But recently, he came back to Dr. Muir wanting to try a new protease inhibitor. Based on his reading, the man believed he could avoid interferon (IFN) and ribavirin (RBV), take a protease inhibitor as monotherapy for 24 weeks and expect a 75% chance of achieving a sustained virologic response (SVR).

Unfortunately, the patient’s expectations were unrealistic on all counts. The new protease inhibitor can only be given in conjunction with IFN and RBV, and the treatment duration varies. For blacks, therapy usually lasts a full 48 weeks, and in clinical trials, only 30% of black patients achieved an SVR with 28 weeks of therapy. Moreover, among black patients in the Phase III trials, SVR rates fell short of the 75% that the patient expected, and in treatment-naïve blacks, only 62% receiving telaprevir and 53% on boceprevir achieved an SVR.

Unrealistic expectations are common among patients with HCV infection who, after years of waiting for better therapies, are eager to try treatment with the new DAs, said Dr. Muir. The DAs on the market today are complex, with varied stoppage rules, monitoring points and some serious adverse events and drug–drug interactions.

“There’s tremendous excitement about these new therapies, but oftentimes, patients’ expectations are not in line with what these drugs can deliver,” said Dr. Muir. Patients need to learn the reality about DAs if they want treatment to succeed.

“The major challenges are preparing patients for the rigors of therapy, checking in frequently to make decisions about the duration of treatment and managing any issues as the patient goes along,” said Dr. Muir. When patients come into the office considering treatment with DAs, the first step is to clarify their expectations, said Dr. Muir. Patients need to learn the reality about DAs if they want treatment to succeed.

Dr. Muir outlines for patients the complex prescribing rules, the contraindications, the lifestyle changes and duration of treatment with DAs. The lifestyle changes can be significant, he cautions patients. Both telaprevir and boceprevir must be taken three times a day, or once every eight hours, and always with a meal. Dr. Muir then asks if the patient still wants treatment when these things are taken into account.

“That’s no small feat. Patients must adhere to that regimen because lapses in the concentration of telaprevir and boceprevir have historically been the risk period for breakthrough variants on therapy,” said Raymond Chung, MD, chief of hepatology and vice-chief of gastroenterology at Massachusetts General Hospital, Boston. Many of Dr. Chung’s patients have 50 to 100 patients in varying stages of DAA treatment,” said Dr. Chung. “Every one of these patients is coming in for frequent visits—weekly in the beginning—and they are very much in need of monitoring, not just for adverse events like rash and anemia but also for fatigue and their ability to carry out work.”

Before patients start the new therapies, gastroenterologists and hepatologists should consider getting a liver biopsy to help guide treatment, said Dr. Muir. Physicians also should confirm a patient’s

**FDA Makes Way for Wider Access to OraQuick HCV Rapid Test**

**CLIA Waiver Expands Use of Rapid HCV Test to More U.S. Clinics**

The FDA recently granted a waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to OraSure Technologies for its OraQuick HCV Rapid Antibody Test for use with fingerstick whole blood and venous whole blood specimens. With this waiver, the OraQuick HCV test now can be used by more than 180,000 facilities, such as outreach clinics, community-based organizations and physician offices, according to a press release from OraSure.

“A CLIA waiver for our OraQuick HCV test represents a critical milestone in our quest to make the test available to the widest possible range of at-risk individuals in the United States,” said Douglas A. Michels, president and CEO of OraSure Technologies. “The CLIA waiver will enable health care providers, those on the front lines of fighting this devastating disease, to use this simple and accurate test in physician offices and outreach settings so more individuals infected with hepatitis C can be diagnosed and treated.”

The OraQuick HCV Rapid Antibody Test is the first and only FDA-approved rapid test for the detection of antibodies to HCV. The test is approved for fingerstick whole blood specimens and venipuncture whole blood specimens in individuals aged 15 years or older, and provides results in 20 minutes. The assay has not been approved for use in patient populations without signs or symptoms of HCV, and its use has not been established for testing patients younger than 15 years of age or for pregnant women.

—Based on a press release from OraSure Technologies