Sentara Health Plans

Medicaid

Needleless Injection

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

All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

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:**
  - 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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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: https://diabetesjournals.org/care/article/36/11/3436/37951/Needle-Free-Jet-Injection-of-Rapid-Acting-Insulin

Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

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.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by

medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

All medically necessary medical equipment and supplies under the Virginia Administrative Code (12VAC30-50-165) may be covered only if they are necessary to carry out a treatment prescribed by a practitioner. Only supplies, equipment, and appliances that are determined medically necessary may be covered for reimbursement by DMAS. (12VAC30-50-165) The following criteria must be satisfied through the submission of adequate and verifiable documentation satisfactory to DMAS, or its contractor. Medically necessary DME and supplies shall be:

- Ordered by the practitioner on the CMN/DMAS-352;
- A reasonable and medically necessary part of the individual's treatment plan;
- Consistent with the individual's diagnosis and medical condition, particularly the functional limitations and symptoms exhibited by the individual; • Not furnished for the safety or restraint of the individual, or solely for the convenience of the family, attending practitioner, or other practitioner or supplier;
- Consistent with generally accepted professional medical standards (i.e., not experimental or investigational);
- Furnished at a safe, effective, and cost-effective level; and
- Suitable for use, and consistent with 42 CFR 440.70(b)(3), that treats a diagnosed condition or assists the individual with functional limitations.

Keywords:

SHP Needleless Injection and Lancet Devices, SHP DME 26, Needleless, lancet, 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 Xl, Vitajet II, AdvantaJet, Freedom Jet, Medi-Jector EZ, Biojector 2000, Comfort-In injector system