NEW YORK
state department of
HEALTH

Nirav R. Shah, M.D., M.P.H.
Commissioner

Sue Kelly
Executive Deputy Commissioner

July 26, 2012

Dear Prescriber,

The New York State Medicaid Drug Utilization Review (DUR) Program prospectively reviews the dispensing guidelines and recommendations for new medications to ensure proper use and to minimize adverse outcomes. In May of 2011, the FDA approved the first two hepatitis C virus (HCV) protease inhibitors, boceprevir (Victrelis®) and telaprevir (Incivek®) for treatment of chronic HCV genotype 1. At the October 20, 2011 Drug Utilization Review (DUR) Board Meeting, Board members reviewed the use of these agents for beneficiaries in the NY Medicaid program.

Recently updated guidelines published by the American Association for the Study of Liver Diseases (AASLD) recommend using either boceprevir or telaprevir in combination with peginterferon alpha and ribavirin to increase the rate of sustained virologic response in both treatment naïve and previously treated patients.[1] In order to be eligible for treatment, patients must be at least 18 years of age and have a diagnosis of chronic HCV genotype 1. In addition to evaluating patient specific factors to determine baseline status and readiness for treatment, close monitoring of HCV RNA is essential for making response-guided decisions to determine duration of treatment.

After considering clinical information and safety concerns regarding the use of boceprevir or telaprevir for patients with chronic HCV, the DUR Board recommends including one of these agents in combination with ribavirin and peginterferon alpha therapy as outlined in the attached summary documents and algorithms.[2,3] Therapeutic decisions for continuation of treatment utilizing follow-up monitoring should be based on the parameters in these algorithms. The algorithms are available in interactive format at the New York State Medicaid Prescriber Education Program website at http://nypep.nysdoh.suny.edu/.

Drug-drug interactions are a significant concern with both boceprevir and telaprevir and must be considered for patients receiving treatment for both HIV and chronic HCV in order to avoid treatment failure. A recent FDA drug safety communication and updated product labeling has recommended against the use of boceprevir with certain HIV protease inhibitors[2,4] as well as the non-nucleoside reverse transcriptase inhibitor, efavirenz.[2] Product labeling for telaprevir also provides data demonstrating significant pharmacokinetic interactions that must be considered with co-administration of anti-HIV medications.[3]

In presenting this information to you, the DUR program recognizes that safe and effective drug therapy depends on assessment of the patient's entire clinical profile. We ask that you consider the information provided regarding the prescribing of boceprevir and telaprevir for your patients.

For additional information on the DUR program and Frequency/Quantity/Duration parameters, please visit: http://nyhealth.gov/health_care/medicaid/program/dur/index.htm.

Thank you for your professional assistance in this matter.

Sincerely,

John F. Naioti, Jr., R.Ph.
DUR Program Manager

1. Ghany M, Nelson DR, Strader DB, Thomas DL, Seeff LB. An update on treatment of genotype 1 chronic hepatitis C virus infection: 2011 practice guidelines by the American Association for the Study of Liver Diseases. *Hepatology.* Sep 2, 2011.
2. Boceprevir (Victrelis®) product labeling. Schering Corporation, a subsidiary of Merck & Co., Inc. Whitehouse Station, NJ; April 2012.
3. Telaprevir (Incivek®) product labeling. Vertex Pharmaceuticals, Inc. Cambridge, MA; March 2012.
4. Food and Drug Administration. FDA Drug Safety Communication: Updated information on drug interactions between Victrelis (boceprevir) and certain boosted HIV protease inhibitor drugs. http://www.fda.gov/Drugs/DrugSafety/ucm301616.htm. Accessed June 6, 2012.