



## Drug Coverage Policy

Effective Date.....5/1/2024

Coverage Policy Number.....IP0425

# Erectile Dysfunction – Alprostadil Products for Individual and Family Plans

- Edex® (alprostadil intracavernosal injection – Endo)

## 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

All of the alprostadil products are indicated for the treatment of **erectile dysfunction** due to neurogenic, vasculogenic, psychogenic, or mixed etiology.<sup>1-4</sup> Additionally, intracavernosal Caverject may be used adjunct to other diagnostic tests in the diagnosis of erectile dysfunction.<sup>1</sup> Injectable alprostadil products include Caverject, Caverject Impulse (disposable, single-dose, dual chamber syringe system), and Edex.<sup>1-3</sup> MUSE is available as a single-use, medicated transurethral system for the delivery of alprostadil directly in the urethra.<sup>4</sup> MUSE is administered by inserting the applicator stem into the urethra after urination.<sup>1</sup>

These products have also been studied for penile rehabilitation.<sup>5</sup> 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.<sup>6-12</sup>

## References

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2. Caverject Impulse® intracavernosal injection [prescribing information]. New York, NY: Pfizer; December 2022.
3. Edex® intracavernosal injection [prescribing information]. Malvern, PA: Endo Pharmaceuticals, Inc.; July 2018.
4. MUSE urethral suppository [prescribing information]. Somerset, NJ: Meda Pharmaceuticals; April 2018.
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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

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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.
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## Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	<ul style="list-style-type: none"> <li>Updated coverage policy title</li> </ul>	5/1/2024

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

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