

Protocol for Omnipod (All Rx Products)

I. Criteria for Approval:

A. May be approved when ALL the following criteria are met:

1. The member is currently established on therapy with an insulin pump
2. The member has a documented frequency of glucose self-testing on average of at least 4 times per day OR is using a continuous glucose monitor (CGM)

OR

1. The diabetes is being managed with multiple daily insulin injections (at least 3 injections per day) with frequent self-adjustments of the insulin dose for at least 6 months
2. Member has a documented frequency of glucose self-testing on average of at least 4 times per day for the past two months OR the member has been using a continuous glucose monitor (CGM) for the past two months
3. A comprehensive diabetes education program has been completed
4. The member has experienced any of the following while on multiple daily injections of insulin (more than 3 injections per day):
 - a. Elevated glycosylated hemoglobin level (for example HbA1c greater than 7 percent)
 - b. History of recurrent hypoglycemia (for example, blood glucose levels less than 70 mg/dL)
 - c. Wide fluctuations in blood glucose before mealtime
 - d. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
 - e. History of severe glycemic excursions

II. Duration of Approval if Requirements Are Met:

A. Approval Duration:

- 12 months

B. Quantity Level Limit:

- Omnipod starter kit: 1 kit/365 days
- Omnipod pod refills: 10 pods/30 days

NOTE:

- 1) Omnipod DASH and Omnipod 5 (and G6 pods) should not be approved unless there is true medical necessity.

- 2) If member already has a functional insulin pump product and is requesting Omnipod DASH or Omnipod 5 (and G6 pods) for convenience, please deny.
- 3) All other diabetes devices except for One Touch, Omnipod DASH, and Omnipod 5 (and G6 pods), should be reviewed through medical.

References

1. Omnipod. 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K192659.pdf. Accessed September 10, 2021.
2. American Diabetes Association. Standards of Medical Care in Diabetes-2021: Diabetes Care January 2021;42(Supplement1): S1-S2.