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: 11/02/2022

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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of alprostadil products are recommended in those who meet the following criteria:

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 criteria (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 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 RECOMMENDED FOR APPROVAL

Coverage of alprostadil products are not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Caverject® intracavernosal injection [prescribing information]. New York, NY: Pfizer; December 2017.
2. Caverject Impulse® intracavernosal injection [prescribing information]. New York, NY: Pfizer; October 2016.
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.