

June 9, 2016

Janet Zastrow United Healthcare Corporate Office 9900 Bren Rd E MN008-T-615 Minnetonka, MN 55343

Dear Ms. Zastrow,

The American Academy of Family Physicians (AAFP) is writing to request that United Healthcare review and, if necessary, consider revising its policies to ensure that United Healthcare's members with Hepatitis C virus (HCV) have access to all physicians with the expertise to treat them. We believe that treatment for chronic HCV should be based on the prescribing physician's expertise rather than a requirement of medical specialist consultation.

According to a November 2013 Centers for Disease Control and Prevention's (CDC) Surveillance report, an estimated 3.2 million people in the United States are living with HCV infection. Historically, Hepatitis C treatments were administered by self-injection of interferon. These injections had terrible side effects and only a 50 percent cure rate. The cost ranged from \$15,000 to \$20,000, depending on the length of treatment. Now, the latest treatments have a 90 percent cure rate and few side effects. Harvoni (ledipasvir and sofosbuvir), one of the most recently approved treatments, is a once-a-day oral pill. However, the cost is \$1,125 per pill. That means a two-month supply is approximately \$63,000, a three-month supply is \$94,500 and a six-month supply is \$189,000, as reported in a Hepatitis Central article.

When Hepatitis C treatments were very complicated and toxic, there were no restrictions on who could prescribe those drugs. Prescriber restrictions are only now being added as newer and more effective medications have come to market, with fewer side effects and are easily administered in oral form. For example, according to a study in the Annals of Internal Medicine, which examined Medicaid reimbursement criteria for Sovaldi (sofosbuvir) in all 50 states and the District of Columbia, "twenty-nine states have restrictions based on prescriber type. In 14 states, the prescriber has to be a specialist (gastroenterology, hepatology, infectious diseases, or liver transplantation), whereas in 15 states treatment decisions can be made by a non-specialist after consultation with a specialist." The decision to restrict the ability to prescribe treatment for HCV is particularly problematic in light of potential shortages in the designated specialties. According to an article in Becker's GI & Endoscopy, it is estimated that by the year 2020, there will be a shortfall of somewhere between 1,000 to 1,500 practicing gastroenterologists in the United States. The shortage of medical subspecialists in general is estimated to be between 3,200 and 8,400 by 2020 according to an Association of American Medical Colleges (AAMC) report.

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Prescriber restrictions particularly disadvantage patients living in rural areas. According to the 2010 U.S. <a href="census">census</a>, about 20 percent of the population lives in rural areas, while nine percent of physicians practice there. The distribution of physicians in rural and urban settings is also unequal with more physicians choosing to work in urban settings for a variety of reasons. The more highly specialized the physician, the less likely he or she will settle in a rural area, as stated in an <a href="article">article</a> regarding physicians and rural America. However, acute Hepatitis C infections rose by 150 percent between 2010 and 2013, with the largest increase in rural areas, <a href="according to the CDC">according to the CDC</a>. Consequently, restriction on HCV treatment that mandate prescription by or consultation with a specialist rather than by a qualified primary care physician disadvantage patients in rural areas, since they often have less access to such specialists.

Finally, the restrictions on HCV treatment in question ignore the fact that primary care physicians, with the appropriate education and experience, have been treating patients with HCV for years. Only recently, when costly new drugs became available, did new restrictions occur.

The AAFP oppose actions by public and private payers that limit patients' access to HCV treatment pharmaceuticals prescribed by a physician using appropriate clinical training and knowledge and oppose any actions that may have the effect of limiting by specialty the use of HCV pharmaceutical products. Thus, we ask United Healthcare to ensure that none of their insurance policies discriminate against physicians treating their patients with HCV.

We appreciate your time and attention to this matter. If you or your staff have any questions about this or if we can provide any other assistance, please contact Brennan Cantrell, Commercial Insurance Strategist, at 913-906-6000 ext. 4134 or bcantrell@aafp.com.

Sincerely,

Robert Wergin, MD, Board Chair