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# Insulin Prior Authorization Program Summary

**FDA LABELED INDICATIONS[1-13,16-24]**

| Agent(s) | Indication(s) | Onset | Peak | Duration |
|---|---|---|---|---|
| **Rapid-Acting Insulins** | | | | |
| Admelog (insulin lispro) | 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 | 15-30 min | 2 hours | Up to 7 hours |
| Apidra (insulin glulisine) | To improve glycemic control in adults and pediatric patients with diabetes mellitus | 10 to 20 min | 30-90 min | 2 to 4 hours |
| Fiasp (insulin aspart) | To improve glycemic control in adult and pediatric patients with diabetes mellitus | 15 to 20 min | 50 to 70 min | ~5 hours |
| Humalog, Humalog Junior, Insulin Lispro, Insulin Lispro Junior | To improve glycemic control in adults and children with diabetes mellitus | 10-20 min | 30-90 min | 3 to 5 hours |
| Lyumjev (insulin lispro-aabc) | To improve glycemic control in adults with diabetes mellitus | 17 min | 120-174 min | 4.6-7.3 hours |
| NovoLog, Insulin Aspart | To improve glycemic control in adults and children with diabetes mellitus | 10 to 20 min | 40 to 50 min | 3 to 5 hours |
| **Short-Acting Insulins** | | | | |
| Humulin R | To improve glycemic control in adult and pediatric patients with diabetes mellitus | 30 to 60 min | 2 to 4 hours | 5 to 8 hours |
| Novolin R[a], ReliOn R[a] | | 30 min | 1.3 to 2 hours | Up to 8 hours |

a – Manufacturer recommends Novolin R should not be used in external insulin pumps due to risk of precipitation

| Intermediate-Acting Insulins | Indication | Onset | Peak | Duration |
|---|---|---|---|---|
| Humulin N | To improve glycemic control in adult and pediatric patients with diabetes mellitus | 1 to 3 hours | 8 hours | Up to 24 hours |
| Novolin N | | 1.5 hours | 4 to 12 hours | Up to 24 hours |
| **Long-Acting Insulins** | | | | |
| Basaglar | To improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus | 1 hour | NA | 24 hours |
| Lantus | To improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus | 1 hour | NA | 24 hours |
| Levemir | To improve glycemic control in adults and pediatric patients with diabetes mellitus | 1.6 hours | NA | Up to 24 hours |
| Semglee | To improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus | 1 hour | NA | 24 hours |
| Toujeo, Toujeo Max | To improve glycemic control in adults and pediatric patients 6 years and older with diabetes mellitus | 6 hours | NA | 24 hours |
| Tresiba | To improve glycemic control in patients 1 year of age and older with diabetes mellitus | 1 hour | NA | At least 42 hours |
| **NPH-Regular Combinations** | | | | |
| Humulin 70/30 | To improve glycemic control in adult patients with diabetes mellitus | 30 to 60 min | Varies | 12 to 16 hours |
| Novolin 70/30, insulin aspart protamine/insulin aspart | To improve glycemic control in adults and pediatric patients with diabetes mellitus | 30 min | 4.2 hours | Up to 24 hours |
| **NPH-Lispro Combinations** | | | | |
| Humalog Mix 75/25, Insulin Lispro Protamine/Insulin Lispro (75/25) | To improve glycemic control in patients with diabetes mellitus | 10 to 15 min | Varies | 16 to 22 hours |
| Humalog Mix 50/50 | | 10 to 15 min | Varies | 16 to 22 hours |
| **NPH – NovoLog Combination** | | | | |
| NovoLog Mix 70/30, Insulin aspart protamine/insulin aspart | To improve glycemic control in patients with diabetes mellitus | 10 to 20 min | 2.4 hours | Up to 24 hours |

**DOSING AND ADMINISTRATION**
Dosing must be individualized. Total daily insulin requirements for type 1 patients can be estimated based on weight, with typical doses ranging from 0.4 to 1.0 units/kg/day. A typical starting dose for patients with type 1 diabetes who are metabolically stable is 0.5 units/kg/day, with half administered as prandial insulin and the other half as basal insulin. Type 2 diabetics usually have insulin started as an addition to a current regimen of other antidiabetic agents. Basal insulin is usually selected first over prandial insulin. Starting doses can be estimated based on body weight (0.1-0.2 units/kg/day) and the degree of hyperglycemia, with individualized titration over days to weeks as needed. Individuals with type 2 diabetes may require prandial insulin in addition to basal insulin. The recommended starting dose of prandial insulin is either 4 units or 10% of the basal dose at the largest meal or the meal with the greatest postprandial excursion. Titration is based on home glucose monitoring or A1C.[14]

**CLINICAL RATIONALE**
The American Diabetes Association Standards of Medical Care in Diabetes recommend the following therapy for type 1 diabetes mellitus:

- Most people with type 1 diabetes should be treated with multiple daily injections of prandial and basal insulin, or subcutaneous insulin infusion
- Most individuals with type 1 diabetes should use rapid-acting insulin analogs to reduce hypoglycemia risk.
- Patients with type 1 diabetes should be trained to match prandial insulin doses to carbohydrate intake, premeal blood glucose, and anticipated physical activity.[14]

For type 2 diabetes mellitus, the American Diabetes Association recommends the following:

- Metformin is the preferred initial pharmacological agent for type 2 diabetes
- The early introduction of insulin should be considered if there is evidence of ongoing catabolism, if symptoms of hyperglycemia are present, or when A1C levels or blood glucose levels are very high
- A patient-centered approach should be used to guide the choice of pharmacological agents. Considerations include comorbidities, hypoglycemia risk, impact on weight, cost, risk of side effects, and patient preferences.
- In patients who need the greater glucose-lowering effect of an injectable medication than can be obtained with oral agents, glucagon-like peptide 1 (GLP-1) receptor agonists are preferred to insulin when possible.[14]

The American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) algorithm for type 2 diabetics recommends starting insulin therapy if the patient has an A1c > 9% and is having hyperglycemia symptoms. Patients with recent-onset type 2 diabetes or who have mild hyperglycemia (A1c < 7.5%), lifestyle therapy plus antihyperglycemic monotherapy (preferably with metformin) is recommended. Patients who present with an A1c > 7.5% should be started initially on metformin plus another agent, one of which is insulin. Patients taking two oral antihyperglycemic agents who have an A1c > 8 and/or long-standing type 2 diabetes are less likely to reach their target with a third oral antihyperglycemic agent. Although adding a GLP-1 receptor agonist as the third agent may lower hyperglycemia, eventually many patients will still require insulin. When insulin becomes necessary, a single daily dose of basal insulin should be added to the regimen. Dosage should be adjusted at regular and at short intervals to achieve the glycemic goal. Patients whose glycemia remains uncontrolled while receiving basal insulin in combination with oral agents or GLP-1 receptor agonists may require mealtime insulin to cover postprandial hyperglycemia.[15]

**References:**
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3. NovoLog (insulin aspart [rDNA origin] injection) solution for subcutaneous use. Novo Nordisk, Inc. November 2019.
4. Apidra (insulin glulisine [rDNA origin] injection) solution for injection. Sanofi-Aventis. November 2019.
5. Humulin R (insulin human injection [rDNA origin]) solution for subcutaneous injection. Eli Lilly and Company. November 2019.
6. Novolin R (human insulin injection [rDNA origin]). Novo Nordisk, Inc. November 2019.
7. Humulin N (insulin [rDNA origin] isophane suspension). Eli Lilly and Company. November 2019.
8. Novolin N (human insulin isophane suspension injection) suspension. Novo Nordisk. November 2019.
9. Novolin 70/30 (70% NPH, Human Insulin Isophane Suspension and 30% Regular, Human Insulin Injection, [rDNA]). Novo Nordisk. November 2019.
10. Humulin 70/30 (70% human insulin isophane suspension and 30% human insulin injection (rDNA origin). Eli Lilly and Company. November 2019.
11. Humalog Mix 75/25 (75% insulin lispro protamine suspension and 25% insulin lispro injection (rDNA origin). Eli Lilly and Company. November 2019.
12. Humalog Mix 50/50 (50% insulin lispro protamine suspension and 50% insulin lispro injection [rDNA origin]). Eli Lilly and Company. November 2019.
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17. Levemir prescribing information. Novo Nordisk, Inc. March 2020.
18. Toujeo prescribing information. Sanofi-Aventis U.S. LLC. December 2019.
19. Tresiba prescribing information. Novo Nordisk Inc. November 2019.
20. Fiasp prescribing information. Novo Nordisk Inc. December 2019.
21. Admelog prescribing information. Sanofi-Aventis US, LLC. November 2019.
22. Basaglar prescribing information. Eli Lilly and Company. November 2019.
23. Lyumjev prescribing information. Eli Lilly and Company. June 2020.
24. Semglee prescribing information. Mylan Specialty L.P. July 2020.


 

## Insulin Prior Authorization

**PREFERRED AGENTS**
- **Rapid, Regular**
  - **Fiasp®** (insulin aspart)
  - **Novolin R®** (regular human insulin)
  - **NovoLog®** (insulin aspart)
  - **Insulin Aspart**
- **Mix, NPH**
  - **Novolin N®** (human insulin NPH)
  - **Novolin 70/30®** (70% human insulin isophane suspension/30% human insulin)
  - **NovoLog 70/30®** (70% insulin aspart protamine/30% insulin aspart)
  - **Insulin aspart protamine/insulin aspart**

**STAND-ALONE AGENTS**
- **Rapid, Regular**
  - **Relion® R** (regular human insulin)
  - **Humulin® R U500** (regular human insulin concentrated)

**NON-PREFERRED PRIOR AUTHORIZATION TARGET AGENTS**
- **Rapid, Regular**
  - **Admelog®** (insulin lispro)
  - **Apidra®** (insulin glulisine)
  - **Humalog®** (insulin lispro)
  - **Humalog® Junior Kwikpen** (insulin lispro)
  - **Humalog® Kwikpen U200** (insulin lispro)
  - **Humulin® R U-100** (regular human insulin)
  - **Insulin Lispro**
  - **Insulin Lispro Junior Kwikpen**
  - **Insulin Lispro Kwikpen**
  - **Lyumjev™** (insulin lispro-aabc)
- **Mix, NPH**
  - **Insulin Lispro Protamine/Insulin Lispro Kwikpen (75/25)**
  - **Humalog® Mix 75/25™** (75% insulin lispro protamine suspension/25% insulin lispro)
  - **Humalog® Mix 50/50™** (50% insulin lispro protamine suspension/50% insulin lispro)
  - **Humulin® N** (human insulin isophane suspension)
  - **Humulin® 70/30** (70% human insulin isophane suspension/30% human insulin)

| Brand (generic) | GPI | Multisource Code |
|---|---|---|
| **Rapid, Regular** | | |
| **Apidra (insulin glulisine) 100 U/mL** | | |
| 10 mL vial, 3 mL pen/cartridge | 27104004****** | M, N, O, Y |
| **Admelog, Humalog, Humalog Junior Kwikpen (insulin lispro), Insulin Lispro 100 U/mL, Insulin Lispro Junior Kwikpen 100 U/ml, Insulin Lispro Kwikpen 100U/mL** | | |
| 10 mL vial, 3 mL pen/cartridge | 27104005****** | M, N, O, Y |
| **Humalog KwikPen (insulin lispro) 200 U/mL** | | |
| 3 mL pen | 27104005****** | M, N, O, Y |
| **Humulin R, Novolin R, ReliOn R (regular human insulin) 100 U/mL** | | |
| 10 mL vial | 27104010002005 | M, N, O, Y |
| **Humulin R (regular human insulin) 500 U/mL** | | |
| 20 mL vial | 27104010002015 | M, N, O, Y |
| 3 mL pen | 2710401000D250 | M, N, O, Y |

| Brand (generic) | GPI | Multisource Code |
|---|---|---|
| **Lyumjev** (insulin lispro-aabc) **100 U/mL** | | |
| 3 mL/pen, 10 mL vial | 27104005****** | M, N, O, Y |
| **Lyumjev** (insulin lispro-aabc) **200 U/mL** | | |
| 3 mL pen | 27104005****** | M, N, O, Y |
| **Novolin R (regular human insulin) 100 U/mL** | | |
| 3 mL pen | 2710401000D220 | M, N, O, Y |
| **Fiasp, NovoLog, Insulin Aspart 100 U/mL** | | |
| 10 mL vial, 3 mL pen/cartridge | 27104002****** | M, N, O, Y |
| **Mix, NPH** | | |
| **Humalog Mix 75/25 (75% insulin lispro protamine/25% insulin lispro), Insulin Lispro Protamine/Insulin Lispro Kwikpen (75/25) 100 U/mL** | | |
| 10 mL vial, 3 mL pen | 27104080****** | M, N, O, Y |
| **Humalog Mix 50/50 (50% insulin lispro protamine/50% insulin lispro) 100 U/mL** | | |
| 10 mL vial, 3 mL pen | 27104080****** | M, N, O, Y |
| **Humulin N, Novolin N** | | |
| 10 mL vial, 3 mL pen | 27104020****** | M, N, O, Y |
| **Humulin 70/30, Novolin 70/30 (70% human insulin isophane/30% regular human insulin) 100 U/mL** | | |
| 10 mL vial, 3 mL pen | 27104090****** | M, N, O, Y |
| **NovoLog 70/30, insulin aspart protamine/insulin aspart (insulin mixed) 100 U/mL** | | |
| 10 mL vial, 3 mL pen | 27104070****** | M, N, O, Y |

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**

**Non-preferred insulin agents** will be approved when ONE of the following is met:

1. BOTH of the following:
    a. The requested agent is a rapid insulin
    **AND**
    b. There is information that the patient is currently using an insulin pump that has an incompatibility with the preferred rapid insulin agent that is not expected to occur with the requested agent

    **OR**
2. The request is for Humalog Mix 50/50 AND ONE of the following
    a. The patient is currently using Humalog Mix 50/50 AND the prescriber states the patient is at risk if switched to a different insulin
    **OR**
    b. The patient has tried and had an inadequate response to a preferred insulin mix

    **OR**
3. BOTH of the following:
    a. The requested agent is a rapid, regular, mix, or NPH insulin
    **AND**
    b. ONE of the following:
        i. The patient has an intolerance, or hypersensitivity to the preferred insulin agents of the same type (rapid or regular, mix or NPH) that is not expected to occur with the requested agent
        **OR**
        ii. The patient has an FDA labeled contraindication to the preferred insulin agent of the same type (rapid or regular, mix or NPH) that is not expected to occur with the requested agent

    **OR**
4. There is information that the patient has a physical or a mental disability that would prevent him/her from using a preferred insulin agent

**OR**

5. The patient is pregnant

**Length of Approval:** 12 months