

Lyumjev[®] (insulin lispro-aabc) – Expanded indication

- On October 14, 2022, the [FDA approved](#) Eli Lilly's [Lyumjev \(insulin lispro-aabc\)](#), to improve glycemic control in adult and pediatric patients with diabetes mellitus.
 - Lyumjev was previously approved for this indication in adults only.
- The approval of Lyumjev for the expanded indication was based on PRONTO-Peds, a 26-week, randomized, active controlled, treat-to-target study in 716 pediatric patients with type 1 diabetes. Patients were randomized to either blinded mealtime Lyumjev, blinded mealtime Humalog, or open-label post-meal Lyumjev, all in combination with basal insulin. Mealtime Lyumjev or Humalog was injected 0 to 2 minutes before the meal and post-meal Lyumjev was injected within 20 minutes after the start of the meal.
 - At week 26, treatment with mealtime Lyumjev provided a mean change in HbA1c that met the pre-specified noninferiority margin (0.4%). In addition, post-meal Lyumjev met the prespecified non-inferiority margin (0.4%) compared to mealtime Humalog.
- Refer to the Lyumjev drug label for complete dosing information in adult and pediatric patients.