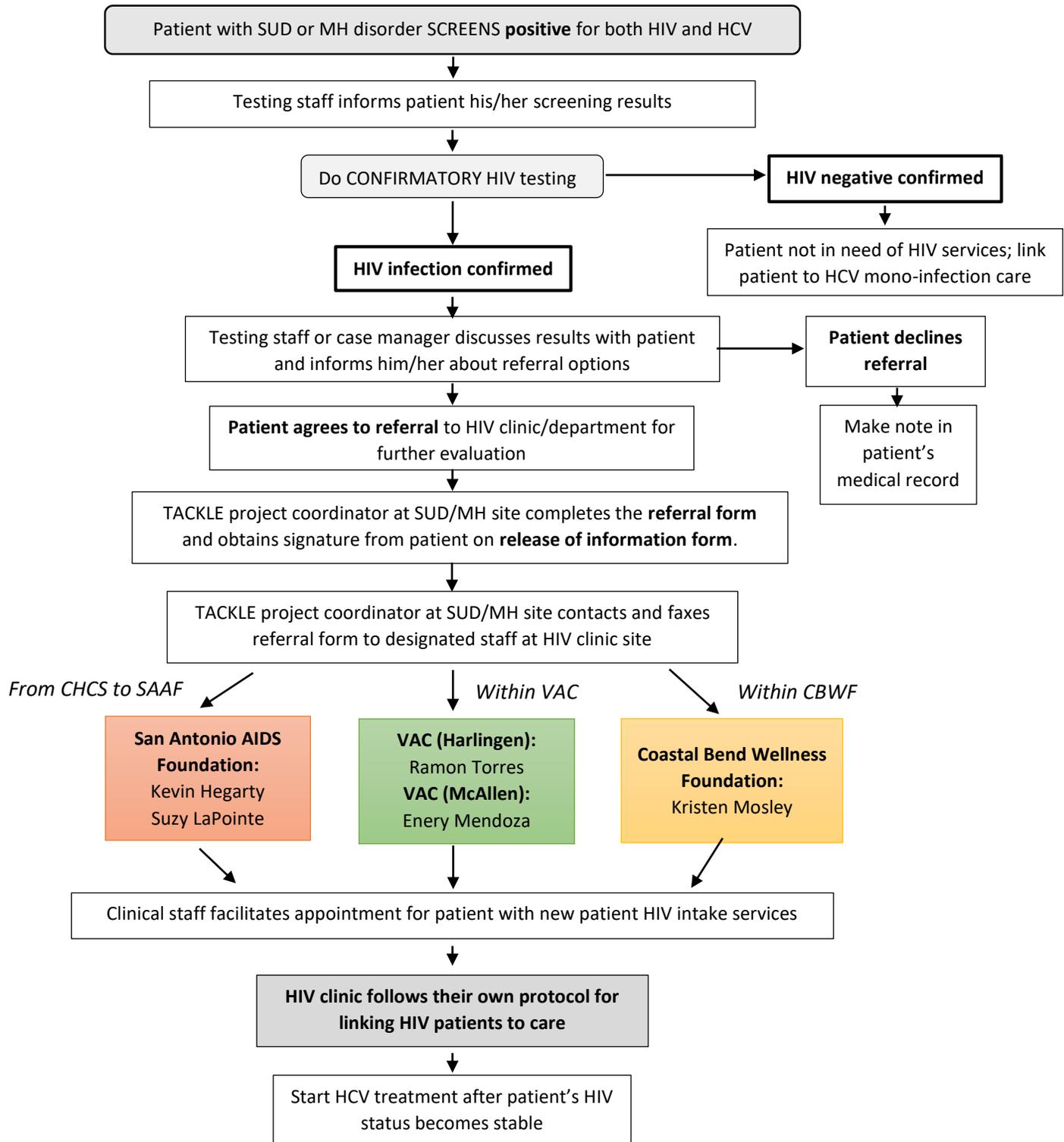
1. Patient with SUD/MH disorder gets screened positive for both HIV and HCV
2. Testing staff contacts patient and gives them their HIV/HCV screening results and determines patient needs.
 - a) Confirmatory testing for HIV infection is conducted.
 - b) Testing staff or case manager informs patient of results.
 - c) An assessment is conducted to help determine choices and options available for treatment based on patient's needs
3. ONLY IF patient tests positive for confirmatory HIV testing and agrees on discussion with case manager that he/she needs referral for further evaluation for treatment, patient is referred for HIV services. Patient needs to be linked for HIV treatment FIRST. They will receive HCV treatment AFTER their HIV status is stable. Referrals refused by patient should be recorded in patient's medical record.
4. Testing staff or case manager informs TACKLE project coordinator at HIV clinic site. TACKLE project coordinator at SUD/MH site to obtain signature from patient on release of information form. Referral forms to be filled by TACKLE project coordinator at SUD/MH site and faxed to designated case management staff at HIV clinical site listed below for linking patient to HIV care:

Clinic	Staff Name	Title/ Role	Phone #	Fax #
SAAF	Kevin Hegarty	Client Services	210-225-4715 (ext. 140)	210-886-0117
	Suzy LaPointe	Client Services	210-225-4715 (ext. 104)	
CBWF	Kristen Mosley	Lead HEI Case Manager	361-814-2001 (ext. 216)	361-814-6502
VAC	Ramon Torres (Harlingen)	Medical Case Manager, Harlingen Coordinator	956-507-4819	956-428-0445
	Enery Mendoza (McAllen)	Medical Case Manager, McAllen Coordinator	956-507-4829	956-429-4970
	<i>*If Ramon and Enery unavailable:</i>			
	Rachel Rodriguez (Harlingen)	Director of Client Services	956-507-4876	956-428-0445

5. Case management who received referral facilitates appointment for patient with intake services at the HIV clinical site, which will include appointments with eligibility office, case manager, physician, and appointment for laboratory tests.
6. Each HIV/HCV clinic to follow their own processes for HIV patient linkage, retention and follow-up

7. TACKLE SUD/MH site project coordinator to follow up every 14 days from date of confirmatory HIV test until 1st appointment with physician documented OR a designation as “failed to link to HIV care within 4 months” is given 4 months after date of confirmatory HIV test.

REFERRAL PROCESS FLOW CHART - FROM SUD/MH SERVICES TO HIV CLINIC



SECTION 4 - MODIFICATIONS TO HIV DRUG REGIMENS PRIOR TO HCV TREATMENT

Modifications or a switch to HIV antiretroviral drug regimens may be necessary prior to commencing HCV treatment. Full details of drug interactions between HCV and HIV drugs are given in the separate drug interaction and side effect protocol. However, the following regimens that are not recommended in co-infected patients should be noted – importantly HIV treatment should never be interrupted to allow HCV treatment (1).

Regimens Not Recommended for Patients with HIV/HCV Coinfection

NOT RECOMMENDED

Antiretroviral treatment interruption to allow HCV therapy is **not** recommended.

Elbasvir/grazoprevir should **not** be used with cobicistat, efavirenz, etravirine, nevirapine, or any HIV protease inhibitor.

Glecaprevir/pibrentasvir should **not** be used with atazanavir, ritonavir-containing antiretroviral regimens, efavirenz, or etravirine.

Sofosbuvir/velpatasvir should **not** be used with efavirenz, etravirine, or nevirapine.

Sofosbuvir/velpatasvir/voxilaprevir should **not** be used with ritonavir-boosted atazanavir, efavirenz, etravirine, or nevirapine.

Sofosbuvir-based regimens should **not** be used with tipranavir.

Paritaprevir/ritonavir/ombitasvir plus dasabuvir should **not** be used with darunavir, efavirenz, ritonavir-boosted lopinavir, ritonavir-boosted tipranavir, etravirine, nevirapine, cobicistat, or rilpivirine.

Paritaprevir/ritonavir/ombitasvir with or without dasabuvir should **not** be used in HIV/HCV-coinfected individuals who are not taking antiretroviral therapy.

Ribavirin should **not** be used with didanosine, stavudine, or zidovudine.

Simeprevir should **not** be used with cobicistat, efavirenz, etravirine, nevirapine, or any HIV protease inhibitor.

If antiretroviral drug changes cannot be made to accommodate alternative HCV DAAs then the preferred HCV regimen is daily daclatasvir plus sofosbuvir with or without ribavirin (1).

SECTION 5 – CHOICE OF HCV TREATMENT REGIMEN PHASE

The decision trees developed by the University of New Mexico Hepatitis C ECHO program (2, 3) will be utilized with minor modification. These have been supplemented with decision trees for genotypes 5 and 6 developed by the TACKLE HIV/HCV program director. These are available in Appendix B

Note that ledispavir/sofosbuvir for 8 weeks is NOT recommended in patients co-infected with HIV/HCV regardless of baseline HCV RNA level (1).

SECTION 6 – HEPATITIS C DRUG ACCESS PHASE

Once a HCV treatment drug choice has been made, refer to separate pharmaceutical protocol and follow the standardized process to obtain the HCV treatment drug.

- Both the research coordinator and the CHW should be informed of the HCV drug choice and the way the drug will be accessed by the treating provider.
- It is primarily the research coordinator's responsibility to work with the CHW to complete the necessary paperwork for HCV drug access
- If drug access is via Medicaid the checklist must be used given numerous requirements some of which are time dependent
- **Drug access applications should be completed and submitted with 5 working days of the research coordinator being informed by the treating provider of the drug choice**
- **If drugs are to be accessed via ADAP (AIDS Drug Access Program) it is essential that eligibility paperwork is checked and up to date prior to commencing HCV treatment as any lapse in eligibility paperwork during treatment may lead to drug access problems.**

SECTION 7 – HEPATITIS C TREATMENT PHASE

Frequency of clinic visits during treatment and laboratory monitoring during treatment

This information is detailed in Appendix A for the following durations of HCV treatment and whether ribavirin is included in the HCV treatment regimen or not:

- 8 weeks – no Ribavirin
- 12 weeks – no Ribavirin

- 16 weeks – no Ribavirin
- 24 weeks – no Ribavirin
- 12 weeks – WITH Ribavirin
- 24 weeks – WITH Ribavirin

SECTION 8 – HEPATITIS C POST-CURE PHASE

Post successful HCV treatment (defined those who achieve a sustained virological response [SVR] at 12 weeks post completion of treatment) all PLWHIV will continue to be screened annually for HCV infection with an HCV RNA viral load.

Additional follow up is recommended as follows (1):

- **Patients who do not have advanced fibrosis (those with Metavir stage F0, F1 or F2)**
Follow up is the same as if they were never infected with HCV
- **Patients with advanced fibrosis (Metavir stage F3 or F4)**
Surveillance for hepatocellular carcinoma with twice yearly liver ultrasound examination
- **Patients who have cirrhosis**
A baseline endoscopy to screen for varices and if found varices should be treated and followed up as indicated
- **Patients who develop persistently abnormal liver function tests after achieving SVR**
Assessment of other causes of liver disease

SECTION 9 – REFERENCES

1. AASLD/IDSA. HCV Guidance: Recommendations for testing, managing, and treating hepatitis C. Accessed 28th August 2018. Available from: <http://www.hcvguidelines.org>.
2. Project Echo. Join the movement. Start an ECHO. Accessed 1st August 2018. Available from: <http://echo.unm.edu/join-the-movement/start-echo/>.
3. Arora S, Thornton K, Murata G, Deming P, Kalishman S, Dion D, et al. Outcomes of treatment for hepatitis C virus infection by primary care providers. N Engl J Med. 2011;364(23):2199-207.

SECTION 10 - APPENDICES

APPENDIX A - HCV Treatment Visits and Laboratory Monitoring

- **8 weeks – no Ribavirin – drug choice is G/P (Mavyret)**

FDA approval does not require laboratory monitoring during treatment for G/P. However, a 4 week HCV RNA viral load is a cautious approach taken by some providers to monitor compliance and this is the approach we have taken. However, if resources are limited week 4 labs can be omitted.

Week of Treatment	Pre-Treatment	Week 0 Start of Tx	Week 2	Week 4	Week 8 End of Tx	Week 20 SVR –Test of Cure
Visit				X	X	X
HCV Genotype	X					
HCV RNA	X			X if RNA detectable re-check at Week 6	X	X
CBC w/Diff	X			X	X	X
Chem 7	X			X	X	X
LFTs	X			X	X	X
HBsAg* HBsAb HBcAb	X					
INR/PT (optional)	X					
Pregnancy Test						

*If resources an issue can screen for Hepatitis B with HBsAg only

- **8 weeks – no Ribavirin – drug choice is LDV/SOF (Harvoni).**

Note: An 8 week course of LDV/SOF can only be considered if patient does NOT have HIV is NOT Black/African-American and if they have an HCV RNA viral load that is LESS THAN OR EQUAL TO 6 million copies/ml

Week of Treatment	Pre-Treatment	Week 0 Start of Tx	Week 2	Week 4	Week 8 End of Tx	Week 20 SVR –Test of Cure
Visit		X	X	X	X	X
HCV Genotype	X					
HCV RNA	X			X if RNA detectable re-check at Week 6	X	X
CBC w/Diff	X			X	X	X
Chem 7	X			X	X	X
LFTs	X			X	X	X
HBsAg* HBsAb HBcAb	X					
INR/PT (optional)	X					
Pregnancy Test						

*If resources an issue can screen for Hepatitis B with HBsAg only

- 12 weeks – no Ribavirin

Week of Treatment	Pre-Treatment	Week 0 Start of Tx	Week 2	Week 4	Week 8	Week 12 End of Tx	Week 24 SVR –Test of Cure
Visit		X	X	X	X	X	X
HCV Genotype	X						
HCV RNA	X			X If RNA detectable re-check at Week 6		X	X
CBC w/Diff	X			X	X	X	X
Chem 7	X			X	X	X	X
LFTs	X			X	X	X	X
HBsAg* HBsAb HBcAb	X						
INR/PT (optional)	X						
Pregnancy Test							

*If resources an issue can screen for Hepatitis B with HBsAg only

- 16 weeks – no Ribavirin

Week of Treatment	Pre-Treatment	Week 0 Start of Tx	Week 2	Week 4	Week 8	Week 12	Week 16 End of Tx	Week 28 SVR –Test of Cure
Visit		X	X	X	X	X	X	X
HCV Genotype	X							
HCV RNA	X			X If RNA detectable re-check at Week 6			X	X
CBC w/Diff	X			X	X	X	X	X
Chem 7	X			X	X	X	X	X
LFTs	X			X	X	X	X	X
HBsAg* HBsAb HBcAb	X							
INR/PT (optional)	X							
Pregnancy Test								

*If resources an issue can screen for Hepatitis B with HBsAg only

- 24 weeks – no Ribavirin

Week of Treatment	Pre-Treatment	Week 0 Start of Tx	Week 2	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24 End of Tx	Week 36 SVR –Test of Cure
Visit		X	X	X	X	X	X	X	X	X
HCV Genotype	X									
HCV RNA	X			X If RNA detectable re-check at Week 6					X	X
CBC w/Diff	X			X	X	X	X	X	X	X
Chem 7	X			X	X	X	X	X	X	X
LFTs	X			X	X	X	X	X	X	X
HBsAg* HBsAb HBcAb	X									
INR/PT (optional)	X									
Pregnancy Test										

*If resources an issue can screen for Hepatitis B with HBsAg only

- **12 weeks – WITH Ribavirin**

When using ribavirin more frequent CBC monitoring and regular tests for pregnancy are required due to risk of anemia and teratogenicity (fetal toxicity)

Week of Treatment	Pre-Treatment	Week 0 Start of Tx	Week 2	Week 4	Week 8	Week 12 End of Tx	Week 24 SVR –Test of Cure
Visit		X	X	X	X	X	X
HCV Genotype	X						
HCV RNA	X			X if RNA detectable re-check at Week 6		X	X
CBC w/Diff	X		X	X	X	X	X
Chem 7	X			X	X	X	X
LFTs	X			X	X	X	X
HBsAg* HBsAb HBcAb	X						
INR/PT (optional)	X						
Pregnancy Test	X	X		X	X	X	

*If resources an issue can screen for Hepatitis B with HBsAg only

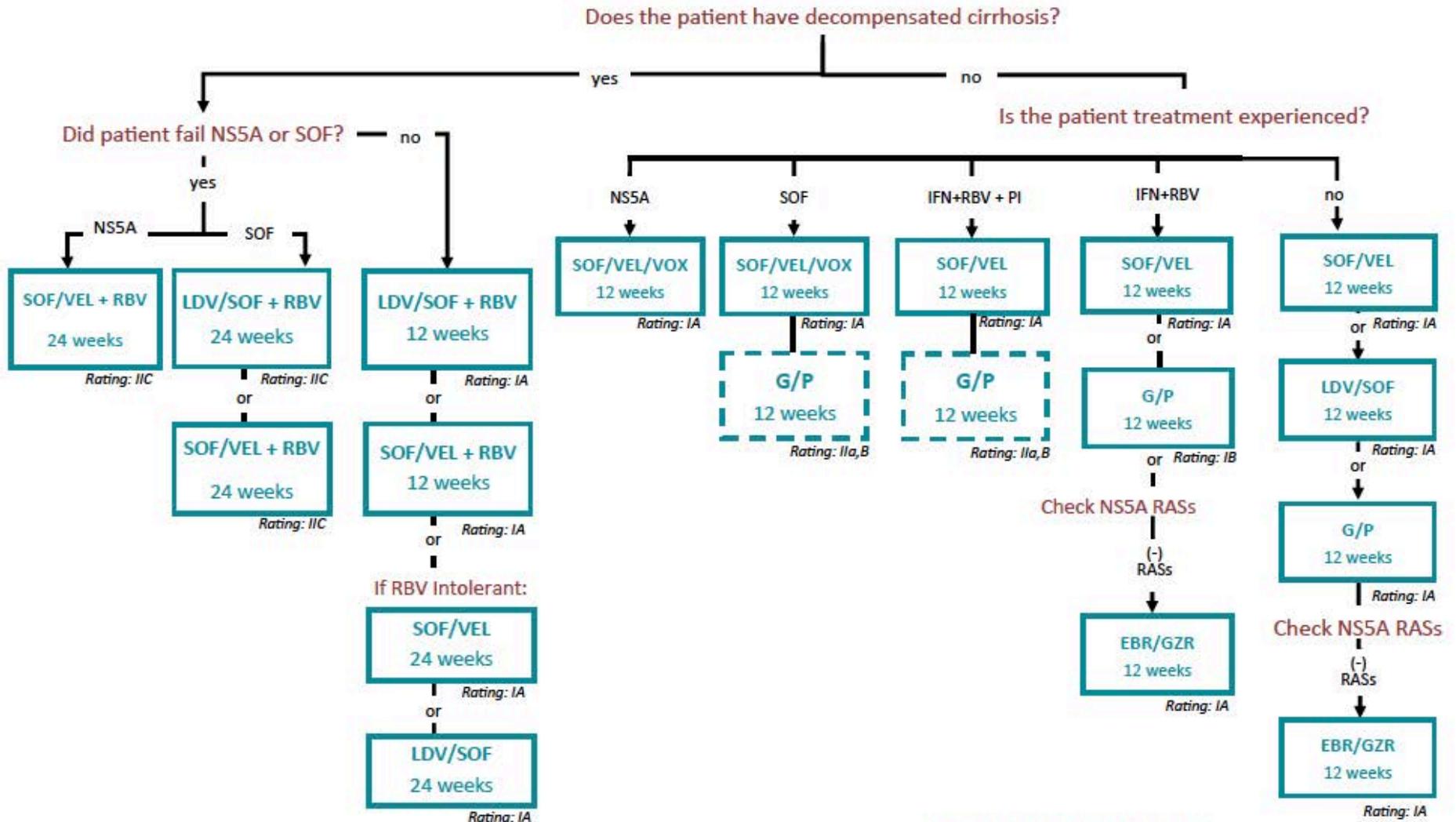
- **24 weeks – WITH Ribavirin**

When using ribavirin more frequent CBC monitoring and regular tests for pregnancy are required due to risk of anemia and teratogenicity (fetal toxicity)

Week of Treatment	Pre-Treatment	Week 0 Start of Tx	Week 2	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24 End of Tx	Week 36 SVR –Test of Cure
Visit		X	X	X	X	X	X	X	X	X
HCV Genotype	X									
HCV RNA	X			X If RNA detectable re-check at Week 6					X	X
CBC w/Diff	X		X	X	X	X	X	X	X	X
Chem 7	X			X	X	X	X	X	X	X
LFTs	X			X	X	X	X	X	X	X
HBsAg* HBsAb HBcAb	X									
INR/PT (optional)	X									
Pregnancy Test	X	X		X	X	X	X	X		

*If resources an issue can screen for Hepatitis B with HBsAg only

- HCV GT1a WITH Cirrhosis



*Rating for Level of Recommendation

These are recommended in the AASLD/IDSA guidelines but have less evidence to support their use and are not ECHO preferred regimens

Direct Acting Antivirals (DAAs):

EBR/GZR: elbasvir/grazoprevir (Zepatier)

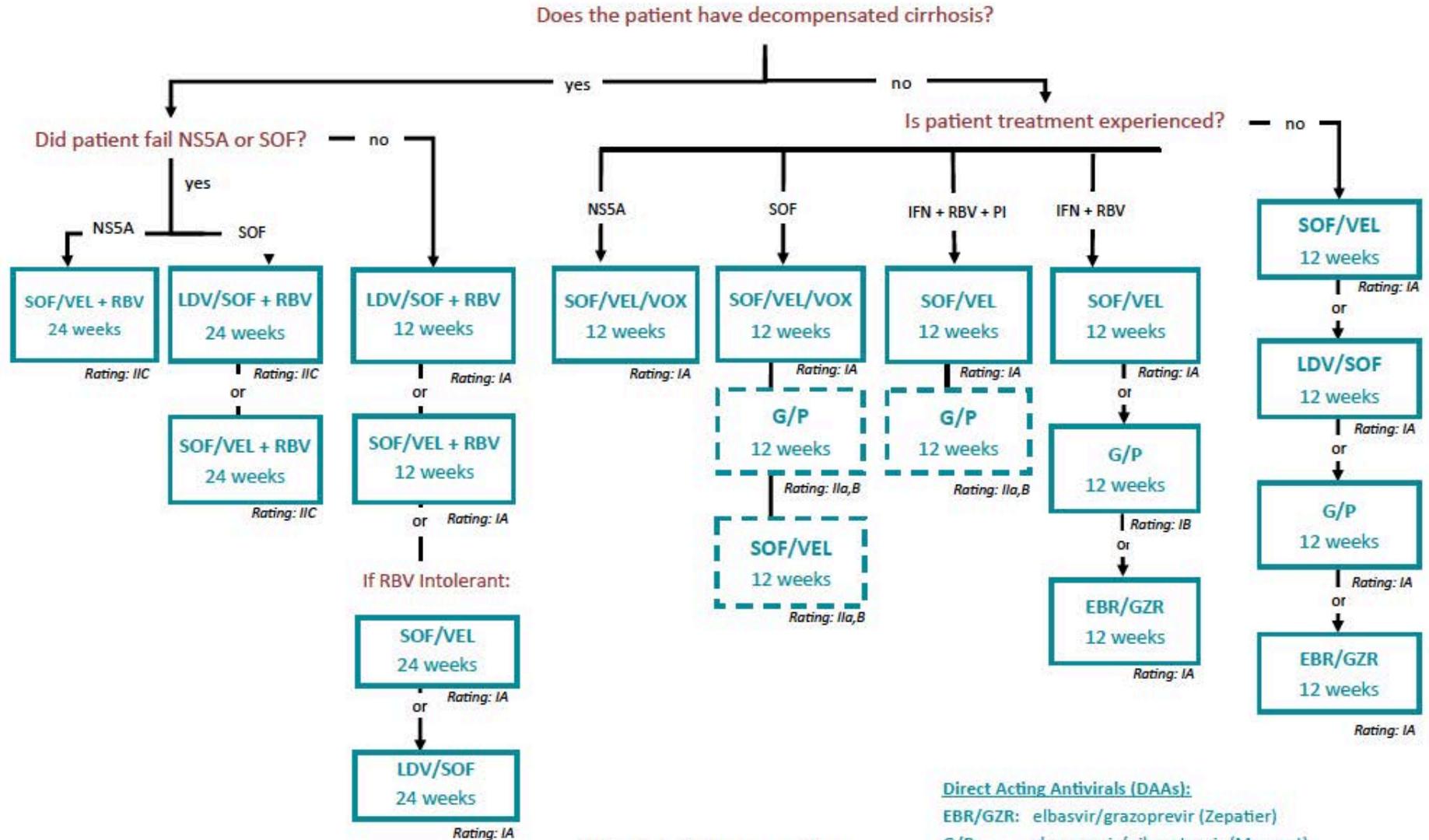
G/P: glecaprevir/pibrentasvir (Mavyret)

LDV/SOF: ledipasvir/sofosbuvir (Harvoni)

SOF/VEL: sofosbuvir/velpatasvir (Epclusa)

SOF/VEL/VOX: sofosbuvir/velpatasvir/voxilaprevir (Vosevi)

- HCV GT1b WITH Cirrhosis

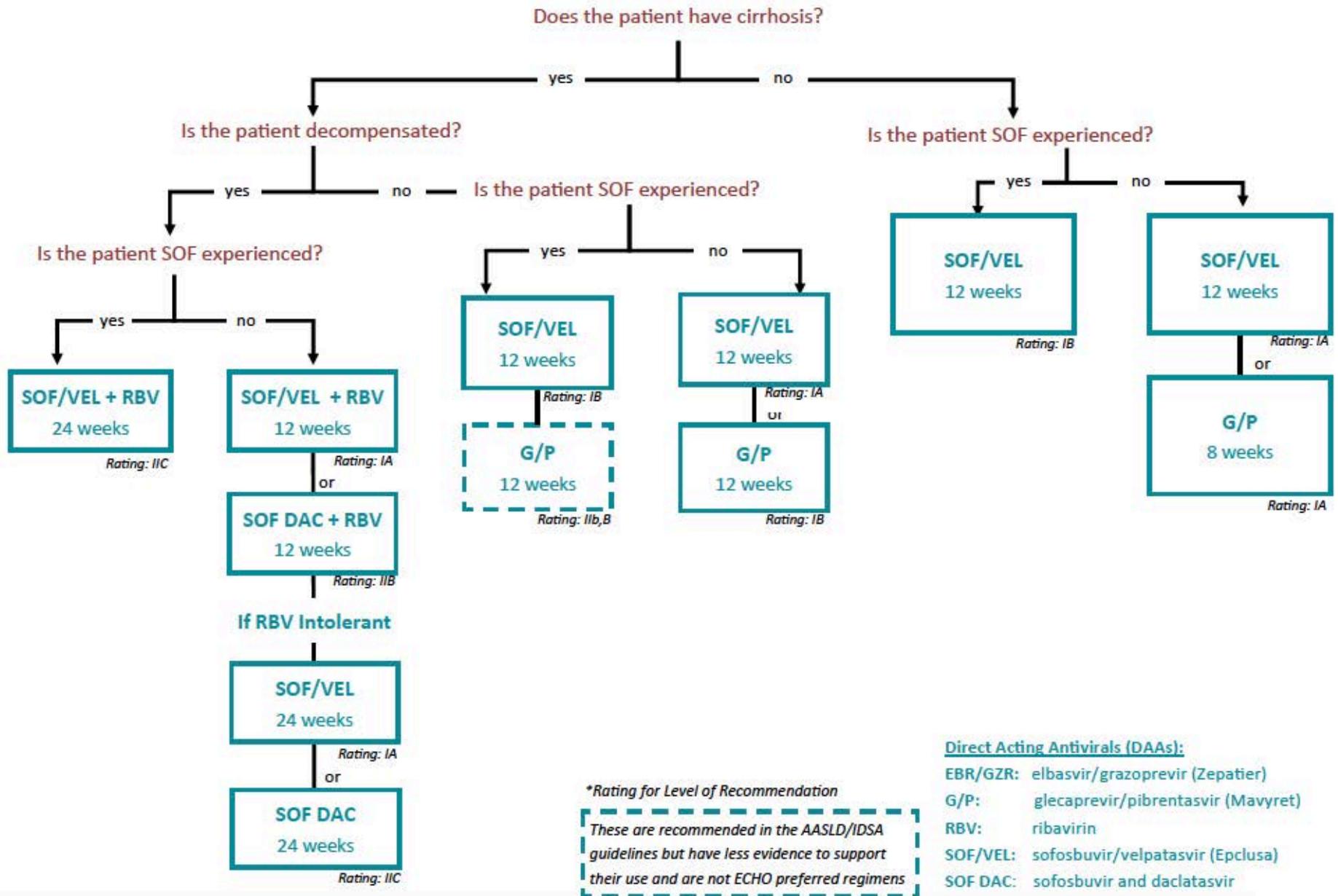


*Rating for Level of Recommendation

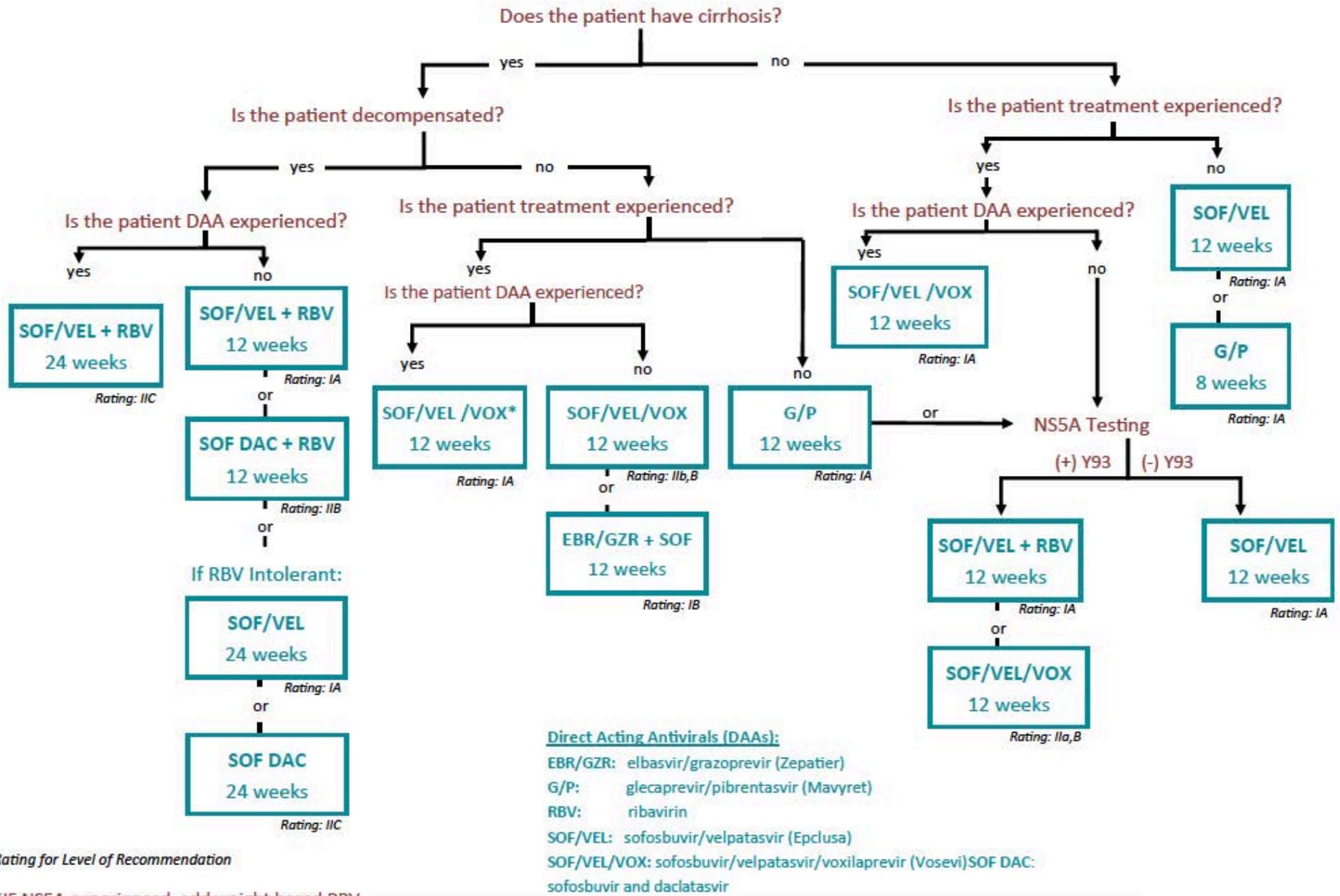
These are recommended in the AASLD/IDSA guidelines but have less evidence to support their use and are not ECHO preferred regimens

- Direct Acting Antivirals (DAAs):**
- EBR/GZR: elbasvir/grazoprevir (Zepatier)
 - G/P: glecaprevir/pibrentasvir (Mavyret)
 - LDV/SOF: ledipasvir/sofosbuvir (Harvoni)
 - RBV: ribavirin
 - SOF/VEL: sofosbuvir/velpatasvir (Epclusa)
 - SOF/VEL/VOX: sofosbuvir/velpatasvir/voxilaprevir (Vosevi)

- HCV GT2



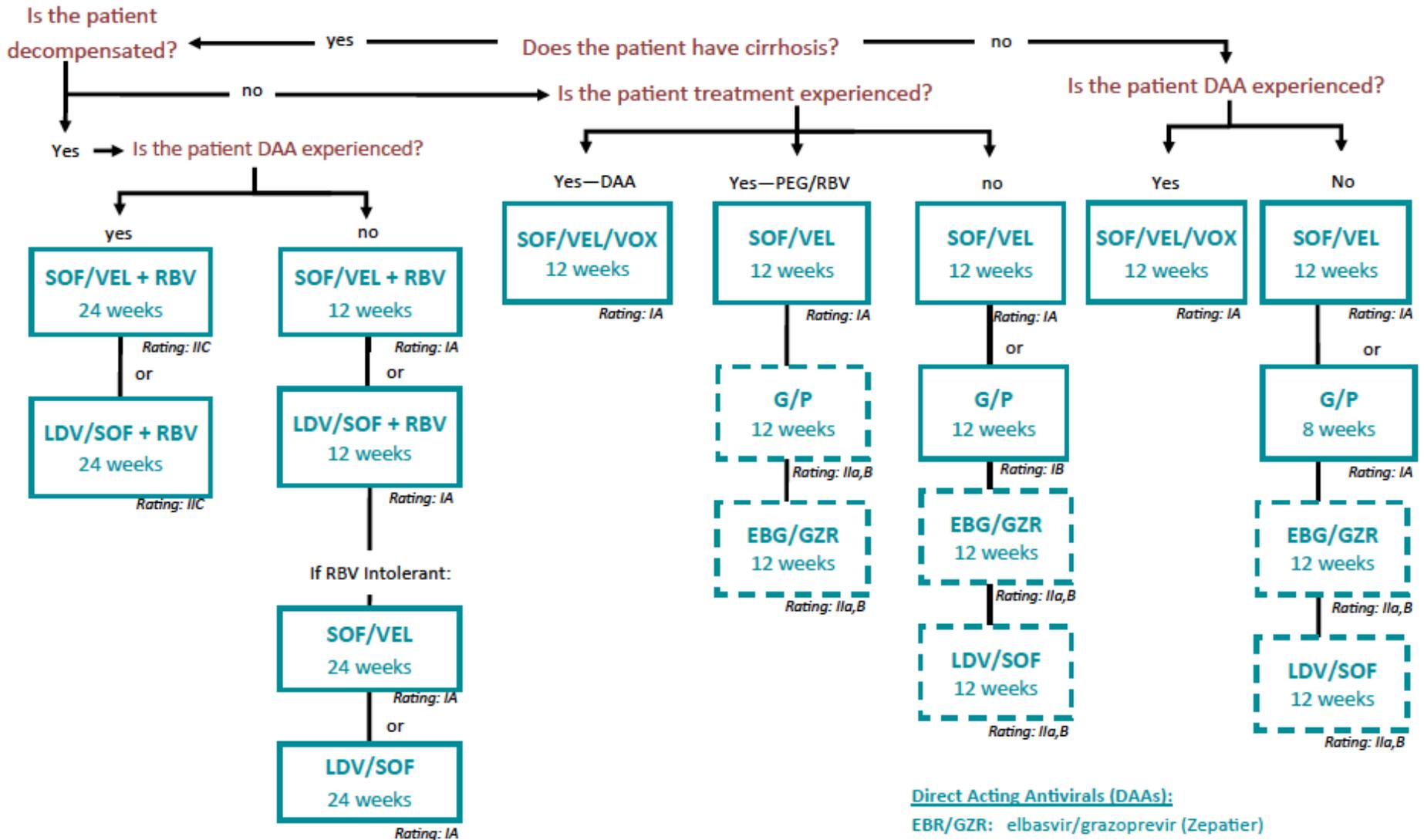
- HCV GT3



*Rating for Level of Recommendation

*IF NS5A-experienced, add weight based RBV

- HCV GT4



*Rating for Level of Recommendation

These are recommended in the AASLD/IDSA guidelines but have less evidence to support their use and are not ECHO preferred regimens

Direct Acting Antivirals (DAAs):

EBR/GZR: elbasvir/grazoprevir (Zepatier)

G/P: glecaprevir/pibrentasvir (Mavyret)

LDV/SOF: ledipasvir/sofosbuvir (Harvoni)

RBV: ribavirin

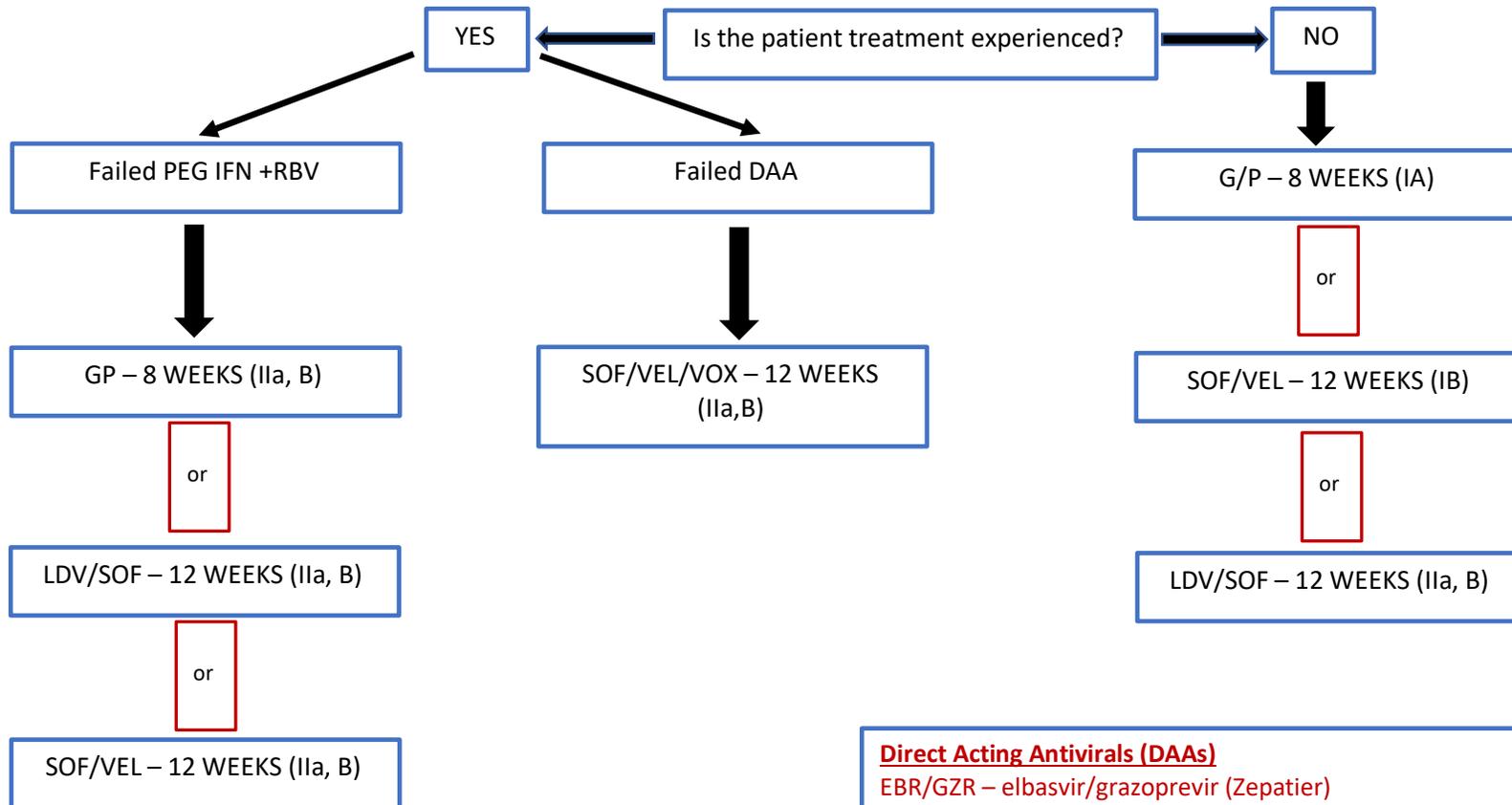
SOF/VEL: sofosbuvir/velpatasvir (Epclusa)

SOF/VEL/VOX: sofosbuvir/velpatasvir/voxilaprevir (Vosevi)

• HCV GT 5 and 6 – No cirrhosis



Version 8.31.18

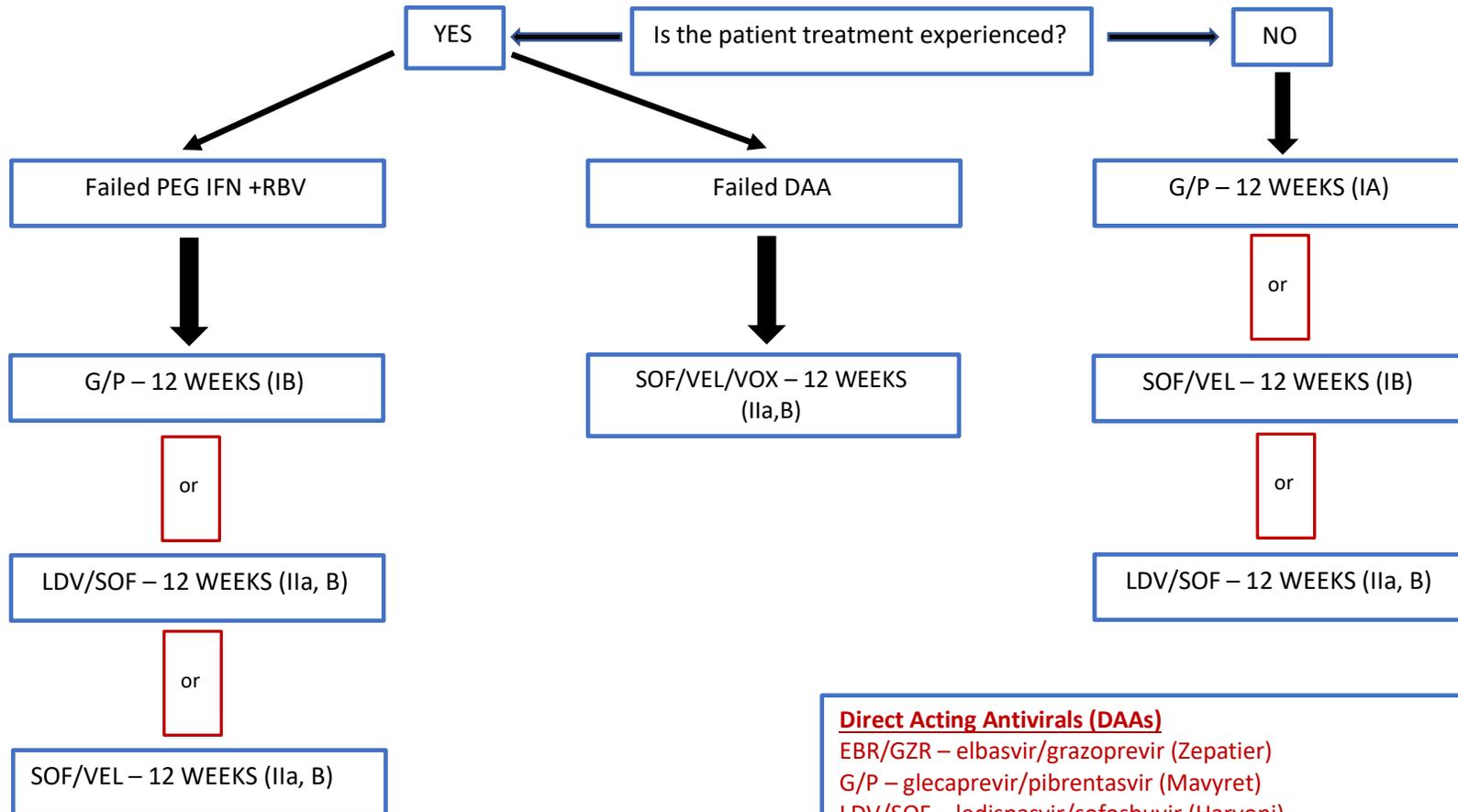


Direct Acting Antivirals (DAAs)
 EBR/GZR – elbasvir/grazoprevir (Zepatier)
 G/P – glecaprevir/pibrentasvir (Mavyret)
 LDV/SOF – ledipasvir/sofosbuvir (Harvoni)
 RBV – ribavirin
 SOF/VEL – sofosbuvir/velpatasvir (Epclusa)
 SOF/VEL/VOX: sofosbuvir/velpatasvir/voxilaprevir (Vosevi)

• HCV GT 5 and 6 – compensated cirrhosis



Version 8.31.18



Direct Acting Antivirals (DAAs)
 EBR/GZR – elbasvir/grazoprevir (Zepatier)
 G/P – glecaprevir/pibrentasvir (Mavyret)
 LDV/SOF – ledipasvir/sofosbuvir (Harvoni)
 RBV – ribavirin
 SOF/VEL – sofosbuvir/velpatasvir (Epclusa)
 SOF/VEL/VOX: sofosbuvir/velpatasvir/voxilaprevir (Vosevi)

- HCV GT 5 and 6 – decompensated cirrhosis

TREATMENT OPTIONS TO BE DECIDED ON A CASE BY CASE BASIS