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## **LAWSUITS CHALLENGE EXCLUSIONS OF COVERAGE FOR CURE TO HEPATITIS C VIRUS**

SEATTLE, Wash. – February 2, 2016 – Group Health Cooperative and BridgeSpan, an affiliate of Regence BlueShield, have been sued for rationing coverage of prescription drugs to cure Hepatitis C virus (“HCV”). In two class action lawsuits recently filed in King County Superior Court, Plaintiffs David Morton and R.K. allege that the insurance companies restrict coverage of direct-acting antiviral (DAA) medications like ledipasvir-sofosbuvir (the name brand is known as Harvoni®) to only those insureds with severe liver damage, even though the medications result in cure rates approaching 100% for all individuals infected with HCV. The cases are *Morton v. Group Health Cooperative*, No. 16-2-02011-9 SEA (Judge Mary E. Roberts), and *R.K. v. BridgeSpan*, No. 16-2-10672-3 SEA (Judge Sean O’Donnell).

HCV causes chronic inflammation throughout the body of those infected and can lead to serious liver damage, infections, liver cancer and death. At least 20,000 people in the United States die each year due to liver disease caused by HCV. Even before the advanced state of the disease, individuals with HCV can suffer from diabetes, lymphoma, fatigue, joint pain, depression, myalgias, arthritis and jaundice. Until the development of DAAs, the standard of care for treatment of HCV was a three-drug treatment containing a protease inhibitor, interferon and ribavirin at a cost of approximately \$170,000 per cure. The treatment provided, at most, a 70% cure rate and was accompanied by significant adverse side effects such as anemia, insomnia, anxiety, depression, nausea, bone pain, muscle, liver failure, joint pain, memory loss and death. See <http://www.cdc.gov/hepatitis/Statistics/index.htm> (last visited 1/25/16).

Starting in 2011, the United States Food and Drug Administration (FDA) began approving DAAs to treat HCV. On October 10, 2014, the FDA approved ledipasvir-sofosbuvir. Treatment guidelines approved by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America confirm that DAAs should be available for “all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy.” See <http://hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy> (last visited 1/25/16). This clinical guidance is consistent with the standard of care in Washington and across the country. The only obstructions to treatment for patients like Mr. Morton and R.K. are insurance company exclusions and limitations.

Both Group Health Cooperative and BridgeSpan have adopted internal coverage policies that restrict coverage of ledipasvir-sofosbuvir to only insureds with advanced liver disease or cirrhosis of the liver and/or certain qualifying co-morbid conditions, such as HIV. Thus, insureds like Mr. Morton and R.K. with little or no liver scarring must wait until their health condition worsens before they are eligible for coverage for the cure. This is contrary to the AASLD guidelines: “[C]linicians should treat HCV-infected patients with antiviral therapy with the goal of achieving an SVR [sustained virologic response or cure], *preferably early in the course of their chronic HCV infection before the development of severe liver disease and other complications.*” See <http://hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy> (last visited 1/25/16) (emphasis added).

Although other health plans and payors in Washington state have adopted similar exclusionary coverage criteria, including Kaiser Permanente, the Uniform Medical Plan (providing coverage for Washington state public employees), and Washington State Medicaid, such limitations on coverage are not supported by clinical evidence and are increasingly out-of-step with coverage provided by national insurers. For example, Premera Blue Cross, Aetna, Cigna, United Healthcare and Blue Shield of California, have removed such restrictions on coverage of DAAs.

“The clinical evidence is crystal clear,” said Michael Ninburg, Executive Director of the Hepatitis Education Project in Seattle, Washington. “DAAs like ledipasvir-sofosbuvir are medically necessary to treat all patients with HCV. Patients should not have to live with a viral time-bomb, waiting until they get so sick they have serious liver disease before they can receive treatment.”

These lawsuits are the first in Washington State and among a handful filed across the country to address patient access to DAA medications to treat HCV. “Health insurance is supposed to cover medically necessary prescription medications when someone has an infectious disease like HCV,” said Eleanor Hamburger of Sirianni Youtz Spoonmore Hamburger. “These lawsuits simply enforce the coverage that the insurance companies agreed to provide.”

Despite insurers' obligation to provide coverage of medically necessary prescription drugs, BridgeSpan's coverage policy cites the high cost of DAAs and their impact on the health system generally to justify the insurer's restrictive coverage. "Right now, patients are caught in the middle of the debate between insurance companies and pharmaceutical companies over the cost of medically necessary DAAs," said Rick Spoonemore of Sirianni Youtz Spoonemore Hamburger. "Once insurance companies are required to cover these life-saving medications, they will have to negotiate with pharmaceutical companies for better deals or the government will have to intervene."

Restrictive coverage guidelines have been put in place by both private and public insurers across the country in reaction to the introduction of this new treatment. For its part, the Centers for Medicare and Medicaid Services issued guidance in November 2015 warning states that exclusions and limitations on public insurance coverage of DAAs may violate federal law. "With both private and public insurers, the issue comes down to the requirement that insurance is required to cover medically necessary care," said Kevin Costello, Litigation Director at the Center for Health Law and Policy Innovation at Harvard Law School. "When an insurer limits coverage only to its sickest members, it amounts to an irrational and short-sighted rationing of care. From the perspective of an individual living with HCV who is excluded from the cure, that care is the very definition of 'medically necessary.'"

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