PA Criteria for Interferon (for the treatment of Hepatitis C)

1. Is the member being treated for a funded condition by the Oregon Health Plan?
   a. If Yes, move to question #2.
   b. If No, Category 1 denial.

2. Is member over the age of 18 years old?
   a. If Yes, move to question #3.
   b. If No, forward to Medical Director for medical appropriateness (Category 5) evaluation.

3. Is the member currently supervised by a gastroenterologist, infectious disease specialist, or hepatologist licensed by the Oregon Medical Board?
   a. If Yes, move to question #4.
   b. If No, forward to Medical Director for medical appropriateness (Category 5) evaluation.

4. Does member have known hypersensitivity reactions (urticaria, angioedema, bronchoconstriction and anaphylaxis) to any component of product?
   a. If No, move to question #5.
   b. If Yes, forward to Medical Director for medical appropriateness (Category 5) evaluation.

5. Does member have Child-Pugh score ≥7 (grade B or C) or decompensate liver disease?
   a. If No, move to question #6.
   b. If Yes, forward to Medical Director for medical appropriateness (Category 5) evaluation.

6. Does member have diagnosis of autoimmune disorder (autoimmune hepatitis, lupus, rheumatoid arthritis)?
   a. If No, move to question #7.
   b. If Yes, forward to Medical Director for medical appropriateness (Category 5) evaluation.
   Rational: Development or exacerbation of autoimmune disorders have been reported in patients on interferon therapy.

7. Has the member been abstinent from drug or alcohol abuse for ≥ 12 months confirmed by a minimum of 6 negative random drug and alcohol screenings performed throughout the previous 12 month period?
   a. If Yes, move to question #8.
   b. If No, forward to Medical Director for medical appropriateness (Category 5) evaluation.

8. Has member undergone a mental health status evaluation performed by either a clinical psychologist or clinical psychiatrist? If member has no prior documented history of mental health intervention, evaluation may take place within 60 days of treatment initiation. If member has documented mental health interventions, a written statement from clinical psychologist or psychiatrist must be included in documentation indicating readiness for treatment.
   a. If Yes, Move to question #9.
   b. If No, forward to Medical Director for medical appropriateness (Category 5) evaluation.

9. Does member have severe or uncontrolled psychiatric disorder?
   a. If No, move to question #10.
   b. If Yes, forward to Medical Director for medical appropriateness (Category 5) evaluation.
   Rational: Life-threatening or fatal neuropsychiatric reactions may manifest in all patients receiving Interferon therapy. Use with extreme caution in all patients who report a history of depression.

10. Is the member currently on any medications that are not recommended for concomitant use (clozapine, telbivudine)?
    a. If No, move to question #11.
    b. If Yes, forward to Medical Director for medical appropriateness (Category 5) evaluation.
11. Does the member have a diagnosis of chronic hepatitis C infection confirmed by detection of anti-HCV antibodies and qualitative HCR RNA analysis?
   a. If Yes, move to question #12.
   b. If No, move to question #13.

12. Is the patient being prescribed the appropriate concomitant therapy based on genotype as seen in the treatment table?
   a. If Yes, move to question #13.
   b. If No, forward to Medical Director for medical appropriateness (Category 5) evaluation.

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Therapy</th>
<th>Duration</th>
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</table>
| Genotype 1 | Interferon + Ribavirin | Initial approval for 24 weeks
Additional therapy authorized based on member response to therapy:
- 48 weeks total if HCV negative at wk 4 or 12
- Additional authorization will not be granted for detectable HCV levels beyond week 24 |
| Genotype 2 | Sovaldi + Ribavirin  | 12 weeks                                                                 |
| Genotype 3 | Interferon + Ribavirin | Treatment recommended for 24 weeks                                       |
| Genotype 4 | Interferon + Ribavirin | Initial approval for 24 weeks
Additional therapy authorized based on member response to therapy:
- 48 weeks total if HCV negative at wk 4 or 12
- Additional authorization will not be granted for detectable HCV levels beyond week 24 |

*Additional authorization will require documentation of viral load testing at week 4, 12, and 24.

13. Has the member met approval criteria for concomitant therapy (Sovaldi, Ribavirin)?
   a. If Yes, Approve for approved duration noted in dosage table.
   b. If No, forward to Medical Director for medical appropriateness (Category 5) evaluation.

<table>
<thead>
<tr>
<th>Guide to Denial Categories</th>
<th>Reason for Denial</th>
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</thead>
<tbody>
<tr>
<td>Category 1</td>
<td>The condition is not on a funded line</td>
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<tr>
<td>Category 3</td>
<td>The use of the medication is considered experimental/ investigational (usually applies to off-label use of a medication)</td>
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<tr>
<td>Category 5</td>
<td>Not medically appropriate</td>
</tr>
<tr>
<td>Category 15</td>
<td>Formulary medications have not been exhausted</td>
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</tbody>
</table>