Bloomberg BNA

BNA's Health Care Policy Report™

VOL. 23, NO. 21 MAY 25, 2015

Coverage

Blue Cross Accused of Bad-Faith Refusal To Pay for Expensive Hep C Drug Treatment

A California woman May 15 accused her insurer of engaging in unreasonable claims review procedures resulting in its refusal to pay for a treatment that would save her life and, potentially, the lives of over 3 million people in the U.S. (*Andre v. Blue Cross of Calif.*, Cal. Super. Ct., No. BC582063, *filed* 5/15/15).

Blue Cross of California, doing business as Anthem Blue Cross, repeatedly ignored physician recommendations and used undisclosed criteria to deny coverage of a new treatment for hepatitis C that has a cure rate of 95 percent to 99 percent, plaintiff Shima Andre alleged in a complaint filed in the California Superior Court, Los Angeles County.

The prescription drug Harvoni received U.S. Food and Drug Administration approval in October 2014, and is alleged to cure most patients within eight to 12 weeks of beginning the treatment. The cost of Harvoni, however, is prohibitively expensive for most individuals. A 12-week regimen costs about $99,000, Andre's complaint said.

Andre's doctor recommended Harvoni for her in October 2014, but Blue Cross denied coverage, saying it wasn't medically necessary because her condition hadn't deteriorated sufficiently in the three years since her diagnosis. Blue Cross upheld the denial through two subsequent appeals.

Medical Necessity. According to the insurer's response to the coverage request, Blue Cross didn't consider Harvoni treatment medically necessary until a patient reached a stage where the ''liver has a certain amount of scarring (advanced fibrosis of stage F3 or greater) on a liver biopsy.'' Hep C is a contagious liver disease, spread through contact with an infected person's blood, that causes severe liver damage, infections, liver cancer, cirrhosis and death.

Ricardo Echeverria, a partner at Shernoff Bidart Echeverria Bentley LLP, Claremont, Calif., who is representing Andre, asked how could a treatment option that is recommended by doctors, constitutes the standard of care in the field and cures the disease not be considered ''medically necessary.''

Echeverria told Bloomberg BNA May 19 that the drug is expensive, but there should be a ''dialogue between the insurer'' and the drugmaker over the cost. ''Don't hold the patients hostage'' to the cost, he said. ''There is nothing preventing'' the insurance and drug industries ''from negotiating a price that works'' for both, he added. He also noted that the FDA didn't limit its approval to patients in later stages of the disease.

Andre alleged that Blue Cross's refusal to pay for her treatment constituted a breach of the implied covenant of good faith and fair dealing and breach of contract. Outside of requiring ''medical necessity,'' nothing in Andre's policy gave Blue Cross the right to deny coverage based on the expense of the treatment, Echeverria said.

If an insurer wants to deny coverage because a patient isn't ''sick enough,'' it ''should say so,'' he added. An insurer could write a policy saying that it won't pay for a certain treatment or won't pay for a treatment until a certain threshold is reached. Here, Blue Cross hasn't changed its policy regarding its payment for hep C treatments and hasn't added any specific limitations regarding Harvoni, Echeverria said.

Emotional Toll on Patient. Andre also is seeking damages for intentional and negligent infliction of emotional distress. According to the complaint, she received her diagnosis in 2011, shortly after getting married. At the time, the prevailing treatment for hep C had a 70 percent cure rate, but had many adverse side effects, including anemia, anxiety, insomnia, depression and memory loss.

Additionally, the disease may be passed from a mother to her child, so Andre put her desire to have children on hold in anticipation that a better treatment soon would be on the market. When Andre, through her doctor, learned of the FDA's approval of Harvoni, she believed she would have access to a cure that came with few side effects. Once cured, she might have children without risk of passing hep C on to them, the complaint said.

Between her diagnosis and the approval of Harvoni, the amount of hep C present in Andre's blood increased steadily, and she began having sharp liver pains. Fibrosis or liver scarring, another manifestation of hep C, remained below stage F3, however. According to the complaint, the degree of scarring varies. A normal liver is designated as stage F0 or stage F1. Stage F3 describes individuals who have severe fibrosis. People with cirrhosis are designated as stage F4.

 ISSN 1068-1213

Growing Concern. Andre included in her complaint a count seeking injunctive relief for a class of similarly situated individuals. She alleged that it is estimated that over 3 million people in the U.S. are living with chronic hep C and that about 15,000 people in the U.S. die each year due to hep C-caused liver disease. In California alone, about 5,000 people per year are infected with the disease.

Andre alleged that Blue Cross engaged in a pattern and practice of denying coverage for Harvoni to patients who have stage F0, stage F1 and stage F2 scarring. Her claim specifically alleged Blue Cross violated Cal. Bus. & Prof. Code § 17200 by engaging in unlawful, unfair and fraudulent conduct.

Echeverria told Bloomberg BNA that his firm has filed a second lawsuit, *Blumenfeld v. Blue Cross of Calif.*, Cal. Super. Ct., *docket number unavailable*, *filed* 5/18/15, and that a number of other people have sought the firm's help since Andre's complaint was announced. The litigation could spread nationwide, he said.

A spokesman for Blue Cross of California declined to comment on the pending litigation.

Previously, a federal district court dismissed a third-party payer's lawsuit seeking to force drugmaker Gilead Sciences Inc. to lower the cost of Harvoni (*Se. Pa. Transp. Auth. v. Gilead Scis., Inc.*, 2015 BL 130626, E.D. Pa., No. 2:14-cv-6978, 5/4/15).

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The Andre complaint is at http://op.bna.com/hl.nsf/r?Open=mapi-9wnqxq.

The Blumenfeld complaint is at http://op.bna.com/hl.nsf/r?Open=mapi-9wphxm.

  HCPR ISSN 1068-1213