

Insulin Pump Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
04-01-2025

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Omnipod 5 dexcom g7g6 int ; Omnipod 5 g7 intro kit (g ; Omnipod 5 libre2 plus g6 ; Omnipod dash intro kit (g ; Omnipod dash pdm kit (gen ; Twiist starter kit	*Insulin Infusion Disposable Pump Kit***		M ; N ; O ; Y	N		
Omnipod 5 dexcom g7g6 pod ; Omnipod 5 g7 pods (gen 5) ; Omnipod 5 libre2 plus g6 ; Omnipod classic pods (gen ; Omnipod dash pods (gen 4)	*insulin infusion disposable pump reservoir***		M ; N ; O ; Y	N		
Ilet insulin infusion kit ; Ilet starter kit - contac ; Ilet starter kit - inset ; Twiist refill kit ; Twiist refill kit/infusio	*insulin infusion pump supplies***		M ; N ; O ; Y	N		
Ilet insulin pump	*insulin infusion pump - device***		M ; N ; O ; Y	N		
Twiist starter kit	*insulin infusion pump - kit***		M ; N ; O ; Y	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
Ilet insulin infusion kit	*insulin infusion pump supplies***		15	Kits	30	DAYS			500500 10015 ; 500500 10115 ; 500500 10215;
Ilet insulin infusion kit	*insulin infusion pump supplies***		20	Kits	30	DAYS			500500 10120;
Ilet insulin infusion kit	*insulin infusion pump supplies***		10	Kits	30	DAYS			500500 10010 ; 500500 10210;

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
Ilet insulin pump	*insulin infusion pump - device***		1	Kit	720	DAYS			50050000101;
Ilet starter kit - contac ; Ilet starter kit - inset	*insulin infusion pump supplies***		1	Kit	720	DAYS			50050000201 ; 50050000301 ; 50050000401;
Omnipod 5 dexcom g7g6 int ; Omnipod 5 g7 intro kit (g ; Omnipod 5 libre2 plus g6 ; Omnipod dash intro kit (g ; Omnipod dash pdm kit (gen ; Omnipod go 10 units/day ; Omnipod go 15 units/day ; Omnipod go 20 units/day ; Omnipod go 25 units/day ; Omnipod go 30 units/day ; Omnipod go 35 units/day ; Omnipod go 40 units/day ; V-go 20 ; V-go 30 ; V-go 40	*insulin infusion disposable pump kit ; *insulin infusion disposable pump kit***	10 UNIT/24 HR ; 15 UNIT/24 HR ; 20 UNIT/24 HR ; 25 UNIT/24 HR ; 30 UNIT/24 HR ; 35 UNIT/24 HR ; 40 UNIT/24 HR	1	Pump	720	DAYS			
Omnipod 5 dexcom g7g6 int ; Omnipod 5 g7 intro kit (g ; Omnipod 5 libre2 plus g6 ; Omnipod dash intro kit (g ; Omnipod dash pdm kit (gen ; Twiist starter kit	*Insulin Infusion Disposable Pump Kit***		1	Kit	720	DAYS			
Omnipod 5 dexcom g7g6 pod ; Omnipod 5 g7 pods (gen 5) ; Omnipod 5 libre2 plus g6 ; Omnipod classic pods (gen ; Omnipod dash pods (gen 4)	*Insulin Infusion Disposable Pump Supplies***		30	Pods	30	DAYS			
Twiist refill kit	*insulin infusion pump supplies***		1	Kit	30	DAYS			
Twiist refill kit/infusio	*insulin infusion pump supplies***		1	Kit	30	DAYS			
Twiist starter kit	*insulin infusion pump - kit***		1	Kit	720	DAYS			98617010100

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Ilet insulin infusion kit ; Ilet starter kit - contac ; Ilet starter kit - inset ; Twiist refill kit ; Twiist refill kit/infusio	*insulin infusion pump supplies***		Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Ilet insulin pump	*insulin infusion pump - device***		Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Omnipod 5 dexcom g7g6 int ; Omnipod 5 g7 intro kit (g ; Omnipod 5 libre2 plus g6 ; Omnipod dash intro kit (g ; Omnipod dash pdm kit (gen ; Omnipod go 10 units/day ; Omnipod go 15 units/day ; Omnipod go 20 units/day ; Omnipod go 25 units/day ; Omnipod go 30 units/day ; Omnipod go 35 units/day ; Omnipod go 40 units/day ; V-go 20 ; V-go 30 ; V-go 40	*insulin infusion disposable pump kit ; *insulin infusion disposable pump kit***	10 UNIT/24HR ; 15 UNIT/24HR ; 20 UNIT/24HR ; 25 UNIT/24HR ; 30 UNIT/24HR ; 35 UNIT/24HR ; 40 UNIT/24HR	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Omnipod 5 dexcom g7g6 int ; Omnipod 5 g7 intro kit (g ; Omnipod 5 libre2 plus g6 ; Omnipod dash intro kit (g ; Omnipod dash pdm kit (gen ; Twiist starter kit	*Insulin Infusion Disposable Pump Kit***		Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Omnipod 5 dexcom g7g6 pod ; Omnipod 5 g7 pods (gen 5) ; Omnipod 5 libre2 plus g6 ; Omnipod classic pods (gen ; Omnipod dash pods (gen 4)	*insulin infusion disposable pump reservoir***		Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Twiist starter kit	*insulin infusion pump - kit***		Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Ilet insulin infusion kit	*insulin infusion pump supplies***		Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Ilet insulin infusion kit	*insulin infusion pump supplies***		Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Ilet insulin infusion kit	*insulin infusion pump supplies***		Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Ilet insulin pump	*insulin infusion pump - device***		Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Select Biosimilar ; Whole Foods
Ilet starter kit - contac ; Ilet starter kit - inset	*insulin infusion pump supplies***		Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Omnipod 5 dexcom g7g6 int ; Omnipod 5 g7 intro kit (g ; Omnipod 5 libre2 plus g6 ; Omnipod dash intro kit (g ; Omnipod dash pdm kit (gen ; Omnipod go 10 units/day ; Omnipod go 15 units/day ; Omnipod go 20 units/day ; Omnipod go 25 units/day ; Omnipod go 30 units/day ; Omnipod go 35 units/day ; Omnipod go 40 units/day ; V-go 20 ; V-go 30 ; V-go 40	*insulin infusion disposable pump kit ; *insulin infusion disposable pump kit***	10 UNIT/24HR ; 15 UNIT/24HR ; 20 UNIT/24HR ; 25 UNIT/24HR ; 30 UNIT/24HR ; 35 UNIT/24HR ; 40 UNIT/24HR	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Omnipod 5 dexcom g7g6 int ; Omnipod 5 g7 intro kit (g ; Omnipod 5 libre2 plus g6 ; Omnipod dash intro kit (g ; Omnipod dash pdm kit (gen ; Twiist starter kit	*Insulin Infusion Disposable Pump Kit***		Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Omnipod 5 dexcom g7g6 pod ; Omnipod 5 g7 pods (gen 5) ; Omnipod 5 libre2 plus g6 ; Omnipod classic pods (gen ; Omnipod dash pods (gen 4)	*Insulin Infusion Disposable Pump Supplies***		Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Twiist refill kit	*insulin infusion pump supplies***		Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Twist refill kit/infusio	*insulin infusion pump supplies***		Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Twist starter kit	*insulin infusion pump - kit***		Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Target Agent(s) will be approved when BOTH of the following are met:</p> <ol style="list-style-type: none"> ONE of the following: <ol style="list-style-type: none"> The patient has been using the requested product within the past 90 days AND is at risk if therapy is changed OR The patient currently has an insulin pump (e.g. Omnipod Eros, Minimed, Guardian) but it is not functioning properly AND is past warranty OR ALL of the following: <ol style="list-style-type: none"> The patient has diabetes mellitus AND requires insulin therapy AND BOTH of the following: <ol style="list-style-type: none"> The patient is on an insulin regimen of 3 or more injections per day AND The patient performs 4 or more blood glucose tests per day or is using Continuous Glucose Monitoring (CGM) AND The patient has completed a comprehensive diabetes education program AND The patient has demonstrated willingness and ability to play an active role in diabetes self-management AND The patient has had ONE of the following while compliant on an optimized multiple daily insulin injection regimen: <ol style="list-style-type: none"> Glycosylated hemoglobin level (HbA1C) greater than 7% OR History of recurring hypoglycemia OR Wide fluctuations in blood glucose before mealtime OR Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL OR History of severe glycemic excursions AND

Module	Clinical Criteria for Approval
	<p>2. ONE of the following:</p> <ul style="list-style-type: none"> A. The patient's age is within the manufacturer recommendations for the requested indication for the requested product OR B. There is support for using the requested product for the patient's age <p>Length of Approval: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p>The requested agent will also be approved when the following are met:</p> <ul style="list-style-type: none"> 1. The member resides in Ohio AND 2. The plan is Fully Insured or HIM Shop (SG) AND BOTH of the following <ul style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. ONE of the following: <ul style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Quantity limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> A. BOTH of the following: <ul style="list-style-type: none"> 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication OR B. BOTH of the following: <ul style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND

Module	Clinical Criteria for Approval
	<div data-bbox="354 178 1421 409"> <ul style="list-style-type: none"> 2. There is support for 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: <ul style="list-style-type: none"> 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication </div> <div data-bbox="233 447 636 480"> <p>Length of Approval: 12 months</p> </div>