Original Effective Date: 10/09/2025
Current Effective Date: 10/09/2025
Last P&T Approval/Version: 07/30/2025
Next Review Due By: 04/2026
Policy Number: C29696-A

InPen (Insulin Smart Pen)

PRODUCTS AFFECTED

InPen (insulin smart pen)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Type 1 and Type 2 Diabetes

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. DIABETES:
   1. Documented diagnosis of insulin dependent type 1 or 2 diabetes
      AND

2. Documentation member will be using either aspart (NovoLog, Fiasp) or lispro (Humalog [U-100]) in the device
   AND
3. Documentation member requires use of InPen as part of a system with Simplera CGM
   AND
4. Documentation member has been approved for use of Simplera CGM

CONTINUATION OF THERAPY:

A. DIABETES:
1. Documentation member continues to use either aspart (NovoLog, Fiasp) or lispro (Humalog [U-100]) in the device
   AND
2. Documentation member continues to need InPen as part of a Smart MDI system with Simplera CGM

DURATION OF APPROVAL:
Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
None

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
1 pen per year

PLACE OF ADMINISTRATION:
The recommendation is that devices in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
N/A

DRUG CLASS:
Needles & Syringes

FDA-APPROVED USES:
The InPen system dose calculator, a component of the InPen system app, is indicated for the management of diabetes by people with diabetes under the supervision of an adult caregiver, or by a patient age 7 and older for calculating an insulin dose or carbohydrate intake based on user entered data.
For an insulin dose based on amount of carbohydrates, a healthcare professional must provide patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the software prior to use.
For an insulin dose based on fixed/variable meal sizes, a healthcare professional must provide patient-specific fixed doses/meal sizes to be programmed into the software prior to use.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
It is estimated by the WHO that there are 463 million people living with diabetes worldwide. Given that there are many long-term complications of uncontrolled diabetes, many new medications and devices are being researched. While there are already disposable injectable insulin pens, as well as other insulin delivery devices, there is always a concern of proper patient education and comprehension when self-dosing insulin. Keeping track of carbohydrates and adjusting insulin dosing based on blood glucose levels are all factors that must be taken into consideration by patients who manage their diabetes. There has been a lot of reform recently regarding emphasis on patient education with injection technique, site rotation, nutrition information, and calculating insulin dosing, however the patient must be willing to follow through with these steps in order to best manage their diabetes and to maintain a healthy lifestyle. New technology has alleviated some of the burden when it comes to keeping track of blood glucose numbers, calculating insulin doses, and monitoring carbohydrate intake, however there is still much that the patient is responsible for.

On June 18th, 2020, the FDA approved Companion Medical's InPen for the management of diabetes. It is now approved with the expanded indication for patients aged 7 years and older or under supervision of an adult caregiver for self-injection of a desired dose of insulin. Previously, it was indicated in patients 12 and older.

InPen requires a prescription and is for home-use only. The pen is compatible with Humalog U-100 3mL cartridges, Novolog U-100 3mL cartridges, and Fiasp U-100 3mL cartridges. The pen does not come with the detachable and disposable pen needles, which are required for use and would need a separate prescription. It allows for the user to dial the desired dose from 0.5-30 units in ½ unit increments. Of note, for insulin dosing that is based on carbohydrate intake, the healthcare provider must provide patient- specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters that must be programmed into the software before use. If insulin dosing is based on fixed/variable meal sizes, HCP must provide patient specific fixed doses or meal sizes, again programmed into software prior to use. It is also recommended to carry a spare device in case the InPen is lost or damaged.

It is contraindicated in anyone who is unable or unwilling to test their blood glucose levels as recommended by a healthcare provider (minimum twice in a day), maintain sufficient diabetes self-care skills (where patient education and comprehension are key), and visit their healthcare provider regularly. InPen is not recommended for the blind or visually impaired, unless assisted by a sighted individual trained to use it. InPen has a significant warning involving pediatric patients due to the potential that they may inadvertently play with the pen or the smartphone app, which could lead to the unintentional logging or delivery of insulin and changes to therapy settings, which would have serious effect and potentially lead to hyperglycemic or hypoglycemic events, and even death.

The Simplera CGM system consists of a sensor and mobile app that perform real-time continuous glucose monitoring (CGM) for the management of diabetes in adults ages 18 years and older.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of InPen are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to InPen include: anyone unable or unwilling to test blood glucose (BG)

levels as recommended by a healthcare provider, maintain sufficient diabetes self-care skills, visit a healthcare provider regularly.

Exclusions/Discontinuation:
Discontinue InPen if member stops using Simplera CGM.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
InPen is available in 3 different colors and two different models:
InPen 100-Blue-Lilly-Humalog DEVI
InPen 100-Grey-Lilly-Humalog DEVI
InPen 100-Pink-Lilly-Humalog DEVI
InPen 100-Blue-Novolog-Fiasp DEVI
InPen 100-Grey-Novolog-Fiasp DEVI
InPen 100-Pink-Novolog-Fiasp DEVI

REFERENCES

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3. Important safety information. (2020, September 24). Retrieved August 11, 2021, from https://www.medtronicdiabetes.com/important-safety-information#smart-pen-system
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SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q3 2025