Original Effective Date: 10/27/2021
Current Effective Date: 10/15/2022
Last P&T Approval/Version: 07/27/2022
Next Review Due By: 07/2023
Policy Number: C21865-A

INPEN (Insulin Smart Pen) Non-Coverage

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

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

DIAGNOSIS:
Type 1 and Type 2 Diabetes

LIMITATIONS/EXCLUSIONS:
InPen is considered not medically necessary for Diabetes, due to insufficient evidence of therapeutic value since clinical benefit has not been established. There was a clinical trial, Connected Pens for Diabetes Study (CUPID), that evaluated the impact of a wireless smart insulin pen and smartphone-based bolus advisor on clinical and psychosocial outcomes in insulin-treated diabetes mellitus patients after 3 months of use. However, due to low enrollment because of selective inclusion/exclusion criteria the clinical trial was terminated.

Molina Healthcare will be continuing to evaluate and update this policy as relevant clinical evidence becomes available to determine whether InPen provides clear clinical benefit or is medically necessary.

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.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

NDC CODE	DESCRIPTION
00002751659	Humalog U-100 cartridges
00169330312	Novolog U-100 cartridges
00169320515	Fiasp U-100 cartridges

AVAILABLE DOSAGE FORMS:
InPen is available in 3 different colors and two different models
InPen Humalog:
Blue-
62088000031
Grey-
62088000032
Pink-62088000033
InPen Novolog/Fiasp:
Blue-
62088000034
Grey-
62088000035
Pink-62088000036

REFERENCES

1. Connected pens for diabetes study. (n.d.). Retrieved August 11, 2021, from https://clinicaltrials.gov/ct2/show/NCT03830216
2. Gildon, B. (2018, November). InPen smart insulin PEN System: Product review and user experience. Retrieved August 11, 2021, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6243223/
3. Important safety information. (2020, September 24). Retrieved August 11, 2021, from https://www.medtronicdiabetes.com/important-safety-information#smart-pen-system
4. Medtronic. (n.d.). Diabetes - Inpen™ Smart Insulin Pen. Retrieved August 11, 2021, from https://www.medtronic.com/us-en/healthcare-professionals/products/diabetes/smart-insulin-pen/prescribing-inpen.html

SUMMARY OF REVIEW/REVISIONS	DATE
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file