

Pharmacy Medical Necessity Policy

Insulin Products – Unified Formulary

Policy Number: 9.335

Version Number: 2.1

Version Effective Date: 1/1/2022

Product Applicability		<input type="checkbox"/> All Plan+ Products
Well Sense Health Plan	Boston Medical Center HealthNet Plan	
<input type="checkbox"/> New Hampshire Medicaid	<input checked="" type="checkbox"/> MassHealth ACO	
	<input checked="" type="checkbox"/> MassHealth MCO	
	<input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct	
	<input type="checkbox"/> Senior Care Options	
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit	
	<input type="checkbox"/> Medical Benefit	

Note: Disclaimer and audit information is located at the end of this document.

Policy

Reference Table:

Drugs that require PA	No PA
Rapid-acting insulin	
Admelog [®] (insulin lispro)	Humalog [®] (insulin lispro) † Novolog [®] (insulin aspart) †
Long-acting Insulin	
Basaglar [®] (insulin glargine) Semglee [®] (insulin glargine-yfgn)	Lantus [®] SoloSTAR (insulin glargine) Lantus [®] vial (insulin glargine)

† This is a brand-name drug with an authorized generic available. Requests for brand name formulations with an interchangeable generic should be reviewed for medical necessity.

Approval Criteria:

<p>Admelog® (insulin lispro)</p>	<ol style="list-style-type: none"> 1. Member has a diagnosis of diabetes mellitus; AND 2. Documentation provided noting an inadequate response to at least 90 days of therapy (within a 6-month time period) or adverse reaction with Apidra® (insulin glulisine), insulin lispro, or insulin aspart (<i>Note: History of claims is not sufficient to meet this requirement</i>)
<p>Basaglar® (insulin glargine)</p>	<ol style="list-style-type: none"> 1. Member has a diagnosis of diabetes mellitus; AND 2. Documentation provided noting an inadequate response to at least 90 days of therapy (within a 6-month time period) or adverse reaction with Lantus® SoloSTAR (insulin glargine) prefilled syringe or Lantus® (insulin glargine vial)(<i>Note: History of claims is not sufficient to meet this requirement</i>); AND 3. Documentation provided noting an inadequate response to at least 90 days of therapy (within a 6-month time period) or adverse reaction with Semglee® (insulin glargine-yfgn) prefilled syringe or vial (<i>Note: History of claims is not sufficient to meet this requirement</i>)
<p>Approval Criteria: Semglee® (insulin glargine)</p>	<ol style="list-style-type: none"> 1. Member has a diagnosis of diabetes mellitus; AND 2. Documentation provided noting an inadequate response to at least 90 days of therapy (within a 6-month time period) or adverse reaction with Lantus® SoloSTAR (insulin glargine) prefilled syringe or Lantus® (insulin glargine vial) (<i>Note: History of claims is not sufficient to meet this requirement</i>)
<p>Duration of Authorization:</p>	<p>Prior authorization may be issued for 1 year.</p>

Responsibility and Accountability

Policy History

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	Created policy for MH Partial Unified Formulary	1/1/2021	P&T Committee

Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date	Approved by
1/19/2021	Updated policy to reflect PUF changes as of 10/30/20	1/19/2021	P&T Committee
5/13/2021	Annual policy review, no changes	9/1/2021	P&T Committee
11/24/2021	MH UPPL Update: Brand-preferred listings and criteria for Humalog and Novolog were removed. Authorized generic footnote in reference table was updated to account for requests for brand Humalog or Novolog. Basaglar criteria was updated to require a step through Semglee. Semglee and Lantus generic names were added/updated in reference table and criteria.	1/1/2022	P&T Committee

Next Review Date

5/2022

Other Applicable Policies

References

1. Admelog (insulin lispro) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; November 2019.
2. American Diabetes Association. Standards of Medical Care in Diabetes – 2020. Diabetes Care. 2020 Jan;43(Supplement 1);S1-S212.
3. Apidra (insulin glulisine) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; November 2019.
4. Basaglar (insulin glargine) [prescribing information]. Indianapolis, IN: Eli Lilly; November 2019.
5. Fiasp (insulin aspart) [prescribing information]. Plainsboro, NJ: Novo Nordisk; December 2019.
6. Humalog (insulin lispro) [prescribing information]. Indianapolis, IN: Eli Lilly; November 2019.
7. Humalog 50/50 (insulin lispro protamine/insulin lispro) [prescribing information]. Indianapolis, IN: Eli Lilly; November 2019.
8. Humalog 75/25 (insulin lispro protamine/insulin lispro) [prescribing information]. Indianapolis, IN: Eli Lilly; November 2019.
9. Lantus (insulin glargine) [prescribing information]. Bridgewater, NJ; Sanofi-Aventis; November 2019.

10. Novolog (insulin aspart) [prescribing information]. Plainsboro, NJ: Novo Nordisk; November 2019.
11. Novolog Mix 70/30 (insulin apart protamine/insulin aspart) [prescribing information]. Plainsboro, NJ: Novo Nordisk; November 2019.
12. Semglee (insulin glargine) [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals, Inc; June 2020.

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.