Insulin Combination Agents (Soliqua, Xultophy) Quantity Limit Program Summary

Quantity limits apply to Medicaid.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
04-01-2024	07-01-2019

FDA APPROVED INDICATIONS AND DOSAGE

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Soliqua 100/33	Insulin Glargine-Lixisenatide Sol Pen-Inj 100-33 Unit-MCG/ML	100-33 UNT-MCG/ML	6	Pens	30	DAYS			
Xultophy 100/3.6	Insulin Degludec-Liraglutide Sol Pen-Inj 100-3.6 Unit-MG/ML	100-3.6 UNIT-MG/ML	5	Pens	30	DAYS			

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Soliqua 100/33	Insulin Glargine-Lixisenatide Sol Pen-Inj 100-33 Unit-MCG/ML	100-33 UNT-MCG/ML	Medicaid
Xultophy 100/3.6	Insulin Degludec-Liraglutide Sol Pen-Inj 100-3.6 Unit-MG/ML	100-3.6 UNIT-MG/ML	Medicaid

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:

Module	Clinical Criteria for Approval
	A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months