APOTHECARY BY DESIGN

Hepatitis C Referral Checklist

The following is a list of lab data and other information that insurers often request in order to begin the prior-authorization process for hepatitis C therapy.

Apothecary By Design hopes you find this information useful. Please contact us with any questions - our dedicated Infectious Disease Team is always ready to help.

877.814.8447 (Portland) 877.343.2597 (Chicago)

STANDARD REQUIREMENTS

□ ABD Hepatitis C Enrollment Form

This statement of medical necessity can be downloaded at our website, www.abdrx.com.

□ Chart notes and patient history

Please include previous treatment and response (if applicable), current medication list, status of drug/alcohol use, medical history, and any comorbidities.

- □ CBC (complete blood count)
- □ CMP (complete metabolic profile)
- □ HCV genotype

□ Fibrosis score

This may include biopsy, FibroSURE, FibroScan, Flexitest, or other test results.

□ HCV RNA quantitative viral load

This measurement should have been performed in the past 90 days.



SUPPLEMENTAL INFORMATION

- □ Recent drug/alcohol screen results
- □ INR (international normalized ratio)

RAV test results

In some cases, a test for the presence of resistance-associated variants is required for authorization.

□ Patient commitment letter

In some states, patients covered by Medicaid are required to sign a commitment letter. ABD can provide you with a template of this letter to give to your patients.

□ Follow-up HCV RNA viral load data

After treatment is initiated, additional viral load lab results may be required at specific intervals in order to secure continued authorization.



WWW.ABDRX.COM INFO@ABDRX.COM WWW.VILLAGEFERTILITYPHARMACY.COM

Portland, Maine (Headquarters and Pharmacy)

P: 877.814.8447 F: 207.899.0968

141 Preble Street Portland, ME 04101 Chicago, Illinois (Regional Pharmacy) P: 877.343.2597 F: 630.357.2989

Warrenville, IL 60555

4580 Weaver Parkway

Village Fertility Pharmacy P: 877.334.1610 F: 877.334.1602

Boston, Massachusetts

335 Bear Hill Road Waltham, MA 02451

HEPATITIS C

Prescription Reference Guide

Portland, ME

Warrenville, IL (207) 899-0939 (630) 357-2900



Daklinza® & Sovaldi®	Genotype	Therapy Duration	Recommended for Patients
	Genotype 1	+ Sovaldi [®] 12 weeks	Without cirrhosis
		+ Sovaldi® + ribavirin 12 weeks	Decompensated cirrhosis (Child-Pugh B or C)
			Post-transplant
		+ Sovaldi® 12 weeks	Without cirrhosis
	Genotype 3	+ Sovaldi® + ribavirin	Decompensated cirrhosis (Child-Pugh B or C)
		12 weeks	Post-transplant
Epclusa®	Genotype	Therapy Duration	Recommended for Patients
	Genotypes 1-6	12 weeks	With cirrhosis or patients with compensated cirhossis (Child-Pugh A)
		+ ribavirin 12 weeks	With decompensated cirrhosis (Child-Pugh B and C)
Harvoni [®]	Genotype	Therapy Duration	Recommended for Patients
	*8 week therapy for t	reatment-naive, non-cirrhotic,	baseline VL under 6 million is appropriate with provider discretion and may actually be required by some insurance formularies.
	Genotype 1	12 weeks	Treatment-naive without cirrhosis or with compensated cirrhosis (Child-Pugh A)
		12 weeks	Treatment-experienced without cirrhosis
		24 weeks	Treatment-experienced with compensated cirrhosis (Child-Pugh A)
		+ ribavirin 12 weeks	Treatment-naive and treatment-experienced with either compensated (Child-Pugh A) or decompensated cirrhosis (Child-Pugh B and C)
	Genotype 1 or 4	+ ribavirin 12 weeks	Treatment-naive and treatment-experienced liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A)
	Genotype 4*,5 or 6	12 weeks	Treatment-naive without cirrhosis or with compensated cirrhosis (Child-Pugh A) as these patients do not require ribavirin per AASLD. *Addition of ribavirin is recommended for genotype 4, treatment experienced, cirrhotic patients
Viekira Pak / XR [®]	Genotype	Therapy Duration	Recommended for Patients
	Genotype 1a	+ ribavirin 12 weeks	Without cirrhosis
		+ ribavirin 24 weeks	With compensated cirrhosis (Child-Pugh A)
	Genotype 1b	12 weeks	With or without compensated cirrhosis (Child-Pugh A)
Technivie®	Genotype	Therapy Duration	Recommended for Patients
	Genotype 4	+ ribavirin 12 weeks	Without cirrhosis or with compensated cirrhosis (Child-Pugh A)
Zepatier®	Genotype	Therapy Duration	Recommended for Patients
	Genotype 1a	12 weeks	Treatment-naive or PegINF/RBV experienced OR PI experienced <u>without</u> baseline NS5A polymorphisms, regardless of cirrhosis
		+ ribavirin 16 weeks	Treatment-naive or PegINF/RBV experienced OR PI experienced <u>with</u> baseline NS5A polymorphisms, regardless of cirrhosis
	Genotype 1b	12 weeks	Treatment-naive or PegINF/RBV experienced, regardless of cirrhosis
	Genotype 4	12 weeks	Treatment-naive, regardless of cirrhosis
		+ ribavirin 16 weeks	Previously treated with PegINF/RBV experiencing a previous on-treatment virologic failure

Accurate as of 3/15/2017. This guide is a brief summary of some of the label indications of the following HCV drugs, with added information from the American Association for the Study of Liver Disease (AASLD) website. Doses of ribavirin are usually weight-based, but may require initial low doses for decompensated patients.

Our pharmacists utilize AASLD recommendations when providing advice on HCV therapy. The full guidelines are comprehensive and constantly changing; they are available at: www.hcvguidelines.org. Our pharmacists are also available for phone consults on more complex patients. *Subject to change.*