The US Food and Drug Administration (FDA) could approve the first biosimilar drug for use in dialysis patients later this year, a prospect that could shake up the market with an alternative to Amgen’s dominant anemia biologic drug Epogen (epoetin alfa) that has been used in Europe for several years.

Biosimilars are essentially the generic versions of biologic drugs, which are compounds that are made by or derived from living organisms rather than manufactured like most drugs. Because biologics—which include compounds such as the erythropoiesis-stimulating agent (ESA) epoetin, monoclonal antibodies, interferons, and human insulin—are derived using organic processes, they cannot be duplicated exactly. They show much more heterogeneity, batch-to-batch variability, and other variations compared with generic drugs, which merely require replication of the chemical formula in a controlled manufacturing process.

As patents on the first biologics began to expire, enabling companies to consider the creation of drugs based on similar principles to compete with them, the need arose for a pathway to approve these biosimilars. Because their equivalence is not as obvious as that of a generic drug, regulators wrestled with the question of what standards would be reasonable to meet without going through the approval process for a brand new drug. The European Union put such a pathway in place in 2005.

In the US, a provision of the Affordable Care Act called the Biologics Price Competition and Innovation Act of 2009 empowered the FDA to implement an abbreviated regulatory approval process for biosimilars. A manufacturer must provide clinical studies showing that a product has no meaningful differences in terms of safety, purity, and potency in comparison to a “reference product”—a specific FDA-approved biologic.

After several years of working out the details, the FDA approved its first biosimilar drug in March—Sandoz’s Zarxio (filgrastim-sndz), a biosimilar to Amgen’s cancer drug Neupogen (filgrastim). The biosimilar widely considered to be next in the pipeline for approval is Hospira’s epoetin zeta, a competitor to Amgen’s epoetin alfa, used to treat anemia in patients with chronic kidney disease (CKD).

A dominant drug
“Epoetin alfa is used in a majority of patients with dialysis-dependent CKD and in many individuals with non-dialysis-dependent CKD.”

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ICD-10 Coding Switch: Short-term Headaches; Long-Term Benefits

On October 1, 2015, US healthcare providers will transition to the tenth version of ICD-10, the World Health Organization (WHO) disease classification system. Approved by WHO in 1990, ICD-10 is now used by more than 115 countries to record morbidity and mortality statistics, and more than 20 countries incorporate ICD-10 into their reimbursement processes. The US version, modified by the National Center for Health Statistics (NCHS) and the Centers for Medicare and Medicaid Services (CMS), includes ICD-10 Clinical Modification (ICD-10-CM), comprising 68,000 codes for use in clinical settings, and the ICD-10 Procedure Coding System (ICD-10-PCS), comprising an additional 75,000 procedure codes.

Methods of disease classification developed in England and France in the 17th and 18th centuries remain the foundation for systems used today to classify morbidity and mortality (1). The United States adopted the World Health Organization (WHO) Manual of the International Statistical Classification of Diseases, Injuries

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Since the adoption of ICD-9 in 1979, an increasing number of patients had severe hypersensitivity reactions, including anaphylaxis, that resulted in some deaths.

Dialysis clinic leaders indicated to the Marwood researchers that the Omontys experience would not affect their attitude toward biosimilars, perhaps because Omontys was a synthetic peptide, not a biologic drug or a biosimilar. “They saw it as an unfortunate incident specific to that product, not an issue that should be extrapolated to other products,” Vukhac said.

**History of use**

Clinic leaders appear more likely to look to the European experience. “There is a history of successful use of Epogen-like products outside the US in sophisticated healthcare markets,” Williams said. “I think that is helpful to the way that people think about these things. The products that are coming into the US are essentially the same ones that they are using in Europe today. It is the same companies, and the same processes that they are using to make these biosimilars, so it is not like we are totally starting from scratch here with the Epogen-like products.”

Vukhac added that doctors are often seen as resistant to change, but the representatives of dialysis clinics interviewed indicated that they are open to switching. “They change their protocols fairly often, so they are pretty adaptive, which may be different from other specialties,” she said.

How fast a biosimilar might penetrate the market is another open question. The Marwood report says: “According to SEC filings, DaVita has a contract with Amgen which runs through the end of 2018 stipulating that it will use Amgen’s product for 90% of its ESA needs. This represents approximately one-third of the dialysis market. Fresenius is not bound by a similar contract, but is likely to take a measured approach as it has done previously with Omontys and most recently Mirelza, Roche’s pegylated ESA.”

The report postulates that small- and medium-sized dialysis organizations will be the most receptive to cost savings that could accrue from biosimilar ESAs. “Smaller clinics have been under quite a bit of financial pressure. There have been cuts to the bundle over the last few years, so I think that finding ways to manage those cuts becomes top of mind,” Williams said.

Dialysis clinics will no doubt welcome the availability of alternative drugs and suppliers that address one of their major costs, and while manyquestions remain, it appears to be only a matter of time until alternatives are available.

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**ICD-10 Coding Switch**

Continued from page 1 and Causes of Death in 1948. The ninth version of this manual (ICD-9) was approved by WHO in 1975, and a version modified for the American hospital system was adopted in 1979. In the US, providers use Current Procedural Terminology (CPT) codes, updated yearly by the American Medical Association, to document and bill for specific medical procedures and services. ICD-9 disease classifications began to be incorporated into claims processing in the 1980s.

**Why switch?**

Since the adoption of ICD-9 in 1979, an explosion of new technologies, new procedures, and new quality measures has produced more detail that can be supported by the current system and codes. Moreover, today’s healthcare is global, and it is becoming increasingly difficult to share data critical to public health and research when classification systems are out of sync. According to the American Health Information Management System, ICD-9 “can’t take healthcare into the future” (2).

Many experts speculate that the increased specificity of ICD-10 codes will reduce the need for repetitive exchanges between providers and insurance companies regarding claims, and ultimately reduce the incidence of rejected claims. In addition, large and small healthcare providers may be able to use the increased specificity such as the coding for underlying causes and comorbidities, to improve patient outcomes and better allocate internal resources.

**No pain, no gain?**

Success of transitions to ICD-10 will depend on many organizations, not just providers: electronic health record (EHR) vendors, insurance companies, and others must also convert their systems. Worst-case scenarios for physician practices during the transition include slowed productivity, higher percentages of rejected claims, and short-term increases in unbillable revenues.

To support the transition, on June 6, 2015, CMS and AMA issued a joint statement highlighting efforts to help physicians make the switch (http://cms.gov/Medicare/Coding/ICD10/Downloads/AMA-CMS-press-release-letterhead-07-05-15.pdf). CMS and AMA will provide educational support before the transition; to address questions post-transition, CMS will set up a communications center and support an ICD-10 ombudsman, and for 12 months post-transition, CMS will allow flexibility in claims and quality reporting.

Many of the new codes relate to the musculoskeletal system, with significant expansions in coding fractures, so some areas of practice will experience more change than others. Nephrology is not anticipating the same level of change as orthopedics, but all coders, physicians, and insurance companies must learn the new chapter organization, new codes, and adapt to providing more, and different kinds of, documentation. Combination codes that include acuity or severity will impact nephrology coding, especially chronic kidney disease (CKD). Diseases closely associated with kidney disease, such as diabetes and hypertension, will add to the learning curve for kidney physicians and staff. Several of the resources listed below focus on the impact of the conversion to ICD-10 on nephrology.

Within and outside the clinic setting, the conversion to ICD-10 may require efforts not yet fully anticipated. The General Equivalence Mappings (GEM) that support the transition from ICD-9 coding to ICD-10 coding in the clinic and hospital settings may not provide comparability ratios for tracking longitudinal data (3). New ICD-10 codes must be incorporated into reporting of quality measures: for example, each AHRQ quality indicator technical specification with ICD-9 CM codes must be converted to ICD-10 CM/PCS codes. After October 1, challenges may arise when ICD-10 codes cannot be used: for instance, in the US, workers’ compensation auto insurance claims are not required to incorporate ICD 10 coding.

While the headlines are predictable, the increased precision of these classifications, the improved integration with electronic health records, and the ability to convey more detailed data about patient outcomes, may prove great aids to nephrologists and others in their ongoing efforts to evolve and improve patient care.

**Resources**

- AMA Support for ICD Transition: http://www.ama-assn.org/ama/wire/blog/ICD-10_Monthly_Promise1
- CMS: 2015 ICD-10 PCS and GEMS
- Road to 10: The Small Physician Practice’s Route to ICD-10 (CMS) http://www.madho10.org/
- ICD 10 Crosswalk for Nephrology http://nephrologypracticesolutions.com/icd-10-crosswalk
- How to document and code for hypertension in ICD 10 http://www.aafp.org/afp/2014/0300/p5.html (includes information specific to hypertension and CKD)

**References**


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**Something to Say**

**ASN Kidney News accepts correspondence in response to published articles. Please submit all correspondence to kidneynews@asn-online.org**