

## PA Criteria for Ribavirin (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. 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 #3.
  - b. If No, Category 3 denial.
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. Is the member pregnant or plan to become pregnant now, during treatment or six months following treatment? **OR** Does the member have a pregnant partner, or a partner who plans to become pregnant now, during treatment, or six months following treatment?

*\*\*If member is female of childbearing age verify documentation of at least 2 forms of effective contraception. Negative pregnancy test is required prior to treatment and should occur monthly during course of treatment.*

  - a. If No, move to question #5.
  - b. If yes, Forward to Medical Director for medical appropriateness (Category 5) evaluation.  
*Rational: ribavirin is Pregnancy Category X and has been shown to cause birth defects and/or death of the exposed fetus.*
5. Does member have Child-Pugh score  $\geq 7$  (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 severe renal impairment (CrCL < 50mL/min)
  - a. If No, move to question #7.
  - b. If Yes, Forward to Medical Director for Medical appropriateness (Category 5) evaluation.
7. Does member have documented hemoglobinopathy (thalassemia, sickle cell anemia)
  - a. If No, move to question #8.
  - b. If Yes, Forward to Medical Director for Medical appropriateness (Category 5) evaluation.
8. Does member have unstable cardiovascular disease?
  - a. If No, move to question #9.
  - b. If Yes, Forward to Medical Director for Medical appropriateness (Category 5) evaluation.  
*Rational: Fatal and nonfatal myocardial infarctions have been reported in patients with anemia caused by ribivirin. Because cardiac disease may be worsened by drug induced anemia, members with a history of significant or unstable cardiac disease should not use ribavirin.*
9. Does member have diagnosis of autoimmune hepatitis?
  - a. If No, move to question #10.
  - b. If Yes, Forward to Medical Director for Medical appropriateness (Category 5) evaluation.

10. Is the member currently on any medications that are not recommended for concomitant use (didanosine)?
- If No, move to question #11.
  - If Yes, Forward to Medical Director for Medical appropriateness (Category 5) evaluation.
11. Is the patient being prescribed the appropriate concomitant therapy based on genotype as seen treatment table?
- If Yes, move to question #12.
  - If No, Forward to Medical Director for Medical appropriateness (Category 5) evaluation.
12. Has member met approval criteria for concomitant therapy (Sovaldi, Interferon)?
- If Yes, Approve.
  - If No, Forward to Medical Director for Medical Appropriateness (Category 5) evaluation

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