# **Insulin** Pen Guidance

## INDICATIONS AND USAGE<sup>1</sup>

An insulin pen is an injection device, used by diabetics to give insulin shots. They are about the size and shape of a magic marker. It delivers insulin into the fatty tissue below the skin (usually in the arm, thigh, or stomach) via a short, thin disposable needle. Current FDA guidance does not recommend the breaking of insulin pen boxes that contain multiple pens, due to the potential for medication and dosing errors.

# CRITERIA (used to determine appropriate utilization)<sup>1</sup>

- 1. Recent updates to the manufacturer's packaging include a statement about dispensing insulin pens in the original sealed cartons only. If the pharmacist chooses to use professional judgement to open the carton, such as in long term care settings, you will not be subject to recovery, if the submitted claim is accurate. Pharmacies should always calculate and bill the true day supply and may reduce the day supply per the plan limitations.
- 2. If exact directions are not provided by the prescriber (I.E. "as directed" or "prn"), the pharmacist must contact the prescriber to obtain mathematically useful directions so an accurate day supply can be calculated and submitted. The prescriber's verbal indications must be documented on the original prescription in accordance with applicable legislation. Documentation should include changes to directions, authorizing agent, date, time and pharmacist's initials.

#### **QUANTITY LIMITS**

- Up to a maximum of 34-day supply on insulin pen products
  - If one box of insulin pens exceeds 34 days supply, run the claim for the correct day supply and get the rejection prior to submitting it for 34 days. The initially submitted correct day supply is captured and retained in the Alaska Medicaid pharmacy system.

### **REFERENCES / FOOTNOTES:**

1. FDA advises health care professionals and patients about insulin pen packaging and dispensing. [press release]. Silver Spring, MD: US Food & Drug Administration; October 13, 2020.https://www.fda.gov/drugs/drug-safety-and-availability/fda-advises-health-care-professionals-and-patients-about-insulin-pen-packaging-and-dispensing?utm\_medium=email&utm\_source=govdelivery\_Accessed on 10/26/2020.

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