

Qualitest Pharmaceuticals Issues Recall of All Accusure Insulin Syringes

Qualitest Pharmaceuticals issued a voluntary nationwide recall of all Accusure Insulin Syringes. The distributed syringes are of the following descriptions and NDC numbers: 28G 1/2cc, NDC 0603-6995-21; 28G 1cc, NDC 0603-6996-21; 29G 1/2cc NDC 0603-6997-21, 29G 1cc, NDC 0603-6998-21, 30G 1/2cc, NDC 0603-999-21, 30G 1cc, NDC 0603-7000-21, 31G 1/2cc, NDC 0603-7001-21; and 31G 1cc, NDC 0603-7002-21. All Accusure Insulin Syringes regardless of lot number are subject to this recall. These syringes were distributed between January 2002 and October 2009 to wholesale and retail pharmacies nationwide (including Puerto Rico). The syringes in these lots may have needles which detach from the syringe, according to a statement from the US Food and Drug Administration (FDA).

If the needle becomes detached from the syringe during use, it can become stuck in the insulin vial, push back into the syringe, or remain in the skin after injection.

Consumers who have any Accusure Insulin Syringes should stop using them and contact Qualitest at 800-444-4011 for reimbursement. You can find the lot number on the white paper backing of each individual syringe. Qualitest is notifying all customers who received these syringes and arranging for the return of any affected product. Consumers with questions may contact Qualitest at 800-444-4011 for more information. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program at www.fda.gov/medwatch/report.htm.

Mayo Clinic Clinicians Develop Tool to Help Type 2 Diabetes Patients

Mayo Clinic clinicians and designers, along with colleagues from other institutions, have developed and tested a tool to involve patients more in their diabetes treatment and medication choices. The tool, a set of decision aid cards, could help patients make decisions about their disease and potentially have improved outcomes. The results of this randomized trial appear in the *Archives of Internal Medicine*.

Victor Montori, MD, a Mayo Clinic endocrinologist, is coauthor of the study. He heads the Knowledge Encounter Research Unit in the Department of Medicine and is a member of the Center for Innovation at Mayo Clinic. The trial was conducted at 11 primary care and family medicine sites within Mayo Health System and Olmsted Medical Center, all in southeast Minnesota, according to a news release. Twenty-one clinicians and 85 patients participated in the trial with 37 patients receiving usual care and 48 patients using the decision aid cards. Health care clinicians, consisting of physicians, physician assistants, and nurse practitioners, were responsible for managing diabetes in adult patients with medication options. The Diabetes Medication Choice decision aid cards were used to help patients and their clinician reach a decision regarding their course of care.

The tool consists of six cards that describe the possible effects of various medication choices on six outcomes: weight change, low blood glucose, blood glucose, daily routine, daily blood glucose testing, and side effects. Clinicians were randomized to either use the decision aid cards (intervention) or discuss medications as usual (control). Data were gathered from a self-administered written survey completed by patients immediately after the patient's visit. Compared with the control patients, those who used the cards found them helpful and felt they were more involved in making decisions about their diabetes medication. Both groups had near-perfect adherence to their medication use; the cards were effective in involving patients with type 2 diabetes in decision making.

Dr. Montori said, "We are going to see if these same tools can impact the health of patients with diabetes in rural communities in southeastern Minnesota . . . to see if these decision aids can in fact provide better patient-centered care for patients with diabetes." For more information, please watch a video about the cards at www.youtube.com/watch?v=60d0RmQtw6k.

Saxagliptin Covered by 44% of Commercial Health Plans, Only <1% of Medicare Plans

HealthLeaders-InterStudy and Fingertip Formulary

find that Bristol-Myers Squibb/AstraZeneca's new agent saxagliptin (Onglyza) is covered by 44% of commercial health plans but <1% of Medicare plans, according to a report. Among plans that have saxagliptin on formulary, the majority have placed the drug on Tier 3.

According to a news release from HealthLeaders-InterStudy, the three-tier open formulary is the most common formulary design in the United States, therefore the positioning of saxagliptin as a primarily Tier 3 benefit is consistent with survey findings that show 40% of surveyed pharmacy directors say they cover emerging agents, including saxagliptin which was approved for the treatment of type 2 diabetes in July, on their highest tier until they can complete an internal review.

"Large plans have most rapidly added saxagliptin to their formularies but mostly as a Tier 3 benefit, likely as a default option until an internal review can be conducted and they can determine whether the drug should be upgraded to Tier 2," said Michael Malecki, PhD, product manager for Formulary Forum. "Our survey found that nearly three-quarters of surveyed pharmacy directors from large plans say they expect their managed care organization to review emerging therapies within 6 months of FDA approval, so we expect the story of [saxagliptin's] coverage to evolve over the coming months."

Diabetes Care Shifting to Earlier, Expanded Insulin Use

Diabetes care is undergoing a paradigm shift in which insulin is being prescribed earlier, for more conditions, in order to delay the onset of full-blown disease, according to a study released today by Scientia Advisors. In light of that trend, as more drugs become generically available, companies offering newer, more expensive drugs will face resistance in markets most constrained by economics.

In the words of Harry Glorikian, Scientia Advisors' managing partner, "While there are exciting developments in the non-insulin oral drug categories, the makers of these newer medications would be wise to stay attuned to how to best position their products—especially when marketing in emerging economies, which are extremely sensitive to costs."

Scientia Advisors is a global management consulting firm specializing in growth strategies for major and emerging companies.

According to Mr. Glorikian: "We expect that as more

drugs are available in generic form, incretin mimetics (which increase insulin secretion) and insulins will generate an increasing share of the revenues. Therapies with benefits beyond glucose management (such as delaying the onset of diabetes or treating co-morbid conditions) will be used earlier in treatment. For a variety of reasons, despite the growing availability of new types of drugs, various forms of insulin will remain the gold standard."

For more information, please visit www.scientiaadv.com.

DexCom Receives CE Mark Approval for SEVEN PLUS Glucose Monitoring System

DexCom, Inc. announced that it has received Conformité Européenne (CE Mark) approval for the SEVEN PLUS continuous glucose monitoring system, enabling commercialization of the system in the European Union and the countries in Asia and Latin America that recognize the CE Mark.

The SEVEN PLUS is DexCom's third-generation device designed to help people with diabetes better manage their diabetes and control their glucose levels. Widely recognized as one of the leading causes of death and disability globally, diabetes is a chronic disease with no known cure that afflicts an estimated 246 million people worldwide, according to the International Diabetes Federation. Diabetes is a leading cause of adult blindness, end stage kidney failure and lower limb amputations. People suffering from diabetes are also more significantly at risk for cardiovascular disease and stroke.

"We are pleased to have CE Mark approval for the SEVEN PLUS and we look forward to working with physicians, nurses and diabetes educators to bring this important technology to patients around the world," said Terrance H. Gregg, DexCom's President and CEO. "We are particularly pleased with the timing of this approval in light of the excitement surrounding continuous glucose monitoring we [saw] at the European Association for the Study of Diabetes meeting in Vienna. We have been working diligently to establish a network of distributors outside the United States and plan to launch the SEVEN PLUS in up to 10 countries in Europe in the fourth quarter."

For more information, please visit www.dexcom.com. ■