



Medication Access Program Newsletter

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The Medication Access Program (MAP) is a statewide program for solid-organ transplant recipients in Georgia that offers information about medication assistance programs and helps with the enrollment into these programs.

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MAP 2006 Status Report

The Medication Access Program (MAP) is a statewide program, available at no cost, for solid-organ transplant recipients in Georgia that offers information about programs that can increase transplant recipients' accessibility to medications (e.g., Medicare, Medicaid, pharmaceutical manufacturer sponsored medication assistance programs). The mission of MAP is to increase access to medications for solid-organ transplant recipients who reside in the State of Georgia. In addition to identifying medication assistance programs, MAP also provides assistance to transplant recipients in the enrollment process necessary to participate in these programs. MAP is available through a grant from the Carlos and Marguerite Mason Trust.

Noncompliance with immuno-suppressants and other critical transplant medications may lead to organ rejection, increased healthcare cost, and decreased quality of life. MAP provides information about and enrollment services into assistance programs concerning immuno-suppressant medications and other medications for concomitant disease states that may develop in transplant recipients. These disease states include, but are not limited to, hypertension, diabetes, pulmonary diseases, and lipid disorders. Additionally MAP is a valuable resource for healthcare professionals and transplant recipients providing the most up-to-date information regarding available medication assistance programs.

From November 1999 through May 2006, MAP has aided over 580 Georgia solid-organ transplant recipients. Through MAP's services, these recipients have received over \$13 million in medications, based on average wholesale prices. We encourage all transplant recipients and healthcare professionals to contact

MAP. MAP personnel may be reached Monday through Friday from 9:00 AM to 5:00 PM by calling (706) 721-0131 or 1-800-736-2273 ext. 0131.



New Medications

Ibandronate (Boniva®)

Ibandronate (Boniva®) manufactured by Roche and GlaxoSmithKline, is an oral bisphosphonate indicated for the prevention and treatment of postmenopausal osteoporosis.^{1,2} Ibandronate inhibits osteoclast activity and reduces bone resorption and turnover. In post-menopausal women, it reduces the elevated rate of bone turnover, leading to, on average, a net gain in bone mass.²

Ibandronate is poorly absorbed in the upper GI tract.^{1,2} The extent of absorption is affected by food and beverages other than water. After absorption, it rapidly binds to bone or is excreted into urine. The half-life of 150mg ibandronate tablets is 37 to 157 hours. Ibandronate is not metabolized by the liver, and as such, no studies have been performed looking at pharmacokinetics in patients with hepatic impairment.² It is not recommended for use in patients with severe renal impairment defined as CrCl < 30 mL/minute.²

Ibandronate is contraindicated in patients who are unable to stand or sit upright for at least 60 minutes. Other contraindications include patients with uncorrected hypocalcemia or severe

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renal impairment. The most commonly reported adverse effects include abdominal pain, hypertension, dyspepsia, arthralgia, nausea, and diarrhea. As the drug does not undergo hepatic metabolism, it does not interfere with the cytochrome P450 system. Possible interactions include other drugs or foods containing cations, such as milk, vitamins, and iron-containing products. As ibandronate may cause some GI irritation, other drugs that cause GI irritation must be cautiously used while patients are on concomitant therapies.^{2,3}

Ibandronate may be dosed as a 2.5mg tablet taken daily or as a 150mg tablet taken monthly. It must be taken after an overnight fast due to poor absorption. Patients should be advised that ibandronate should be taken in the morning with a full 8 ounce glass of plain water at least 1 hour before drinking or eating anything or taking any oral medications. This medication should not be taken with any other drinks, including mineral water, sparkling water, coffee, tea, milk, or juice, nor should it be taken with vitamins, antacids, or iron-containing products, since these may result in decreased absorption. After taking ibandronate, patients must wait an hour before lying down. This drug must be taken on the same day of each month.^{2,3}

There is a support program available designed to help enhance compliance and persistence of therapy. For more information on this program please call 1-888-MYBONIVA.

References:

1. The Medical Letter. Vol. 47, Issue 1207, April 25, 2005
2. www.midatlanticosteo.org/documents/Boniva%20PI.pdf (Accessed May 5, 2005)
3. www.4boniva.com/patient_info.asp (Accessed May 5, 2005)

Authored by Bridget Mills, Pharm.D., RPh.

Rosiglitazone (Avandia®) Therapy of PTDM

Insulin is the usual therapy of choice for treating posttransplant diabetes mellitus (PTDM) due to its safety and efficacy. However, the burden of daily injections remains an obstacle to patient compliance. A trial sponsored by GlaxoSmithKline suggests a method to decrease the number of injections by using rosiglitazone (Avandia®). The ability of the oral antidiabetic agent rosiglitazone to eliminate the need for insulin, control blood glucose, and maintain target HbA_{1c} levels of at least 6.5% or less was measured. Rosiglitazone, a thiazolidinedione, works to increase the body's sensitivity to insulin without interfering with the metabolism of cyclosporine or tacrolimus.

The trial consisted of 40 transplant patients (8 renal and 32 liver); none were treated for diabetes prior to transplant. Eighty-three percent (n=33) were receiving tacrolimus and 17% (n=7) cyclosporine as part of their immunosuppression regimen. Eighty-seven percent were initially treated with prednisone. All patients were diagnosed with PTDM and initially treated with a sulfonylurea or insulin (NPH and regular twice daily) to achieve blood glucose control; thirty-three patients were treated with insulin, while 7 were treated with a sulfonylurea. The mean insulin requirement was 50 units per day. Within 8 weeks of diagnosis, patients received 4mg/day of rosiglitazone. Patients were followed for 3 to 12 months and required to perform home blood glucose monitoring 4 times/day. Measurements such as SCr, serum electrolytes, weight, and levels of cyclosporine or tacrolimus were obtained weekly, and HbA_{1c} levels were obtained every 2 to 3 months. Dosage adjustments of rosiglitazone were made up to a maximum dose of 4mg twice daily; insulin was tapered. Target trough levels of cyclosporine were 100-150mg/dL. Upon discontinuation of insulin, one of three sulfonylureas was added to aid in

maintaining blood glucose control if target levels could not be maintained with rosiglitazone alone: glipizide (n=12), glimiperide (n=9), or glyburide (n=4).

Of the 33 patients who were initially treated with insulin, 30 were able to discontinue it within 3 to 4 months. Only 3 out of the 40 had to continue taking insulin despite treatment with a sulfonylurea and rosiglitazone and were termed insulin dependent. Thirty percent of patients were able to maintain target blood glucose with rosiglitazone alone; 62.5% had to take a sulfonylurea and rosiglitazone to remain in target. Thirteen percent developed edema during the trial, but all were able to continue therapy with rosiglitazone; none developed pulmonary edema, a serious side effect of rosiglitazone. Mean HbA_{1c} levels were maintained at 5.6% ± 0.8. These results were accomplished without changing renal or hepatic function. Associated rosiglitazone side effects, including increased cholesterol, edema, fatigue, and hypoglycemia, had a 1 to 10% incidence in clinical testing, while less common side effects (congestive heart failure or exacerbation of heart failure and elevated liver function) occurred in less than 1% of patients. Patients with New York Heart Association Class III or IV heart failure or certain liver problems should not use rosiglitazone. The decision to begin therapy with rosiglitazone should be made by a physician, and the benefits and risks should be weighed carefully.

Reference:

Villanueva, G, Baldwin, D. Rosiglitazone Therapy of Posttransplant Diabetes Mellitus. *Transplantation* 2005; 80: 1402.

Authored by Julie Williamson

The MAP newsletter is published quarterly to present topics of interest to the transplant community. If you would like to submit material to be considered for publication in the newsletter, please contact MAP at:

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