Linagliptin approved for type 2 diabetes

FDA on May 2 approved linagliptin, a dipeptidyl peptidase-4 inhibitor, for the improvement of blood glucose control in adults with type 2 diabetes mellitus.

The drug is available under the brand name Tradjenta by Boehringer Ingelheim and Eli Lilly and Company, which earlier this year formed an alliance to develop new medications for diabetes.

According to the FDA-approved labeling for linagliptin, the drug is indicated, in combination with diet and exercise, to improve glycemic control in adults with type 2 diabetes. Linagliptin is not suitable for use in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

Like other drugs in its class, linagliptin inhibits the degradation of incretins, causing an increase in insulin release and a decrease in circulating levels of glucagon.

The recommended dosage of linagliptin is 5 mg taken once daily with or without food. No dosage adjustments are needed in patients with kidney or liver disease, according to the labeling.

In clinical trials, linagliptin was studied as monotherapy and in combination with metformin, glimepiride, or pioglitazone.

As monotherapy compared with placebo, linagliptin resulted in improvements in trial participants’ glycosylated hemoglobin, fasting blood glucose, and postprandial glucose levels. The addition of linagliptin to metformin, glimepiride, or pioglitazone therapy likewise improved these indicators of glycemic control.

The labeling warns that the use of linagliptin in combination with a sulfonylurea or other insulin secretagogue may result in hypoglycemia. To lower the risk of hypoglycemia, a reduction in the secretagogue dosage is recommended for patients who take such a medication along with linagliptin.

Inducers of P-glycoprotein or cytochrome P-450 isoenzyme 3A4 may decrease patients’ exposure to linagliptin. The labeling for the antidiabetic drug strongly recommends that users take alternatives to those medications.

Home-based medication management system looks to future

A federally recognized program that uses pharmacists’ medication therapy management skills is targeting hospital-to-home transitions in an attempt to reduce hospital readmission rates.

June Simmons, president of the Partners in Care Foundation in San Fernando, California, said her organization’s Web-based medication reconciliation program, the HomeMeds Medication Management Improvement System, is being tested in two California hospitals to gather basic information about patients’ medication regimens.

Soon after the patients are discharged, Simmons said, a care manager visits them at home and uses the HomeMeds system to analyze the medications being taken. The care manager then works with a pharmacist or other medication expert to resolve any therapeutic duplication issues and other drug-related problems.

“The hospital, of course, does medication reconciliation when someone is leaving the hospital,” Simmons said. “But very often, the big thrill is to go to the home and then see what’s really there. And there are often big surprises.”

Simmons said medication-related issues are a major reason for hospital readmissions. Her organization’s care-transition work coincides with efforts by the Centers for Medicare and Medicaid Services (CMS) to decrease 30-day readmission rates for Medicare beneficiaries.

CMS in 2009 began reporting hospitals’ 30-day readmission rates for Medicare beneficiaries diagnosed with pneumonia, acute myocardial infarction, or heart failure. Last year’s health care re-
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Form laws authorized CMS to financially penalize hospitals whose readmission rates for these patients are considered excessive. Penalties will be applied to fiscal year 2013 payments, and the agency has announced its intent to increase the number of conditions subject to the penalties in later years.

The Department of Health and Human Services in April announced that it would commit $500 million to support partnerships between hospitals and community-based organizations to help patients safely make the transition to postacute care. Simmons said HomeMeds is well suited to participate in this endeavor.

With funding from the John A. Hartford Foundation and the U.S. Administration on Aging (AOA), HomeMeds evolved over two decades as a collaboration between a “home care team” and consultant pharmacists, said Denee Frey, a home- and long-term-care pharmacist who serves as project consultant for the Partners in Care Foundation.

“The idea behind HomeMeds involves somebody being in the home to be able to identify medications that are being taken by a patient,” Frey said.

The person who visits the patient’s home may be a nurse, nutritionist, social worker, or other professional who may or may not have a clinical background, she said.

Ideally, Frey said, the visitor has a laptop or iPad equipped with the HomeMeds software and enters information about the patient’s medications while in the patient’s home. The software identifies potential medication-related problems and indicates whether a medication consultant—this is usually a pharmacist—needs to help resolve them.

Communication with the pharmacist takes place by e-mail or fax, and the pharmacist is responsible for verifying the appropriateness of the patient’s medications and the accuracy of the medication list compiled during the home visit. The pharmacist follows up with the prescriber and documents any intervention.

The pharmacist or other medication expert may be employed by or work under contract or as a volunteer for the entity that implements the HomeMeds program. Pharmacists who work with HomeMeds clients come from many different areas of practice, Frey said.

“We’ve had feedback from our pharmacists that they really like this role—that it’s been a new role for them to collaborate with community-based agencies,” she said.

Frey said the software is set up to help the person doing the home visit to catch obvious medication problems, such as a patient who is taking both generic furosemide and brand-name Lasix.

“Therapeutic duplication is the most common problem that we identify, by far, in all the studies we’ve done,” Frey said.

Simmons said therapeutic duplication often occurs when a patient takes a drug at home, receives during hospitalization a similar drug that is on the hospital’s formulary, and continues with both drugs after discharge.

Another reason therapeutic duplication may occur is that similar medications are prescribed by specialists who do not communicate with each other, she said.

“You can have a lot of good-faith, solid medical interventions that happen to overlap because [prescribers] aren’t aware of each other. They’re all solving the same problem, or similar problems, or different problems in similar ways,” Simmons said. “The results can be quite damaging for the patient.”

Simmons said HomeMeds has not been configured to track cost savings related to the avoidance of medication errors or hospital readmissions, but she would like to see such features embedded in the system as it evolves.

The HomeMeds system is recognized by the Agency for Healthcare Research and Quality as a strong, evidence-based intervention for improving the health of community-living seniors.

HomeMeds in mid-May was in use in 26 sites in seven states, with additional sites under review for implementing the program, said Sandy Atkins, vice president of Partners in Care’s Institution for Change. Users of HomeMeds include Medicaid waiver programs, assisted-living facilities, Indian tribal communities, and AOA care management clients.

More than 7000 medication assessments have been conducted using HomeMeds, Atkins said.

Although HomeMeds is geared toward the home environment, Frey said she is hopeful that a future iteration of the program will be able to integrate with electronic medical records systems used by hospitals.

Simmons said places where older adults gather in the community, like senior centers, are another place HomeMeds could conceivably be used in the future.

—Kate Traynor
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