omnipod® 5
automated insulin delivery system

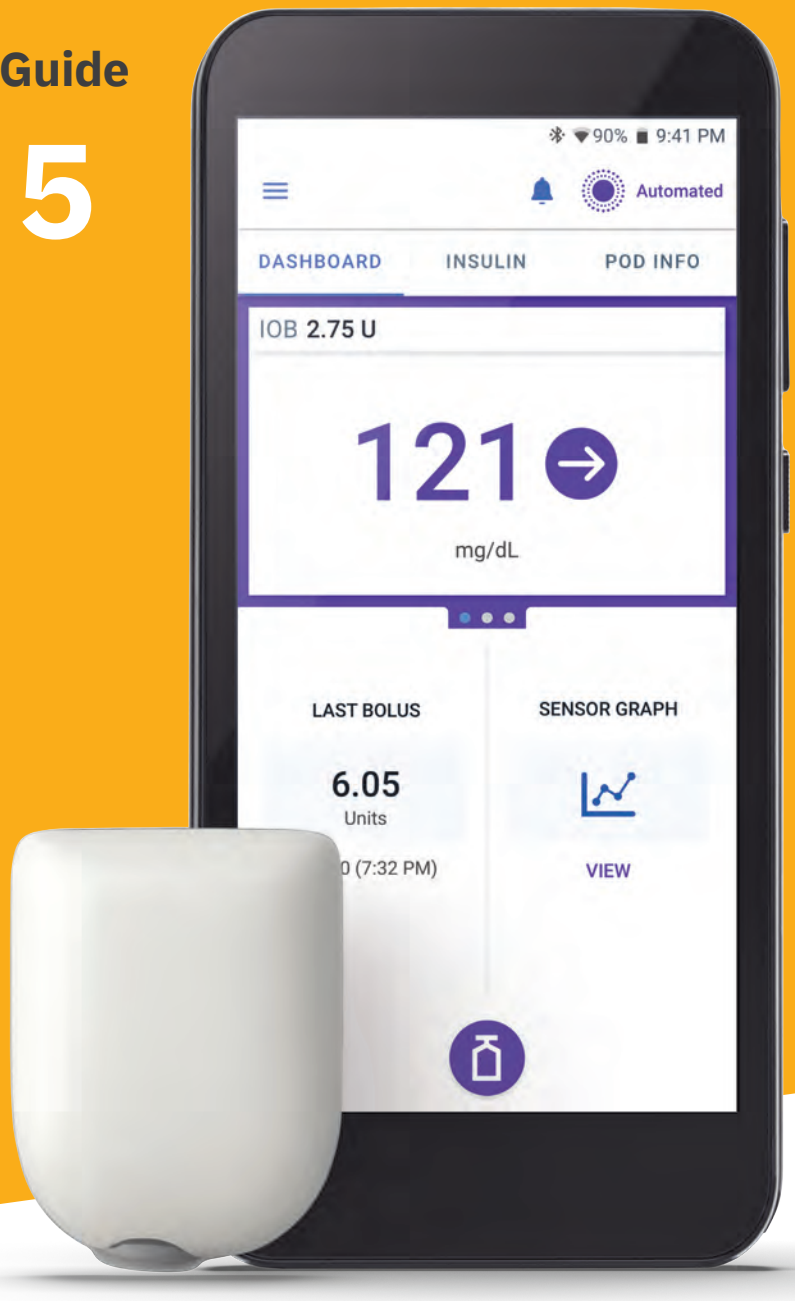
Prior Authorization Resource Guide

OMNIPOD® 5

Automated Insulin Delivery System

This resource provides guidance on completing **Prior Authorizations (PA)** to support access for patients prescribed Omnipod 5.

Over **95% approval rate** when complete PA is submitted.*



Pod shown without the necessary adhesive.

Exact PA criteria vary from plan to plan. Refer to the appropriate PA for your patient's health plan.

Please see **Important Safety Information** for Omnipod® 5 Automated Insulin Delivery System on the reverse.

What you need to know for successful PA submissions for Omnipod® 5

The following example of a PA highlights key considerations when completing a PA.

Key reminders:

- You may need to complete a PA request before your patient's insurance will cover Omnipod
- Accurate and detailed information in the PA request are crucial to avoid denials for unclear eligibility
- Incomplete or incorrect documentation may result in denial

1

Provider Information		Patient Information	
Name: Jane Doe		**Name:** John Smith	
NPI number: 1234567890		**Member ID:** 1111111111	
Office address: 10 Main Street		**DOB:** 1/1/1960	
City: New York		**Phone:** 555-123-5678	
State: NY	ZIP: 10001	**Height:** 5′ 8″	**Weight:** 235 lb
Phone: 555-123-4567		**Medication allergies:** NKDA	**ICD-10:** E10.65
Fax: 555-123-6789		**Diagnosis:** type 1 diabetes with hyperglycemia	

2

Medication Information	
Medication name: Omnipod 5 DexG7G6 Pods (Gen 5)	Quantity: 10 Pods/30 Days
Route of administration: Subcutaneous	Duration of therapy: Lifetime
Directions for use: Change Pod every 72 hours	
Therapy status: Initial Continuation	If continuation, provide start date:
Have you attached documentation (eg, HbA1c, medical history, etc) to support this request? (Yes) No	

3

Medication History—provide evidence of prior use		
Drug name, strength, dosage	**Dates of therapy**	**Reason for discontinuation (if applicable)**
Humalog U-100, 2 units with each meal	1/30/21 – 10/25/22	Suboptimal glycemic control
Lantus U-100, 20 units qd	1/30/21 – 10/25/22	Suboptimal glycemic control

4

Clinical Rationale for use of medication	
Refer to the next page for sample clinical rationale to justify coverage for Omnipod 5.	
(Please attach clinical note)	
I certify that the information on this form is accurate as of this date. **Prescriber signature:** *Jane Doe*	**Date:** 11/1/2022

1

The Provider Information and Patient Information sections require that identifying details be provided. It is important to document the patient's medication allergies as well as the diagnosis and ICD-10 code.

Diagnosis	Corresponding ICD-10 code
Type 1 Diabetes	E10.[XX]
Type 2 Diabetes	E11.[XX]

The Medication Information section requires details related to the patient's prescription.

2

Topic	Medication details	
Medication name	• Omnipod 5 DexG7G6 Intro Kit (Gen 5) • Omnipod 5 DexG7G6 Pods (Gen 5)	• Omnipod 5 Libre2Plus G6 Intro Kit (Gen 5) • Omnipod 5 Libre2Plus G6 Pods (Gen 5)
Quantity	• Intro Kit – 1 Kit • 10/30 days (72-hour change) • 15/30 days (48-hour change)	• 30/90 days (72-hour change) • 45/90 days (48-hour change)
Route of administration	Subcutaneous	
Directions for use	Change Pod every 72 or 48 hours based on total daily insulin requirements • ≤65 units total/day: 3-day change • 66 units-100 units total/day: 2-day change	
Duration of therapy	Lifetime	
Therapy status	• Initial: New to Omnipod 5 • Continuation: Currently using Omnipod 5	

3

The Medication History section documents the patient's previous and current use of relevant medications, including basal and/or bolus insulin and oral antihyperglycemic therapies. This section also helps highlight tried and failed treatments.

4

The Clinical Rationale section is crucial for justifying the treatment choice. Including the following rationale, where applicable, can effectively demonstrate the necessity for Omnipod 5.

Initial therapy

- Patient has previously used insulin pump therapy and has responded well to treatment
- Patient has required ≥3 insulin injections per day for the last [xx time frame]
- Patient requires frequent self-adjustment of insulin dosage
- Patient has checked blood sugar ≥4 times per day for the last [xx time frame]
- Patient has completed diabetes education management due to ongoing educational support from managing HCP
- Patient is motivated to operate insulin pump and understands importance of nutrition, including carbohydrates
- Patient has failed insulin therapy if one or more of the following applies (select all that apply):
  - HbA1c >7% or outside individualized targets
  - Unexplained, nocturnal, or severe hypoglycemia
  - Dawn phenomenon (ie, wakes up with blood sugar ≥200 mg/dL)
  - Wide and unpredictable (erratic) swings in blood glucose levels
- Patient has complications of diabetes (eg, retinopathy, neuropathy, nephropathy, amputation, foot ulcer, etc)
- Patient has comorbidities (ie, cardiovascular disease, chronic kidney disease, hypertension)
- Patient has brittle diabetes with recurrent episodes of diabetic ketoacidosis, hypoglycemia, or both, resulting in recurrent and/or prolonged hospitalization

Continuation of therapy

- Patient is currently using Omnipod 5 and is responding well to therapy. Discontinuation could result in deterioration of blood sugar control leading to further diabetes complications

Use CoverMyMeds for PA submission to ensure correct PA completion and faster time to determination.

- Start a PA request on **covermymeds.com** or open a pharmacy-initiated request
- Enter **patient contact** information
- **Submit the PA** to plan; once plan determination is received, office will be notified

Explore Omnipod 5 Formulary Coverage Resources on omnipod.com/hcp/insurance-coverage.

- See additional coverage options
- Look up formulary coverage in your area

Have additional questions? ASPN Pharmacy can help.

Call 866-347-0036 option 2 to speak with a live Specialist for support.

800-591-3455 • omnipod.com/hcp

Important Safety Information

The Omnipod® 5 Automated Insulin Delivery System is a single hormone insulin delivery system intended to deliver U-100 insulin subcutaneously for the management of type 1 diabetes in persons aged 2 and older and type 2 diabetes in persons 18 years of age and older. The Omnipod 5 System is intended for single patient use.
The Omnipod 5 System is indicated for use with NovoLog,® Humalog,® and Admelog.®

The Omnipod 5 ACE Pump (Pod) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Omnipod 5 ACE Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. SmartAdjust™ technology is intended for use with compatible integrated continuous glucose monitors (iCGM and alternate controller enabled (ACE) pumps to automatically increase, decrease, and pause delivery of insulin based on current and predicted glucose values. The Omnipod 5 SmartBolus Calculator is intended to calculate a suggested bolus dose based on user-entered carbohydrates, most recent sensor glucose value (or blood glucose reading if using fingerstick), rate of change of the sensor glucose (if applicable), insulin on board (IOB), and programmable correction factor, insulin to carbohydrate ratio, and target glucose value.

Warning: SmartAdjust technology should NOT be used by anyone under the age of 2 years old. SmartAdjust technology should also NOT be used in people who require less than 5 units of insulin per day as the safety of the technology has not been evaluated in this population.

The Omnipod 5 System is NOT recommended for people who are unable to monitor glucose as recommended by their healthcare provider, are unable to maintain contact with their healthcare provider, are unable to use the Omnipod 5 System according to instructions, are taking hydroxyurea as it could lead to falsely elevated CGM values and result in over-delivery of insulin that can lead to severe hypoglycemia, and do NOT have adequate hearing and/or vision to allow recognition of all functions of the Omnipod 5 System, including alerts, alarms, and reminders. Device components including the Pod, CGM transmitter, and CGM sensor must be removed before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. In addition, the Controller and smartphone should be placed outside of the procedure room. Exposure to MRI, CT, or diathermy treatment can damage the components. Visit www.omnipod.com/safety for additional important safety information.

Warning: DO NOT start to use the Omnipod 5 System or change settings without adequate training and guidance from a healthcare provider. Initiating and adjusting settings incorrectly can result in over-delivery or under-delivery of insulin, which could lead to hypoglycemia or hyperglycemia.

*Represents percentage of Omnipod 5 DexG7G6 Intro Kit claims with a 90-day look forward status of filled or reversed among claims with an initial status of Prior Authorization Required. Includes completed PAs only. Based on claims from January 2024 to December 2024. Source: IQVIA OPCL

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