



# Peg-interferon Prior Authorization Program Summary

## POLICY REVIEW CYCLE

**Effective Date**  
11-01-2025

**Date of Origin**

## POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Pegasys	peginterferon alfa-	180 MCG/0.5ML ; 180 MCG/ML	M ; N ; O ; Y	N		

## CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Pegasys	peginterferon alfa-	180 MCG/0.5ML ; 180 MCG/ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p><b>Initial Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>1. ONE of the following:           <ol style="list-style-type: none"> <li>A. The patient has a diagnosis of chronic hepatitis B AND BOTH of the following:               <ol style="list-style-type: none"> <li>1. The chronic hepatitis B infection has been confirmed by serological markers <b>AND</b></li> </ol> </li> </ol> </li> </ol>

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	<p>2. The patient has not been administered peg-interferon for 48 weeks or longer for treatment of chronic hepatitis B <b>OR</b></p> <p>B. The patient has a diagnosis of chronic hepatitis C genotype 1, 2, 3, or 4 AND the requested agent will be used in a treatment regimen AND length of therapy recommended for the patient's genotype as noted in Table 1 or 2 (FDA labeling) <b>OR</b></p> <p>C. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></p> <p>D. The patient has another non-oncology indication that is supported in compendia for the requested agent and route of administration <b>OR</b></p> <p>E. The patient has an oncology indication that is supported in compendia for the requested agent and route of administration (i.e., indication must be supported in compendia by ALL requirements [e.g., performance status, disease severity, previous failures, monotherapy vs. combination therapy]) <b>AND</b></p> <p>2. If the patient has an FDA labeled indication, then ONE of the following:</p> <p>A. The patient's age is within FDA labeling for the requested indication for the requested agent <b>OR</b></p> <p>B. There is support for using the requested agent for the patient's age for the requested indication <b>AND</b></p> <p>3. The requested quantity (dose) is within FDA labeled dosing or supported in compendia for the requested indication <b>AND</b></p> <p>4. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p><b>Compendia Allowed:</b> NCCN 1, 2a, or 2b recommended use, AHFS, or DrugDex 1, 2a, or 2b level of evidence</p> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p> <p>BCBSIL and BCBSMT: 12 months</p> <p>ALL other plans:</p> <ul style="list-style-type: none"> <li>• <b>Hepatitis B:</b> Up to 48 weeks total length of treatment</li> <li>• <b>Hepatitis C:</b> Up to the duration as determined in Table 1 or 2</li> <li>• <b>All other indications:</b> 12 months or for the duration supported in FDA labeling or compendia whichever is shorter</li> </ul> <p><b>Table 1: Sovaldi + PEG + RBV Treatment Recommendations based on FDA labeling</b></p> <table border="1" data-bbox="235 1444 1227 1617"> <thead> <tr> <th>Genotype*</th> <th>FDA labeled regimen</th> <th>Duration of therapy</th> </tr> </thead> <tbody> <tr> <td>1a or 1b</td> <td>Sofosbuvir + PEG-IFN +RBV</td> <td>12 weeks</td> </tr> <tr> <td>4</td> <td>Sofosbuvir + PEG-IFN + RBV</td> <td>12 weeks</td> </tr> </tbody> </table> <p>*Includes patients with HCV/HIV co-infection</p> <p><b>Table 2: Pegasys + RBV Treatment Recommendations based on FDA labeling</b></p> <table border="1" data-bbox="235 1789 1227 1967"> <thead> <tr> <th>Genotype</th> <th>FDA labeled regimen</th> <th>Duration of therapy</th> </tr> </thead> <tbody> <tr> <td>1 or 4</td> <td>Pegasys + RBV</td> <td>48 weeks</td> </tr> <tr> <td>2 or 3</td> <td>Pegasys + RBV</td> <td>24 weeks</td> </tr> <tr> <td>5 or 6</td> <td>There is insufficient data for dosage and duration</td> <td></td> </tr> </tbody> </table>	Genotype*	FDA labeled regimen	Duration of therapy	1a or 1b	Sofosbuvir + PEG-IFN +RBV	12 weeks	4	Sofosbuvir + PEG-IFN + RBV	12 weeks	Genotype	FDA labeled regimen	Duration of therapy	1 or 4	Pegasys + RBV	48 weeks	2 or 3	Pegasys + RBV	24 weeks	5 or 6	There is insufficient data for dosage and duration	
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	<p><b>The requested agent will also be approved when ONE of the following is met:</b></p> <ol style="list-style-type: none"> <li>1. The request is for a BCBS MT Fully Insured or MT HIM member <b>AND</b> <ol style="list-style-type: none"> <li>A. The patient is under the age of 18 years old <b>AND</b></li> <li>B. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li>C. The patient has an indication that is supported in TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <b>AND</b></li> <li>D. There is support for an age in the patient’s given age bracket in TWO articles from major peer-reviewed professional medical journals as generally safe and effective. The age brackets are: 1. infancy (birth up to, but not including, 2 years of age), 2. childhood (2 years of age through 11 years of age), 3. adolescence (12 years of age through 17 years of age). Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <b>OR</b></li> </ol> </li> <li>2. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ol style="list-style-type: none"> <li>A. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li>B. The requested indication is a rare disease <b>AND</b></li> <li>C. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>2. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></li> </ol> </li> </ol> </li> <li>3. ALL of the following: <ol style="list-style-type: none"> <li>A. The member resides in Ohio <b>AND</b></li> <li>B. The plan is Fully Insured or HIM Shop (SG) <b>AND</b></li> <li>C. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li>D. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>2. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></li> <li>3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required]</li> </ol> </li> </ol> </li> </ol> <p><b>Non-oncology compendia allowed:</b> DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p><b>Oncology compendia allowed:</b> NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p>

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	<p>ALL other plans: 12 months</p> <p><b>Renewal Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] <b>AND</b></li> <li>ONE of the following: <ol style="list-style-type: none"> <li>The patient has a diagnosis of chronic hepatitis B AND the patient has NOT been administered peg-interferon for 48 weeks or longer for treatment of chronic hepatitis B <b>OR</b></li> <li>The patient has a diagnosis of chronic hepatitis C genotype 1, 2, 3, or 4 AND the patient did not complete the duration of therapy for the treatment regimen recommended for the patient's genotype as noted in Table 1 or 2 <b>OR</b></li> <li>The patient has a diagnosis other than chronic hepatitis B or C AND has had clinical benefit with the requested agent <b>AND</b></li> </ol> </li> <li>The requested quantity (dose) is within FDA labeled dosing or supported in compendia for the requested indication <b>AND</b></li> <li>The patient does NOT have any FDA labeled contraindications to the requested agent</li> </ol> <p><b>Compendia Allowed:</b> NCCN 1, 2a, or 2b recommended use, AHFS, or DrugDex 1, 2a, or 2b level of evidence</p> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p> <p>BCBSIL and BCBSMT: 12 months</p> <p>ALL other plans:</p> <ul style="list-style-type: none"> <li><b>Hepatitis B:</b> Up to duration to complete 48 weeks total length of treatment</li> <li><b>Hepatitis C:</b> Up to the duration to complete the regimen as determined in Table 1 or 2</li> <li><b>All other indications:</b> 12 months or for duration supported in FDA label or compendia whichever is shorter</li> </ul> <p><b>Table 1: Sovaldi + PEG-IFN + RBV Treatment Recommendations based on FDA labeling</b></p> <table border="1" data-bbox="235 1501 1230 1675"> <thead> <tr> <th>Genotype*</th> <th>FDA labeled regimen</th> <th>Duration of therapy</th> </tr> </thead> <tbody> <tr> <td>1a or 1b</td> <td>Sofosbuvir + PEG-IFN + RBV</td> <td>12 weeks</td> </tr> <tr> <td>4</td> <td>Sofosbuvir + PEG-IFN + RBV</td> <td>12 weeks</td> </tr> </tbody> </table> <p>*Includes patients with HCV/HIV co-infection</p> <p><b>Table 2: Pegasys + RBV Treatment Recommendations based on FDA labeling</b></p> <table border="1" data-bbox="235 1848 1230 1959"> <thead> <tr> <th>Genotype</th> <th>FDA labeled regimen</th> <th>Duration of therapy</th> </tr> </thead> <tbody> <tr> <td>1 or 4</td> <td>Pegasys + RBV</td> <td>48 weeks</td> </tr> <tr> <td>2 or 3</td> <td>Pegasys + RBV</td> <td>24 weeks</td> </tr> </tbody> </table>	Genotype*	FDA labeled regimen	Duration of therapy	1a or 1b	Sofosbuvir + PEG-IFN + RBV	12 weeks	4	Sofosbuvir + PEG-IFN + RBV	12 weeks	Genotype	FDA labeled regimen	Duration of therapy	1 or 4	Pegasys + RBV	48 weeks	2 or 3	Pegasys + RBV	24 weeks
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