Drug Coverage Policy

Effective Date.....2/1/2025
Coverage Policy Number.....IP0425

Erectile Dysfunction – Alprostadil Products for Individual and Family Plans

- Edex® (alprostadil intracavernosal injection – Endo)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Medical Necessity Criteria

For plans that do NOT include coverage for sexual dysfunction, medical necessity review may be required in addition to the Step Therapy requirements for non-sexual dysfunction uses. Refer to the customer's benefit plan document for coverage details.

Edex is considered medically necessary when ONE of the following criteria are met:

1. **Erectile Dysfunction.** Individual meets the following criteria:
   A. Medication is prescribed by, or in consultation with, a urologist.

      Edex for Erectile Dysfunction

Where covered, a maximum quantity limitation of 6 cartridge kits per 30 days is allowed.

2. **Prophylaxis after Radical Prostatectomy (Early Penile Rehabilitation).** Individual meets **ALL** of the following criteria:
    A. Treatment-naïve
    B. Therapy will be started within 6 months of surgery
    C. Medication is prescribed by, or in consultation with, a urologist

3. **Individual with a History of Radical Prostatectomy who is Continuing Alprostadil Therapy.** Individual meets **ALL** of the following criteria:
    A. Started on alprostadil therapy post-operatively and is continuing therapy
    B. Has not received 6 months of therapy
    C. Medication is prescribed by, or in consultation with, a urologist

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Continuation of Edex is considered medically necessary for **ALL** covered diagnoses when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration:
- Erectile dysfunction: Up to 12 months
- Prophylaxis after Radical Prostatectomy (Early Penile Rehabilitation) in treatment-naïve individuals: Up to 6 months
- Individual with a History of Radical Prostatectomy: Up to 6 months

Reauthorization approval duration:
- Erectile dysfunction: Up to 12 months
- Prophylaxis after Radical Prostatectomy (Early Penile Rehabilitation) in treatment-naïve individuals: Not applicable for continuation beyond initial 6 months
- Individual with a History of Radical Prostatectomy: Not applicable for continuation beyond initial 6 months

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven.

Background

OVERVIEW
Caverject, Caverject Impulse, Edex, and Muse are indicated for the treatment of **erectile dysfunction** due to neurogenic, vasculogenic, psychogenic, or mixed etiology.[1-4] Additionally, Caverject may be used as an adjunct to other diagnostic tests in the diagnosis of erectile

dysfunction.[1] Injectable alprostadil products include Caverject, Caverject Impulse (disposable, single-dose, dual chamber syringe system), and Edex.[1-3] MUSE is available as a single-use, medicated transurethral system for the delivery of alprostadil directly in the urethra.[4] MUSE is administered by inserting the applicator stem into the urethra after urination.[1]

These products have also been studied for penile rehabilitation.[5] Alprostadil may help the recovery of erectile function by promotion of cavernosal oxygenation levels. Several studies have demonstrated the efficacy of alprostadil injections and MUSE for early penile rehabilitation post-radical prostatectomy.[6-12]

References

1. Caverject® intracavernosal injection [prescribing information]. New York, NY: Pfizer; March 2023.
2. Caverject Impulse® intracavernosal injection [prescribing information]. New York, NY: Pfizer; December 2022.
3. Edex® intracavernosal injection [prescribing information]. Malvern, PA: Endo; March 2024.
4. MUSE urethral suppository [prescribing information]. Somerset, NJ: Meda; April 2018.
5. Kim ED. Local therapies to heal the penis: Fact of fiction? *J Androl.* 2009;30:384-390.
6. Montorsi F, Guazzoni G, Strambi LF, et al. Recovery of spontaneous erectile function after nerve-sparing radical retropubic prostatectomy with and without early intracavernous injections of alprostadil: Results of a prospective, randomized trial. *J Urol.* 1997;158:1408-1410.
7. Yiou R, Cunin P, de la Taille A, et al. Sexual rehabilitation and penile pain associated with intracavernous alprostadil after radical prostatectomy. *J Sex Med.* 2011;8:575-582.
8. Raina R, Lakin MM, Thukral M, et al. Long-term efficacy and compliance of intracorporeal (IC) injection for erectile dysfunction following radical prostatectomy: SHIM (IIEF-5) analysis. *Int J Impot Res*. 2003;15(5):318-322.
9. Claro J, Aboim J, Maringolo M, et al. Intracavernous injection in the treatment of erectile dysfunction after radical prostatectomy: an observational study. *Sao Paulo Med J*. 2001;119:135-137.
10. Raina R, Pahlajani G, Agarwal A, et al. The early use of transurethral alprostadil after radical prostatectomy potentially facilitates an earlier return of erectile function and successful sexual activity. *BJU Int.* 2007;100:1317-1321.
11. Raina R, Agarwal A, Ausmundson S, et al. Long-term efficacy and compliance of MUSE for erectile dysfunction following radical prostatectomy: SHIM (IIEF-5) analysis. *Int J Impot Res.* 2005;17:86-90.
12. Raina R, Nandipati KC, Agarwal A, et al. Combination therapy: Medicated urethral system for erection enhances sexual satisfaction in sildenafil citrate failure following nerve-sparing radical prostatectomy. *J Androl.* 2005;26:757-760.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	• Updated coverage policy title	5/1/2024
Annual Revision	No criteria changes	2/1/2025

The policy effective date is in force until updated or retired.