Recalls, warnings and label changes

Label and packaging changes to over-the-counter topical antiseptic products for preoperative or preinjection skin preparation, due to reports of infections. The FDA is requesting that the products be packaged in single-use containers and labeled as either sterile or non-sterile. Clinicians should not dilute the products and should consider them as a possible source when investigating postoperative or postinjection infections.

A label change on regadenoson (Iozine II) to add new information regarding the rare but serious risk of heart attack and death. The label now recommends avoiding use of these drugs in patients with signs or symptoms of unstable angina or cardiovascular instability, and having cardiac resuscitation equipment and trained staff readily available before administering either drug.

A warning on clozapine (Onfi) about the risk of serious skin reactions. Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) can occur at any time during treatment with clozapine, but the likelihood is greater during the first 8 weeks of treatment or when the drug is stopped and then restarted. Patients should be closely monitored for signs or symptoms of SJS/TEN, especially during the first 8 weeks, and then restarted. Patients should be closely monitored for signs or symptoms of SJS/TEN, especially during the first 8 weeks of treatment or when the drug is stopped and then restarted.

A recall of a lot of Baxter International Inc.’s nitroglycerin in 5% dextrose injection due to particulate matter found in 1 vial. If infused, particulate matter could lead to potential venous and/or arterial thrombosis or embolism or infarction. A recall of a lot of sterile products compounded by Nature’s Pharmacy and Compounding Center (injectable drugs and eye drops, distributed in North Carolina) due to sterility assurance concerns during a recent FDA inspection.

A recall of Hospira’s GemStar infusion system because the proximal and distal pressure sensor calibration can drift. A pump with this issue may shut down, not detect occlusions or issue false occlusion alarms. Potential risks include a delay or interruption in therapy or over-infusion.

A recall of Spacelabs Healthcare, Inc.’s anesthesia workstations and service kits because the bag-to-vent switch in CAS U/V Absorbers may fail due to loose fastening in an absorber, which could impede the ability to provide ventilation in bag mode.

Approvals

The first generic versions of ranabeprazole sodium (Aciplex) delayed-release tablets, used to treat gastroesophageal reflux disease in adults and adolescents. The first generic versions of alendoxetone (Cymbalta) delayed-release capsules to treat depression and other conditions.

Miscellaneous

The FDA is asking clinicians to encourage patients to take acetaminophen safely this cold and flu season. Consumer resources are available on the FDA website.

Due to a disruption in supply of atropine (Atopen), atropine/pralidoxime chloride (DuoDote), morphine sulfate, pralidoxime chloride, and diazepam auto-injectors manufactured by Meridian Medical Technologies, the FDA announced in September 2013 that certain lots of DuoDote can be used for an additional year beyond the manufacturer’s original labeled expiration date. The agency is continuing to assess whether further extension is possible and whether dates can be extended for additional lots. The potential use of the other products beyond their labeled expiration dates is also being examined. Products nearing or beyond their labeled expiration dates should be retained until further guidance is provided by the FDA.

The FDA recently removed the prescribing and dispensing restrictions on rosiglitazone-containing drugs (Avandia, Avandamet, Avandaryl) that were put in place in 2010, based on updated data that do not show an increased risk of heart attack with rosiglitazone compared to metformin or sulfonylureas. Although some scientific uncertainty about the cardiovascular safety of rosiglitazone still remains, concern is substantially reduced, the agency said.

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interactions between the furnishing practitioner and the beneficiary described by the required face-to-face visit component of the transitional care management (TCM) services, reported as CPT 99489, are sufficiently similar to services currently on the list of Medicare telehealth services for these services to be added under category 1.

CMS finalized telehealth proposals to define rural Health Professional Shortage Areas (HPSAs) as those located in rural census tracts as determined by the Office of Rural Health Policy (ORHP) and to establish and maintain geographic eligibility for an originating site on an annual basis. Also finalized was a policy change establishing that geographic eligibility for an originating site would be established and maintained on an annual basis, consistent with other telehealth payment policies.

Without this change, the status of a geographic area’s eligibility for telehealth originating site payment is concurrently effective with the effective date for changes in designations that are made outside CMS. This policy is expected to reduce the likelihood that mid-year changes to geographic designations would result in sudden disruptions to beneficiaries’ access to services and unexpected changes in eligibility for established telehealth originating sites. It is also expected to help avoid the operational difficulties associated with administering mid-year Medicare telehealth payment changes.