

Non-Preferred Insulin Products Drug Use Criteria

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Includes:

Basaglar Kwikpen®	<i>insulin glargine</i>
Humalog®, Humalog Mix Pen®	<i>insulin lispro, insulin lispro protamine/insulin lispro</i>
Humulin/Novolin R, N, 70/30 Pen®	<i>insulin regular, insulin NPH, insulin 70/30</i>
Lantus Solostar®, Lantus®	<i>insulin glargine</i>
Levemir Flextouch®, Levemir®	<i>insulin detemir</i>
Novolog®, NovoLog Mix Pen®	<i>insulin aspart, insulin aspart protamine/insulin aspart</i>
Tresiba®	<i>insulin degludec</i>
Toujeo®	<i>insulin glargine</i>

*Any other insulin pen delivery system and non-preferred insulin will also be included in this drug use criteria.

**Preferred insulins include: Semglee® vials and pens; Admelog® vials and pens: insulin R, N, and 70/30 (vials only)

GUIDELINE FOR USE:

Initial Request:

1. Is the prior authorization request for insulin pens?
 - a. If yes, go to #2
 - b. If no, go to #3
2. Does the member have one of the following: dexterity issues, visual impairment, and/or age less than 18 with Type 1 diabetes?
 - a. If yes, go to #3
 - b. If no, deny as criteria not met. Insulin pen delivery devices are a covered benefit for members with dexterity issues, visual impairment, and children with Type 1 diabetes.
3. Has the member trialed and failed or have a contraindication to a preferred formulary product?
 - a. If yes, approve for 1 year.
 - b. If no, deny as criteria not met. Trial/failure or contraindication to preferred formulary product required.

Rationale:

To promote the least costly insulins as first line therapy. To ensure the use of insulin pen delivery devices for Advanced Health members with dexterity or visual impairment making it unsafe for the

member to use a vial and syringe for insulin administration. Items of convenience are not a covered benefit on the Oregon Health Plan.

FDA Approved Indication:

Admelog® is a rapid-acting human insulin analog 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 safety and effectiveness of Admelog® have not been established in pediatric patients younger than 3 years of age with type 1 diabetes mellitus or in pediatric patients with type 2 diabetes mellitus.*

Basaglar® is a long-acting insulin indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. **The safety and effectiveness of Basaglar® in pediatric patients younger than 6 years of age with type 1 diabetes and pediatric patients with type 2 diabetes has not been established.*

Humalog® is a rapid-acting human insulin analog indicated to improve glycemic control in adults and children with diabetes mellitus. **Humalog® has not been studied in pediatric patients younger than 3 years of age. Humalog® has not been studied in pediatric patients with type 2 diabetes.*

Humulin N® is an intermediate-acting insulin indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus. **Humulin N® has not been studied in pediatric patients.*

Humulin R® is a short-acting human insulin indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus.

Humulin 70/30® is a mixture of human insulin isophane, an intermediate-acting insulin, and human insulin, a short-acting insulin, indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus.

Lantus® is a long-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. **The safety and effectiveness of Lantus® in pediatric patients younger than 6 years of age with type 1 diabetes and pediatric patients with type 2 diabetes have not been established.*

Levemir® is a long-acting human insulin analog indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus. **Levemir® has not been studied in pediatric patients younger than 2 years of age.*

Novolog® is an insulin analog indicated to improve glycemic control in adults and children with diabetes mellitus. **The safety and effectiveness of Novolog® to improve glycemic control have been established in pediatric patients. Use of Novolog® for this indication is supported by evidence from an adequate and well-controlled study in 283 pediatric patients with type 1 diabetes mellitus aged 6 to 18 years and from studies in adults with diabetes mellitus.*

Semglee® is a long-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. **The safety and effectiveness of Semglee® to improve glycemic control in pediatric patients with type 1 diabetes mellitus have been established in pediatric patients. The use of Semglee® for this indication is based*

upon an adequate and well-controlled trial of another insulin glargine product in pediatric patients age 6 to 15 with type 1 diabetes and additional data in adults with type 1 diabetes.

Tresiba® is a long-acting human insulin analog indicated to improve glycemic control in patients 1 year of age and older with diabetes mellitus. **The safety and effectiveness of Tresiba® have not been established in pediatric patients less than 1 year old.*

Toujeo® is a long-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients 6 years and older with diabetes mellitus. **The safety and effectiveness of Toujeo® to improve glycemic control in type 1 and type 2 diabetes mellitus have been established in pediatric patients 6 years of age and older. The safety and effectiveness of Toujeo® have not been established in pediatric patients less than 6 years of age.*

References:

1. Oregon Administration Rule: 410-120-0000(145)(c-d) Definition of Medically Appropriate
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5. *Humulin N® Prescribing Information*. Retrieved April 5, 2021. <http://pi.lilly.com/us/HUMULIN-N-USPI.pdf>. Revised November 2019.
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7. *Humulin 70/30® Prescribing Information*. Retrieved April 5, 2021. <http://pi.lilly.com/us/HUMULIN-7030-USPI.pdf>. Revised November 2019.
8. *Lantus® Prescribing Information*. Retrieved April 5, 2021. <https://products.sanofi.us/lantus/lantus.html>. Revised November 2019.
9. *Levemir® Prescribing Information*. Retrieved April 5, 2021. <https://www.novo-pi.com/levemir.pdf>. Revised March 2020.
10. *Novolog® Prescribing Information*. Retrieved April 5, 2021. https://www.novo-pi.com/novolog_ES.pdf. Revised March 2021.
11. *Semglee® Prescribing Information*. Retrieved April 5, 2021. <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?type=display&setid=970259e5-179a-4116-9d09-f3f8ad052283#section-8.3>. Revised June 2020.
12. *Tresiba® Prescribing Information*. Retrieved April 5, 2021. <https://www.novo-pi.com/tresiba.pdf>. Revised November 2019.
13. *Toujeo® Prescribing Information*. Retrieved April 5, 2021. <https://products.sanofi.us/toujeo/toujeo.pdf>. Revised December 2020.