BlueCross BlueShield of Illinois
BlueCross BlueShield of Montana
BlueCross BlueShield of New Mexico
BlueCross BlueShield of Oklahoma
BlueCross BlueShield of Texas

Insulin Combination Step Therapy with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date **Date of Origin**
05-01-2024

POLICY AGENT SUMMARY STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Soliqua 100/33	insulin glargine-lixisenatide sol pen-inj	100-33 UNT-MCG/ML	M ; N ; O	N		
Xultophy 100/3.6	insulin degludec-liraglutide sol pen-inj	100-3.6 UNIT-MG/ML	M ; N ; O	N		

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 – STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Soliqua 100/33	insulin glargine-lixisenatide sol pen-inj	100-33 UNT-MCG/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2023 ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024
Xultophy 100/3.6	insulin degludec-liraglutide sol pen-inj	100-3.6 UNIT-MG/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2023 ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024

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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	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2023 ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Xultophy 100/3.6	Insulin Degludec-Liraglutide Sol Pen-Inj 100-3.6 Unit-MG/ML	100-3.6 UNIT-MG/ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2023 ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

TARGET AGENT(S)	PREREQUISITE AGENT(S)
Soliqua Xultophy	Any diabetic agent [i.e., agents containing metformin, agents containing insulin, agents containing DPP-4 inhibitors, agents containing SGLT2 inhibitors, sulfonylureas, dopamine receptor agonists-ergot derivatives (e.g., bromocriptine), d-phenylalanine derivatives, meglitinide analogues, alpha-glucosidase inhibitors, thiazolidinediones, sulfonylurea-thiazolidinedione combinations]

Target Agent(s) will be approved when ONE of the following is met:

1. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR**
2. The prescriber states the patient is currently being treated with a requested agent **AND** the patient is currently stable on the requested agent **OR**
3. The patient has tried and had an inadequate response to a diabetic agent [i.e., agents containing metformin, agents containing insulin, agents containing DPP-4 inhibitors, agents containing SGLT2 inhibitors, sulfonylureas, dopamine receptor agonists-ergot derivatives (e.g., bromocriptine), d-phenylalanine derivatives, meglitinide analogues, alpha-glucosidase inhibitors, thiazolidinediones, sulfonylurea-thiazolidinedione combinations] **OR**
4. A diabetic agent [i.e., agents containing metformin, agents containing insulin, agents containing DPP-4 inhibitors, agents containing SGLT2 inhibitors, sulfonylureas, dopamine receptor agonists-ergot derivatives (e.g., bromocriptine), d-phenylalanine derivatives, meglitinide analogues, alpha-glucosidase inhibitors, thiazolidinediones, sulfonylurea-thiazolidinedione combinations] was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event **OR**
5. The patient has an intolerance or hypersensitivity to a diabetic agent [i.e., agents containing metformin, agents containing insulin, agents containing DPP-4 inhibitors, agents containing SGLT2 inhibitors, sulfonylureas, dopamine receptor agonists-ergot derivatives (e.g., bromocriptine), d-phenylalanine derivatives, meglitinide analogues, alpha-glucosidase inhibitors, thiazolidinediones, sulfonylurea-thiazolidinedione combinations] that is not expected to occur with the requested agent **OR**

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Module	Clinical Criteria for Approval
	6. The patient has an FDA labeled contraindication to ALL diabetic agents [i.e., agents containing metformin, agents containing insulin, agents containing DPP-4 inhibitors, agents containing SGLT2 inhibitors, sulfonylureas, dopamine receptor agonists-ergot derivatives (e.g., bromocriptine), d-phenylalanine derivatives, meglitinide analogues, alpha-glucosidase inhibitors, thiazolidinediones, sulfonylurea-thiazolidinedione combinations] that is not expected to occur with the requested agent **OR** 7. A diabetic agent [i.e., agents containing metformin, agents containing insulin, agents containing DPP-4 inhibitors, agents containing SGLT2 inhibitors, sulfonylureas, dopamine receptor agonists-ergot derivatives (e.g., bromocriptine), d-phenylalanine derivatives, meglitinide analogues, alpha-glucosidase inhibitors, thiazolidinediones, sulfonylurea-thiazolidinedione combinations] is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; **OR** cause a significant barrier to the patient's adherence of care; **OR** worsen a comorbid condition; **OR** decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; **OR** cause an adverse reaction or cause physical or mental harm **OR** 8. A diabetic agent [i.e., agents containing metformin, agents containing insulin, agents containing DPP-4 inhibitors, agents containing SGLT2 inhibitors, sulfonylureas, dopamine receptor agonists-ergot derivatives (e.g., bromocriptine), d-phenylalanine derivatives, meglitinide analogues, alpha-glucosidase inhibitors, thiazolidinediones, sulfonylurea-thiazolidinedione combinations] is not in the best interest of the patient based on medical necessity **OR** 9. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as a diabetic agent [i.e., agents containing metformin, agents containing insulin, agents containing DPP-4 inhibitors, agents containing SGLT2 inhibitors, sulfonylureas, dopamine receptor agonists-ergot derivatives (e.g., bromocriptine), d-phenylalanine derivatives, meglitinide analogues, alpha-glucosidase inhibitors, thiazolidinediones, sulfonylurea-thiazolidinedione combinations] and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event **OR** 10. The requested agent is medically necessary and appropriate for the patient **OR** 11. The patient has a diagnosis of type 2 diabetes with/or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

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: 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

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