



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGINTERFERON ALFA 2A OR 2B

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGINTERFERON ALFA-2A	PEGASYS, PEGASYS PROCLICK	24035		GPI-10 (1235306005)	
PEGINTERFERON ALFA-2B	PEGINTRON	21367		GPI-10 (1235306010)	FDB: GCN ≠ 29809, 29811, 29812

GUIDELINES FOR USE

1. Is the request for the treatment of chronic hepatitis C virus infection (HCV)?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #2.

2. Is the request for Pegasys?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have chronic hepatitis B **AND** meet the following criterion?

- Therapy is prescribed by or in consultation with a gastroenterologist, infectious disease specialist, a physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient between 3 to 17 years of age and meet **ALL** of the following criteria?

- The patient does NOT have cirrhosis
- The patient has serum HBeAg-positive chronic hepatitis B
- The patient has evidence of viral replication with elevated serum alanine aminotransferase (ALT)

If yes, **approve for 24 weeks by HICL or GPI-10 with a quantity limit of #4 per 28 days.**

If no, continue to #5.

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GUIDELINES FOR USE (CONTINUED)

5. Is the patient 18 years of age or older and meet **ALL** of the following criteria?
- The patient has serum HBeAg-positive or HBeAg-negative chronic hepatitis B
 - The patient has compensated liver disease with evidence of viral replication and liver inflammation

If yes, **approve for 24 weeks by HICL or GPI-10 with a quantity limit of #4 per 28 days.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGINTERFERON ALFA-2A or 2B (Pegasys, PegIntron)** requires the following rule(s) be met for approval:

- A. You have chronic hepatitis B (a type of liver infection)
- B. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive condition), infectious disease specialist (a doctor who specializes in the treatment of infections), a doctor specializing in the treatment of hepatitis such as a hepatologist (liver doctor), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
- C. **If you are between 3 to 17 years of age, approval also requires:**
 1. You do NOT have cirrhosis (liver damage)
 2. Your blood test shows you have HBeAg (marker of active virus multiplying in the body)-positive chronic hepatitis B
 3. You have evidence of viral replication (virus is multiplying in the body) with elevated serum alanine aminotransferase (ALT: a type of liver enzyme test)
- D. **If you are 18 years of age or older, approval also requires:**
 1. Your blood test shows you have HBeAg (marker of active virus multiplying in the body)-positive or HBeAg-negative chronic hepatitis B
 2. You have compensated liver disease (a type of liver condition) with evidence of viral replication and liver inflammation

Note: Pegasys and PegIntron will not be approved for the treatment of hepatitis C.

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pegasys/PegIntron.

REFERENCES

- Pegasys [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; March 2021.
- PegIntron [Prescribing Information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp., January 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 05/01/23

Created: 02/14

Client Approval: 04/23

P&T Approval: 01/17