

Lyumjev™ (insulin lispro-aabc) – New drug approval

- On June 15, 2020, [Eli Lilly announced](#) the FDA approval of [Lyumjev \(insulin lispro-aabc\)](#), to improve glycemic control in adults with diabetes mellitus.
- Lyumjev is a novel formulation of insulin lispro, developed to speed the absorption of insulin into the blood stream. Insulin lispro is also available as brand [Humalog®](#) and [Admelog®](#) as well as an [authorized brand alternative \(ABA\)](#) to Humalog.
 - Humalog and the ABA are indicated to improve glycemic control in adults and children with diabetes mellitus.
 - Admelog is indicated to improve glycemic control in adults and pediatric patients 3 years and older with type 1 diabetes mellitus and adults with type 2 diabetes mellitus.
- The efficacy of Lyumjev was established in two, 26-week, randomized, active controlled, treat-to-target studies in adult patients. PRONTO-T1D was a study in 1,222 patients with type 1 diabetes. Patients were randomized to either blinded mealtime Lyumjev, blinded mealtime Humalog, or open-label postmeal Lyumjev, all in combination with a basal insulin.
 - At week 26, treatment with mealtime Lyumjev provided a mean reduction in hemoglobin A1c (HbA1c) that met the pre-specified noninferiority margin (0.4%) vs. mealtime Humalog (treatment difference: -0.08; 95% CI: -0.16, 0.00).
 - In addition, postmeal Lyumjev met the prespecified non-inferiority margin (0.4%) vs. mealtime Humalog (treatment difference: 0.14; 95% CI: 0.05, 0.22).
 - Insulin doses were similar in all treatment groups at baseline and at 26 weeks.
- PRONTO-T2D was a study in 673 patients with type 2 diabetes who at study entry were on up to three oral antidiabetic medications, basal insulin and at least one prandial insulin injection or premixed insulin with at least two injections daily. Patients were allowed to continue on metformin and/or a sodium glucose co-transporter 2 (SGLT2) inhibitor and were randomized to either mealtime Lyumjev or to mealtime Humalog, both in combination with a basal insulin.
 - At week 26, treatment with mealtime Lyumjev provided a mean reduction of HbA1c from baseline that met the prespecified non-inferiority margin (0.4%) vs. mealtime Humalog (treatment difference; 0.03; 95% CI: -0.08, 0.13).
 - Insulin doses were similar in both treatment groups at baseline and at 26 weeks.
- Lyumjev is contraindicated during episodes of hypoglycemia and in patients with hypersensitivity to insulin lispro-aabc or one of the excipients in Lyumjev.
- Warnings and precautions for Lyumjev include never share a Lyumjev prefilled pen, cartridge, or syringe between patients; hyperglycemia or hypoglycemia with changes in insulin regimen; hypoglycemia; hypoglycemia due to medical errors; hypokalemia; hypersensitivity and allergic reactions; and fluid retention and heart failure with concomitant use of peroxisome proliferator-activated receptor (PPAR)-gamma agonists.
- The most common adverse reactions with Lyumjev use were hypoglycemia, injection site reactions, allergic reactions, rash, pruritus, lipodystrophy, and weight gain.
- The recommended dose of Lyumjev should be individualized and adjusted based on the patient's metabolic needs, glucose monitoring results, and glycemic control goal.

- For subcutaneous injection, Lyumjev should be administered at the start of a meal or within 20 minutes after starting a meal subcutaneously into the abdomen, upper arm, thigh, or buttocks.
 - For intravenous injection (U-100 formulation only), Lyumjev should be administered only under medical supervision with close monitoring of glucose and potassium levels to avoid hypoglycemia and hypokalemia.
 - Refer to the Lyumjev drug label for additional dosing and administration recommendations.
- The list price of Lyumjev will be the same as the list price for Humalog.
 - Eli Lilly's launch plans for Lyumjev are pending. Lyumjev 100 units/mL (U-100) will be available as:
 - 10 mL multiple-dose vial
 - 3 mL single-patient-use KwikPen[®]
 - 3 mL single-patient-use Junior KwikPen[®]
 - 3 mL single-patient-use Tempo Pen[™]
 - 3 mL single-patient-use cartridges
 - Lyumjev will also be available as a 200 units/mL (U-200) 3 mL single-patient-use KwikPen[®].



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