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First biosimilar rapid-acting insulin approved

- **The Food and Drug Administration has approved Merilog (insulin-aspart-szjj), the first rapid-acting insulin biosimilar to Novolog (insulin aspart).**
- **The biosimilar product is expected to be a cost savings for many patients.**

The Food and Drug Administration (FDA) has approved insulin-aspart-szjj (Merilog), the first rapid-acting insulin biosimilar to insulin aspart (Novolog). Merilog is approved in two forms, a 3-mL prefilled pen and a 10-mL multidose vial, to improve glycemic control in adults and pediatric patients with diabetes. Like Novolog, Merilog should be administered subcutaneously five to 10 minutes prior to a meal.

A biosimilar product is a biological product that has been compared to an FDA-approved biologic (referred to as the reference product) and found to have no clinically meaningful differences from the reference product in terms of safety, purity, and potency.

A 30-day supply of Merilog is expected to be sold for $35 or less for all patients, no matter their income or insurance coverage. Novolog's price points include $139.71 for FlexPen, $72.34 for a 10-mL vial, and $134.37 for a PenFill Cartridge, although patients with insurance whose coverage includes NovoLog may pay as little as $35 for a 30-day supply.[1] Thus, Merilog should be a cost savings for most patients.

Merilog is the third approved biosimilar insulin. There are two biosimilars for insulin glargine (Lantus): insulin glargine-aglr (Rezvoglar, approved in December 2021) and insulin glargine-yfgn (Semglee, approved in July 2021).[1]

Nurses should expect to start seeing prescriptions for Merilog as early as this summer and should be prepared to answer questions about this biosimilar product. NPs may wish to consider switching patients to Merilog if they have difficulty paying for Novolog; more affordability should promote adherence to treatment.

For complete prescribing information for Merilog, see www.accessdata.fda.gov/drugsatfda_docs/label/2025/761325Orig1s000lbl.pdf.

REFERENCE

1. Myshko, D. Formulary Watch. FDA approves first biosimilar of Novolog. *Managed Healthcare Executive*. February 19, 2025. https://www.managedhealthcareexecutive.com/view/fda-approves-first-biosimilar-of-novolog

DOI-10.1097/AJN.0000000000000093

Subcutaneous infusions treat "off" periods in Parkinson disease

- **A newly approved pump, Onapgo, provides constant infusion of apomorphine to reduce the "off" periods in Parkinson disease.**
- **Another recently approved pump, Vyalev, provides constant subcutaneous infusion of carbidopa/levodopa.**

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According to the Michael J. Fox Foundation for Parkinson's Research, nearly 1 million people in the United States have Parkinson disease, a chronic, progressive, neurologic movement disorder in which less dopamine is produced, leading to resting tremor, slowness (bradykinesia), muscle stiffness, and walking and balance difficulties. Other non–movement-related symptoms of Parkinson disease, such as constipation, depression, anxiety, fatigue, and memory problems, are also related to dopamine deficiency.

Dopamine is a neurotransmitter made in brain cells that works primarily in the central nervous system to coordinate and create smooth movement. In the brain, it also provides pleasurable reward and motivation and feelings of happiness, alertness, and focus. Acetylcholine promotes muscle contraction throughout the body, including the heart and motor fibers (when it stimulates the peripheral nervous system) and aids memory and cognition (when it stimulates the central nervous system). Acetylcholine is an excitatory neurotransmitter, while dopamine can be either an excitatory or inhibitory neurotransmitter. Dopamine and acetylcholine are normally in balance in order to appropriately stimulate the nervous system.

Treatment of Parkinson disease focuses on decreasing the effects of acetylcholine or increasing the amount of dopamine to rebalance the two neurotransmitters. One problem with drug therapy, however, is that patients can experience "off" times, when the therapy does not control the symptoms of Parkinson disease or there are motor fluctuations (changes in the ability to move). Both motor and nonmotor symptoms of Parkinson disease can be affected during "off" times, which often happens when circulating drug levels are low, such as just before a dose of medication is due.

The Food and Drug Administration (FDA) has now approved a pump to provide continuous subcutaneous infusions of the previously approved drug apomorphine hydrochloride (Apokyn). Apomorphine is a dopaminergic agonist approved in 2004 for intermittent subcutaneous dosing. The trade name for the continuous infusion is Onapgo. The drug is not related to morphine and is not a controlled substance. Approval was based on results of a randomized, double-blind, placebo-controlled clinical trial. Those who received the drug had nearly two hours less of "off" time than those who received placebo.

The most common adverse effects of Onapgo include infusion site nodules, nausea, somnolence, infusion site erythema, dyskinesia, headache, and insomnia.

Nurses should be aware that premedicating can minimize the risk of nausea and vomiting from Onapgo, which can be severe. The labeling states that generic oral trimethobenzamide can be given three days prior to the initial dose of Onapgo. Trimethobenzamide should only be used while symptoms last and should not exceed two months' duration. Trimethobenzamide increases the risk of somnolence, dizziness, and falls. Alternatively, Onapgo therapy can be started without antiemetics, at a low infusion rate and titrated upward as tolerated. Nurses should avoid administering serotonin antagonist antiemetics, such as ondansetron, as they may induce drug reactions to Onapgo, including profound hypotension and loss of consciousness.

Nurses and NPs should study the Onapgo infusion set and pump kit directions (see www.onapgo.com/onapgo_IFU.pdf). Patients should be provided with instructions on how to insert the cannula and connect the infusion set. Patients must insert the cannula into the subcutaneous space, never into a vein, as this route can cause thrombus formation or pulmonary embolism. The infusion site should be changed daily, and a new infusion set should be used to prevent infections.

For complete prescribing information for Onapgo, see www.accessdata.fda.gov/drugsatfda_docs/label/2025/214056s000lbl.pdf.

The FDA also approved Vyalev, a drug and pump to treat motor fluctuations from Parkinson disease that delivers a continuous infusion of levodopa and carbidopa. Levodopa converts to dopamine in the brain. Carbidopa prevents levodopa from being broken down in the peripheries and reaching the brain. The combination of levodopa and carbidopa has been used to treat Parkinson disease since 1975. A clinical trial of Vyalev found that patients with advanced Parkinson disease treated with subcutaneous infusions had about three more hours daily of "on" time compared with patients taking the medication orally.

For complete prescribing information for Vyalev, see www.accessdata.fda.gov/drugsatfda_docs/label/2024/216962s000lbl.pdf.

DOI-10.1097/AJN.0000000000000093a

New sodium channel blocker for moderate to severe acute pain

- **The Food and Drug Administration has approved suzetrigine (Journeaux), a sodium channel blocker and nonopioid, to treat moderate to severe acute pain. It is not believed to be addictive.**
- **Drug interactions through the cytochrome P-450 (CYP) isoenzyme CYP3A are possible, as is interference with some hormonal birth control. Nurses should use a drug database to confirm that other prescribed therapy will not interact with suzetrigine.**

The Food and Drug Administration has approved suzetrigine (Journeaux), a nonopioid, to treat moderate to severe acute pain. Suzetrigine is part of a new class of drugs called sodium channel blockers. It selectively blocks sodium voltage-gate channel 1.8 ($Na_V1.8$), found in peripheral sensory neurons, including the dorsal root ganglia neurons. By blocking $Na_V1.8$, the transmission of pain signals (action potentials) is inhibited. By blocking pain signals only in the periphery, suzetrigine works differently from opioids, which work in the brain. Oral suzetrigine is believed to be nonaddictive.[1]

Suzetrigine's efficacy was determined in two randomized, double-blind, placebo- and active-controlled trials of patients with acute postsurgical pain, one after abdominoplasty and the other after bunionectomy. Both trials found suzetrigine's pain-relieving effects to be statistically significantly superior to placebo.

Suzetrigine's most common adverse effects are itching, muscle spasms, increased blood levels of creatine phosphokinase (CPK), and rash. Although some trial participants' CPK levels rose to more than three times the upper limit of normal, there were no associated liver problems or serious adverse effects, and no patients had to stop treatment.

Suzetrigine has several potential drug interactions. Suzetrigine is metabolized by the cytochrome P-450 (CYP) isoenzyme CYP3A. Strong and moderate CYP3A inhibitors increase the circulating levels of suzetrigine and its active metabolite, thus increasing the risk of adverse effects. Therefore, concomitant use of suzetrigine with strong CYP3A inhibitors is contraindicated. If using suzetrigine with moderate CYP3A inhibitors, the dose of suzetrigine should be reduced. Grapefruit juice inhibits CYP3A, so it should be avoided while taking suzetrigine. Conversely, suzetrigine is an inducer of CYP3A and may lead to lower blood levels and loss of effectiveness of the substrate drug. Some hormonal birth control is less effective while on suzetrigine and using a nonhormonal form of birth control should be recommended.

Nurses and NPs should use a drug database to confirm that other prescribed therapies are not CYP3A inhibitors or substrates, or if a loss of effectiveness from birth control is expected.

Nurses should confirm that the patient has normal hepatic function prior to starting suzetrigine. If the patient has severe hepatic impairment, suzetrigine should not be used. Moderate hepatic impairment increases the risk of adverse effects from suzetrigine and requires a lower dose.

Nurses should instruct patients to take the first dose of suzetrigine on an empty stomach, as food decreases the initial concentration of the drug and its onset of action. The remaining doses can be taken with or without food. After the loading dose, doses 2, 3, and 4 are taken every 12 hours. Doses 5 and beyond are taken every 24 hours.

For complete prescribing information for suzetrigine, see www.accessdata.fda.gov/drugsatfda_docs/label/2025/219209Orig1s000lbl.pdf. ▼

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DOI-10.1097/AJN.0000000000000093b