

RETRODUR INTERVENTION NOTICE: PEGYLATED INTERFERONS

July 13, 2011

Dear Prescriber,

The New York State Medicaid Drug Utilization Review (DUR) Program retrospectively reviews the prescribing and dispensing of outpatient prescription medications in order to ensure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical outcomes. At the December 9, 2010 Drug Utilization Review (DUR) Board Meeting, the Board members reviewed pegylated interferon utilization within the NY Medicaid program.

Guidelines for management of chronic hepatitis C, based on the most recent information published in 2009 by the American Association for the Study of Liver Diseases (AASLD)* and from the American Gastroenterology Association (AGA), were presented to the Board as well as the most current FDA approved labeling. While considering utilization data and clinical information, the Board expressed concerns including safety, the potential for adverse events and the risk of misuse. The Board recommended **duration limits for pegylated interferons** based on genotype.

The DUR Board took the following action(s) regarding pegylated interferons:

- Duration limits were recommended for pegylated interferons to ensure appropriate utilization. Prior authorization will be required for the initial 14 weeks of therapy to determine the appropriate duration of therapy based on genotype. Further documentation is required for the continuation of therapy at weeks 14 and 26.
- Further documentation required for the continuation of therapy at weeks 14 and 26 includes:
 - After 12 weeks of therapy, obtain a quantitative HCV RNA. Continuation is supported if the patient has an undetectable HCV RNA or at least a 2-log decrease compared to baseline.
 - After 24 weeks of therapy, obtain a HCV RNA. Continuation for genotype 1 and 4 is supported if the patient has an undetectable HCV RNA.

New York State Medicaid pharmacy claim data indicates that you have written prescription(s) for pegylated interferon therapy. Please consider this information when prescribing pegylated interferon therapy, as the DUR Program is concerned that there may be utilization of this medication that is not consistent with current treatment guidelines and FDA approved labeling regarding proper dosing, administration and duration of therapy.

Please consider clinical appropriateness and cost effectiveness when prescribing pegylated interferon therapy. In presenting this information to you, the Drug Utilization Review Program recognizes that safe and effective pharmacotherapy depends on the assessment of the patient's entire clinical profile. We ask that you consider the information provided regarding the prescribing of pegylated interferon therapy for your patients.

Thank you for your professional assistance in this matter.

Sincerely,

John F. Naioti, Jr., R.Ph.
Manager, Drug Utilization Review Program

*Ghany MG, Strader DB, Thomas DL, Seeff LB. Diagnosis, management, and treatment of hepatitis C: an update. *Hepatology*. Apr 2009;49(4):1335-1374.