

IN OTHER NEWS...

\$10 Patient Rebate Coupon for Kytril



Visit www.kytril.com to download a \$10 patient rebate coupon for Kytril. This offer has been extended until **December 31, 2005**. The coupon is not valid for prescriptions reimbursed or paid under Medicare, Medicaid or any similar federal or state healthcare program, including any state medical or pharmaceutical assistance programs.

RECENT CMS POLICY CHANGES

On Friday April 15, CMS issued several important clarifications and policy changes for codes pertaining to drug administration and the Demonstration Project of 2005. *These new policies are effective for dates of service from March 15, 2005 but the carriers are not obligated to implement them until **May 16, 2005**.*

These revisions include the following information:

Short Infusions: The CPT Editorial Panel has now revised the description for 2006, and CMS has adopted the revised interpretation for the remainder of 2005. **Infusions of 15 minutes or less are now to be reported using the code for pushes.** The language has also been revised so that, although short infusions are reported using the code for pushes, they are not to be considered pushes.

Concurrent Infusions: In the case of multiple drugs infused concurrently, it was unclear whether the new code for concurrent infusions (G0350) should be reported for each drug. CMS has now clarified that **payment for only one concurrent infusion per encounter will be allowed.**

CMS has also clarified the Demonstration Project of 2005: There is no requirement for the physician to sign off the demonstration assessment prepared by the nurse prior to billing for the demonstration codes, however, CMS has indicated that it is "preferable" for the physician to sign-off before the codes are billed.

The following websites are available for the complete policy revisions and clarifications:

- > www.cms.hhs.gov/manuals/transmittals/comm_date_dsc.asp (Scroll down to file #R1480TN)
- > www.cms.hhs.gov for CMS FAQs. (Click on "FAQs" then on the FAQs page select "Physicians" as the category and the "Drug Administration Services" as the subcategory.)

FDA APPROVES VELCADE FOR SECOND LINE TREATMENT OF MYELOMA

On March 25, 2005 the U.S. Food and Drug Administration (FDA) approved Millennium Pharmaceuticals, Inc.'s supplemental New Drug Application (sNDA) for VELCADE. This approval expands the label to include the treatment of patients with multiple myeloma (MM) who have received at least one prior therapy.



VELCADE is the only drug therapy that has demonstrated a significant survival advantage as compared to a standard therapy in relapsed MM. Initial accelerated approval for relapsed and refractory MM was granted in May 2003. VELCADE is now fully approved in relapsed MM.

The approval was based on data from the randomized phase III APEX study that compared single-agent VELCADE to a traditional MM therapy, high-dose dexamethasone. The study demonstrated a significant survival advantage with VELCADE ($p < 0.05^*$) in patients who had received one to three prior therapies. Importantly, this pronounced survival advantage was also observed in the second-line MM patients. The safety profile of VELCADE remained consistent with previous phase II findings. This indication doubles the number of U.S. patients who could potentially benefit from VELCADE to approximately 22,000.

The approval of this supplementary filing comes approximately 22 months after the initial FDA approval of VELCADE® (bortezomib) for Injection. VELCADE, the first of a new class of medicines called proteasome inhibitors, is the first treatment in more than a decade to be approved for patients with multiple myeloma, a cancer of the blood. For more information about VELCADE clinical trials, patients and physicians can contact the Millennium Medical Product Information Department at 1-866-VELCADE (1-866-835-2233).