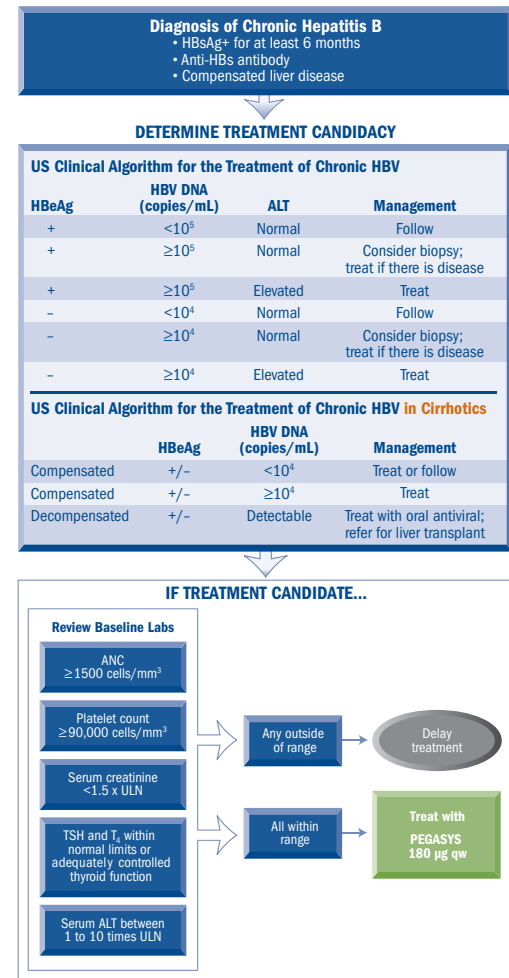


## HBV Patient Treatment Algorithm<sup>5,6</sup>



## Recommendations for Laboratory Tests and Scheduling<sup>5,6,7,8</sup> HBV Patients

Standard hematological and biochemical laboratory tests are recommended for all patients initiating PEGASYS therapy.

Laboratory Test Descriptions
<ul style="list-style-type: none"> <li>• Liver Evaluation*: Liver Biopsy and Ultrasound/CT/MRI</li> <li>• HBV Markers: HBV-DNA (PCR), HBsAg, HBeAg, Anti-HBs, Anti-HBe</li> <li>• Hematological Tests: WBC, ANC, Plt, Hgb, Hct</li> <li>• Liver Function Tests: ALT, AST, Bilirubin</li> <li>• Biochemical Tests: Cr, Glu, other biochemical tests as needed</li> <li>• Thyroid Tests: TSH, T<sub>4</sub></li> <li>• Clinical Evaluation: Mood Evaluation, Weight Evaluation, Adverse Events, Adherence, Eye Exam<sup>1</sup>, Cardiac Evaluation<sup>2</sup>, Medical History, Child-Pugh Score<sup>3</sup></li> <li>• Pregnancy Test</li> </ul>

\* Liver Biopsy and Ultrasound/CT/MRI are at the provider's discretion.

<sup>1</sup> Eye exam required at baseline and periodically for patients at risk.

<sup>2</sup> Cardiac exam performed as needed for patients at risk.

<sup>3</sup> Child-Pugh score evaluated at baseline and if patient shows signs of liver toxicity or decompensation.

Lab Tests	Baseline through 12 Weeks of PEGASYS Therapy for Chronic HBV Infected Patients				
	Baseline	Week 1-2	Week 4	Week 8	Week 12
Liver Evaluation* • Liver Biopsy • Ultrasound/CT/MRI	✓				
HBV Markers • HBV DNA • HBV Antigens (HBsAg, HBeAg) • HBV Antibodies (Anti-HBs, Anti-HBe)	✓				✓
Hematological Tests	✓	✓	✓	✓	✓
Liver Function Tests	✓	✓	✓	✓	✓
Biochemical Tests	✓		✓	✓	✓
Thyroid Tests	✓				✓
Clinical Evaluation	✓	✓	✓	✓	✓
Pregnancy Test	✓				

- **Every 12 Weeks**
  - Hematological Tests (WBC, ANC, Plt, Hgb, Hct)
  - Liver Function Tests (ALT, AST, Bilirubin)
  - Biochemical Tests (Cr, Glu, other biochemical tests as needed)
  - TSH
  - Clinical Evaluation (Mood, Weight, Adverse Events, Adherence)
- **Week 24**
  - HBV-DNA
- **Week 48, 72**
  - HBV-DNA
  - HBeAg and Anti-HBe only in patients who were HBeAg-positive at baseline
  - HBsAg and Anti-HBs can be assessed at week 72 if patient has had a defined therapeutic response.

### ALT Flare Management

Patients may have transient elevations in their liver enzymes (ALT "flares") during all hepatitis B therapies. Patients experiencing ALT flares should have their liver function monitored at a greater frequency than normal. Most patients experiencing ALT flares during PEGASYS therapy can be managed on treatment with the following dose modifications.

### Dose Modifications During ALT Flares

#### >5 x ULN:

- Consider reducing (135 µg) or temporarily discontinuing therapy.
- PEGASYS therapy can be reinstated once ALT flares subside.

#### >10 x ULN:

- Consider discontinuation of therapy.

## One standard PEGASYS dose for all hepatitis patients

### PEGASYS and COPEGUS Dosing Recommendations

Indication	PEGASYS Dose	COPEGUS Dose	Length of Therapy
<b>HCV Monoinfection</b>			
Genotypes 1, 4	180 µg qw	<75 kg=1000 mg/day ≥75 kg=1200 mg/day	48 weeks
Genotypes 2, 3	180 µg qw	800 mg/day	24 weeks
<b>HCV/HIV Coinfection</b>			
For all genotypes	180 µg qw	800 mg/day	48 weeks
<b>HBV Infection</b>			
HBeAg positive and HBeAg negative	180 µg qw	Not used	48 weeks

If severe adverse reactions or laboratory abnormalities develop during combination COPEGUS/PEGASYS therapy, the dose should be modified or discontinued, if appropriate, until the adverse reactions abate. If intolerance persists after dose adjustment, COPEGUS/PEGASYS therapy should be discontinued.

For additional information on dose modifications, please see complete product information.



Please see accompanying complete product information and references for PEGASYS and COPEGUS.



Pharmaceuticals

Hoffmann-La Roche Inc.  
340 Kingsland Street  
Nutley, New Jersey 07110-1199  
www.rocheusa.com

## Pocket guide to hepatitis treatment with PEGASYS and COPEGUS

### Treatment criteria for all hepatitis patients

PEGASYS is indicated for the broadest range of hepatitis patients

Patients Eligible for Treatment With PEGASYS (alone or in combination with COPEGUS)
<p>Patients with chronic hepatitis C virus infection who have compensated liver disease and have not been previously treated with interferon alpha, including:</p> <ul style="list-style-type: none"> <li>• Patients with histological evidence of cirrhosis (Child-Pugh class A)</li> <li>• Patients with clinically stable HIV disease*</li> </ul>
<p>Patients with HBeAg-positive chronic hepatitis B who have compensated liver disease and evidence of viral replication and liver inflammation<sup>†</sup></p>
<p>Patients with HBeAg-negative chronic hepatitis B who have compensated liver disease and evidence of viral replication and liver inflammation<sup>†</sup></p>

PEGASYS and COPEGUS Contraindications
Hypersensitivity to either PEGASYS or COPEGUS or any of their components
Autoimmune hepatitis
Hepatic decompensation with Child-Pugh score >6 (class B and C) in cirrhotic patients before or during treatment (hepatitis C [HCV] or hepatitis B [HBV])
Hepatic decompensation with Child-Pugh score ≥6 in cirrhotic HCV/HIV-coinfected patients before or during treatment
Neonates and infants due to benzyl alcohol in PEGASYS
Women who are pregnant and the male partners of pregnant women
Patients with hemoglobinopathies (eg, thalassemia major, sickle-cell anemia)

\*Antiretroviral therapy not required or receiving stable antiretroviral therapy.  
<sup>†</sup>Treatment with PEGASYS alone.

(Continued)

This pocket guide has been provided as a resource and should not replace the medical judgment of the healthcare provider.



PEGASYS<sup>®</sup>  
(Peginterferon alfa-2a)

COPEGUS<sup>®</sup>  
(Ribavirin, USP)

## Treatment criteria for all hepatitis patients

### Assessing the Child-Pugh score gives key information

Hepatitis patients may have advanced liver disease leading to decompensation, making them inappropriate candidates for treatment with PEGASYS + COPEGUS. The Child-Pugh scoring system can be used to evaluate patients' levels of hepatic decompensation to determine if therapy is right for them.

To determine the Child-Pugh score for hepatic decompensation, points should first be applied to each of the 5 factors below and then added together to determine the class.

#### Child-Pugh Classification of Cirrhosis<sup>1</sup>

Factor	Units	1	2	3
Serum bilirubin	μmol/L mg/dL	<34 <2.0	34-51 2.0-3.0	>51 >3.0
Serum albumin	g/L g/dL	>35 >3.5	30-35 3.0-3.5	<30 <3.0
Prothrombin time	Second Prolonged INR	0-4 <1.7	4-6 1.7-2.3	>6 >2.3
Ascites		None	Easily controlled	Poorly controlled
Hepatic encephalopathy		None	Minimal	Advanced

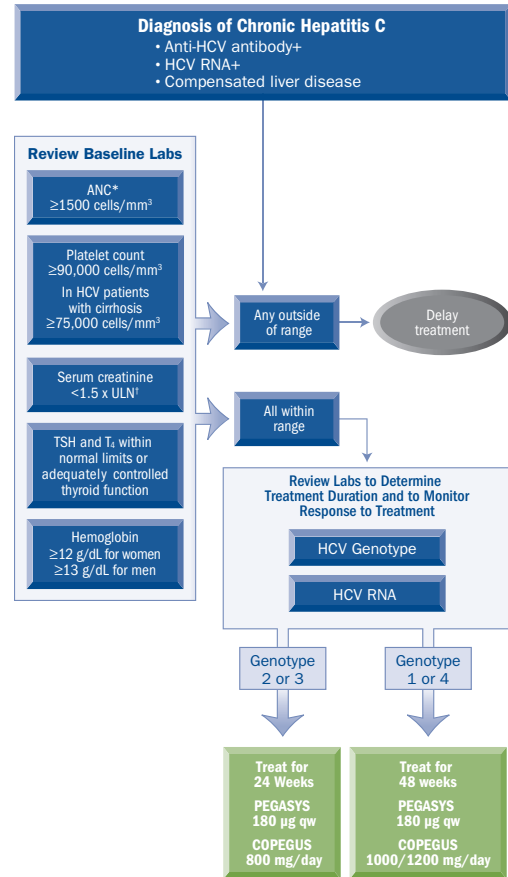
#### Child-Pugh Class Assignment<sup>1</sup>

Total Points	Class	Liver Status
5-6	A	Compensated
7-9	B	Decompensated
10-15	C	Decompensated

Adapted from *Harrison's Principles of Internal Medicine*.

## HCV Patient Treatment Algorithm

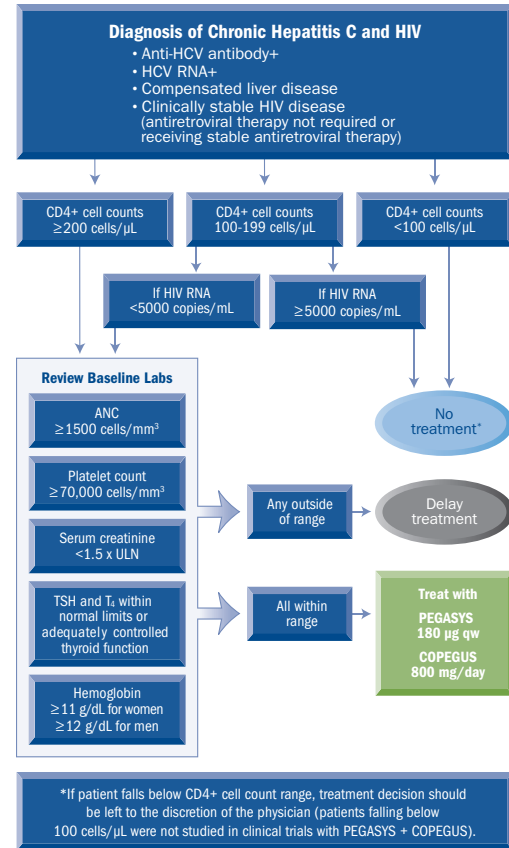
The entrance criteria used for the clinical studies of PEGASYS may be considered as a guideline to acceptable baseline values for initiation of treatment.



\*ANC is absolute neutrophil count.  
†ULN is upper limit of normal.

## HCV/HIV Coinfected Patient Treatment Algorithm

The entrance criteria used for the clinical studies of PEGASYS may be considered as a guideline to acceptable baseline values for initiation of treatment.



## Recommendations for Laboratory Tests and Scheduling<sup>2, 3, 4</sup>

### HCV Monoinfected and HCV/HIV Coinfected Patients

Standard hematological and biochemical laboratory tests are recommended for all patients initiating PEGASYS therapy.

Laboratory Test Descriptions
<ul style="list-style-type: none"> <li>Liver Evaluation: Liver Biopsy, HCV Genotype, HCV RNA</li> <li>Hematological Tests: WBC, ANC, Plt, Hgb, Hct</li> <li>Liver Function Tests: ALT, AST, Bilirubin</li> <li>Biochemical Tests: Cr, Glu, other biochemical tests as needed</li> <li>Thyroid Tests: TSH, T<sub>4</sub></li> <li>Clinical Evaluation: Mood Evaluation, Weight Evaluation, Adverse Events, Adherence, Eye Exam<sup>1</sup>, Cardiac Evaluation<sup>1</sup>, Medical History, Child-Pugh Score<sup>2</sup></li> <li>HIV Markers: HIV RNA, CD4 Count, CD4%</li> <li>Pregnancy screening for women of childbearing potential must be performed before initiation of therapy and again monthly during combination therapy and for 6 months after discontinuing therapy.</li> </ul>

<sup>1</sup> Eye exam required at baseline and periodically for patients at risk.

<sup>2</sup> Cardiac exam performed as needed for patients at risk.

<sup>3</sup> Child-Pugh score evaluated at baseline and if patient shows signs of liver toxicity or decompensation.

Lab Tests	Baseline	Week 1-2	Week 4	Week 6	Week 8	Week 12
Liver Evaluation* • HCV RNA • HCV Genotype • Liver Biopsy	✓ ✓ ✓					✓
Hematological Tests	✓	✓	✓	✓	✓	✓
Liver Function Tests	✓	✓	✓	✓	✓	✓
Biochemical Tests	✓		✓		✓	✓
Thyroid Tests	✓					✓
Clinical Evaluation	✓	✓	✓	✓	✓	✓
HIV Markers	✓					✓
Pregnancy Test	✓		✓		✓	✓

### Recommendations for Laboratory Tests and Scheduling Week 12 through 72 of PEGASYS Therapy for HCV Monoinfected Genotype 1, 4 Patients and HCV/HIV Coinfected Patients

- Every 4 Weeks**
  - Hematological Tests (WBC, ANC, Plt, Hgb, Hct)
  - Liver Function Tests (ALT, AST, Bilirubin)
  - Biochemical Tests (Cr, Glu, other biochemical tests as needed)
  - Clinical Evaluation (Mood, Weight, Adverse Events, Adherence)
  - Pregnancy Test
- Every 12 Weeks**
  - TSH
  - HIV Markers if coinfecting (HIV RNA, CD4 Count, CD4%)
- Week 48 and 72**
  - HCV RNA

### Recommendations for Laboratory Tests and Scheduling Week 12 through 48 of PEGASYS Therapy for HCV Monoinfected Genotype 2, 3 Patients

- Every 4 Weeks**
  - Hematological Tests (WBC, ANC, Plt, Hgb, Hct)
  - Liver Function Tests (ALT, AST, Bilirubin)
  - Biochemical Tests (Cr, Glu, other biochemical tests as needed)
  - Clinical Evaluation (Mood, Weight, Adverse Events, Adherence)
  - Pregnancy Test
- Every 12 Weeks**
  - TSH
- Week 24 and 48**
  - HCV RNA

For Important Safety Information, please see accompanying brochure, *Guide to hepatitis treatment with PEGASYS and COPEGUS*.