PRIOR AUTHORIZATION POLICY

POLICY: Erectile Dysfunction – Alprostadil Products Prior Authorization Policy
- Caverject® (alprostadil intracavernosal injection – Pfizer)
- Caverject Impulse® (alprostadil intracavernosal injection – Pfizer)
- Edex® (alprostadil intracavernosal injection – Endo)
- MUSE® (alprostadil urethral suppository – MEDA)

REVIEW DATE: 11/01/2023

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. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

All of the alprostadil products are indicated for the treatment of **erectile dysfunction** due to neurogenic, vasculogenic, psychogenic, or mixed etiology.[1-4] Additionally, intracavernosal Caverject may be used 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]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of alprostadil products. Intravenous (IV) or other routes of administration of alprostadil is not covered by this policy. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with alprostadil products as well as the monitoring required for adverse events and long-term efficacy, some approvals require alprostadil products to be prescribed by or in consultation with a physician who specializes in the condition being treated.

- **Caverject® (alprostadil intracavernosal injection (Pfizer)**
- **Caverject Impulse® (alprostadil intracavernosal injection – Pfizer)**
- **Edex® (alprostadil intracavernosal injection – Endo)**
- **MUSE® (alprostadil urethral suppository – MEDA)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Erectile Dysfunction**. Approve for 1 year.

Other Uses with Supportive Evidence

2. **Prophylaxis after Radical Prostatectomy (Early Penile Rehabilitation).** Approve for 1 year in treatment-naïve patients if they meet both of the following (A and B).
   A) Therapy will be started within 6 months of surgery; AND
   B) The medication is prescribed by or in consultation with an urologist

3. **Patient with a History of Radical Prostatectomy who is Continuing Alprostadil Therapy (e.g., Edex, Caverject, MUSE).** Approve for 1 year if patient was started on therapy post-operatively and is currently continuing therapy.

CONDITIONS NOT COVERED

- **Caverject® (alprostadil intracavernosal injection (Pfizer)**
- **Caverject Impulse® (alprostadil intracavernosal injection – Pfizer)**
- **Edex® (alprostadil intracavernosal injection – Endo)**
- **MUSE® (alprostadil urethral suppository – MEDA)**

is(are) considered experimental, investigational or unproven for ANY other use(s).

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 Pharmaceuticals, Inc.; July 2018.
4. MUSE urethral suppository [prescribing information]. Somerset, NJ: Meda Pharmaceuticals; 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/02/2022
Annual Revision	No criteria changes.	11/01/2023