Anthem UM Services, Inc. c/o 8640 Evans Road, Mail Stop B401-03 St. Louis, MO 63134

**Anthem UM** Services, Inc.

October 29, 2014

2014192419 - 11228 CID PCM-UMCPA SHIMA ANDRE 8787 SHOREHAM DR WEST HOLLYWOOD, CA 90069



Date Created: 10/28/2014 Reference Number: 26279025 Member Name: SHIMA ANDRE Medication: Harvoni Tablet Provider: Dr. CLEMENT YANG

Denial Reason: MEDICAL NECESSITY

## Dear SHIMA ANDRE:

Anthem UM Services, Inc. provides utilization management services for Anthem Blue Cross and Anthem Blue Cross Life and Health Insurance. We want you to understand how your health plan works so you can get the most from your health plan benefits. Certain medications within your health plan require review to see if they are covered under your description of benefits. Coverage for the requested medication is denied because the medication does not meet the criteria of "medical necessity" under your description of benefits. Medications that are considered not medically necessary are not covered according to your description of benefits. To assist our medical director in making this decision, we have put a process in place to send all information about the service to a clinical reviewer with appropriate credentials.

Based on their opinion, we have determined that coverage for the requested medication is denied.

Our clinical reviewer concluded the following: because of details we received about your liver illness (hepatitis C). We may approve HARVONI when the liver has a certain amount of scarring (advanced fibrosis of stage F3 or greater) on a liver biopsy. Records we received do not show that your liver has this amount of scarring on a liver biopsy. We did not receive a copy of the liver biopsy results. We based this decision on your health plan's prior authorization criteria for HARVONII. Harry Weisman, MD. Your provider may call our medical reviewer at 800-794-0838 to discuss this determination

This review was completed by: Harry Weisman MD

In making medical necessity determinations that are consistent with our contract language, medical reviewers follow established criteria and guidelines when available and applicable to

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the member's situation, including the health plan's medical policies, clinical guidelines, and/or other available information such as peer reviewed or evidence based literature. Medical policies are available on our website at www.anthem.com/pharmacyinformation. To request the applicable criteria used in this case, or to request an explanation of the clinical judgment for this determination, or diagnosis and description when available, or any other documents related to this determination, please call Customer Service at 866 297-1013 and it will be provided free of charge. Refer to the subscriber's description of benefits under the section marked exclusions for information on medication.

**Member:** Your provider will receive a copy of this letter. If you have questions about this determination you may call customer service at the number on your health plan identification card. Please see the attached for your additional member rights.

**Provider:** If you have not already done so and would like to discuss this determination with our clinical reviewer, please contact us at 800-794-0838 before all applicable appeals have been completed. At the time of your call, please provide the following:

- Member Name
- Reference Number (from top of this letter)
- Requested Medication
- Member Policy ID Number
- Date of Service

This decision doesn't mean that you can't or shouldn't receive this medication. Only you and your health care providers can decide whether you need it. But, this decision means that if you do receive the medication, it won't be covered by your plan.

If you or your provider disagrees with this decision, please see the attached information for additional rights.

Sincerely,

Michael M. Su, MD, MBA Medical Director Utilization Management

cc: Dr. CLEMENT YANG



Clement C Yang, MD 200 N Robertson Blvd Ste 303 Beverly Hills CA 90211-6001 Phone: 310-385-3466

Fax: 310-385-3217

January 13, 2015

RE: Shima Andre DOB 03/22/73

To Whom It May Concern:

Ms.ShimaAndre was denied Hepatitis C treatment with Harvoni therapy. The denial was appealed and the appeal was also denied. I have never received the appeal denial letter after asking for it multiple times. I was also not given the information to appeal this case to the independent review board after numerous requests and was denied a peer-to-peer review opportunity.

Per current AASLD Recommendations for Testing, Managing, and Treating Hepatitis C<sup>1</sup>, successful hepatitis C treatment results in sustained virologic response, which is the virologic cure of this disease, and as such, is expected to benefit nearly all chronically infected persons. Evidence clearly supports treatment in ALL HCV-infected persons, except those with limited life expectancy (< 12 months).

Ms. Andre was denied HCV treatment with Harvoni because she does not have stage F3 or F4 fibrosis. AASLD does **NOT** recommend that <u>only</u> these patients be treated, but suggests that urgent prioritization for treatment should be given to these patients based on available resources. Since there is no shortage or limited availability of Harvoni therapy requested for this patient, this denial is not warranted.

AASLD guidelines also advise to prioritize treatment for patients at elevated risk of HCV transmission and that HCV treatment would yield transmission reduction benefits. These patients include HCV-infected women of child-bearing potential wishing to get pregnant. Ms. Andre is a young female, planning to have children as soon as possible.

The cure rates with Harvoni exceed 90% while the older therapies had 30% or less cure rates, and the treatment is highly successful for Genotype 1, which is the type Ms Andre carries. It is my opinion that Ms. Andre should be approved for this therapy and there is no valid reason for denying her HCV treatment with Harvoni at this time.

Sincerely,

Clement Yang, MD