Fiasp® (insulin aspart) – New drug approval

- On September 29, 2017, Novo Nordisk announced the FDA approval of Fiasp (insulin aspart) to improve glycemic control in adults with diabetes mellitus.

- Fiasp is a fast-acting mealtime insulin and a new formulation of NovoLog® (insulin aspart), in which the addition of niacinamide helps to increase the speed of the initial insulin absorption, resulting in an onset of appearance in the blood in approximately 2.5 minutes.

- The efficacy of Fiasp was evaluated in three active-controlled trials involving 1,224 adults with type 1 (T1DM) and type 2 diabetes (T2DM).

    - In T1DM patients, mealtime Fiasp and post-meal Fiasp led to non-inferior glycemic control compared to mealtime NovoLog, both in combination with insulin detemir.
    - In T2DM patients, mealtime Fiasp provided non-inferior glycemic control compared to mealtime NovoLog, both in combination with metformin.
    - In addition, in T2DM patients, mealtime Fiasp in a basal-bolus regimen with metformin also provided statistically significant improvement in the overall glycemic control compared to basal insulin therapy alone with metformin.

- Fiasp is contraindicated during episodes of hypoglycemia and in patients with known hypersensitivity to insulin aspart or one of the excipients in Fiasp.

- Warnings and precautions of Fiasp include never share a Fiasp FlexTouch pen between patients, hyperglycemia or hypoglycemia with changes in insulin regimen, hypoglycemia, hypoglycemia due to medication errors, hypokalemia, hypersensitivity and allergic reactions, and fluid retention and heart failure with concomitant use of PPAR-gamma agonists.

- Adverse reactions with Fiasp use include hypoglycemia, allergic reactions, hypersensitivity, injection site reactions, lipodystrophy, and weight gain.

- The dose of Fiasp should be individualized and adjusted based on the patient's route of administration, individual metabolic needs, blood glucose monitoring results, and glycemic control goal.

    - When administered subcutaneously, Fiasp should be injected at the start of a meal or within 20 minutes after starting a meal into the abdomen, upper arm or thigh. Fiasp should generally be used in regimens with an intermediate- or long-acting insulin.
    - Administration of Fiasp by intravenous infusion should only be given under medical supervision after diluting to a concentration from 0.5 to 1 unit/mL insulin aspart in infusion systems using polypropylene infusion bags.

- Fiasp will launch at the same list price as NovoLog and will be offered with a Savings Card program for eligible patients with commercial insurance in order to reduce co-payments. Fiasp will also be available to eligible patients through the Novo Nordisk Patient Assistance Program.

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- Novo Nordisk's launch plans for Fiasp are pending. Fiasp will be available as a multi-dose vial and a single-patient-use FlexTouch® pen containing 100 units/mL.