

Drug Policy

Policy:	InPen Smart Insulin Pen	Annual Review Date: 12/21/2023 Last Revised Date: 12/21/2023
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OVERVIEW

InPen is the only FDA-cleared smart insulin pen system that combines a reusable Bluetooth-enabled insulin pen and mobile app. InPen is a prescription-only product that records insulin injections and recommends doses based on current blood glucose, insulin dose, and current active insulin. The pen injector is compatible with Lily Humalog U-100 3 mL cartridges, Novo Nordisk U-100 3 mL cartridges, and Novo Nordisk Fiasp U-100 3 mL cartridges. The pen injector allows the user to dial the desired dose from 0.5 to 30 units in one-half unit increments. The InPen system is not intended for anyone unable or unwilling to test blood glucose (BG) levels as recommended by a healthcare provider, maintain sufficient diabetes self-care skills, or visit a healthcare provider regularly. InPen is not recommended for the blind or visually impaired without the assistance of a sighted individual with appropriate training.

POLICY STATEMENT

This policy involves the use of InPen. Prior authorization is recommended for pharmacy benefit coverage of InPen. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of InPen is recommended in those who meet the following criteria:

1. Diabetes Mellitus

Criteria. *Patient must meet the following criteria*

- A. The patient is 7 years of age or older OR is younger than 7 years of age and will be using InPen with adult supervision; AND
- B. The patient will be using InPen with Humalog, Novolog, or Fiasp; AND
- C. The patient will use U-100 insulin only; AND
- D. The patient has access to a device with the ability to install and use the InPen app (e.g. smartphone, tablet, etc. with iOS 10 or later or Android 6 or later); AND
- E. The patient is able and willing to visit a healthcare provider regularly and test blood glucose levels as recommended by their provider.

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Initial Approval/ Extended Approval.

A) *Initial Approval:* 1 year

B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

InPen has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Companion Medical [webpage]. 2020. *Clinicians*. Available at: <https://www.companionmedical.com/clinicians/>. Accessed on 14 December 2023.
2. Companion Medical [webpage]. 2020. *Important Safety Information*. Available at: <https://www.companionmedical.com/important-safety-information/>. Accessed on 14 December 2023.
3. Companion Medical. 2020. *InPen Healthcare Professional Brochure* [online]. Available at: <https://www.companionmedical.com/guides/InPen-Healthcare-Professional-Brochure.pdf>. Accessed on 14 December 2023.
4. Medtronic Diabetes [webpage]. 2022. *InPen Smart Insulin Pen System*. Available at: <https://www.medtronicdiabetes.com/products/inpen-smart-insulin-pen-system>. Accessed on 14 December 2023.
5. Medtronic Diabetes [webpage]. 2022. *Important Safety Information*. Available at: <https://www.medtronicdiabetes.com/important-safety-information#smart-pen-system>. Accessed on 14 December 2023.