

Needleless Injection, DME 26

Table of Content

[Description & Definitions](#)
[Criteria](#)
[Document History](#)
[Coding](#)
[Special Notes](#)
[References](#)
[Keywords](#)

[Effective Date](#) 10/2000
[Next Review Date](#) 01/2026
[Coverage Policy](#) DME 26
[Version](#) 9

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.*

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

Document History:

Revised Dates:

- 2025: No change to criteria. Updated to new policy format.
- 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

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

The preceding codes are included above for informational purposes only and may not be all inclusive. Additionally, inclusion or exclusion of a treatment, procedure, or device-code(s) does not constitute or imply member coverage or provider reimbursement.

Special Notes: *

- Coverage: See the appropriate benefit document for specific coverage determination. Individual specific benefits take precedence over medical policy.
- Application to products: Policy is applicable to Sentara Health Plan Medicaid products.
- Authorization requirements: Pre-certification by the Plan is required.
- Special Notes:
 - Medicaid
 - 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 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.

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).

Code of Federal Regulations. Title 29 Subtitle B Chapter XVII Part 1910 Subpart Z § 1910.1030. 1.1.2025. Retrieved 1.3.2025. <https://www.ecfr.gov/current/title-29/subtitle-B/chapter-XVII/part-1910/subpart-Z/section-1910.1030>

Office of Combination Products Office of Special Medical Programs Office of the Commissioner Food and Drug Administration. Guidance for Industry and FDA Staff: Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products. 6.2013. Retrieved 1.3.2025. <https://www.fda.gov/media/76403/download>

Hayes. A symplr Company. Health Technology Assessment. Jan 10,2014. Needle-Free Insulin Injection Systems. Retrieved 1.3.2025. <https://evidence.hayesinc.com/report/dir.needle105>

Centers for Medicare and Medicaid Services. CMS.gov. NCD Insulin Syringe (40.4) Version 1. No date. Retrieved 1.3.2025. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=133>

Centers for Medicare and Medicaid Services. CMS.gov. NCD Home Blood Glucose Monitors (40.2) Version 2. 6.19.2006. Retrieved 1.3.2025. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=222>

Centers for Medicare and Medicaid Services. CMS.gov. LCD Glucose Monitors (L33822) Revision 16. 10.1.2024. Retrieved 1.3.2025. <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822>

Department of Medical Assistance Services. DMAS.gov. Procedure Fee Files & CPT Codes. 2025. <https://www.dmas.virginia.gov/for-providers/rates-and-rate-setting/procedure-fee-files-cpt-codes/#searchCPT>

National Comprehensive Cancer Network. NCCN.org. Retrieved 1.3.2025. <https://www.nccn.org/search-result?indexCatalogue=nccn-search-index&searchQuery=needleless%20devices>

American Diabetes Association. Needle-Free Jet Injection of Rapid-Acting Insulin Improves Early Postprandial Glucose Control in Patients With Diabetes. 10.2013. Retrieved 1.3.2025. <https://doi.org/10.2337/dc13-0492>

Sanghi, D.K., Tiwle, R. INTERNATIONAL JOURNAL OF PHARMACEUTICAL, CHEMICAL AND BIOLOGICAL SCIENCES. AN UPDATE: ON NEEDLE FREE INJECTIONS. 2023. Retrieved 1.3.2025. <https://www.ijpcbs.com/articles/an-update-on-needle-free-injections.pdf>

Phatale, V., Vaiphei, K. K., Jha, S., Patil, D., Agrawal, M., & Alexander, A. (2022). Overcoming skin barriers through advanced transdermal drug delivery approaches. Journal of controlled release : official journal of the Controlled Release Society, 351, 361–380. Retrieved 1.3.2025. <https://doi.org/10.1016/j.jconrel.2022.09.025>

MCG Informed Care Strategies. 28th Edition. 2024. Retrieved 1.3.2024. <https://careweb.careguidelines.com/ed28/index.html>

Keywords:

SHP Needleless Injection and Lancet Devices, SHP DME 26, Needleless, lancet, iport, injector, sharps phobia, diabetes, insulin, 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