



Coverage Guidelines: Hepatitis C Medications

Infergen (interferon alfacon-1), PEG-Intron (peginterferon alfa-2b), Pegasys (peginterferon alfa-2a), and Copegus/Rebetol (ribavirin)

Policy

Network Health covers pegylated/nonpegylated interferon and ribavirin for *Network Health Forward*[®] and *Network Health Together*[®] members based on the 2009 practice guidelines published by the American Association for the Study of Liver Disease on the Diagnosis, Management, and Treatment of Hepatitis C. Infergen, PEG-Intron, Pegasys, and Copegus/Rebetol are only available through our specialty pharmacy program as a pharmacy benefit. Pegasys is Network Health's preferred pegylated interferon. PEG-Intron is **not** on Network Health's *Preferred Drug List*. Network Health covers PEG-Intron when a member has tried and failed therapy with Pegasys or when a provider submits detailed clinical documentation regarding the inappropriateness of a therapy trial with Pegasys.

Covered conditions

Network Health covers the following Hepatitis C medications based on the listed criteria:

1. Hepatitis C genotypes 1, 4, 5, 6 treatment with pegylated interferon and ribavirin

- Network Health will approve initial prior authorization requests for 16 weeks when a member meets all of the following criteria:
 - Evaluation by a gastroenterologist or infectious disease specialist
 - Documentation of HCV genotype 1, 4, 5, 6
 - Detectable HCV RNA level
 - Evidence of liver fibrosis or cirrhosis (e.g., biopsy or Fibroscan) or clinical justification by the treating provider that this test is contraindicated or not warranted
- Network Health will approve reauthorization requests for additional treatment beyond 16 weeks if:
 - At week 12, a patient demonstrates a complete EVR, defined as HCV RNA negative from baseline; Network Health will approve treatment for an additional 32 weeks (48 weeks total treatment) **or**
 - At week 12, a patient demonstrates a partial EVR, defined as HCV RNA decrease more than two log from baseline; Network Health will approve treatment for an additional 8 weeks; **and** if at week 24, a patient demonstrates a complete EVR, defined as HCV RNA negative from baseline; Network Health will approve treatment for an additional 24 weeks (48 weeks total treatment)

2. Hepatitis C (all genotypes) with human immunodeficiency virus (HIV) co-infection treatment with pegylated interferon and ribavirin

- Network Health will approve initial prior authorization requests for 48 weeks when a member meets all of the following criteria:

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- Evaluation by a gastroenterologist or infectious disease specialist
- Documentation of any HCV genotype with HIV co-infection
- Detectable HCV RNA level

3. Hepatitis C genotypes 2 and 3 treatment with pegylated interferon and ribavirin

- Network Health will approve initial prior authorization requests for 24 weeks total treatment when a member meets all of the following criteria:
 - Evaluation by a gastroenterologist or infectious disease specialist
 - Documentation of HCV genotype 2 or 3
 - Detectable HCV RNA level

4. Hepatitis C (all genotypes) treatment with interferon alfacon-1 (with or without ribavirin) or pegylated interferon monotherapy

- Network Health will approve initial prior authorization requests for 48 weeks total treatment when a member meets all of the following criteria:
 - Evaluation by a gastroenterologist or infectious disease specialist
 - Documentation of (any) HCV genotype
 - Detectable HCV RNA level
 - Documentation of intolerance/contraindication to ribavirin (not needed for combination therapy with interferon alfacon-1)

5. Retreatment of Hepatitis C (all genotypes) with pegylated interferon and ribavirin for nonresponders or relapsers initially treated with nonpegylated interferon with or without ribavirin or monotherapy with pegylated interferon

- Network Health will approve initial prior authorization requests for 48 weeks total treatment when a member meets all of the following criteria:
 - Evaluation by a gastroenterologist or infectious disease specialist
 - Documentation of (any) HCV genotype
 - Detectable HCV RNA level
 - Previous treatment failure with nonpegylated interferon with or without ribavirin **or** previous treatment failure with peginterferon monotherapy
 - Evidence of significant liver fibrosis (particularly bridging) or cirrhosis (e.g., biopsy or Fibroscan) or clinical justification by the treating provider that this test is contraindicated or not warranted

Definitions

Complete EVR is when a patient is HCV RNA negative at week 12 of therapy compared to baseline level.

Early virological response (EVR) is a measure of a patient's HCV RNA at week 12 of treatment to determine if therapy is effective.

Genotype is a specific type of Hepatitis C virus.

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HCV RNA level is a measurement of the amount of Hepatitis C virus in the blood.

Hepatitis C virus (HCV) is a blood-borne virus that causes liver inflammation that could lead to fibrosis or cirrhosis.

HIV co-infection is when a patient is infected with both HIV and HCV.

Nonresponder is when a patient fails to clear HCV RNA from the bloodstream after 24 weeks of therapy.

Partial EVR is two or more log reductions in HCV RNA level compared to baseline HCV RNA level.

Relapser is when a patient has a reappearance of HCV RNA in the blood after discontinuing therapy.

Sustained virological response (SVR) is a patient who is HCV RNA negative 24 weeks after completing treatment.

Guidelines references

1. Garcia, R., Keeffe, E.B., Lam, K.D., Nguyen, G., Nguyen, M.H., Trinh, H.N. (2008). Higher rate of sustained virologic response in chronic hepatitis C genotype 6 treated with 48 weeks versus 24 weeks of peginterferon plus ribavirin. *American Journal of Gastroenterology*. 103 (5), 1131-1135.
2. Ghany, M.G., Strader, D.B., Thomas, D.L., Seeff, L.B. (2009). Diagnosis, Management, and Treatment of Hepatitis C: An Update. AASLD Practice Guideline. *Hepatology*, 49 (4), 1335-1374.