Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Effective Date	5/1/14	NA	NA	5/1/14	NA	5/1/14	6/1/14	5/1/14	6/1/14	5/1/14	5/1/14	NA	NA	6/1/14

*FHK- Florida Healthy Kids

Medication	Comments
Roferon-A (interferon alfa-2a)	N/A
Infergen (interferon alfacon-1)	N/A
Intron A (interferon alfa-2b)	N/A

OVERRIDE(S)

Prior Authorization of Benefits

APPROVAL DURATION

- Initial Treatment of Hepatitis C Genotype 1: 15 weeks
- Treatment of Hepatitis C Genotype 2 or 3: 24 weeks
- Continued Treatment of Hepatitis C Genotype 1: One year from the start of initial treatment
- Treatment of Hepatitis C with contraindication to ribavirin: 48 weeks
- All other FDA approved or medically accepted diagnoses: 1 year

APPROVAL CRITERIA

Requests for a non-pegylated interferon may be approved if patient meets the criteria under one of the selected diagnosis:

I. The patient is using for an FDA approved or medically accepted diagnosis other than Chronic Hepatitis C **OR**

II. Hepatitis C Genotype 1:

A. Intron-A or Roferon-A in combination with ribavirin may be approved in patients *less than 18 years of age or with renal failure* who have confirmed hepatitis C (HCV) genotype 1 with compensated liver disease for up to an initial 12 weeks of therapy when the following criteria have been met:
1. Detectable HCV RNA; **AND**
2. Liver biopsy (unless contraindicated) shows some fibrosis and inflammation or necrosis; **AND**
3. Patient is treatment naïve.

B. Infergen in combination with ribavirin may be approved in patients *who have not responded to therapy with a pegylated interferon and ribavirin* who have confirmed hepatitis C (HCV) genotype 1 with compensated liver disease for up to an initial 12 weeks of therapy when the following criteria have been met:
1. Detectable HCV RNA.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

C. Non-Pegylated interferons in combination with ribavirin may be approved in patients with HCV genotype 1 currently receiving therapy who require an additional 36 weeks of treatment (to complete a total of 48 weeks) of therapy when the following criteria has been met:

1. Patients have documented early viral response (EVR). An EVR is defined as a decrease in HCV RNA > 2 $\log^{10}$ (i.e. from 1,200,000 to 12,000) from baseline OR a decrease in HCV RNA to undetectable levels at week 12 of initial therapy.

III. Hepatitis C Genotype 2 or 3:

A. Non-Pegylated interferon in combination with ribavirin may be approved in *patients less than 18 years of age or with renal failure* who have confirmed hepatitis C (HCV) genotype 2 or 3 for a course of treatment not to exceed 24 weeks in duration for patients with all the following conditions:

1. Detectable HCV RNA, **AND**
2. Compensated liver disease, **AND**
3. Patient is treatment naïve.

B. Infergen in combination with ribavirin may be approved in patients *who have not responded to therapy with a pegylated interferon and ribavirin* who have confirmed hepatitis C (HCV) genotype 2 or 3 with compensated liver disease for up to an initial 24 weeks of therapy when the following criteria have been met:

1. Detectable HCV RNA.

IV. Hepatitis C Antiviral Therapy in Patients with a Contraindication to Ribavirin:

A. Non-Pegylated interferon monotherapy may be approved in patients *less than 18 years of age or with renal failure* with a contraindication to ribavirin and confirmed hepatitis C (HCV) with compensated liver disease for up to 48 weeks when the following criteria have been met:

1. Any genotype; **AND**
2. Detectable HCV RNA; **AND**
3. If liver biopsy is performed, fibrosis and inflammation or necrosis are present; **AND**
4. Patient is treatment naïve.

B. Infergen may be approved in patients *who have not responded to therapy with a pegylated interferon* who have confirmed hepatitis C (HCV) with compensated liver disease for up to 48 weeks of therapy when the following criteria have been met:

1. Detectable HCV RNA.