Peginterferon Prior Authorization

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	PRIOR AUTHORIZATION CRITERIA FOR APPROVAL **Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of chronic hepatitis B AND BOTH of the following: 1. The chronic hepatitis B infection has been confirmed by serological markers **AND** 2. The patient has not been administered peg-interferon for 48 weeks or longer for treatment of chronic hepatitis B **OR** B. The patient has a diagnosis of chronic hepatitis C genotype 1, 2, 3, or 4 AND the requested agent will be used in a treatment regimen AND length of therapy recommended for the patient's genotype as noted in Table 1, 2, or 3 (FDA labeling) **OR** C. The patient has a diagnosis of polycythemia vera **OR** D. The patient has a diagnosis of essential thrombocythemia **OR** E. The patient has a diagnosis of mycosis fungoides/Sezary syndrome **OR** F. The patient has another FDA approved indication for the requested agent and route of administration **OR** G. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The requested quantity (dose) does not exceed the maximum FDA labeled or compendia supported dose for the requested indication **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** NCCN 1 or 2a recommended use **Length of approval:** • **Hepatitis B:** Up to 48 weeks total length of treatment • **Hepatitis C:** Up to the duration as determined in Table 1, 2, or 3 • **Polycythemia vera or essential thrombocythemia:** 6 months • **Mycosis fungoides/Sezary syndrome:** 12 weeks

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- **All other indications:** 12 months or for duration supported in FDA label or compendia whichever is shorter

Table 1: Sovaldi + PEG + RBV Treatment Recommendations based on FDA approved labeling

Genotype*	FDA approved regimen	Duration of therapy
1a or 1 b	Sofosbuvir + PEG-IFN +RBV	12 weeks
4	Sofosbuvir + PEG-IFN + RBV	12 weeks

*Includes patients with HCV/HIV co-infection

Table 2: Pegasys + RBV Treatment Recommendations based on FDA labeling

Genotype	FDA approved regimen	Duration of therapy
1 or 4	Pegasys + RBV	48 weeks
2 or 3	Pegasys + RBV	24 weeks
5 or 6	There is insufficient data for dosage and duration	

Renewal Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**
2. ONE of the following:
   A. The patient has a diagnosis of chronic hepatitis B AND the patient has NOT been administered peg-interferon for 48 weeks or longer for treatment of chronic hepatitis B **OR**
   B. The patient has a diagnosis of chronic hepatitis C genotype 1, 2, 3, or 4 AND the patient did not complete the duration of therapy for the treatment regimen recommended for the patient's genotype as noted in tables 1, 2, or 3 **OR**
   C. The patient has another diagnosis AND has shown clinical benefit with the requested agent **AND**
3. The requested quantity (dose) does not exceed the maximum FDA labeled or compendia supported dose for the requested indication **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent

Compendia Allowed: NCCN 1 or 2a recommended use

Length of approval: Hepatitis B: Up to duration to complete 48 weeks total length of treatment **Hepatitis C:** Up to the duration to complete the regimen as determined in Table 1, 2, or

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	3 **All other indications:** 12 months or for duration supported in FDA label or compendia whichever is shorter **Table 1: Sovaldi + PEG-IFN + RBV Treatment Recommendations based on FDA approved labeling** **Genotype*** / **FDA approved regimen** / **Duration of therapy** 1a or 1b / Sofosbuvir + PEG-IFN + RBV / 12 weeks 4 / Sofosbuvir + PEG-IFN + RBV / 12 weeks *Includes patients with HCV/HIV co-infection **Table 2: Pegasys + RBV Treatment Recommendations based on FDA labeling** **Genotype** / **FDA approved regimen** / **Duration of therapy** 1 or 4 / Pegasys + RBV / 48 weeks 2 or 3 / Pegasys + RBV / 24 weeks 5 or 6 / There is insufficient data for dosage and duration /