



MEDICATION POLICY

Generic Name: Pegylated Interferons

Therapeutic Class or Brand Name: Pegylated Interferons

Applicable Drugs (if Therapeutic Class):

PegIntron® (peginterferon alfa-2b), Pegasys® (peginterferon alfa-2a)

Date of Origin: 2/1/13

Date Last Reviewed/Revised: 7/30/16

GPI Code: 1235306005, 1235306010

Prior Authorization Criteria (may be considered medically necessary when criteria I through IV are met):

- I. Documented diagnosis of Chronic Hepatitis B (CHB) infection and criterion A is met:
 - A. Patient has not received previous treatment with a pegylated interferon product (i.e. PegIntron® or Pegasys®).
- II. Documentation of patient's Hepatitis treatment history and baseline viral load.
- III. Minimum age requirement: 3 years old.
- IV. Prescriber is a Gastroenterologist, Infectious Disease Specialist, or Hepatologist.

Exclusion Criteria:

- Autoimmune hepatitis.
- Hepatic decompensation in patients with cirrhosis.

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- 4 syringes/vials per 28 days.

Approval Length:

- **Authorization:** 48 weeks.
- **Re-Authorization:** N/A

Appendix:

Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.



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N/A

References:

1. <http://hcvguidelines.org/full-report-view>.
2. <http://blue.regence.com/trgmedpol/drugs/dru044.pdf>.
3. <http://blue.regence.com/trgmedpol/drugs/dru144.pdf>.
4. http://www.bcbsnc.com/assets/services/public/pdfs/formulary/pegasys_criteria.pdf.
5. www.drugs.com.
6. <https://npsonline.pti-nps.com>.
7. [Medi-Span](#).
8. http://www.gene.com/download/pdf/pegasys_prescribing.pdf.
9. http://www.merck.com/product/usa/pi_circulars/p/pegintron/pegintron_pi.pdf.

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Historical Tracking Of Changes Made To Policy																																																																
7/30/2016	<p>1. Changed "I. Documented diagnosis of one of the following conditions A or B AND must meet criteria listed under applicable diagnosis: A. Chronic Hepatitis B (CHB) infection and criterion 1 is met: 1. Patient has not received previous treatment with a pegylated interferon product (i.e. PegIntron® or Pegasys®); B. Chronic Hepatitis C (CHC) Infection with confirmed genotypes 2, 3, 4, 5, or 6 AND criteria 1 through 3 are met: 1. Documentation that patient meets ONE of the following criteria a, b, or c: a. Has a Metavir score of F3 (advanced fibrosis) or F4 (compensated cirrhosis); b. Is post-liver transplant; c. Has clinically severe extrahepatic manifestations of hepatitis C infection as evidenced by one of the following i or ii: i. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis); ii. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis; 2. Documentation that patient meets ONE of the following criteria a, b, or c: a. Patient has genotypes 2, 5, or 6; b. Patient has genotype 3 AND criteria i or ii is met: i. Patient has a documented contraindication to Zepatier™; ii. Patient has failed prior treatment with peginterferon + ribavirin OR Sovaldi® + ribavirin; c. Patient has genotype 4 AND criterion i is met: i. Patient has a documented contraindication to Zepatier™; 3. Documentation that patient's hepatitis C drug therapy is prescribed as outlined in the table under Authorization in the Approval Length section" to "I. Documented diagnosis of Chronic Hepatitis B (CHB) infection and criterion A is met: A. Patient has not received previous treatment with a pegylated interferon product (i.e. PegIntron® or Pegasys®)" under Prior Authorization Criteria.</p> <p>2. Changed the following after Authorization below Approval Length from: "See tables directly below. Table 1 contains information for Hepatitis B, and table 2 contains information for Hepatitis C."</p> <p style="text-align: center;">Table 2. Authorization Information for Hepatitis B.</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th style="background-color: #f8d7da;">Drug Therapy</th> <th style="background-color: #f8d7da;">Authorization Duration</th> </tr> </thead> <tbody> <tr> <td></td> <td>TN</td> </tr> <tr> <td>Peginterferon</td> <td>48 weeks</td> </tr> </tbody> </table> <p>TN = treatment naïve</p> <p style="text-align: center;">Table 2. Authorization Information for Hepatitis C.</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th rowspan="2" style="background-color: #f8d7da;">Drug Therapy</th> <th rowspan="2" style="background-color: #d4edda;">Cirrhosis</th> <th colspan="10" style="background-color: #d1ecf1;">Authorization Duration</th> </tr> <tr> <th colspan="2" style="background-color: #d1ecf1;">G2</th> <th colspan="2" style="background-color: #d1ecf1;">G3</th> <th colspan="2" style="background-color: #d1ecf1;">G4</th> <th colspan="2" style="background-color: #d1ecf1;">G5</th> <th colspan="2" style="background-color: #d1ecf1;">G6</th> </tr> <tr> <th></th> <th></th> <th>TN</th> <th>TE</th> <th>TN</th> <th>TE</th> <th>TN</th> <th>TE</th> <th>TN</th> <th>TE</th> <th>TN</th> <th>TE</th> </tr> </thead> <tbody> <tr> <td rowspan="2" style="background-color: #f8d7da;">Sovaldi® + pegIFN/RBV</td> <td style="background-color: #d4edda;">No</td> <td></td> <td>12w²</td> <td>12w</td> <td>12w^{1,2}</td> <td>12w</td> <td>12w</td> <td>12w</td> <td>12w</td> <td>12w</td> <td>12w¹</td> </tr> <tr> <td style="background-color: #d4edda;">Comp</td> <td></td> <td>12w^{1,2}</td> <td>12w</td> <td>12w^{1,2}</td> <td>12w</td> <td>12w</td> <td>12w</td> <td>12w</td> <td>12w</td> <td>12w¹</td> </tr> </tbody> </table> <p>TN = treatment naïve; TE = treatment experienced; Comp = compensated; RBV = ribavirin; pegIFN = peginterferon; w = weeks ¹For patients who have failed pegIFN/RBV. ²For patients who have failed sofosbuvir + RBV.</p> <p>to: "48 weeks".</p>	Drug Therapy	Authorization Duration		TN	Peginterferon	48 weeks	Drug Therapy	Cirrhosis	Authorization Duration										G2		G3		G4		G5		G6				TN	TE	TN	TE	TN	TE	TN	TE	TN	TE	Sovaldi® + pegIFN/RBV	No		12w ²	12w	12w ^{1,2}	12w	12w	12w	12w	12w	12w ¹	Comp		12w ^{1,2}	12w	12w ^{1,2}	12w	12w	12w	12w	12w	12w ¹
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Sovaldi® + pegIFN/RBV	No		12w ²	12w	12w ^{1,2}	12w	12w	12w	12w	12w	12w ¹																																																					
	Comp		12w ^{1,2}	12w	12w ^{1,2}	12w	12w	12w	12w	12w	12w ¹																																																					
3/21/2016	<p>1. Changed "member" to "patient" throughout policy.</p> <p>2. Changed "B. Chronic Hepatitis C (CHC) Infection with confirmed genotypes 2, 3, 4, 5, or 6 AND criteria 1 AND 2 are met: ...2. Pegylated interferon must be used in combination with Sovaldi® + ribavirin AND member must also meet criteria listed with applicable genotype in a through d: a. If member has genotype 2, member must have failed prior treatment with one of the following i or ii: i. Peginterferon + ribavirin; ii. Sovaldi® + ribavirin; b. If member has genotype 3, member must meet one of the following criteria i or ii: i. Member is treatment-naïve; ii. Member has failed prior treatment with</p>																																																															

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one of the following aa or ab: aa Peginterferon + ribavirin; ab Sovaldi® + ribavirin; c. If member has genotype 4, member must meet both of the following criteria i and ii: i. Member has a documented contraindication to both Harvoni® AND Technivie™; ii. Member is treatment-naïve or has failed prior treatment with peginterferon + ribavirin; d. If member has genotype 5 or 6, member must have a documented contraindication to Harvoni®” to “B. Chronic Hepatitis C (CHC) Infection with confirmed genotypes 2, 3, 4, 5, or 6 AND criteria 1 through 3 are met: ... 2. Documentation that patient meets ONE of the following criteria a, b, or c: a. Patient has genotypes 2, 5, or 6; b. Patient has genotype 3 AND criteria i or ii is met: i. Patient has a documented contraindication to Zepatier™; ii. Patient has failed prior treatment with peginterferon + ribavirin OR Sovaldi® + ribavirin; c. Patient has genotype 4 AND criterion i is met: i. Patient has a documented contraindication to Zepatier™; 3. Documentation that patient's hepatitis C drug therapy is prescribed as outlined in the table under Authorization in the Approval Length section” **under Prior Authorization Criteria.**

3. **Changed section following Authorization under Approval Length from:**
Authorization: See table directly below.

Patient Characteristics		Authorization Information	
Hepatitis Type, Genotype	Hepatitis Treatment History	Treatment	Authorization Duration
CHB	Treatment-naïve*	peginterferon alfa	48 weeks
CHC Genotype 2	Treatment-experienced	Sovaldi® + peginterferon alfa + ribavirin	12 weeks
CHC Genotypes 3, 4, 5, or 6	Treatment-naïve/ Treatment-experienced	Sovaldi® + peginterferon alfa + ribavirin	12 weeks

*No previous treatment with a pegylated interferon product (i.e. PegIntron® or Pegasys®).

to:

Authorization: See tables directly below. Table 1 contains information for Hepatitis B, and table 2 contains information for Hepatitis C.

Table 2. Authorization Information for Hepatitis B.

Drug Therapy	Authorization Duration
	TN
Peginterferon	48 weeks

TN = treatment naïve

Table 2. Authorization Information for Hepatitis C.

Drug Therapy	Cirrhosis	Authorization Duration									
		G2		G3		G4		G5		G6	
		TN	TE	TN	TE	TN	TE	TN	TE	TN	TE
Sovaldi® + pegIFN/RBV	No		12w ²	12w	12w ^{1,2}	12w	12w	12w	12w ¹	12w	12w ¹
	Comp		12w ^{1,2}	12w	12w ^{1,2}	12w	12w	12w	12w ¹	12w	12w ¹

TN = treatment naïve; TE = treatment experienced; Comp = compensated;

RBV = ribavirin; pegIFN = peginterferon; w = weeks

¹For patients who have failed pegIFN/RBV.

²For patients who have failed sofosbuvir + RBV.

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	4. Changed “ http://www.hcvguidelines.org/fullreport ” to “ http://hcvguidelines.org/full-report-view ” under References.						
	5. Removed “ http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Pegasys&PegIntron.pdf ” from References because link is no longer valid.						
2/19/2016	1. Changed “Preferred: PegIntron® (peginterferon alfa-2b); Non-Preferred: Pegasys® (peginterferon alfa-2a)” to “PegIntron® (peginterferon alfa-2b), Pegasys® (peginterferon alfa-2a)” under Applicable Drugs.						
	2. Removed “Non-preferred Pegasys® requires a documented clinical reason why the member cannot use the preferred product PegIntron®” from Prior Authorization Criteria.						
12/4/2015	1. Changed “2. Pegylated interferon must be used in combination with ONE of the following regimens a through c: a. Sovaldi® and ribavirin for genotypes 2 (treatment-experienced members), 3, 4, or 5; b. Ribavirin for genotype 5; c. Sovaldi® and ribavirin for genotype 6 and criterion i must be met: i. Member must have a documented contraindication to Harvoni®” to “2. Pegylated interferon must be used in combination with Sovaldi® + ribavirin AND member must also meet criteria listed with applicable genotype in a through d: a. If member has genotype 2, member must have failed prior treatment with one of the following i or ii: i. Peginterferon + ribavirin; ii. Sovaldi® + ribavirin; b. If member has genotype 3, member must meet one of the following criteria i or ii: i. Member is treatment-naïve; ii. Member has failed prior treatment with one of the following aa or ab: aa. Peginterferon + ribavirin; ab. Sovaldi® + ribavirin; c. If member has genotype 4, member must meet both of the following criteria i and ii: i. Member has a documented contraindication to both Harvoni® AND Technivie™; ii. Member is treatment-naïve or has failed prior treatment with peginterferon + ribavirin; d. If member has genotype 5 or 6, member must have a documented contraindication to Harvoni®” under Prior Authorization Criteria.						
	2. Changed “II. There is documentation of member's Hepatitis treatment history” to “II. Documentation of member’s Hepatitis treatment history and baseline viral load” under Prior Authorization Criteria.						
	3. Removed the following row from the table following Authorization under Approval Length:						
		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%;">CHC Genotype 5</td> <td style="width: 25%;">Treatment-naïve/ Treatment-experienced</td> <td style="width: 25%;">peginterferon alfa + ribavirin</td> <td style="width: 25%; text-align: center;">48 weeks</td> </tr> </table>	CHC Genotype 5	Treatment-naïve/ Treatment-experienced	peginterferon alfa + ribavirin	48 weeks	
CHC Genotype 5	Treatment-naïve/ Treatment-experienced	peginterferon alfa + ribavirin	48 weeks				
5/20/2015	1. Changed “1. Documentation that member meets ONE of the following criteria a through i: a. Has a Metavir score of F2 (fibrosis), F3 (advanced fibrosis), or F4 (compensated cirrhosis); b. Is post-liver transplant; c. Has clinically severe extrahepatic manifestations of hepatitis C infection as evidenced by one of the following i or ii: i. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis); ii. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis; d. Is coinfecting with HIV-1; e. Is coinfecting with Hepatitis B virus (HBV); f. Has other coexistent liver disease [i.e. nonalcoholic steatohepatitis (NASH)]; g. Has debilitating fatigue as evidenced by the documentation of significant limitations of instrumental activities of daily living (i.e. meal preparation, household chores, etc.); h. Has Type 2 diabetes mellitus (insulin resistant); i. Has porphyria cutanea tarda” to “A. Chronic Hepatitis C (CHC) Infection with confirmed genotypes 2, 3, 4, 5, or 6 AND criteria 1 AND 2 are met: 1. Documentation that member meets ONE of the following criteria a, b, or c: a. Has a Metavir score of F3 (advanced fibrosis) or F4 (compensated cirrhosis); b. Is post-liver transplant; c. Has clinically severe extrahepatic manifestations of hepatitis C infection as evidenced by one of the following i or ii: i. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis); ii. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis” under Prior Authorization Criteria.						
4/1/2015	1. Changed “A. Chronic Hepatitis C (CHC) Infection with confirmed genotypes 2, 3, 4, 5, or 6 AND criteria 1 AND 2 are met: 1. Documentation that member meets ONE of the following criteria a, b, or c: a. Has a Metavir score of F3 (advanced fibrosis) or F4 (compensated cirrhosis); b. Is post-liver						

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	transplant; c. Has clinically severe extrahepatic manifestations of hepatitis C infection as evidenced by one of the following i or ii: i. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis); ii. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis” to “1. Documentation that member meets ONE of the following criteria a through i: a. Has a Metavir score of F2 (fibrosis), F3 (advanced fibrosis), or F4 (compensated cirrhosis); b. Is post-liver transplant; c. Has clinically severe extrahepatic manifestations of hepatitis C infection as evidenced by one of the following i or ii: i. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis); ii. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis; d. Is coinfectd with HIV-1; e. Is coinfectd with Hepatitis B virus (HBV); f. Has other coexistent liver disease [i.e. nonalcoholic steatohepatitis (NASH)]; g. Has debilitating fatigue as evidenced by the documentation of significant limitations of instrumental activities of daily living (i.e. meal preparation, household chores, etc.); h. Has Type 2 diabetes mellitus (insulin resistant); i. Has porphyria cutanea tarda” under Prior Authorization Criteria.
2/13/2015	<p>2. Changed “Chronic Hepatitis C (CHC) Infection with confirmed genotypes 3, 4, 5, or 6 AND criteria 1 AND 2 are met” to “Chronic Hepatitis C (CHC) Infection with confirmed genotypes 2, 3, 4, 5, or 6 AND criteria 1 AND 2 are met” under Prior Authorization Criteria.</p> <p>3. Changed “Sovaldi® and ribavirin for genotypes 3, 4, or 5” to “Sovaldi® and ribavirin for genotypes 2 (treatment-experienced members), 3, 4, or 5” under Prior Authorization Criteria.</p>
2/12/2015	<p>1. Changed Prior Authorization Criteria from: “I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis: A. Chronic Hepatitis B infection and criterion 1 is met: 1. Patient has not received previous treatment with a pegylated interferon product (i.e. PegIntron® or Pegasys®); B. Chronic Genotype 1 Hepatitis C Virus infection AND pegylated interferon will be used in combination with a hepatitis C virus protease inhibitor [i.e. Incivek® (telaprevir) or Victrelis® (boceprevir)] and criteria 1 through 2 are met: 1. Prior authorization has been approved for either Incivek® (telaprevir) or Victrelis® (boceprevir); 2. There is documentation of member’s treatment history (see Appendix); C. Chronic Hepatitis C infection and pegylated interferon will NOT be used in combination with a hepatitis C virus protease inhibitor [i.e. Incivek® (telaprevir) or Victrelis® (boceprevir)] and criteria 1 through 4 are met: 1. Detectable HCV RNA levels are higher than 50 IU/ml; 2. Pegylated interferon will be used in combination with ribavirin, unless ribavirin is contraindicated; 3. Patient has not received previous treatment with a pegylated interferon product (i.e. PegIntron® or Pegasys®); 4. There is documentation that pegylated interferon will not be used with a hepatitis C protease inhibitor [i.e. Incivek® (telaprevir) or Victrelis® (boceprevir)]; II. Minimum age requirement: 3 years old; III. Prescriber is a Gastroenterologist, Infectious Disease Specialist, or Hepatologist; Non-preferred Pegasys® requires a documented clinical reason why the patient cannot use the preferred product PegIntron®” to: “I. Documented diagnosis of one of the following conditions A or B AND must meet criteria listed under applicable diagnosis: A. Chronic Hepatitis B (CHB) infection and criterion 1 is met: 1. Member has not received previous treatment with a pegylated interferon product (i.e. PegIntron® or Pegasys®); B. Chronic Hepatitis C (CHC) Infection with confirmed genotypes 3, 4, 5, or 6 AND criteria 1 AND 2 are met: 1. Documentation that member meets ONE of the following criteria a, b, or c: a. Has a Metavir score of F3 (advanced fibrosis) or F4 (compensated cirrhosis); b. Is post-liver transplant; c. Has clinically severe extrahepatic manifestations of hepatitis C infection as evidenced by one of the following i or ii: i. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis); ii. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis; 2. Pegylated interferon must be used in combination with ONE of the following regimens a through c: a. Sovaldi® and ribavirin for genotypes 3, 4, or 5; b. Ribavirin for genotype 5; c. Sovaldi® and ribavirin for genotype 6 and criterion i must be met: i. Member must have a documented contraindication to</p>

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	<p>Harvoni®; II. There is documentation of member's Hepatitis treatment history; III. Minimum age requirement: 3 years old; IV. Prescriber is a Gastroenterologist, Infectious Disease Specialist, or Hepatologist; V. Non-preferred Pegasys® requires a documented clinical reason why the member cannot use the preferred product PegIntron®”.</p> <p>2. Changed Authorization under Approval Length from “For use without a hepatitis C protease inhibitor for chronic hepatitis B or chronic hepatitis C: see Table 1 directly below; For use with Incivek® (telaprevir) and ribavirin: see Table 2 directly below; For use with Victrelis® (boceprevir) and ribavirin: see Table 3 directly below” to “See table directly below”.</p> <p>3. Added the following table under Authorization under Approval Length:</p> <table border="1" style="width: 100%; border-collapse: collapse; margin: 5px 0;"> <thead> <tr> <th colspan="2" style="text-align: center;">Patient Characteristics</th> <th colspan="2" style="text-align: center;">Authorization Information</th> </tr> <tr> <th style="text-align: center;">Hepatitis Type, Genotype</th> <th style="text-align: center;">Hepatitis Treatment History</th> <th style="text-align: center;">Treatment</th> <th style="text-align: center;">Authorization Duration</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">CHB</td> <td>Treatment-naïve*</td> <td>peginterferon alfa</td> <td style="text-align: center;">48 weeks</td> </tr> <tr> <td style="text-align: center;">CHC Genotype 2</td> <td>Treatment-experienced</td> <td>Sovaldi® + peginterferon alfa + ribavirin</td> <td style="text-align: center;">12 weeks</td> </tr> <tr> <td style="text-align: center;">CHC Genotypes 3, 4, 5, or 6</td> <td>Treatment-naïve/ Treatment-experienced</td> <td>Sovaldi® + peginterferon alfa + ribavirin</td> <td style="text-align: center;">12 weeks</td> </tr> <tr> <td style="text-align: center;">CHC Genotype 5</td> <td>Treatment-naïve/ Treatment-experienced</td> <td>peginterferon alfa + ribavirin</td> <td style="text-align: center;">48 weeks</td> </tr> </tbody> </table> <p>*No previous treatment with a pegylated interferon product ((i.e. PegIntron® or Pegasys®)).</p> <p>4. Changed Re-Authorization under Approval Length from “For use without a hepatitis C protease inhibitor for chronic hepatitis B or chronic hepatitis C: see Table 1 directly below; For use with Incivek® (telaprevir) and ribavirin: see Table 2 directly below; For use with Victrelis® (boceprevir) and ribavirin: see Table 3 directly below” to “N/A”.</p> <p>5. Deleted “Table 1. Authorization Criteria and Duration of Approval for Pegylated Interferons when NOT used in combination with a hepatitis C virus protease inhibitor [i.e. Incivek® (telaprevir) or Victrelis® (boceprevir)]”, “Table 2: Authorization Criteria and Duration of Approval for Pegylated Interferons when Administered with Incivek® (telaprevir)”, and “Table 3: Authorization Criteria for Pegylated Interferons when Administered with Victrelis® (boceprevir)” under Approval Length.</p> <p>6. Deleted “Definitions of Member Treatment History” table from Appendix.</p> <p>7. Added “http://www.hcvguidelines.org/fullreport” under References.</p> <p>8. Changed “http://www.bcbsnc.com/assets/services/public/pdfs/formulary/peginterferon_um_criteria.pdf” to “http://www.bcbsnc.com/assets/services/public/pdfs/formulary/pegasys_criteria.pdf” under References.</p>			Patient Characteristics		Authorization Information		Hepatitis Type, Genotype	Hepatitis Treatment History	Treatment	Authorization Duration	CHB	Treatment-naïve*	peginterferon alfa	48 weeks	CHC Genotype 2	Treatment-experienced	Sovaldi® + peginterferon alfa + ribavirin	12 weeks	CHC Genotypes 3, 4, 5, or 6	Treatment-naïve/ Treatment-experienced	Sovaldi® + peginterferon alfa + ribavirin	12 weeks	CHC Genotype 5	Treatment-naïve/ Treatment-experienced	peginterferon alfa + ribavirin	48 weeks
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1/28/2014	<p>1. Adapted policy to new format.</p> <p>2. Changed name of policy from “Pegasys®/PegIntron®” to “Pegylated Interferons”.</p> <p>3. Changed Applicable Drugs from “N/A” to “Preferred: PegIntron® (peginterferon alfa-2b); Non-Preferred: Pegasys® (peginterferon alfa-2a)”.</p> <p>4. Added “1235306010” to GPI Code.</p> <p>5. Changed Prior Authorization Criteria from: “Documented diagnosis of Chronic Hepatitis B AND/OR Chronic Hepatitis C” to: “I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis: A. Chronic Hepatitis B infection and criterion 1 is met: 1. Patient has not received previous treatment with a pegylated interferon product (i.e. PegIntron® or Pegasys®); B. Chronic Genotype 1 Hepatitis C Virus infection AND pegylated interferon will be used in combination with a hepatitis C virus protease inhibitor [i.e. Incivek® (telaprevir) or Victrelis® (boceprevir)] and criteria 1 through 2 are met: 1. Prior authorization has been approved for either Incivek® (telaprevir) or</p>																										

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MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
	<p>Victrelis® (boceprevir); 2. There is documentation of member’s treatment history (see Appendix); C. Chronic Hepatitis C infection and pegylated interferon will NOT be used in combination with a hepatitis C virus protease inhibitor [i.e. Incivek® (telaprevir) or Victrelis® (boceprevir)] and criteria 1 through 4 are met: 1. Detectable HCV RNA levels are higher than 50 IU/ml; 2. Pegylated interferon will be used in combination with ribavirin, unless ribavirin is contraindicated; 3. Patient has not received previous treatment with a pegylated interferon product (i.e. PegIntron® or Pegasys®); 4. There is documentation that pegylated interferon will not be used with a hepatitis C protease inhibitor [i.e. Incivek® (telaprevir) or Victrelis® (boceprevir)]; II. Minimum age requirement: 3 years old; III. Prescriber is a Gastroenterologist, Infectious Disease Specialist, or Hepatologist; IV. Non-preferred Pegasys® requires a documented clinical reason why the patient cannot use the preferred product PegIntron®”.</p> <p>6. Added “Autoimmune hepatitis; Hepatic decompensation in patients with cirrhosis” to Exclusion Criteria.</p> <p>7. Changed Authorization under Approval Length from “One 48-week supply” to “For use without a hepatitis C protease inhibitor for chronic hepatitis B or chronic hepatitis C: see Table 1 directly below. For use with Incivek® (telaprevir) and ribavirin: see Table 2 directly below. For use with Victrelis® (boceprevir) and ribavirin: see Table 3 directly below”.</p> <p>8. Changed Re-Authorization under Approval Length from “Coverage may be extended to 72 weeks in patients with a documented late viral response (defined as failure to clear the virus until weeks 12-24 of treatment). This means that if a patient’s viral load is between 49 and 65,000,000 at any point between weeks 12 and 24, a total of 72 weeks’ treatment may be authorized” to “For use without a hepatitis C protease inhibitor for chronic hepatitis B or chronic hepatitis C: see Table 1 directly below. For use with Incivek® (telaprevir) and ribavirin: see Table 2 directly below. For use with Victrelis® (boceprevir) and ribavirin: see Table 3 directly below”.</p> <p>9. Added “Table 1. Authorization Criteria and Duration of Approval for Pegylated Interferons when NOT used in combination with a hepatitis C virus protease inhibitor [i.e. Incivek® (telaprevir) or Victrelis® (boceprevir)]”, “Table 2: Authorization Criteria and Duration of Approval for Pegylated Interferons when Administered with Incivek® (telaprevir)”, and “Table 3: Authorization Criteria for Pegylated Interferons when Administered with Victrelis® (boceprevir)” tables under Approval Length.</p> <p>10. Added “Definitions of Member Treatment History” table to Appendix.</p> <p>11. Updated references to include specific Utah Medicaid and Regence policies referred to, bcbsnc policy, Medi-Span, and package inserts.</p>

Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.