

# **Needleless Injection**

<b>Table of Content</b>
Purpose
Description & Definitions
<u>Criteria</u>
Coding
Document History
<u>References</u>
<u>Special Notes</u>
<u>Keywords</u>

Effective Date	10/2000
<u>Next Review Date</u>	01/9/2024
Coverage Policy	DME 26
<u>Version</u>	8

# Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details <u>\*</u>.

#### Purpose:

This policy addresses Needleless Injection and their accessories.

# **Description & Definitions:**

Needleless Injection deliver medications either without a needle stick, the use of a tiny jet stream, or a single pulse of laser light and disposable devices are worn for short periods of time to decrease repeated punctures to the skin.

### Criteria:

Needleless injection systems are considered medically necessary with 1 or more of the following:

- Documentation includes All of the following:
  - Documented evidence that individual is unable to perform insulin injection/standard blood glucose monitoring with a traditional delivery device after adequate training and is unable to use the traditional device
  - Documented evidence of "sharps phobia" such as repeated episodes of vasovagal reaction to injection or standard blood glucose monitoring making puncture technique impossible
  - Documentation of contact with diabetes educator for training to ensure proper technique and instruction has been offered to individual using traditional device
- Individuals with **All of the following**:
  - o Predisposed to prolonged hyperinsulinemia and subsequent hypoglycemia
  - Demonstrate better glycemic control with the jet injector compared with conventional needle and syringe
- Individuals who are predisposed to lipoatrophy since jet injections may be less likely to lead to this
  complication compared with needle injection
- Individuals with gestational diabetes who experience postprandial hyperglycemia with needle injection since it may reduce the risk of neonatal macrosomia

The following **do not** meet the definition of medical necessity, to include but not limited to:

- Insuflon
- Laser lancet devices

Coding:		
Medically necessary with criteria:		
Coding	Description	
A4210	Needle-free injection device, each	
E1399	Durable medical equipment, miscellaneous	
Considered Not Medically Necessary:		
Coding	Description	
A4257	Replacement lens shield cartridge for use with laser skin piercing device, each	
E0620	Skin piercing device for collection of capillary blood, laser, each	

# **Document History:**

Revised Dates:

- 2024: January
- 2023: January
- 2021: January, May
- 2019: November
- 2011: June
- 2009: June
- 2008: June, August
- 2007: September
- 2006: October
- 2003: October
- 2002: October

### **Reviewed Dates:**

- 2022: January
- 2021: August
- 2020: September
- 2019: April
- 2018: August
- 2017: November
- 2016: June
- 2015: June
- 2014: June
- 2013: June
- 2012: June
- 2010: June
- 2009: August
- 2006: December
- 2005: December
- 2004: October, December

#### Effective Date:

October 2000

#### **References:**

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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AN UPDATE: ON NEEDLE FREE INJECTIONS. (2023). Retrieved Dec 2023, from International Journal Of Pharmaceutical, Chemical And Biological Sciences: <u>https://www.ijpcbs.com/articles/an-update-on-needle-free-injections.pdf</u>

Code of Federal Regulations Title 21 CFR Sec. 880.5430 Nonelectrically powered fluid injector. (2023, Oct 17). Retrieved Dec 2023, from FDA:

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Comfort In injector system. (2023). Retrieved Dec 2023, from Comfort In: https://injectneedlefree.com/

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Needle-Free Insulin Injection Systems. (2014). Retrieved Dec 2023, from HAYES: https://evidence.hayesinc.com/report/dir.needle105/organizations.html

Needle-Free Jet Injection of Rapid-Acting Insulin Improves Early Postprandial Glucose Control in Patients With Diabetes. (2014). Retrieved Dec 2023, from American Diabetes Association: <u>https://diabetesjournals.org/care/article/36/11/3436/37951/Needle-Free-Jet-Injection-of-Rapid-Acting-Insulin</u>

#### Special Notes: \*

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving, and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

#### MUST SEE MEMBER BENEFIT FOR DETERMINATION.

We only cover DME that is Medically Necessary and prescribed by an appropriate Provider. We also cover colostomy, ileostomy, and tracheostomy supplies, and suction and urinary catheters. We do not cover DME used primarily for the comfort and wellbeing of a Member. We will not cover DME if We deem it useful, but not absolutely necessary for Your care. We will not cover DME if there are similar items available at a lower cost that will provide essentially the same results as the more expensive items.

Pre-Authorization is Required for All Rental Items.

Pre-Authorization is Required for All Repair and Replacement.

# Keywords:

SHP Needleless Injection and Lancet Devices, SHP DME 26, Needleless, Iancet, iport, injector, sharps phobia, diabetes, insuflon, hyperinsulinemia, subsequent hypoglycemia, needle, syringe, needle-free injectors, Jet injector, Bi-3m Needle-Free Injector System, Pharmajet Needle-Free Injector, Stratis Injector, Hypex(Tm) Jet Injector, Med-E-Jet Injector, Injet-100, Medajet XI, Vitajet II, AdvantaJet, Freedom Jet, Medi-Jector EZ, Biojector 2000, Comfort-In injector system