



Federal Employee Program.

PEGASYS, PEGINTRON, AND RIBAVIRIN

Pegasys (peginterferon alfa-2a), PegINTRON (peginterferon alfa-2b), Ribavirin (Moderiba, Rebetol, RibaPak, Ribasphere, RibaTab, ribavirin tablets/capsules)

Pre - PA Allowance

None

Prior-Approval Requirements

Pegasys or PegINTRON alone for Hepatitis C

Age 18 years of age or older for

Diagnosis

Patient must have the following:

1. Chronic hepatitis C

AND ALL of the following:

- a. Detectable viral load in the serum
- b. Compensated liver disease
- c. **NOT** previously treated with interferon alfa
- d. Significant intolerance or contraindication to ribavirin or other antiviral agents
- e. **Genotype 1 only**: HCV viral load will be drawn at treatment week 24

Pegasys with ribavirin or PegINTRON with ribavirin for Hepatitis C

Age 5 years of age or older for Pegasys with ribavirin
3 years of age or older for PegINTRON with ribavirin

Diagnosis

Patient must have the following:

1. Chronic hepatitis C

AND ALL of the following:

- a. Detectable viral load in the serum
- b. Compensated liver disease
- c. Viral genotype must be provided and if genotype 1 must **NOT** be an appropriate candidate for treatment with a protease inhibitor
- d. Females of reproductive potential **only**: patient is not pregnant and will be advised to use effective contraception during therapy and for 6 months after the final dose of ribavirin
- e. Males with female partners of reproductive potential **only**: the patient's

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partner is not pregnant, and the patient will be advised to use effective contraception during therapy and for 6 months after the final dose of ribavirin

- f. **Genotype 1 only:** HCV Viral load will be drawn at treatment week 24

Pegasys for Hepatitis B

Age 3 years of age or older

Diagnosis

Patient must have the following:

1. Chronic hepatitis B

AND ALL of the following:

- a. Compensated liver disease
- b. Evidence of viral replication

Pegasys for Myeloproliferative Neoplasms**Diagnoses**

Patient must have **ONE** the following:

1. Myelofibrosis
 - a. Symptomatic lower-risk myelofibrosis
2. Polycythemia Vera
 - a. Symptomatic **OR** high-risk
 - b. Inadequate response or loss of response to hydroxyurea or interferon therapy, if Pegasys not previously used
3. Essential Thrombocythemia
 - a. Symptomatic **OR** high-risk
 - b. Inadequate response or loss of response to hydroxyurea or interferon therapy, if Pegasys not previously used

Prior - Approval Limits

Hepatitis C: Genotype 1	
Medication	Duration

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Pegasys with or without ribavirin	7 months
Pegintron with or without ribavirin	7 months
Hepatitis C: Genotypes 2 and 3	
Medication	Duration
Pegasys with or without ribavirin <i>No HIV Co-infection</i>	6 months
Pegasys with or without ribavirin <i>With HIV Co-infection</i>	12 months
Pegintron with or without ribavirin	6 months
Hepatitis C: Genotypes 4, 5 and 6	
Medication	Duration
Pegasys with or without ribavirin	12 months
Pegintron with or without ribavirin	12 months
Hepatitis B	
Medication	Duration
Pegasys	12 months
Myeloproliferative Neoplasms	
Medication and Diagnosis	Duration
Pegasys	12 months

Prior – Approval *Renewal* Requirements

Pegasys or PegINTRON alone for Hepatitis C

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Hepatitis C

AND ALL of the following:

- a. Genotype 1
- b. **UNDETECTABLE** viral load after the initial 24 weeks of therapy

Pegasys with ribavirin or PegINTRON with ribavirin for Hepatitis C

Age 5 years of age or older for Pegasys with ribavirin
3 years of age or older for PegINTRON with ribavirin



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Diagnosis

Patient must have the following:

1. Hepatitis C

AND ALL of the following:

- a. Genotype 1
- b. **UNDETECTABLE** viral load after initial 24 weeks of therapy

Pegintron with ribavirin only: OR ONE of the following:

1. History of null or partial response to previous (non-protease inhibitor) treatment

Pegasys for Myeloproliferative Neoplasms

Diagnoses

Patient must have **ONE** the following:

1. Myelofibrosis
2. Polycythemia Vera
3. Essential Thrombocythemia

Prior - Approval *Renewal* Limits

Hepatitis C: Genotype 1	
Medication	Duration
Pegasys with or without ribavirin	5 months
Pegintron with or without ribavirin	5 months
Hepatitis C: Genotypes 2, 3, 4, 5, 6	
Medication	Duration
Pegasys with or without ribavirin <i>Regardless of HIV co-infection</i>	No Renewal
Pegintron without ribavirin	No Renewal
Pegintron with ribavirin <i>History of null or partial response to previous (non-protease inhibitor) treatment</i>	12 months
Hepatitis B	
Medication	Duration



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Pegasys	No Renewal
Myeloproliferative Neoplasms	
Medication and Diagnosis	Duration
Pegasys	12 months