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Newsletter

Volume 11 No. 34 **May 2001**

TO: Physicians, Certified Nurse Practitioners, Clinical Nurse Specialists, Independent Clinics, Federally Qualified Health Centers (FQHCs) **– For Action Only**
Providers of Pharmaceutical Services, Health Maintenance Organizations **– For Information Only**

SUBJECT: **Information on the use of Bisphosphonates and Acid-Related Drugs (ARDs)**

EFFECTIVE: Immediately

PURPOSE: To alert health care providers of the decision by the New Jersey Drug Utilization Review Board (NJDURB) to adopt criteria requiring the First Health Services Corporation to retrospectively notify prescribers of a possible clinical issue in patients concomitantly taking bisphosphonates and ARDs.

These criteria shall apply to Medicaid fee-for-service (FFS), NJ FamilyCare FFS, Pharmaceutical Assistance to the Aged and Disabled (PAAD), Cystic Fibrosis, and AIDS Drug Distribution Program (ADDP) pharmacy claims.

BACKGROUND: The NJDURB is responsible for retrospectively monitoring drug utilization based on drug utilization review (DUR) standards approved by the Commissioners of Human Services and Health and Senior Services. The NJDURB is composed of NJ licensed physicians and pharmacists appointed by the State Legislature and approved by the Governor.

The NJDURB uses educational outreach letters to assist prescribers in identifying potentially inappropriate drug utilization. Examples of such utilization include potential drug-drug interactions, drug-disease conflicts and the improper dosing of medications.

The NJDURB recently identified a patient population taking both bisphosphonates and ARDs. ARDs include proton pump inhibitors and H-2 antagonists. The NJDURB has determined that certain patients may be utilizing bisphosphonates improperly, leading to unnecessary gastrointestinal irritations and the avoidable use of ARDs.

It is important to note that the information contained in this Newsletter is not intended to interfere with the medical necessity decisions of health care providers; nor is this information intended, in any way, to discourage the appropriate use of bisphosphonates and/or ARDs. This information is only intended to alert prescribers to a possible clinical situation and the need for physicians to properly instruct patients in regard to the dosing and administration of bisphosphonates and to be alert to signs of adverse gastrointestinal events.

ACTION:

1. Prescribers will be notified by First Health Services through the use of an educational outreach letter (attached) of those patients concurrently utilizing a bisphosphonate and an ARD.

2. Pharmacies will receive a point-of-sale (POS) response from the State's claims processing system identifying those patients concurrently utilizing a bisphosphonate and an ARD. The POS response received by pharmacies will include Error Code 870.

3. Bisphosphonates include the drugs alendronate and risedronate.

4. ARDs include the drugs cimetidine, famotidine, lansoprazole, nizatidine, omeprazole, rabeprazole, pantoprazole, ranitidine and sucralfate. It is important to note that prescribers and pharmacists will be alerted to this potential clinical situation for ARDs that are available by prescription only. Pharmacists will need to monitor similar interactions, which may occur involving over-the-counter acid suppression medications.

5. An educational outreach letter will be sent by First Health Services only to prescribers of bisphosphonate. A sample educational outreach letter is attached for your review.

If you have any questions regarding this Newsletter, please contact the Chief, Pharmaceutical Services, Division of Medical Assistance and Health Services, at (609) 588-2724. First Health Services may be contacted 24-hours a day, seven (7) days a week at 1-877-888-2939.

Attachment

RETAIN THIS NEWSLETTER NUMERICALLY BEHIND THE NEWSLETTER TAB (BLUE TAB MARKED "5")

The NJDURB is recommending that you counsel your patient in the correct method of administering bisphosphonates. **Please read and answer this questionnaire and return the completed questionnaire to First Health Services**.

FIRST HEALTH SERVICES <Date>
P.O. BOX 3721
PRINCETON, NEW JERSEY 08543

<Prescriber name>
<Prescriber address>
<Fax number>

Re: <Patient Name>

Dear <prescriber name>

The New Jersey Drug Utilization Review Process was implemented to monitor prescriptions for patients who may be at high risk of adverse reactions. New Jersey <NJ Program Code> program uses therapy guidelines developed by a state board of physicians and pharmacists based on national and international treatment guidelines. The program reviews the medication profiles of all patients and compares the data with the developed guidelines. The Drug Utilization Review Process identifies patients who may be at higher risk of increased medical utilization based upon these guidelines.

As part of the State of New Jersey Drug Utilization Program, the medications prescribed to your patient <patient name> were reviewed. Your patient is currently taking a bisphosphonate: <Actonel, Fosamax> to treat osteoporosis along with a <proton pump inhibitor or H_2 Antagonist>.

Oral Bisphosphonates currently available are very effective in preventing and reversing the damage of osteoporosis and in dramatically decreasing the number of fractures suffered by osteoporotic patients. However, bisphosphonates have been associated with significant upper gastrointestinal side effects due to tablet contact injury. To reduce the possibility of esophageal side effects, careful adherence to dosing instructions is critical. Though there is no drug-drug interaction associated with concurrent use of these agents, H_2-Blockers and the proton pump inhibitors may have little effect on the development or treatment of GI complications in patients taking bisphosphonates. The package labeling of both Fosamax and Actonel recommends that patients experiencing symptoms of esophageal injury should stop their medication until they can consult their physician.

If your patient has been prescribed a proton pump inhibitor or an H2-Blocker since the initiation of bisphosphonate therapy, **it is important to confirm that your patient is taking the medication correctly.** Recommendations for taking bisphosphonates are at the end of this notice, on page 2. Of note, these products are meant to be taken concurrently with calcium and vitamin D for maximum effectiveness, so the recommendations for correctly taking them are extremely important. Should you desire, please share these recommendations with your patient. If your patient had been prescribed a proton pump inhibitor or an H_2-Blocker prior to the initiation of bisphosphonate therapy, it is important to monitor for increases in gastrointestinal symptomatology. **It is also important to monitor any change in utilization of over-the-counter acid suppression medications.**

As a method for the New Jersey State Drug Utilization Review Board to measure the effectiveness of this notice, please complete and fax the following questionnaire to First Health Services (Fax number: 1-877-480-1539) or mail to the address above. Note: no specific patient, pharmacy or physician information will be tracked; only the number of responses to the categories listed below.

Please indicate below, by checking **all/any** boxes that apply:

- ❑ No change in therapy needed
- ❑ Patient did not have a good understanding in the proper method of administering the bisphosphonate
- ❑ Patient did have a good understanding in the proper method of administering the bisphosphonate
- ❑ GI effects are unrelated to the bisphosphonate use
- ❑ The benefit of the bisphosphonate use outweighs the GI risk
- ❑ Bisphosphonate dosage changed
- ❑ Bisphosphonate discontinued

Comments:

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If you have any questions, please call First Health Services at 1-877-888-2939. If you would like to receive a summary of the data, it will be available at the website, www.njdur.org after it is compiled. You can also receive a summary by calling 1-877-266-3589. We thank you in advance for your cooperation and for responding promptly.

INSTRUCTIONS FOR ADMINISTRATION

Alendronate (Fosamax®) tablets usual recommended dosing:
Take alendronate tablet by mouth in the morning, after you have risen for the day. Swallow the tablet with a full glass (6 to 8 fluid ounces) of plain water first thing in the morning. Do not take the tablet with mineral water, coffee, tea, or juice. Do not chew or suck the tablet. Do not eat or drink anything before you take your tablet and do not eat breakfast, drink, or take any other medicines for at least 30 minutes after taking alendronate. If you can wait for 2 hours before eating, your body will absorb even more of the medicine. After taking alendronate, remain sitting or standing upright (do not lie down) for at least 30 minutes and until after your first food of the day to avoid irritation of your throat. **Wait 1 hour after your alendronate dose before taking any iron supplements, vitamins with minerals, or antacids containing calcium, magnesium, or aluminum.**

Reference: Package Insert, Merck & Co. Inc., issued November 1999.

Risedronate (Actonel®) tablets usual recommended dosing:
Swallow the tablet with 6 to 8 fluid ounces of plain water. Take the medicine first thing in the morning. Do not eat or drink anything before you take your medicine and do not eat for at least 30 minutes afterwards. To avoid irritation of your throat, do not lay down for at least 30 minutes after taking risedronate**. Wait 1 hour after your risedronate dose before taking any iron supplements, vitamins with minerals, or antacids containing calcium, magnesium, or aluminum.**

Reference: Package Insert, Aventis Pharmaceutical, Inc., issued April 2000.