Monitoring Patients Who Are Starting HCV Treatment, Are on Treatment, or Have Completed Therapy

Pretreatment and On-Treatment Monitoring

Recommended Assessments Prior to Starting DAA Therapy

RECOMMENDED	RATING
Staging of hepatic fibrosis is essential prior to HCV treatment (see Testing and Linkage to Care and see When and in Whom to Treat). Assessment of potential drug-drug interactions with concomitant medications is recommended prior to starting DAA therapy and, when possible, an interacting co-medication should be stopped or switched to an alternative with less risk for potential interaction during HCV treatment. (See Table of Drug Interactions with Direct-Acting Antivirals and Selected Concomitant Medications below or use an online resource such as University of Liverpool interaction checker.) Patients should be educated about the proper administration of DAA medications (eg, dose, frequency of medicines, food effects, missed doses, adverse events, etc), the crucial importance of adherence, and the need to inform the healthcare provider about any changes to their medication regimen. **The following laboratory tests are recommended within 6 months prior to starting DAA therapy:** • Complete blood count (CBC) • International normalized ratio (INR) • Hepatic function panel (ie, serum albumin, total and direct bilirubin, alanine aminotransferase [ALT], aspartate aminotransferase [AST], and alkaline phosphatase levels) • Estimated glomerular filtration rate (eGFR) **The following laboratory tests are recommended any time prior to starting DAA therapy:** • Quantitative HCV RNA (HCV viral load) • If a nonpangenotypic DAA will be prescribed, then test for HCV genotype and subtype.	I, C
The safety of ribavirin-free DAA regimens in humans has not been established during pregnancy and for nursing mothers, so counseling should be offered to women of childbearing age before beginning HCV treatment. (See ribavirin pregnancy recommendations below.)	I, C
All patients initiating DAA therapy should be assessed for active hepatitis B virus (HBV) coinfection with HBV surface antigen (HBsAg) testing, and for evidence of prior infection with HBV core antibody (anti-HBc) and HBV surface antibody (anti-HBs) testing.	IIa, B

Recommended Assessments Prior to Starting DAA Therapy

Patients found or known to be HBsAg-positive should be assessed for whether their HBV DNA level meets AASLD criteria for HBV treatment and initiation of antiviral therapy for HBV.	Strong, Moderate[a]
All patients should be assessed for HIV coinfection prior to initiating DAA therapy.	IIa, B
Testing for the presence of resistance-associated substitutions (RASs) prior to starting treatment should be performed as recommended in the Initial Treatment and the Retreatment sections. Additional information about RAS testing can be found in the HCV Resistance Primer.	IIb, B
Patients scheduled to receive an HCV NS3 protease inhibitor (ie, grazoprevir, voxilaprevir, glecaprevir) should be assessed for a history of decompensated liver disease and liver disease severity using the Child-Turcotte-Pugh (CTP) score (see third-party calculator). • Patients with current or prior history of decompensated liver disease or with a current CTP score ≥7 should **not** receive treatment with regimens that contain NS3 protease inhibitors due to increased blood levels and/or lack of safety data.	I, A

[a] Unlike the AASLD/IDSA HCV guidance, the AASLD guidelines for treatment of chronic hepatitis B uses the GRADE system to rate recommendations; please see that document for further information about this rating system.

Recommended Monitoring During Antiviral Therapy

RECOMMENDED	RATING
Clinic visits or telephone contact are recommended as clinically indicated during treatment to ensure medication adherence and monitor for adverse events and potential drug-drug interactions (see table of Drug Interactions with Direct-Acting Antivirals and Selected Concomitant Medications below), especially with newly prescribed medications.	I, B
Inform patients taking diabetes medication of the potential for symptomatic hypoglycemia. On-treatment and posttreatment monitoring for hypoglycemia is recommended.	I, C
Inform patients taking warfarin of the potential for changes in their anticoagulation status. On-treatment and posttreatment INR monitoring for subtherapeutic anticoagulation is recommended.	I, C
Patients receiving elbasvir/grazoprevir should be monitored with a hepatic function panel at 8 weeks and again at 12 weeks if receiving 16 weeks of treatment.	I, B
A ≥10-fold increase in ALT values from baseline at any time during treatment should prompt discontinuation of DAA therapy (especially with signs or symptoms of liver inflammation or increasing conjugated bilirubin, alkaline phosphatase, or INR). An increase in ALT <10-fold from baseline that is accompanied by any weakness, nausea, vomiting, jaundice, or significantly increased bilirubin, alkaline phosphatase, or INR should also prompt discontinuation of DAA therapy. Asymptomatic increases in ALT <10-fold from baseline should be closely monitored with repeat testing at 2-week intervals. If levels remain persistently elevated, consideration should be given to	I, B

Recommended Monitoring During Antiviral Therapy	
discontinuation of DAA therapy.	
Quantitative HCV viral load testing is recommended 12 or more weeks after completion of therapy to document sustained virologic response (SVR), which is consistent with cure of chronic HCV infection.	I, B
For HBsAg-positive patients not already receiving HBV suppressive therapy because their baseline HBV DNA level does not meet treatment criteria, one of two approaches may be taken: • Initiate prophylactic HBV antiviral therapy for those with low or undetectable HBV DNA levels. If this course is elected, pending further data, prophylaxis should be continued until 12 weeks after completion of DAA therapy. • Monitor HBV DNA levels monthly during and immediately after DAA therapy. Antiviral treatment for HBV should be given in the event of a rise in HBV DNA >10-fold above baseline or to >1000 IU/mL in those with a previously undetectable or unquantifiable HBV DNA level.	IIa, B

Posttreatment Follow-Up for Patients in Whom Treatment Failed

Recommended Monitoring for Patients in Whom Treatment Failed to Achieve a Sustained Virologic Response	
RECOMMENDED	RATING
Retreatment for chronic HCV is recommended utilizing the regimens recommended in the Retreatment section.	I, C
Disease progression assessment every 6 to 12 months with a hepatic function panel, complete blood count (CBC), and international normalized ratio (INR) is recommended if patients are not retreated or fail a second or third DAA treatment course.	I, C
Surveillance for hepatocellular carcinoma with liver ultrasound examination, with or without alpha fetoprotein (AFP), every 6 months is recommended for patients with cirrhosis[a] in accordance with the AASLD guidance on the diagnosis, staging, and management of hepatocellular carcinoma.	Low, Conditional[b]
For patients with cirrhosis, endoscopic surveillance for varices should be performed in accordance with the AASLD guidance on portal hypertension bleeding in cirrhosis.	Guidance[b]

[a] For decompensated cirrhosis, please refer to the appropriate section.
[b] Unlike the AASLD/IDSA HCV guidance, the AASLD guidelines use the GRADE system to rate recommendations; please see that document for further information about this rating system.

The Following Monitoring Is Not Recommended During or After Therapy	
NOT RECOMMENDED	RATING

The Following Monitoring Is Not Recommended During or After Therapy	
Monitoring for HCV drug resistance-associated substitutions (RASs) during or after therapy is not recommended unless retreatment will be performed. RAS testing is recommended in advance of retreatment therapy. See the Retreatment section for recommendations regarding RAS testing prior to retreatment. Additional information about RAS testing can be found in the HCV Resistance Primer.	IIb, C

Posttreatment Follow-Up for Patients Who Achieved a Sustained Virologic Response

Recommended Follow-Up for Patients Who Achieved a Sustained Virologic Response (SVR)	
RECOMMENDED	RATING
For noncirrhotic patients, recommended follow-up is the same as if they were never infected with HCV.	I, B
Assessment for HCV recurrence is recommended only if the patient develops unexplained hepatic dysfunction, or annual assessment if the patient has ongoing risk factors for HCV infection. In such cases, a quantitative HCV-RNA test rather than an HCV-antibody test is recommended to assess for HCV recurrence.	I, A
Surveillance for hepatocellular carcinoma is recommended for patients with cirrhosis,[a] in accordance with the AASLD guidance on the diagnosis, staging, and management of hepatocellular carcinoma.	Strong, Moderate[b]
For cirrhotic patients, upper endoscopic surveillance is recommended in accordance with the AASLD guidance on portal hypertension bleeding in cirrhosis.	Guidance[b]
Assessment for other causes of liver disease is recommended for patients who develop persistently abnormal liver tests after achieving SVR.	I, C

[a] For decompensated cirrhosis, please refer to the appropriate section.
[b] Unlike the AASLD/IDSA HCV guidance, the AASLD guidelines use the GRADE system to rate recommendations; please see that document for further information about this rating system.

Monitoring for HCV Infection During Chemotherapy and Immunosuppression	
NOT RECOMMENDED	RATING
Prospective monitoring for HCV recurrence among patients who achieved SVR and are receiving immunosuppressive drug therapy (eg, systemic corticosteroids, antimetabolites, chemotherapy, biologics agents, etc) is **not** routinely recommended.	III, C

Additional Considerations If Treatment Includes Ribavirin

Recommended Monitoring During Antiviral Therapy That Includes Ribavirin

RECOMMENDED	RATING
More frequent assessment for drug-related adverse events (ie, CBC for patients receiving ribavirin) is recommended as clinically indicated.	I, C

Recommended Monitoring for Pregnancy-Related Issues Prior to and During Antiviral Therapy That Includes Ribavirin

RECOMMENDED	RATING
Women of childbearing potential and their partners should not receive ribavirin during or for at least 6 months prior to pregnancy.	I, C
Women of childbearing potential should be counseled not to become pregnant while receiving a ribavirin-containing antiviral regimen, and for at least 6 months after stopping the regimen.	I, C
Male partners of women of childbearing potential should be cautioned to prevent pregnancy while they are receiving a ribavirin-containing antiviral regimen, and for up to 6 months after stopping the regimen.	I, C
Serum pregnancy testing is recommended for women of childbearing potential prior to beginning treatment with a regimen that includes ribavirin.	I, C
Assessment of contraceptive use and of possible pregnancy is recommended at appropriate intervals during (and for 6 months after) ribavirin treatment for women of childbearing potential, and for female partners of men who receive ribavirin treatment.	I, C

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