Reference number(s)
3762-C

Initial Prior Authorization with Quantity Limit
Disposable Insulin Pumps

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name
Omnipod (all prescription products)
V-Go (all products)

Coverage Criteria

Authorization may be granted for the requested medical device when the following criteria are met:

- The request is for other Omnipod products (e.g., Omnipod DASH, Omnipod 5) or V-Go and ONE of the following criteria are met:
    - The patient is NOT currently established on therapy with an insulin pump and ALL of the following criteria are met:
        - The patient is managing their diabetes with multiple daily insulin injections
        - The patient has completed a comprehensive diabetes education program
        - The patient has documented frequency of glucose self-testing an average of at least 4 times per day OR the patient is using a continuous glucose monitor (CGM)
        - If the patient does NOT have a diagnosis of type 1 diabetes, then the patient has experienced an elevated glycosylated hemoglobin level (e.g., HbA1c greater than 7 percent) while on multiple daily injections of insulin (i.e., at least 3 injections per day) for at least 6 months OR the patient has experienced ANY of the following while on multiple daily injections of insulin (i.e., at least 3 injections per day) for at least 3 months: history of recurrent hypoglycemia (e.g., blood glucose levels less

than 70 mg/dL), wide fluctuations in blood glucose before mealtime, “dawn” phenomenon with fasting blood sugars frequently exceeding 200 mg/dL, history of severe glycemic excursions
        - If additional quantities of Omnipod pods are being requested, then the patient requires more than 200 units of insulin within a 72-hour period
    - The patient is currently established on therapy with an insulin pump and ALL of the following criteria are met:
        - The patient has documented frequency of glucose self-testing an average of at least 4 times per day OR the patient is using a continuous glucose monitor (CGM)
        - If additional quantities of Omnipod pods are being requested, then the patient requires more than 200 units of insulin within a 72-hour period

Type 2 Diabetes Mellitus

Authorization may be granted for the requested medical device when the patient has a diagnosis of type 2 diabetes mellitus when the following criteria is met:

- The request is for Omnipod GO and ALL of the following criteria are met:
    - The patient does NOT require bolus or mealtime insulin
    - The patient has completed a comprehensive diabetes education program
    - The patient meets ONE of the following:
        - The patient has documented frequency of glucose self-testing at least once daily
        - The patient has been using a continuous glucose monitor (CGM)
    - The patient has a hypersensitivity to an ingredient in ALL available basal insulin (e.g., long-acting insulin, intermediate-acting insulin)

Quantity Limits Apply

Omnipod GO: 10 pods (2 kits) per 25 days or 30 pods (6 kits) per 75 days

Other Omnipod products (e.g., Omnipod 5, Omnipod Dash):

Omnipod starter kit: 1 kit per 999 days

Omnipod pod refills: 10 pods per 25 days or 30 pods per 75 days for patients using less than 200 units of insulin per 72-hour period

Omnipod pod refills: 15 pods per 25 days or 45 pods per 75 days for patients using greater than 200 units of insulin per 72-hour period

V-Go: 30 pumps per 25 days or 90 pumps per 75 days

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 3762-C: DOA: 12 months

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15. Grunberger G, Handelsman Y, Bloomgarden ZT, et al. American Association of Clinical Endocrinologists and American College of Endocrinology 2018 Position Statement on Integration of Insulin Pumps and Continuous Glucose Monitoring in Patients with Diabetes Mellitus. *Endocr Pract*. 2018;24(3):302-308.
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Document History

Written by: UM Development (KC)

Date Written: 04/2020

Revised: (KC) 10/2020 (no clinical changes), (ME) 10/2021 (no clinical changes); (ASA) 08/2022 (no clinical changes), 03/2023 (added criteria for additional quantities [15 per month]), 10/2023 (added Omnipod GO); (DFW) 03/2024 (no clinical changes), 06/2024 (changes to duration of MDI), 09/2024 (removed self-adjustment of insulin dose requirement, removed duration requirement for SMBG/CGM use for new starts, removed elevated A1C/complications requirement for T1DM)

Reviewed: Medical Affairs (CHART) 05/28/2020, 10/29/20, (CHART) 09/30/21, 08/25/2022, 03/30/2023, 10/26/2023, 03/28/2024, 07/11/2024, 10/24/2024

MD Committee: 10/2020, 11/2021, 08/2022

External Review: 06/2020 (FYI), 12/2022 (MD Subcommittee), 06/2023 (MD Subcommittee), 06/2024 (MD Subcommittee)

CRITERIA FOR APPROVAL

1	Is this request for Omnipod GO? [If Yes, then go to 2. If No, then go to 8.]	Yes	No
2	Does the patient have a diagnosis of type 2 diabetes mellitus? [If Yes, then go to 3. If No, then no further questions.]	Yes	No
3	Does the patient require bolus or mealtime insulin? [If Yes, then no further questions. If No, then go to 4.]	Yes	No

4	Has the patient completed a comprehensive diabetes education program? [If Yes, then go to 5. If No, then no further questions.]	Yes	No
5	Does the patient have documented frequency of glucose self-testing at least once daily OR has the patient been using a continuous glucose monitor (CGM)? [If Yes, then go to 6. If No, then no further questions.]	Yes	No
6	Does the patient have a hypersensitivity to an ingredient in ALL available basal insulin (e.g., long-acting insulin, intermediate-acting insulin)? [If Yes, then go to 7. If No, then no further questions.]	Yes	No
7	Does the patient require MORE than the plan allowance of 10 pods (2 kits) per month? [No further questions] RPH Note: If yes, then deny and enter a partial approval for 10 pods (2 kits) / 25 days or 30 pods (6 kits) / 75 days of Omnipod GO.	Yes	No
8	Is the patient currently established on therapy with an insulin pump? [If Yes, then go to 9. If No, then go to 10.]	Yes	No
9	Does the patient have documented frequency of glucose self-testing an average of at least 4 times per day OR is the patient using a continuous glucose monitor (CGM)? [If Yes, then go to 15. If No, then no further questions.]	Yes	No
10	Has the patient been managing their diabetes with multiple daily insulin injections? [If Yes, then go to 11. If No, then no further questions.]	Yes	No
11	Has the patient completed a comprehensive diabetes education program? [If Yes, then go to 12. If No, then no further questions.]	Yes	No
12	Does the patient have documented frequency of glucose self-testing an average of at least 4 times per day OR is the patient using a continuous glucose monitor (CGM)? [If Yes, then go to 13. If No, then no further questions.]	Yes	No
13	Does the patient have a diagnosis of type 1 diabetes mellitus? [If Yes, then go to 15. If No, then go to 14.]	Yes	No
14	Has the patient experienced an elevated glycosylated hemoglobin level (e.g., HbA1c greater than 7 percent) while on multiple daily injections of insulin (i.e., at	Yes	No

	least 3 injections per day) for at least 6 months or has the patient experienced ANY of the following while on multiple daily injections of insulin (i.e., at least 3 injections per day) for at least 3 months: A) history of recurrent hypoglycemia (e.g., blood glucose levels less than 70 mg/dL), B) wide fluctuations in blood glucose before mealtime, C) "dawn" phenomenon with fasting blood sugars frequently exceeding 200 mg/dL, D) history of severe glycemic excursions? [If Yes, then go to 15. If No, then no further questions.]		
15	Is this request for an Omnipod product (e.g., Omnipod DASH or Omnipod 5)? [If Yes, then go to 16. If No, then go to 25.]	Yes	No
16	Does the patient require more than 200 units of insulin within a 72-hour period? [If Yes, then go to 21. If No, then go to 17.]	Yes	No
17	Does the patient require a starter kit? [If Yes, then go to 18. If No, then go to 20.]	Yes	No
18	Has the patient received a starter kit within the past five years? [If Yes, then no further questions. If No, then go to 19.] RPH Note: If yes, then deny and enter a partial approval for 10 pods / 25 days or 30 pods / 75 days of the requested Omnipod product.	Yes	No
19	Does the patient require MORE than the plan allowance of 10 pods per month? [No further questions] RPH Note: If yes, then deny and enter a partial approval for 10 pods / 25 days or 30 pods / 75 days of the requested Omnipod product AND a partial approval for one Omnipod starter kit only.	Yes	No
20	Does the patient require MORE than the plan allowance of 10 pods per month? [No further questions] RPH Note: If yes, then deny and enter a partial approval for 10 pods / 25 days or 30 pods / 75 days of the requested Omnipod product.	Yes	No
21	Does the patient require a starter kit? [If Yes, then go to 22. If No, then go to 24.]	Yes	No
22	Has the patient received a starter kit within the past five years? [If Yes, then no further questions. If No, then go to 23.]	Yes	No

	RPH Note: If yes, then deny and enter a partial approval for 15 pods / 25 days or 45 pods / 75 days of the requested Omnipod product.		
23	Does the patient require MORE than the plan allowance of 15 pods per month? [No further questions] RPH Note: If yes, then deny and enter a partial approval for 15 pods / 25 days or 45 pods / 75 days of the requested Omnipod product AND a partial approval for one Omnipod starter kit only.	Yes	No
24	Does the patient require MORE than the plan allowance of 15 pods per month? [No further questions] RPH Note: If yes, then deny and enter a partial approval for 15 pods / 25 days or 45 pods / 75 days of the requested Omnipod product.	Yes	No
25	Does the patient require MORE than the plan allowance of 30 V-GO pumps per month? [No further questions] RPH Note: If yes, then deny and enter a partial approval for 30 pumps / 25 days or 90 pumps / 75 days of V-Go.	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Go to 8	
2.	Go to 3	Deny	Your plan only covers this product when it is used for certain health conditions. Covered use is type 2 diabetes. Your plan does not cover this product for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this product, you may have to meet other criteria. You can request the policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis - Omnipod Go]
3.	Deny	Go to 4	We have denied your request because your plan does not cover this product if you need mealtime or bolus insulin. We reviewed the

			information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this product, you may have to meet other criteria. You can request the policy for more details. You can also request other plan documents for your review. [Short Description: Exclusion]
4.	Go to 5	Deny	Your plan only covers this product when you have done a program to teach you about diabetes. We reviewed information we had. Your request has been denied because you have not done a program to teach you about diabetes. Your doctor can send us any new or missing information for us to review. For this product, you may have to meet other criteria. You can request the policy for more details. You can also request other plan documents for your review. [Short Description: Education requirement]
5.	Go to 6	Deny	Your plan only covers this product if you will be using this product as a part of a certain treatment plan. We have denied your request because A) You are not testing your blood sugar at least 1 time per day, or B) You are not using a continuous glucose monitor (CGM). We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this product, you may have to meet other criteria. You can request the policy for more details. You can also request other plan documents for your review. [Short Description: Not established on BGM or CGM - Omnipod GO]
6.	Go to 7	Deny	Your plan only covers this product when you had a reaction to an ingredient in all basal insulins (e.g., long-acting insulin, intermediate-acting insulin). We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this product, you may have to meet other criteria. You can request the policy for more details. You can also request other plan documents for your review.

			[Short Description: Hypersensitivity to basal insulin]
7.	Deny	[PA approved for 12 months. Approve Omnipod GO: 10 pods (2 kits)/25 days or 30 pods (6 kits) /75 days]. Approve, 12 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this product up to the amount your plan covers (10 pods [2 kits] per 30 days). Your request for more product has been denied. Your doctor can send us any new or missing information for us to review. For this product, you may have to meet other criteria. You can request the policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – Omnipod GO]
8.	Go to 9	Go to 10	
9.	Go to 15	Deny	Your plan only covers this product if you will be using this product as a part of a certain treatment plan. We reviewed information we had. Your request has been denied because A) You are not using a continuous glucose monitor (CGM), or B) You are not testing your blood sugar at least 4 times per day. Your doctor can send us any new or missing information for us to review. For this product, you may have to meet other criteria. You can request the policy for more details. You can also request other plan documents for your review. [Short Description: Not established on BGM or CGM]
10.	Go to 11	Deny	Your plan only covers this product if you have been using multiple daily insulin shots. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this product, you may have to meet other criteria. You can request the policy for more details. You can also request other plan documents for your review. [Short Description: Disease category/stage/severity]

11.	Go to 12	Deny	Your plan only covers this product when you have done a program to teach you about diabetes. We reviewed information we had. Your request has been denied because you have not done a program to teach you about diabetes. Your doctor can send us any new or missing information for us to review. For this product, you may have to meet other criteria. You can request the policy for more details. You can also request other plan documents for your review. [Short Description: Education requirement]
12.	Go to 13	Deny	Your plan only covers this product if you will be using this product as a part of a certain treatment plan. We reviewed information we had. Your request has been denied because A) You are not using a continuous glucose monitor (CGM), or B) You are not testing your blood sugar at least 4 times per day. Your doctor can send us any new or missing information for us to review. For this product, you may have to meet other criteria. You can request the policy for more details. You can also request other plan documents for your review. [Short Description: Not established on BGM or CGM]
13.	Go to 15	Go to 14	
14.	Go to 15	Deny	Your plan only covers this product if you have been using 3 or more shots of insulin per day for at least 6 months and your A1C is high or you have been using 3 or more shots of insulin per day for at least 3 months and you are having a lot of low blood sugars, big differences in your blood sugars before meals, high fasting blood sugars or big changes in your blood sugars. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this product, you may have to meet other criteria. You can request the policy for more details. You can also request other plan documents for your review. [Short Description: Multiple daily injections, complication or inadequate response]

15.	Go to 16	Go to 25	
16.	Go to 21	Go to 17	
17.	Go to 18	Go to 20	
18.	Deny	Go to 19	We have denied your request because it is for more than the amount your plan covers (quantity limit). Your plan covers 1 starter kit every 5 years. We have partially approved your request for pods up to the amount your plan covers (10 pods per 30 days). We reviewed the information we had. Your request for more product has been denied. Your doctor can send us any new or missing information for us to review. For this product, you may have to meet other criteria. You can request the policy for more details. You can also request other plan documents for your review. [Short Description: Quantity Limit, Exceeds max limit: Starter Kit, Partial Denial - Omnipod Pods 10 per month]
19.	Deny	[PA approved for 12 months. Approve Omnipod starter kit: 1 kit/999 days, Omnipod pods: 10 pods/25 days or 30 pods/75 days]. Approve, 12 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this product up to the amount your plan covers (10 pods per 30 days). Your request for more product has been denied. Your doctor can send us any new or missing information for us to review. For this product, you may have to meet other criteria. You can request the policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – Omnipod 10 pods per month]
20.	Deny	[PA approved for 12	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for

		months. Approve Omnipod pods only: 10 pods/25 days or 30 pods/75 days]. Approve, 12 Months	this product up to the amount your plan covers (10 pods per 30 days). Your request for more product has been denied. Your doctor can send us any new or missing information for us to review. For this product, you may have to meet other criteria. You can request the policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – Omnipod 10 pods per month]
21.	Go to 22	Go to 24	
22.	Deny	Go to 23	We have denied your request because it is for more than the amount your plan covers (quantity limit). Your plan covers 1 starter kit every 5 years. We have partially approved your request for pods up to the amount your plan covers (15 pods per 30 days). We reviewed the information we had. Your request for more product has been denied. Your doctor can send us any new or missing information for us to review. For this product, you may have to meet other criteria. You can request the policy for more details. You can also request other plan documents for your review. [Short Description: Quantity Limit, Exceeds max limit: Starter Kit, Partial Denial-Omnipod Pods 15 per month]
23.	Deny	[PA approved for 12 months. Approve Omnipod starter kit: 1 kit/999 days Omnipod pods: 15 pods/25 days or 45 pods/75 days]. Approve, 12	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this product up to the amount your plan covers (15 pods per 30 days). Your request for more product has been denied. Your doctor can send us any new or missing information for us to review. For this product, you may have to meet other criteria. You can request the policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – Omnipod 15 pods per month]

		Months	
24.	Deny	[PA approved for 12 months. Approve Omnipod pods only: 15 pods/25 days or 45 pods/75 days]. Approve, 12 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this product up to the amount your plan covers (15 pods per 30 days). Your request for more product has been denied. Your doctor can send us any new or missing information for us to review. For this product, you may have to meet other criteria. You can request the policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – Omnipod 15 pods per month]
25.	Deny	[PA approved for 12 months. Approve V-Go 30 pumps/25 days or 90 pumps/75 days]. Approve, 12 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this product up to the amount your plan covers (30 pumps per 30 days). Your request for more product has been denied. Your doctor can send us any new or missing information for us to review. For this product, you may have to meet other criteria. You can request the policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – V-Go]