

## **POSITION PAPER #02-0209 (February 2009)**

### **Title: *Consistency and Uniformity by Medicaid in the Approval of Use of Food and Drug Administration (FDA)-Approved Medications***

**Prepared by:** The Florida Viral Hepatitis Council (VHC). The VHC is a partnership between the state of Florida, Department of Health (DOH) and non-governmental community members that provides guidance to the DOH Hepatitis Prevention Program and is responsible for writing a comprehensive hepatitis prevention plan. The group is made up of twenty members from medical, public health, academic, research, clinical and other related areas. The VHC meets twice a year and includes consumers (individuals who have been diagnosed and treated for viral hepatitis) in its membership.

**Goal:** Increase the consistency by which Medicaid approves the use of hepatitis medications for eligible patients by licensed medical care givers.

**Statement of the Problem:** Hepatitis C is the leading cause of liver transplants in the United States. Based on Centers for Disease Control and Prevention (CDC) estimates, nearly 300,000 Floridians are infected with hepatitis C. Additionally, there may be upwards of 120,000 Floridians infected with hepatitis B.

Nearly 50% of individuals with hepatitis C do not respond to the first-line treatment options. There are FDA approved pharmacological agents currently available for individuals who do not respond to the standard treatment. Although these non-responder agents are well-recognized by the scientific community and are validated in peer-reviewed literature, there is often resistance by Medicaid and other third-party payers to approve their use.

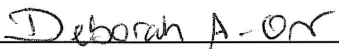
Every twelve minutes, a new name is added to a list of patients in need of a liver transplant in the United States. Currently, over 17,000 Americans are on a waiting list for a liver transplant. There were 5,941 liver transplants performed in the US in 2007. In Florida, 557 liver transplants were performed in 2007.

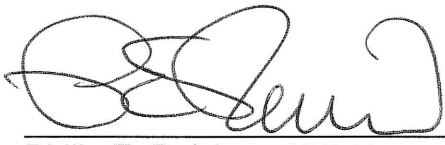
Without available aggressive treatment, individuals infected with hepatitis C are likely to progress through the stages of liver disease. Approximately 20% to 30% will develop cirrhosis (scarring of the liver), increased risk of liver cancer, and death. The average cost of a liver transplant is \$300,000-\$400,000 per patient, plus about \$150,000 per year for follow-up care and medication. Not including the follow-up costs, the cost of liver transplants alone is about \$336 million each year in Florida.

With consistent treatment provided to those same 557 individuals, many transplants could have been avoided. The cost of the recommended treatment

for hepatitis C is about \$30,000 per patient plus an additional estimated cost of \$3,000 per patient for evaluative tests. Treatment and testing for the same 557 individuals would cost about \$15.6 million. Even if some of those individuals were to still progress to liver failure and require a transplant, the savings difference could still be over \$300 million.

**Recommendation:** The Florida Viral Hepatitis Council recommends that the Medicaid Program and all third party payers rapidly and consistently approve FDA approved medications for treatment of hepatitis C. This would prevent the burden of the cost of liver transplants. By consistently allowing the use of approved, accepted, and available medical therapies, we could limit the number of hepatitis C patients who progress to latter stage liver disease and save significant health care dollars. Over 5,000 of the estimated 300,000 individuals currently infected with hepatitis C in Florida could be prevented from requiring a liver transplant. This would be a \$3 billion savings over the next ten years.

  
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