Simplified HCV Treatment Algorithm for Treatment-Naive Adults With Compensated Cirrhosis

WHO IS *NOT* ELIGIBLE FOR SIMPLIFIED TREATMENT

Patients who have any of the following characteristics:

- **Current or prior** episode of decompensated cirrhosis, defined as Child-Turcotte-Pugh (CTP) score ≥7 (ascites, hepatic encephalopathy, total bilirubin >2.0 mg/dL, albumin ≤3.5 g/dL, or INR ≥1.7)
- Prior hepatitis C treatment
- End-stage renal disease (ie, eGFR <30 mL/min/m^2) (see Patients with Renal Impairment section)
- HIV or HBsAg positive
- Current pregnancy
- Known or suspected hepatocellular carcinoma
- Prior liver transplantation

(See HCV guidance for treatment recommendations for these patients.)

WHO IS ELIGIBLE FOR SIMPLIFIED TREATMENT

- Adults with chronic hepatitis C (any genotype) who have compensated cirrhosis (Child-Pugh A) and have not previously received hepatitis C treatment
- Liver biopsy is not required. For the purpose of this guidance, a patient is presumed to have cirrhosis if they have a FIB-4 score >3.25 **or** any of the following findings from a previously performed test.
  - Transient elastography indicating cirrhosis (eg, FibroScan stiffness >12.5 kPa)
  - Noninvasive serologic tests above proprietary cutoffs indicating cirrhosis (eg, FibroSure, Enhanced Liver Fibrosis Test, etc)
  - Clinical evidence of cirrhosis (eg, liver nodularity and/or splenomegaly on imaging, platelet count <150,000/mm^3, etc)
  - Prior liver biopsy showing cirrhosis

PRETREATMENT ASSESSMENT*

- **Calculate FIB-4 score.**
- **Calculate CTP score:** Patients with a CTP score ≥7 (ie, CTP B or C) have decompensated cirrhosis and this simplified treatment approach is not recommended.
- **Ultrasound of the liver** (conducted within the prior 6 months): Evaluate to exclude HCC and subclinical ascites.
- **Medication reconciliation**: Record current medications, including over-the-counter drugs and herbal/dietary supplements.
- **Potential drug-drug interaction assessment:** Drug-drug interactions can be assessed using the AASLD/IDSA guidance or the University of Liverpool drug interaction checker.
- **Education:** Educate the patient about proper administration of medications, adherence, and prevention of reinfection.
- **Pretreatment laboratory testing** (see next column)

Within 3 months of initiating treatment

- Complete blood count (CBC)
- International normalized ratio (INR)
- Hepatic function panel (ie, albumin, total and direct bilirubin, alanine aminotransferase [ALT], and aspartate aminotransferase [AST])
- Calculated glomerular filtration rate (eGFR)

Any time prior to starting antiviral therapy

- Quantitative HCV RNA (HCV viral load)
- HIV antigen/antibody test
- Hepatitis B surface antigen
- HCV genotype (if treating with sofosbuvir/velpatasvir)

Before initiating antiviral therapy

- Serum pregnancy testing and counseling about pregnancy risks of HCV medication should be offered to women of childbearing age.

RECOMMENDED REGIMENS*

Genotype 1-6:

Glecaprevir (300 mg)/pibrentasvir (120 mg) taken with food for a duration of 8 weeks

Genotype 1, 2, 4, 5, or 6:

Sofosbuvir (400 mg)/velpatasvir (100 mg) for a duration of 12 weeks

NOTE: Patients with genotype 3 require baseline NS5A resistance-associated substitution (RAS) testing. Those without Y93H can be treated with 12 weeks of sofosbuvir/velpatasvir. If Y93H is present, see HCV guidance for treatment recommendations.

ON-TREATMENT MONITORING

- Providers may order blood tests to monitor for liver injury during treatment because hepatic decompensation (eg, jaundice, etc) occurs rarely among patients with cirrhosis receiving HCV antiviral treatment.
- Patients should see a specialist if they develop worsening liver blood tests (eg, bilirubin, AST, ALT, etc); jaundice, ascites, or encephalopathy; or new liver-related symptoms.
- Inform patients taking diabetes medication of the potential for symptomatic hypoglycemia. Monitoring for hypoglycemia is recommended.
- Inform patients taking warfarin of the potential for changes in their anticoagulation status. Monitoring INR for subtherapeutic anticoagulation is recommended.
- An in-person or telehealth/phone visit may be scheduled, if needed, for patient support, assessment of symptoms, and/or new medications.

POST-TREATMENT ASSESSMENT OF CURE (SVR)

- Assessment of quantitative HCV RNA and a hepatic function panel are recommended 12 weeks or later following completion of therapy to confirm HCV RNA is undetectable (virologic cure) and transaminase normalization.
- Assessment for other causes of liver disease is recommended for patients with elevated transaminase levels after achieving SVR.

FOLLOW-UP AFTER ACHIEVING VIROLOGIC CURE (SVR)

- Ultrasound surveillance for HCC (with or without alpha-fetoprotein testing) every 6 months is recommended for patients with cirrhosis in accordance with AASLD guidance.
- Upper endoscopic surveillance for esophageal varices is recommended in accordance with AASLD guidance on portal hypertensive bleeding in cirrhosis
- Patients with ongoing risk for HCV infection (eg, IV drug use or MSM engaging in unprotected sex) should be counseled about risk reduction, and tested for HCV RNA annually and whenever they develop elevated ALT, AST, or bilirubin.
- Patients should abstain from alcohol to avoid progression of liver disease.

FOLLOW-UP FOR PATIENTS WHO DO *NOT* ACHIEVE A VIROLOGIC CURE

- Patients in whom initial HCV treatment fails to achieve cure (SVR) should be evaluated for retreatment by a specialist, in accordance with AASLD/IDSA guidance.
- Ultrasound surveillance for hepatocellular carcinoma (with or without alpha-fetoprotein testing) every 6 months is recommended for patients with cirrhosis, in accordance with AASLD guidance.
- Assessment for disease progression every 6 to 12 months with a hepatic function panel, CBC, creatinine, and INR is recommended.
- Patients should abstain from alcohol to avoid progression of liver disease.

AASLD

* More detailed descriptions of the patient evaluation process and antivirals used for HCV treatment can be found at www.hcvguidelines.org.

IDSA

SIMPLIFIED HEPATITIS C TREATMENT CHECKLIST

Step 1. Calculate FIB-4 https://www.hepatitisc.uw.edu/page/clinical-calculators/fib-4	
Fibrosis assessment:	
❑ Send for FibroScan or obtain serum fibrosis test if FIB-4 > 1.45 (or >2 for those age 65y+) to < 3.25	
❑ Treat as cirrhotic if: FIB- 4 >3.25, or liver biopsy showed cirrhosis or FibroScan >12kPa or a serum fibrosis test (FibroTest-Quest or Fibrosure-LabCorp) suggests cirrhosis, or there is clinical evidence of cirrhosis.	
Step 2. Complete Pretreatment Labs & Assessment:	
Labs **Immediately Prior:**	❑ Pregnancy Test
Acceptable within 3 mos if cirrhosis or 6 mos if no cirrhosis:	❑ CBC ❑ Hepatic function panel and eGFR ❑ PT/INR
Acceptable within 6 months:	❑ HCV RNA ❑ AFP
Anytime prior:	❑ Genotype (not necessary with pangenotypic treatment but consider if patient has cirrhosis and planning to treat with Sofobuvir/Velpatasvir (Epclusa) ❑ HIV antigen/antibody[1] ❑ Hepatitis B surface antigen[1]
Patient Assessment (See **Health Summary** for more detailed information on pre-treatment assessment)	
❑ Hepatitis A vaccine status (if unknown: draw HAV antibody total IgG), vaccinate if not immune	
❑ Hepatitis B vaccine status (if unknown: draw HBcAb & HBsAb), vaccinate if not previously vaccinated and not immune). If full hepatitis B vaccine series has been given previously, no need to vaccinate if HBsAb is negative. If HBcAb is positive, no need to vaccinate (patient is immune.	
❑ Review drug-drug interactions: www.hep-druginteractions.org	
❑ Have patient complete Audit-C & PHQ-9 or other mental health screen and refer to Behavioral Health/Substance Use Treatment Program if indicated.	
❑ If patient is actively injecting drugs, connect with harm reduction services.	
❑ Counsel about pregnancy prevention (ethinyl estradiol not recommended with Mavyret)	
❑ Review medication specific information packet with patient at Treatment Start	
Step 3: Calculate Child-Turcotte Pugh (CTP) Score. https://www.hepatitisc.uw.edu/page/clinical-calculators/ctp	
If CTP > 6, refer patient to Hepatology for treatment.	
Step 4: Identify insurer and determine if Prior Authorization needed. If no PA needed, write prescription/start treatment.	
If no insurance, link to patient assistance programs: https://www.abbvie.com/patients/patient-assistance.html https://www.gileadadvancingaccess.com/financial-support/uninsured	

[1] - If HepB sAg+ or HIV+, patient is not eligible for simplified treatment. Consult with Hepatology specialist for treatment recommendations.

SIMPLIFIED HEPATITIS C TREATMENT CHECKLIST

Monitoring During Treatment

- ❑ Consider in-person or telehealth/phone visit as clinically indicated during treatment to ensure medication adherence, monitor for adverse events and potential drug-drug interactions, especially with newly prescribed medications.
- ❑ Lab monitoring not required but can be considered if clinically indicated.
- ❑ Instruct patients taking diabetes meds to monitor for hypoglycemia.
- ❑ Inform patients taking warfarin of potential need to change dose and monitor INR for sub-therapeutic anticoagulation.
- ❑ Refer to Hepatology or other specialist, if worsening liver blood tests (e.g. bilirubin, AST, ALT); jaundice, ascites, or encephalopathy; or new liver-related symptoms.
- ❑ Instruct patient re: importance of having follow up labs 12 weeks after treatment completion to test for cure.

IMPORTANT!!! Test for Cure

- ❑ **12 weeks or more after treatment completed, obtain HCV RNA and LFTs. Negative HCV RNA at this time is proof of cure of hepatitis C.**

Monitoring After Treatment (for those who have achieved a cure)

If ALT/AST remain elevated, assess for other causes of liver disease, see Elevated LFTs Algorithm

For patients determined pretreatment to have no-moderate fibrosis (F0-F2) including patients with FIB-4 $\leq$ 1.45, no liver specific follow-up is necessary.

For those determined pretreatment to have advanced fibrosis (F3):

- ❑ RUQ US & AFP q 6 months; yearly CBC, LFTs, & AFPs
- ❑ Liver Field Clinic appointment and FibroScan every 2 years. FibroScan to be done in Field Clinic.

For those determined pretreatment to have cirrhosis (F4):

RUQ US & AFP q 6 months; yearly CBC, CMP, AFP, PT/INR

- ❑ Yearly Liver Field Clinic appointment. FibroScan to be done at discretion of provider.

Counsel persons with risk for HCV infection (ongoing IVDU, MSM having unprotected sex) about risk reduction and obtain HCV RNA yearly to test for reinfection.

Follow-Up for Patients Who Do Not Achieve Cure

- ❑ Refer patient to Hepatology or other specialist for evaluation for re-treatment
- ❑ If unable to retreat, assess for liver disease progression every 6-12 months with LFT, CBC and INR
- ❑ Counsel patients to avoid excess alcohol use and those with advanced fibrosis/cirrhosis to abstain from alcohol to avoid progression of liver disease.

Hepatitis C Treatment Information – Initial treatment (Epclusa®/Mavyret™)

You will be taking medication to cure hepatitis C (HCV). The medications for HCV treatment are FDA approved. This guide provides information you will want to know about the medication. It is meant to guide you during treatment and answer questions you may have. Please read this carefully and ask any questions you may have before you begin the medication.

PREGNANCY & BREASTFEEDING WARNING

It is not known if Epclusa® or Mavyret™ will harm an unborn or breastfeeding baby, so it is recommended not to get pregnant or breastfeed while taking this medicine. Women who become pregnant while taking these medications will want to discuss risks versus benefits of continuing treatment with their health care provider. Small studies evaluating the safety of these types of medications in pregnancy have shown high cure rates (100%) and no safety concerns. However, these are small studies and more information is needed before these medications can be recommended for use during pregnancy.

If you will be taking Mavyret™ you will need to stop using ethinyl estradiol-containing medicines (e.g. most birth control pills) before you start treatment. Plan to change to another method of birth control about 2 weeks before starting Mavyret and continuing for 2 weeks after finishing the medication. Progestin-only (e.g. mini pill, Depo shot, Nexplanon™) and barrier contraceptives (condom, diaphragm) are safe to use while taking Mavyret™.

PLEASE NOTE:

It will be important for you to share that you are taking HCV medication with medical, mental health, dental providers, and pharmacist(s) prior to starting any new medications. You must let your provider who is treating your HCV know about any new medications you are prescribed before starting them. This includes vitamins and other supplements.

If you have ever had hepatitis B infection, the virus could become active again during or after taking HCV treatment. You will have blood tests to check for hepatitis B infection before starting treatment (HBsAg, HBcAb). If you have hepatitis B (HBsAg positive), you will have HBV DNA levels (virus count) checked before and while on treatment.

If you have decompensated (severe) liver disease or have ever had liver decompensation you should not take Mavyret.

Hepatitis C Treatment Information – Initial treatment (Epclusa®/Mavyret™)

YOUR TREATMENT REGIMEN AND INDICATION (for persons who have not had previous treatment)

____ Epclusa® one tablet daily for 12 weeks:

□ You do not have cirrhosis.

□ You have compensated (mild) cirrhosis.

____ Epclusa® one tablet daily for 24 weeks:

□ You have decompensated cirrhosis and are ribavirin ineligible.

____ Mavyret™ three tablets daily for 8 weeks:

□ You do not have cirrhosis.

□ You have compensated (mild) cirrhosis.

DURING TREATMENT

- You will want to call or see your provider if you have any questions or concerns
- Female patients of childbearing potential should use contraception and consider doing a monthly pregnancy test.
- If you are taking medication for diabetes you should monitor for symptoms of low blood sugar. Check your glucose level if not feeling well. Contact your diabetes provider for guidance if your blood sugar is low.
- If you are taking warfarin you may experience changes in your anticoagulation levels. Tell your warfarin prescriber that you are taking HCV medication. Your INR needs to be monitored more frequently on treatment.
- If you have cirrhosis, your provider may order blood tests to monitor for liver injury during treatment.
- Prevent the spread of HCV. Avoid sharing needles, drug works, razors, toothbrushes, or nail clippers. Cover all cuts and clean blood spills with dilute bleach water. If you inject drugs use a syringe service program to get free sterile needles, syringes and other supplies. Remember to practice safe sex.
- Do not drink alcohol or use drugs because these hurt the liver.

AFTER TREATMENT

- **VERY IMPORTANT!!! Three months after completing treatment you will need a blood test to see if you are cured of HCV. There is no way to know if you are cured without this test.**
- If your liver blood levels remain elevated after treatment your provider will want to test for other causes of liver disease like fatty liver.

- If you have advanced liver fibrosis or cirrhosis prior to treatment you will continue to need a liver ultrasound and alpha fetoprotein (AFP) cancer screening blood test every six months.
- If you have ongoing risk of HCV get a yearly HCV RNA (virus test).

BENEFITS OF TREATMENT

If you have no hepatitis C in your blood 12 weeks **after** the end of treatment, you are cured. Cure of HCV improves quality of life including physical, emotional and social health. Persons who are cured experience many health benefits including decreased liver inflammation and reduced risk for progression of liver fibrosis (scarring). Cirrhosis can resolve and other signs of liver disease improve. There is more than 70% reduction in the risk of liver cancer and 90% reduction in risk of liver related mortality and need for liver transplant. Treatment of HCV also decreases the transmission of infection to others.

It is possible to experience serious side effects on treatment, which will require you to stop the medication. You may still benefit from treatment even if it does not get rid of your hepatitis C, as it may slow down the disease.

To take care of your liver and prevent the spread of hepatitis C

- Do not share needles or other drug works, toothbrushes, razors, or nail clippers.
- Cover cuts to prevent blood exposure.
- Practice safe sex

If you have any questions about treatment, contact the Liver Disease & Hepatitis Program @ 907-729-1560 or your primary care provider.

TREATMENT MEDICATIONS AND SIDE EFFECTS

Epclusa® is a tablet that contains sofosbuvir 400mg and velpatasvir 100mg. Take Epclusa® once daily by mouth with or without food. Store the medication at room temperature. If you miss a dose, take the missed dose as soon as you remember the same day. Do not take more than 1 tablet of Epclusa® in a day. Take your next dose at your regular time the next day.

- **The most common side effects in clinical trials were headache (22%) and feeling tired/fatigue (15%).**

Tell your healthcare provider if you are taking any medicines including prescription and over-the-counter, vitamins, or herbal supplements. Epclusa® and other medications can affect each other and cause you to not have enough or have too much Epclusa® or other medicine in your

body. The following is a list of some medicines that are known to interact with Epclusa® (this list is not all inclusive):

Stomach/Digestive medicine (for indigestion, heartburn, or stomach ulcers) -

- Proton pump inhibitors are not recommended. If medically necessary omeprazole (Prilosec®) no more than 20 mg daily is okay taken 4 hours after Epclusa®. In this case, Epclusa® should be taken with food. Esomeprazole (Nexium®), lansoprazole (Prevacid®), rabeprazole (Aciphex®), and pantoprazole (Protonix®) have not been studied with Epclusa®.
- Antacids that contains aluminum or magnesium hydroxide (such as Rolaids®, Maalox® and Mylanta®) must be taken 4 hours before or 4 hours after you take Epclusa®.
- H2 blockers must be taken at the same time or 12 hours apart from Epclusa®. Famotidine (Pepcid AC®) no more than 40 mg twice daily is okay. Nizatidine (Axid®) and cimetidine (Tagamet®) have not been studied with Epclusa®.

Heart/Cardiovascular medications -

- Amiodarone (Cordarone®, Nexterone®, Pacerone®). When taken with Epclusa® there is risk of slowing heart rate that can cause near-fainting, fainting, dizziness or lightheadedness, extreme tiredness, weakness, shortness of breath, chest pain, confusion, or memory problems). Taking amiodarone with Epclusa is not recommended.
- Digoxin (Lanoxin®). Monitoring of digoxin levels recommended during treatment.
- Warfarin (Coumadin®) Fluctuations of INR values may occur. Frequent monitoring of INR during and post-treatment is recommended.
- Rosuvastatin (Crestor®) No more than 10mg daily is okay. Monitor for muscle pain and weakness.
- Atorvastatin (Lipitor®) Monitor for muscle pain and weakness.

Seizure medications -

- Carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®); Oxcarbazepine (Trileptal®, Oxtellar XR®); Phenytoin (Dilantin®, Phenytek®); Phenobarbital (Luminal®); Primidone (Mysoline®)

HIV/Other Infectious Diseases and medications -

- Efavirenz (ATRIPLA®); Tipranavir (Aptivus®) used in combination with ritonavir (Norvir®)
- Rifabutin (Mycobutin®); Rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®); Rifapentine (Priftin®)
- Regimens containing tenofovir disproxil fumarate (DF) (ATRIPLA®, COMPLERA®, STRIBILD®, TRUVADA®, VIREAD®). Dosages may need to be adjusted.
- Topotecan (Hycamtin®)

Herbal supplement –

- St. John's wort (Hypericum perforatum) or a product that contains St. John's wort

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Mavyret™ is 3 tablets containing a total daily dose of glecaprevir 300mg and pibrentasvir 120mg. You will take 3 tablets of Mavyret™ by mouth at the same time daily with food. Store the medication at room temperature. Do not miss or skip any doses.

If you miss a dose, take the missed dose as soon as possible that same day. **Exception: If it is less than 6 hours before the next time you are to take Mavyret™ then skip the missed dose. Take the next day's dose at your usual time. Continue taking Mavyret™ daily (3 tablets each day at the same time) until all of your medication is gone.

- **The most common side effects in clinical trials were headache (≈18%) and tiredness (≈15%).**
- **For persons who inject drugs, diarrhea (6%) and nausea (6%) were observed, also.**
- **For persons taking Suboxone®, Sublocade® or naltrexone/Vivitrol®; nausea (11%), and diarrhea (6%) were also observed.**
- **Liver problems may be worsening if you develop nausea, tiredness, yellow skin/eyes, bleeding/bruising more than usual, confusion, poor appetite, diarrhea, brown urine, dark or bloody stool, swelling in the stomach area, or pain in the right upper stomach area or vomiting of blood. If this happens seek care immediately and inform the liver clinic or your provider.**

Do not take the following medications with Mavyret™ (this list may not be all inclusive):

- Rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®). Atazanavir (Reyataz®, Evotaz™)

The following medicines are not recommended to be used with Mavyret™:

- Carbamazepine (Carbatrol®, Equetro®, Tegretol®, Tegretol® XR)
- Ethinyl estradiol-containing medications; combination birth control pills or patches, such as Lo Loestrin™ FE, Norinyl™, Ortho Tri-Cyclen Lo™, Ortho Evra™; hormonal vaginal rings such as NuvaRing®; hormonal replacement therapy medicine Fem HRT™.
- St. John's wort (Hypericum perforatum) or a product that contains St. John's wort
- Efavirenz (ATRIPLA®, Sustiva®); Tipranavir (Aptivus®); Darunavir (Prezista®, Prezcobix®); Lopinavir (Kaletra®); Ritonavir (Norvir®)
- Cyclosporine (Gengraf®, Neoral®, Sandimmune®)
- Atorvastatin (Lipitor®, Caduet®), Lovastatin (Mevacor®, Altoprev®), Simvastatin (Zocor®, Vytorin®)

The following medicines require dose adjustment and/or monitoring when taken with Mavyret™:

- Cholesterol lowering medications: Pravastatin (Pravachol®), Rosuvastatin (Crestor®), Fluvastatin (Lescol®), Pitavastatin (Livalo®)
- Digoxin (Lanoxin™, Lanoxicaps®). Dabigatran etexilate (Pradaxa®)
- Warfarin (Coumadin®) Fluctuations of INR values may occur. Frequent monitoring of INR during and post-treatment is recommended.

AUDIT-C Questionnaire

Patient Name _____ Date of Visit _____

1. Within the past year, how often did you have a drink of alcohol?

- ☐ a. Never
- ☐ b. Monthly (e.g. Special occasions/Rare)
- ☐ c. 2-4 times a month (e.g. 1x on weekend - “Fridays only” or “every other Thursday”)
- ☐ d. 2-3 times a week (e.g. weekends – Friday-Saturday or Saturday-Sunday)
- ☐ e. 4 or more times a week (e.g. daily or most days/week)

2. Within the past year, how many standard drinks containing alcohol did you have on a typical day?

- ☐ a. 1 or 2
- ☐ b. 3 or 4
- ☐ c. 5 or 6
- ☐ d. 7 to 9
- ☐ e. 10 or more

3. Within the past year, how often did you have six or more drinks on one occasion?

- ☐ a. Never
- ☐ b. Less than monthly
- ☐ c. Monthly
- ☐ d. Weekly
- ☐ e. Daily or almost daily

AUDIT-C - Overview

The AUDIT-C is a 3-item alcohol screen that can help identify persons who are hazardous drinkers or have active alcohol use disorders (including alcohol abuse or dependence). The AUDIT-C is a modified version of the 10 question AUDIT instrument.

Clinical Utility

The AUDIT-C is a brief alcohol screen that reliably identifies patients who are hazardous drinkers or have active alcohol use disorders.

Scoring

The AUDIT-C is scored on a scale of 0-12.

Each AUDIT-C question has 5 answer choices. Points allotted are:
a = 0 points, b = 1 point, c = 2 points, d = 3 points, e = 4 points

- **In men**, a score of 4 or more is considered positive, optimal for identifying hazardous drinking or active alcohol use disorders.
- **In women**, a score of 3 or more is considered positive (same as above).
- However, when the points are all from Question #1 alone (#2 & #3 are zero), it can be assumed that the patient is drinking below recommended limits and it is suggested that the provider review the patient's alcohol intake over the past few months to confirm accuracy.[3]
- Generally, the higher the score, the more likely it is that the patient's drinking is affecting his or her safety.

Psychometric Properties

For identifying patients with heavy/hazardous drinking and/or Active-DSM alcohol abuse or dependence

	Men[1]	Women[2]
≥3	Sens: 0.95 / Spec. 0.60	Sens: 0.66 / Spec. 0.94
≥4	Sens: 0.86 / Spec. 0.72	Sens: 0.48 / Spec. 0.99

For identifying patients with active alcohol abuse or dependence

≥ 3	Sens: 0.90 / Spec. 0.45	Sens: 0.80 / Spec. 0.87
≥ 4	Sens: 0.79 / Spec. 0.56	Sens: 0.67 / Spec. 0.94

1. *Bush K, Kivlahan DR, McDonell MB, et al. The AUDIT Alcohol Consumption Questions (AUDIT-C): An effective brief screening test for problem drinking. Arch Internal Med. 1998 (3): 1789-1795.*
2. *Bradley KA, Bush KR, Epler AJ, et al. Two brief alcohol-screening tests from the Alcohol Use Disorders Identification Test (AUDIT): Validation in a female veterans affairs patient population. Arch Internal Med Vol 163, April 2003: 821-829.*
3. *Frequently Asked Questions guide to using the AUDIT-C can be found via the website: www.oqp.med.va.gov/general/uploads/FAQ%20AUDIT-C*

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

NAME: _____ **DATE:** _____

Over the *last 2 weeks,* how often have you been bothered by any of the following problems?
(use "✓" to indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself in some way	0	1	2	3
add columns:		+	+	

(Healthcare professional: For interpretation of TOTAL, please refer to accompanying scoring card.) **TOTAL:**

10. If you checked off *any* problems, how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?

- **Not difficult at all** _____
- **Somewhat difficult** _____
- **Very difficult** _____
- **Extremely difficult** _____

Fold back this page before administering this questionnaire

INSTRUCTIONS FOR USE

for doctor or healthcare professional use only

PHQ-9 QUICK DEPRESSION ASSESSMENT

For initial diagnosis:

1. Patient completes PHQ-9 Quick Depression Assessment on accompanying tear-off pad.

2. If there are at least 4 ✓s in the blue highlighted section (including Questions #1 and #2), consider a depressive disorder. Add score to determine severity.

3. ***Consider Major Depressive Disorder***
—if there are at least 5 ✓s in the blue highlighted section (one of which corresponds to Question #1 or #2)

Consider Other Depressive Disorder
—if there are 2 to 4 ✓s in the blue highlighted section (one of which corresponds to Question #1 or #2)

Note: Since the questionnaire relies on patient self-report, all responses should be verified by the clinician and a definitive diagnosis made on clinical grounds, taking into account how well the patient understood the questionnaire, as well as other relevant information from the patient. Diagnoses of Major Depressive Disorder or Other Depressive Disorder also require impairment of social, occupational, or other important areas of functioning (Question #10) and ruling out normal bereavement, a history of a Manic Episode (Bipolar Disorder), and a physical disorder, medication, or other drug as the biological cause of the depressive symptoms.

To monitor severity over time for newly diagnosed patients or patients in current treatment for depression:

1. Patients may complete questionnaires at baseline and at regular intervals (eg, every 2 weeks) at home and bring them in at their next appointment for scoring or they may complete the questionnaire during each scheduled appointment.

2. Add up ✓s by column. For every ✓: Several days = 1 More than half the days = 2 Nearly every day = 3

3. Add together column scores to get a TOTAL score.

4. Refer to the accompanying PHQ-9 Scoring Card to interpret the TOTAL score.

5. Results may be included in patients' files to assist you in setting up a treatment goal, determining degree of response, as well as guiding treatment intervention.

PHQ-9 SCORING CARD FOR SEVERITY DETERMINATION

for healthcare professional use only

Scoring—add up all checked boxes on PHQ-9

For every ✓: Not at all = 0; Several days = 1;
More than half the days = 2; Nearly every day = 3

Interpretation of Total Score

Total Score	Depression Severity
1-4	Minimal depression
5-9	Mild depression
10-14	Moderate depression
15-19	Moderately severe depression
20-27	Severe depression