

# Medicare Part D Excluded Drugs

A case for niacin

by Eric Hewitt

**M**edicare Part D was created as part of the Medicare Modernization Act passed by Congress in 2003. On January 1, 2006, for the first time in U.S. history, a prescription drug benefit available to all senior citizens over the age of 65 began. Medicare Part D was designed to enlist private third-party payors to provide the government-funded benefit. These third-party payors were allowed to set their own formularies, co-pays and premiums as long as they met a minimum benefit set forth by federal legislation. Although the government allowed formulary decisions to be made by individual payors, it did restrict certain drug classes from being covered under the Part D benefit. In all, there are nine classes of medication that are excluded by federal law from coverage by Prescription Drug Plans (PDPs).<sup>1</sup> (Table 1) Therefore, Part D beneficiaries covered solely by a standard Part D plan will be required to pay out-of-pocket if prescribed a medication within one of the nine excluded drug classes.

Patients eligible for both Medicare and Medicaid (dual eligible) were automatically enrolled in a Part D plan for their drug coverage. Medicaid patients, who previously had their drug benefit covered by the state of Wisconsin, will now have their benefit assigned to a private third-party payor with government supplementation. This change in the Medicaid program was designed to leave the list of covered medications unchanged for dual eligible beneficiaries. However, as a result of this change, the state of Wisconsin discovered that some medications previously covered by the Medicaid program were listed as excluded Part D medications and would not be covered by the PDPs. Thus, in order to prevent dual eligible patients from paying

out-of-pocket for these medications, the Medicaid program decided to continue coverage of these drugs. A complete list of excluded Part D medications that are covered by the state of Wisconsin for the dual eligible patients appears in Table 2 (page 54). In addition to the initial confusion regarding coverage of the excluded drug classes, additional confusion surrounding drug classification and whether certain drugs would be considered excluded drugs became apparent in early January 2006. This was of particular concern with Niaspan<sup>®</sup>. Niaspan<sup>®</sup> is the prescription version of extended-release niacin (vitamin B<sub>3</sub>) that is used to treat patients with high cholesterol. Consequently, the question became whether Niaspan<sup>®</sup> is considered a prescrip-

On April 11, 2006, CMS clarified Part D coverage of prescription niacin stating that after further review, prescription niacin products used at doses much higher than appropriate for nutritional supplementation should not be considered prescription vitamins for purposes of Part D coverage. Therefore, they are no longer universally excluded from coverage under the Medicare prescription drug program. Plans will not be required to add these drugs to their formularies, but will have the option to begin covering these drugs immediately. Please consult the PSW website for the specific document that addresses this change.

tion vitamin and therefore a non-covered Part D medication or an antihyperlipidemic and therefore covered. The Centers for Medicare & Medicaid Services (CMS) clarified this point by stating that Niaspan<sup>®</sup> is considered a prescription vitamin under Part D and cannot be covered by standard Part D basic plans. However, because of the confusion surrounding this issue and the fact that many PDPs had originally listed it on their formularies, CMS is allow-

ing those PDPs who had originally placed it on their formularies to cover Niaspan<sup>®</sup> until June 1, 2006. After June 1, PDPs are only allowed to cover Niaspan<sup>®</sup> within their enhanced plans. However, the cost of Niaspan<sup>®</sup> will not count toward the patient's out-of-pocket expenses.

For many senior citizens, this lack of coverage of Niaspan<sup>®</sup> will require them to change medications before June 1. If a patient wishes to change medications or niacin dosage forms, there are a few things to keep in mind. The first is that there are four different dosage forms of niacin, each with its own side effect profile. The four dosage forms are immediate-release niacin, long-acting niacin (Slo-Niacin<sup>®</sup>), extended-release niacin (Niaspan<sup>®</sup>), and No-flush<sup>®</sup> niacin.<sup>2-4</sup>

Immediate-release niacin (nicotinic acid) is available over-the-counter and has more flushing associated with it as compared to the other dosage forms. Often the flushing can be severe and limits the use of this dosage form. In order to minimize or avoid the flushing side effect, patients may be counseled to take a 325 mg aspirin tablet (unless otherwise contraindicated) 30 minutes prior to taking the niacin product. Nonpharmacologic approaches to reducing flushing include avoiding other vasodilators such as alcohol, spicy foods, hot drinks and long hot showers. The recommended starting dose of immediate-release niacin is 50-100 mg two to three times daily with meals. This dose should be titrated slowly over several weeks until an adequate response is achieved. The maximum recommended dose of immediate-release niacin is 4,500 mg daily. This dosage form is the most cost effective and viable option for patients who cannot pay out-of-pocket for Niaspan<sup>®</sup> or whose prescribers do not see another therapy as an option for them.

The long-acting form of niacin is known as Slo-Niacin<sup>®</sup> and it is also available over-the-counter. This dosage form is associated with even less flushing than either the immediate- or extended-release niacin products, but the risk of hepatotoxicity is much greater. This is especially true when the therapy is combined with a statin. The starting dose of long-acting niacin is 250-500 mg daily. This form, like the others, should be titrated slowly to a maximum dose of 2,000 mg daily.

As mentioned previously, Niaspan® is the extended-release form of niacin and is available by prescription only. Niaspan® is significantly more expensive than the over-the-counter products, and it has been associated with significantly less flushing. If flushing does occur, however, the same treatment approaches listed above can be used. The recommended starting dose is 500 mg at bedtime and the dose should be titrated by 500 mg monthly until a desired response is seen. The maximum dose of Niaspan® is 2,000 mg daily.

The final niacin dosage form is No-flush® niacin. No-flush® niacin (inositol hexanicotinate) has been shown to be ineffective in treating patients with high triglyceride concentrations in numerous studies.<sup>5,6</sup> Therefore, this dosage form should not be recommended to treat dyslipidemia.

Regardless of dosage form, niacin products have a few significant precautions and contraindications. The first caution is in hyperuricemic patients. Niacin, particularly at high doses, has been shown to cause increased uric acid concentrations, which can increase the potential for gout flare-ups. Similarly, caution should be used in patients with diabetes as niacin can exacerbate hyperglycemia. As for its contraindications, niacin should be avoided in patients with chronic liver disease, severe gout, active peptic ulcer disease or arterial bleeding.

Caution must also be exercised when switching from one niacin agent or dosage form to another. When switching between dosage forms, it is important to note that a simple 1:1 conversion does not apply. Regardless of which conversion is intended, the original niacin agent must be

stopped and the new form should be initiated at its starting dose and titrated slowly. Following this procedure for conversion between niacin products may reduce the potential for side effects and hepatotoxicity in particular.

Once the patient is started on a niacin product, it is recommended that baseline LFTs (including AST and ALT), fasting glucose, and uric acid levels be drawn. The LFTs should be repeated every six to 12 weeks for the first year and periodically thereafter. Both the fasting glucose and uric acid levels should be repeated at six to eight weeks and annually thereafter.

As time runs out on PDP ability to cover Niaspan®, patients may have related questions for the community or health system pharmacist. As pharmacists, we can educate patients and prescribers about the excluded Part D drug classes and the importance of properly managing niacin therapy. ●

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**TABLE 1. EXCLUDED DRUG CLASSES UNDER MEDICARE PART D**

- Agents for anorexia, weight loss or weight gain
- Agents when used to promote fertility
- Agents when used for cosmetic purposes or hair growth
- Agents when used for the symptomatic relief of cough and colds
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations
- Nonprescription drugs
- Outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer or designee as a condition of sale
- Barbiturates
- Benzodiazepines

#### Vivotif®

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cines has been studied specifically in travelers, but instead they have been studied in countries with endemic typhoid. Therefore, no efficacy studies have been completed in the United States due to the very low incidence of typhoid fever. However, the results of the clinical trials support the expectation that Vivotif® will provide immunization protection to people from non-typhoid endemic areas.<sup>2</sup>

As seen in the above clinical trials, the Vivotif® vaccine does not fully protect all recipients against typhoid. The efficacies of the parenteral and oral vaccines have been found to range from 52% to 77%.<sup>2</sup> Because neither vaccine is completely protective, patients should be instructed to take all the necessary precautions to avoid contact or ingestion of contaminated food and water.

In conclusion, the oral typhoid vaccine, Vivotif®, is a well-tolerated and effective vaccine for travelers to under-developed countries. The main disadvantages of Vivotif® include adherence issues with every other day dosing on an empty stomach, and the need for product refrigeration to maintain efficacy. In addition, Vivotif® is contraindicated in acute illness and the immunocompromised. The parenteral typhoid vaccination is a suitable alternative for typhoid prevention in immunocompromised patients. Overall, clinical judgment weighing the risks and benefits along with proper patient counseling are important for the safe and effective use of Vivotif®.

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