

Basaglar became available in the U.S. in December 2016.

Rosier notes that Basaglar is a follow-on biologic and not considered a “biosimilar” or “generic” for the brand product Lantus (insulin glargine). Basaglar was approved through the abbreviated 505(b)(2) process, which uses the FDA’s initial findings for the reference product, Lantus, to demonstrate safety and efficacy. The follow-on biologic is not interchangeable for Lantus at the point of sale. Basaglar was approved via a New Drug Application (NDA) and is considered a brand name drug.

Follow-On Biologics Can Reduce Costs

Payers commonly expect follow-on biologics to reduce costs by 15% for early entrants when there is no other biosimilar competition, such as in Basaglar’s case. Up to a 30% discount is expected when there is more than one biosimilar entrant, and this is often cited by payers as the threshold at which they will prefer the biosimilar.

In recent years, Basaglar rapidly won exclusive contracts with some major payers. UnitedHealth Group moved Basaglar to Tier 1 and moved Lantus from Tier 3 to excluded status for the 2017 benefit year. Similarly, CVS Health Corp. said in August 2016 that it would remove Lantus from the insulin class in its standard formulary, replacing it with Basaglar.

Like Basaglar, which first became available in Europe under the brand name Abasaglar in 2015, other biosimilar insulin glargine analogs also are now on European markets and soon may be coming to the U.S.

Merck told investors in July 2017 that the FDA had granted tentative approval for Lusdana Nexvue (insulin glargine injection), another follow-on biologic insulin drug.

But the drug won’t come to market yet because of a lawsuit filed by Sanofi in September 2016 claiming patent infringement, Merck said. That lawsuit invokes a stay of up to 30 months or until a final court decision. It is expected to hit the U.S. market in early 2018. Lantus won European Commission marketing authorization in January 2017.

Independent investment research firm Market Realist on Oct. 13 predicted that Basaglar would witness steady growth in 2018. “In 1H17 [i.e., first half of 2017], Eli Lilly’s Basaglar generated revenues of around \$132.6 million, compared with \$27.2 million in 1H16. In 2Q17, Basaglar generated revenues of around \$86.6 million, compared with \$16.3 million in 2Q16. In 2Q17, Basaglar witnessed ~88% growth on a QoQ [i.e., quarter-over-quarter] basis.”

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by Diana Manos

OIG ‘Blesses Obvious Conflicts Of Interest’ With New MTM Pilot

A new advisory letter from the HHS Office of Inspector General (OIG) says the federal government is willing to overlook the risk of illegal kickbacks to approve a new medication therapy management (MTM) pilot. One industry insider calls it a dramatic switch from what OIG has allowed for years, possibly indicating a potential change in the agency’s stance.

The proposed program would focus on Medicare Advantage (MA) plan beneficiaries who were admitted to the hospital with one of the five diagnoses that are eligible under the Hospital Readmission Reduction Program, and

allow participating pharmacists to view certain clinical data elements that would help in determining a patient’s eligibility for receiving MTM services under the pilot. One of the program’s goals would be to “gain insight into the degree to which technology that provides MTM pharmacists with real-time access to discharge information can help improve transitions of care and decrease re-hospitalizations,” according to the Dec. 4 letter from Robert DeConti, assistant inspector general for legal affairs with OIG.

The pilot will involve an MA plan, a hospital, an IT vendor and a drug manufacturer. The pharma company would fund the program for up to \$257,000, paid as the project hits milestones including contract signing, deployment of the interface built by the IT vendor, completion of data analytics and completion of the project summary.

OIG Will Not Impose Sanctions

OIG won’t impose administrative sanctions on any of the participating organizations, it said in the letter, despite the fact that the proposed arrangement could generate “prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present.”

“I think it’s sort of interesting in that the OIG has decided that this is the place where it’s going to ‘bless’ the obvious conflicts of interests that exist,” says Jim Notaro, who serves on the Pharmacy Quality Alliance’s MTM Medication Therapy Problem Resolution Measure Development Team and on the National Council for Prescription Drug Programs’ MTM and Pharmacist Clinical Services Task Group.

Notaro, who is also president and founder of Buffalo, N.Y.-based Clinical

Support Services, a medication management software and services company, tells AIS Health that more than 20 years ago, companies like his were paid by pharmaceutical companies to ensure patients were on the right medications following a hospital discharge. That sort of service thrived because many physicians didn't have the infrastructure to track patients who aren't presenting in their offices, he says. OIG eventually stepped in to prohibit such arrangements.

But with this latest advisory letter, OIG is permitting—at least for this pilot—what it has prohibited for the last decade and a half, Notaro says. “In one fell swoop, they have reversed themselves,” he says. The approval of this pilot has begun to “chip away at the edges” of the OIG’s stance that pharmaceutical companies can provide only nominal support or gifts to providers, or in this case, to the hospital.



As drugs become more complex, [pharma firms] will need to package their drugs with the infrastructure that allows patients to optimally use the medication.

“The concept is generally good,” Notaro says of OIG’s decision. “With the right protections in the marketplace, it’s a good thing. As drugs become more complex, [pharma firms] will need to package their drugs with the infrastructure that allows patients to optimally use the medication. Some of this infrastructure might include medication management programs. Many new drugs are really difficult to use. It’s not enough anymore to put them into a bottle and make sure they are pure.”

Pharmaceutical companies “should be allowed to provide some infrastructure, and I think MTM is perfect

infrastructure,” he says. Notaro’s main question, however, is: “what are the parameters that the OIG will set for these types of programs moving forward?”

AMCP Will Manage the Pilot

According to the HHS advisory, an unnamed trade association will manage the pilot, and AIS Health has discovered it is the Academy of Managed Care Pharmacy (AMCP). “We’re actually the association involved in this initiative. But it’s still in the very early stages, so we’re not saying much yet,” Neal Learner, a spokesperson for AMCP, tells AIS Health.

An AMCP background document obtained by AIS Health further explains the arrangement. “AMCP would serve as the Pilot Project’s project manager, and at the Pilot Project’s conclusion, AMCP would analyze the data and author a project summary,” says the document. “If successful, AMCP will also develop a training and implementation toolkit that could be provided to managed-care professionals regarding the benefits of the type of technology used in the Pilot Program and how to implement and effectively use such technologies. The toolkit will be branded with pharmaceutical manufacturer’s name but would be product-neutral (e.g., it might report on the impact that the Pilot Program had on drug utilization at the drug class level, such as ‘anticoagulant’ or ‘benzodiazepine,’ but not at the individual drug level).”

Although the advisory opinion indicates the collaborators have not yet identified an insurer partner, they intend to select an MA prescription drug plan with enough beneficiaries with the five diagnoses to enable the pilot to evaluate at least 200 patients.

“I think that in this case, AMCP is playing the role of ‘honest broker,’”

Notaro says. “This type of pilot provides a template for pharma-supported MTM and possibly for value-based contracts.”

According to AMCP, the trade association will “engage, align, and manage the various contracts between the collaborators.” The Medicare Advantage plan and the hospital will enter into a contract with AMCP to fulfill their obligations under the pilot. Also, collaborations, agreements and operative documents under the pilot will have “no direct or indirect bearing on formulary recommendations or referrals of business, nor would it be intended to induce or reward a purchase, recommendation, or prescribing decision in favor of any of pharmaceutical manufacturer’s products.”

Read the OIG letter at <http://bit.ly/2ysjAdl>. Contact AMCP via Neal Learner at nlearner@amcp.org and Notaro at jnotaro@csshealth.com. ✦

by Diana Manos

Diplomat Makes Additional Push Into PBM Space With LDI Deal

Just weeks after disclosing plans to enter the PBM industry with the purchase of National Pharmaceutical Services (NPS), specialty pharmacy services provider Diplomat Pharmacy, Inc. said it would double down on its PBM presence with plans to purchase Leehar Distributors, LLC, doing business as LDI Integrated Pharmacy Services.

Diplomat said it will pay \$515 million cash and approximately \$80 million in common stock for LDI, whose expected 2017 revenue is \$388 million. When Diplomat unveiled the deal Nov. 15, it said that it expected the acquisition to close within 30 to 60 days. Based in St. Louis, LDI has