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IN BRIEF

Merilog — A NovoLog Biosimilar

The FDA has approved *Merilog* (Sanofi), a biosimilar to rapid-acting insulin aspart (*NovoLog*), for treatment of patients with type 1 or type 2 diabetes. *Merilog* is the first rapid-acting insulin biosimilar product to become available in the US.

Pronunciation Key

Merilog: mer ih lawg

REGULATORY STATUS — A biosimilar is a biologic product that is highly similar in composition, strength, and biological properties and has no clinically meaningful differences in safety, purity, and potency to the FDA-approved reference product. Although *Merilog* has been designated as a biosimilar to the reference product *NovoLog*, it has not received interchangeability status from the FDA. *Merilog* cannot be substituted as a lower-cost alternative to *NovoLog* by the pharmacist without permission from the prescriber.

CLINICAL STUDIES — FDA approval of *Merilog* was based on the results of an open-label trial (GEMELLI 1) in 597 patients with type 1 or type 2 diabetes. Patients were randomized to receive mealtime *Merilog* or *NovoLog*, each in addition to long-acting insulin glargine (*Lantus*). The mean decrease in A1C levels from baseline to 26 weeks with *Merilog* was noninferior

to that with *NovoLog* (−0.38% with *Merilog* vs −0.30% with *NovoLog*). Fasting plasma glucose, postprandial glucose excursions, and adverse effects were also similar between the two groups.¹

DOSAGE AND ADMINISTRATION — Like *NovoLog*, *Merilog* is supplied in 3-mL prefilled pens and 10-mL multidose vials containing 100 units/mL of insulin aspart. The drug should be administered subcutaneously into the abdomen, thigh, buttocks, or upper arm 5-10 minutes before a meal. The injection site should be rotated to minimize the risk of lipodystrophy and cutaneous amyloidosis.

COST — The wholesale acquisition cost (WAC) for one *Merilog* 3-mL pen is \$26.90 and for one 10-mL vial is \$69.60; the cost for one *NovoLog* 3-mL pen is \$27.90 and for one 10-mL vial is \$72.30.² The Medicare Part D negotiated rate for a 30-day supply of *NovoLog* is \$119. ■

1. SK Garg et al. Efficacy and safety of insulin aspart biosimilar SAR341402 versus originator insulin aspart in people with diabetes treated for 26 weeks with multiple daily injections in combination with insulin glargine: a randomized open-label trial (GEMELLI 1). *Diabetes Technol Ther* 2020; 22:85.
2. Approximate WAC. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. June 5, 2025. Reprinted with permission by First Databank, Inc. All rights reserved. ©2025. www.fdbhealth.com/policies/drug-pricing-policy.

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