Pharmacy Medical Necessity Guidelines: Insulin Products

Effective: January 1, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Per the American Diabetes Association, basal insulin is the most convenient initial insulin regimen for patients with type 2 diabetes. Basal insulin can be added to metformin as well as other oral antidiabetic agents. Rapid-acting insulin can be added before meals to improve post-prandial glucose levels and reach A1C targets.

Table 1. Coverage of Rapid-Acting and Long-Acting Insulins for Tufts Health Together

Insulin Name	Dosage Forms	Coverage
Rapid-Acting Insulins		
Humalog (insulin lispro)	KwikPen, Junior KwikPen, vial, cartridge	Covered;BP
Novolog (insulin aspart)	FlexPen, FlexTouch, Penfill cartridge, vial	Covered;BP
Admelog (insulin lispro)	SoloStar, vial	PA
Apidra (insulin glulisine)	SoloStar, vial	PA
Fiasp (insulin aspart)	FlexTouch, Penfill cartridge, vial	PA
Rapid-Acting Insulin Mixes		
Humalog Mix 50/50 (insulin lispro protamine/ insulin lispro)	KwikPen, vial	Covered;BP
Humalog Mix 75/25 (insulin lispro protamine/ insulin lispro)	KwikPen, vial	Covered;BP
Novolog Mix 70/30 (insulin aspart protamine/ insulin aspart)	FlexPen, vial	Covered;BP
Long-Acting Insulins		
Basaglar (insulin glargine)	KwikPen	PA
Lantus (insulin glargine)	SoloStar, vial	Covered
Semglee (insulin glargine)	Pen, vial	PA

BP = Brand Preferred; PA = Prior Authorization

COVERAGE GUIDELINES

The plan may authorize coverage of a non-preferred insulin product when the following criteria are met:

Admelog (insulin lispro):

1. The Member has an appropriate diagnosis

AND

2. The Member has an inadequate response to at least 90 days of therapy (within a 6-month time period) or adverse reaction with Apidra (insulin glulisine), Humalog (insulin lispro), or insulin aspart (note: pharmacy claims history is not sufficient to meet this requirement)

Apidra (insulin glulisine), Fiasp (insulin aspart)
1. The Member has an appropriate diagnosis

AND

2. The Member has an inadequate response to at least 90 days of therapy (within a 6-month time period) or adverse reaction to Humalog (insulin lispro) or Novolog (insulin aspart) (note: pharmacy claims history is not sufficient to meet this requirement)

Basaglar (insulin glargine)
1. The member has an appropriate diagnosis

AND

2. The Member had had an inadequate response to at least 90 days of therapy (within a 6-month time period) or adverse reaction with Lantus (insulin glargine) (note: pharmacy claims history is not sufficient to meet this requirement)

Semglee (insulin glargine)
1. The Member has an appropriate diagnosis

AND

2. The Member had an inadequate response to at least 90 days of therapy (within a 6-month period) or adverse reaction with Lantus SoloStar (insulin glargine) prefilled syringe or Lantus vial (note: pharmacy claims history is not sufficient to meet this requirement)

LIMITATIONS
None

CODES
None

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.

APPROVAL HISTORY
November 24, 2020: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.