

PRIOR AUTHORIZATION CRITERIA

BRAND NAME	PEG-INTRON	
(generic)	PEG-INTRON KIT	
	(peginterferon alfa-2b)	
Status: CVS Caremark Criteria		MDC
Type: Initial Prior Authorization		Ref # 3805-A

FDA-APPROVED INDICATIONS¹

Chronic Hepatitis C

Pegintron is indicated for treatment of chronic hepatitis C (CHC) in patients with compensated liver disease.

Compendial Uses²

1. Myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, and myelofibrosis)
2. Systemic mastocytosis

<u>CRITERIA FOR APPROVAL</u>			
1	Does the patient have a diagnosis of chronic hepatitis C virus (HCV) infection that has been confirmed by the presence of hepatitis C virus ribonucleic acid (HCV RNA) in the serum? [If no, skip to question 3.]	Yes	No
2	Does the patient have compensated liver disease? [No further questions.]	Yes	No
3	Does the patient have a diagnosis of myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, or myelofibrosis)? [If yes, no further questions.]	Yes	No
4	Does the patient have a diagnosis of systemic mastocytosis?	Yes	No

Guidelines for Approval					
Duration of Approval	12 months	Duration of Approval	12 months	Duration of Approval	12 months
Set 1: Hep C		Set 2: Myeloproliferative neoplasm		Set 3: Systemic mastocytosis	
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)
1	None	3	1	4	1
2					3

Mapping Instructions			
	Yes		No
1.	Go to 2		Go to 3
2.	Approve, 12 months		Deny
3.	Approve, 12 months		Go to 4
4.	Approve, 12 months		Deny

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCES

1. Pegasys [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; January 2019.
2. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. <http://www.hcvguidelines.org>. Last changes made November 6, 2019. Accessed April 19, 2020.
3. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed April 21, 2020.

DOCUMENT HISTORY

Written: Specialty Clinical Development (PK) 06/2020
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