

Liver Clinic

February 8, 2016

Attn: blank

RE:

Member Appeals

To Whom it May Concern:

I am appealing the denial of coverage of Harvoni 90-400 for my patient _____. According to your denial letter, January 28th, the patient did not meet the criteria for coverage.

_____ has chronic Hepatitis C. She is a Genotype 1, with a Viral Load of 2,046,549. She has a Fibrosis score of F0, a Fibrotest of 0.21. Even though _____ does not have F3 or F4 liver disease, *she is more likely achieve SVR12 than persons with F3-F4 liver disease.* She understands what is required of her in order to be successfully treated and is eager to get started.

The current treatment guidelines for AASLD (The American Association for the Study of Liver Disease) and IDSA (Infectious Disease Society of America) (<http://www.hcvguidelines.org/fullreport>) state the "Successful hepatitis C treatment results in sustained virologic response (SVR), which is tantamount to virologic cure, 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 (less than 12 months) due to non-liver-related comorbid conditions." Per Gilead Sciences Inc studies, treatment with Harvoni in patients with Genotype 1, are treatment naïve, with or without cirrhosis and a pre-treatment HCV RNA of >6 million IU/ml, on treatment for 12 weeks, have a 99% SVR rate.

The idea that because the drugs are so expensive, that care should be held for only the sickest patients, is completely erroneous. Hepatitis C treatment is neither unnecessary nor wasteful. It is safe, highly effective, curative treatment for a life-threatening infection. Treatment improves quality of life and reduces mortality at **all stages** of the disease. Notice has been sent to state Medicaid directors informing them that the federal law requires them to cover effective, clinically appropriate, and medically necessary treatments. November 16, 2015, AASLD issued a statement calling again for the removal of all restrictions on access to the drugs.

A study done out of the University of California on cost effectiveness of treating Hep. C early verses treating only more advanced fibrosis patients, was published in the Online First section of JAMA Internal Medicine Nov. 23, 2015. The study shows that "Treating Hepatitis C sooner rather than later—even at the early stages of liver fibrosis—is worth the thousands of dollars it costs to pay for the new, more effective drugs." The results showed that it would cost about \$53 billion over a 5 year period to treat

50% of people infected in the U.S., while waiting to treat 50% of patients who are at stage 3 or 4 fibrosis only dropped the estimated cost to \$30 billion.

It is also estimated that approximately \$3 billion in lifetime health care could be saved by treating patients at all stages, instead of just patients at stage 3 or 4. "Earlier treatment would avoid extra costs down the line to treat sicker patients who have greater liver damage from long-term infection".

When we, as medical providers, entered into our profession we took an oath that we would use our skills to the best of our ability to assure optimal drug therapy outcomes for the patients that we serve. This is the 1st time in 20 years that we have been able to offer our patients an effective cure for HCV, achievement of SVR, and having the chance to eradicate a disease that is currently the #1 reason for liver transplant in the U.S. Treatment naïve patients without advanced disease progression have the best chance of achieving these goals. I have complied with all the required documentation and justification for prescribing effective therapy for _____. I am requesting an expedited review to overturn this denial and allow treatment for _____ to start without further delay.

In addition; clearance of _____ virus will prevent her from spreading the virus to others. This is a public health issue with legal implications. A denial for a well-documented treatment to clear the Hepatitis C virus with a 94-98 % cure rate presumes that the insurance company is willing to assume this public health risk. Denial personally obscures _____ from ultimately curing a potentially lethal virus that is and will lead to progressive debility and increased cost to her insurance company of the known progression of this curable disease. Please reconsider your denial of treatment for the medical-legal issues that this raises.

Please contact me at 509-248-3263 Ext. 6313 if you have additional questions. Thank you in advance for your time and consideration.

Sincerely,

Tanda M Ferguson, RN MN CCRN FNP-C
Memorial Cornerstone Liver Clinic