

**Regence BlueCross BlueShield of Oregon · Regence BlueShield
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Medication Policy Manual

Policy No: dru115

Topic: Infergen[®], interferon alfacon-1

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Revised/Effective Date: May 8, 2009

Next Review Date: May 2010

IMPORTANT REMINDER

This Medical Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medical policy is to provide a guide to coverage. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

Interferon alfacon-1 (Infergen[®]) is a recombinant interferon which modifies immune and virus-infected cells. It is used for the treatment of hepatitis C.

Policy/Criteria

- I. Interferon alfacon-1 in quantities up to 3 injections per week (12 injections per month) may be considered medically necessary in patients with chronic hepatitis C and may be covered without prior authorization.

- II. Administration and Quantity Limitations
 - A. Regence considers interferon alfacon-1 to be a self-administered medication.
 - B. Quantities exceeding 3 injections per week (12 injections per month) for 48 weeks are considered not medically necessary.

- III. Interferon alfacon-1 is considered investigational for all other conditions, including, but not limited to, the treatment of neuroendocrine tumors. ^[12]

Position Summary

- National treatment guidelines recommend peginterferon and ribavirin as initial therapy in patients requiring treatment for chronic hepatitis C. ^[1, 2]
- Interferon alfacon-1 is indicated for the treatment of chronic hepatitis C infection in patients with compensated liver disease. ^[3]
- Interferon alfacon-1 is FDA approved in the following doses:
 - * Treatment-naïve: 9 mcg administered three times weekly for 24 weeks.
 - * Relapsers or non-responders who tolerated previous interferon therapy: 15 mcg administered three times weekly for up to 48 weeks. ^[3]

Clinical Efficacy

- The efficacy of interferon alfacon-1 in the treatment of previously untreated chronic hepatitis C patients was established in a randomized, double-blind clinical trial of 704 patients. ^[4]
 - * Patients received interferon alfacon-1 dosed at 9 mcg three times weekly for 24 weeks.
 - * The primary endpoint was ALT normalization at 24 weeks, which is of uncertain clinical significance.
- There are no published studies comparing three-times-weekly dosing versus daily (higher, more frequent doses) of interferon alfacon-1 in patients who did not respond to or relapsed from interferon therapy.
- Several different interferon alfacon-1 dosing schedules have been evaluated in patients who had inadequate responses to standard interferon therapy. Because these have been performed in different populations in different studies with varying results, it is impossible to conclude that higher doses or more frequent doses are safer or more effective. ^[5–8, 11, 13]
- There are insufficient data to demonstrate that patients who have had an inadequate response to peginterferon and ribavirin therapy will have positive treatment results and improved health outcomes with high dose or prolonged administration of interferon alfacon-1. Only abstracts of small, open-label and retrospective data are available. ^[9, 10]
- A small case-series of 12 patients investigated the treatment of neuroendocrine tumors using octreotide and interferon alfacon-1. Well designed randomized, controlled trials are needed to establish the safety and efficacy of interferon alfacon-1 for this diagnosis. ^[12]

Safety

- The most common adverse reactions seen in clinical trials (reported in $\geq 5\%$ of patients treated with interferon alfacon-1) include headache, fatigue, insomnia, and flu-like symptoms. ^[3]
- Serious adverse effects seen in clinical trials include pancreatitis, bone marrow suppression, colitis, and hypertension. ^[3]

References

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13. Bacon BR et al. Retreating Chronic Hepatitis C with Daily Interferon Alfacon-1/Ribavirin After Nonresponse to Pegylated Interferon/Ribavirin: DIRECT Results. *Hepatology* 2009 Feb 2 [Epub ahead of print].

Cross References
Pegasys [®] , peginterferon alfa-2a dru044
PEG-Intron [®] , peginterferon alfa-2b dru144

Codes	Number	Description
N/A		