

Clinical Policy: Alprostadil (Caverject, Edex, Muse)

Reference Number: CP.CPA.02

Effective Date: 11.16.16

Last Review Date: 08.21

Line of Business: Commercial

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Alprostadil (Caverject[®], Edex[®], Muse[®]) is a prostaglandin E1 (PGE1) agonist.

FDA Approved Indication(s)

Caverject is indicated:

- For the treatment of erectile dysfunction;
- As an adjunct to other diagnostic tests in the diagnosis of erectile dysfunction.

Edex is indicated for the treatment of erectile dysfunction due to neurogenic, vasculogenic, psychogenic, or mixed etiology.

Muse is indicated for the treatment of erectile dysfunction. Studies that established benefit demonstrated improvements in success rates for sexual intercourse compared with similarly administered placebo.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Caverject, Edex, and Muse are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Erectile Dysfunction (must meet all):

1. Member is male;
2. Age \geq 18 years;
3. Failure of ONE oral Phosphodiesterase Type 5 (PDE5) inhibitor* (e.g., sildenafil) unless clinically significant adverse effects are experienced or all are contraindicated;
**Prior authorization may be required.*
4. Dose does not exceed either of the following (a, b, or c):
 - a. Caverject: 60 mcg per dose with no more than 3 doses weekly;
 - b. Edex: 40 mcg per dose with no more than 3 doses weekly;
 - c. Muse: two systems per 24-hour period.

Approval duration: 6 months or to member's renewal period, whichever is longer

B. Other diagnoses/indications:

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

II. Continued Therapy

A. Erectile Dysfunction (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed either of the following (a, b, or c):
 - a. Caverject: 60 mcg per dose with no more than 3 doses weekly;
 - b. Edex: 40 mcg per dose with no more than 3 doses weekly;
 - c. Muse: two systems per 24-hour period.

Approval duration: 6 months or to member's renewal period, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

PDE5: Phosphodiesterase Type 5

PGE1: Prostaglandin E1

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
Cialis [®] (tadalafil)	Daily: 2.5-5 mg PO QD PRN: 10 mg PO before sexual activity. Dosing range: 5 - 20 mg. The maximum recommended dosing frequency is ONCE per day.	QD dosing (5 mg/day) PRN dosing (20 mg/day)
sildenafil (Viagra [®])	50 mg PO 1 hour (0.5-4 hours) before sexual activity. Dosing range: 25-100 mg.	100 mg/day

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
	The maximum recommended dosing frequency is ONCE per day.	
Levitra [®] (vardenafil)	10 mg PO 60 minutes before sexual activity. Dosing range: 5-20 mg. The maximum recommended dosing frequency is ONCE per day.	20 mg/day
Staxyn [®] (vardenafil)	Place 1 tablet (10 mg) on the tongue 60 minutes before sexual activity. The maximum recommended dosing frequency is ONCE per day.	10 mg/day
Stendra [™] (avanafil)	100 mg PO 30 minutes before sexual activity. Dosing range: 50-200 mg. The maximum recommended dosing frequency is ONCE per day.	200 mg/day

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Muse: hypersensitivity, abnormal penile anatomy (urethral stricture, balanitis [inflammation/infection of the glans of the penis], severe hypospadias and curvature, and in patients with acute or chronic urethritis), use in men for whom sexual activity is inadvisable, use for sexual intercourse with a pregnant woman unless a condom barrier is used.
 - Caverject, Edex: Men who have conditions that predispose them to priapism, such as sickle cell anemia or sickle cell trait, multiple myeloma, or leukemia; treatment of erectile dysfunction in men with fibrotic conditions of the penis, such as anatomical deformation, angulation, cavernosal fibrosis, or Peyronie’s disease; men with penile implants.
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Alprostadil (Caverject)	Initial dosage titration should be done in the physician’s office. Dosage range: 1.25 - 60 mcg intracavernosally prior to sexual activity. The recommended frequency of injection is no more than 3 times weekly, with at least 24 hours between each dose.	60 mcg/dose, with at least 24 hours between doses, and no more than 3 doses weekly
Alprostadil (Edex)	Initial dosage titration should be done in the physician’s office. Dosage range: 1.25 - 40 mcg intracavernosally prior to sexual activity. The recommended frequency of injection is no more than 3	40 mcg/dose, with at least 24 hours between doses, and no more than 3 doses weekly

Drug Name	Dosing Regimen	Maximum Dose
	times weekly, with at least 24 hours between each dose.	
Alprostadil (Muse)	Initial: 125 - 250 mcg. Titrate on separate occasions to lowest dose required to achieve an erection sufficient for sexual intercourse.	2 systems per 24 hour period

VI. Product Availability

Drug	Availability
Alprostadil (Caverject)	Dry lyophilized powder vials: 20 mcg, 40 mcg Impulse syringe kits, freeze-dried powder in a dual-chamber syringe: 10 mcg, 20 mcg
Alprostadil (Edex)	Kits (with diluent): 10 mcg, 20 mcg, 40 mcg
Alprostadil (Muse)	Urethral pellet system: 125 mcg, 250 mcg, 500 mcg, 1000 mcg

VII. References

1. Caverject Prescribing Information. New York, NY: Pharmacia and Upjohn; December 2017. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a295fc1e-d82c-4f44-bc2d-a552bf594c98>. Accessed April 6, 2021.
2. Caverject Impulse Prescribing Information. New York, NY: Pharmacia and Upjohn; October 2016. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4dec1dbd-c63b-4a1b-81cb-c8d29696cc40>. Accessed April 6, 2021.
3. Edex Prescribing Information. Malvern, PA: Endo Pharmaceuticals; July 2018. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e8b8ec8d-1318-43e4-a182-446e9f9579de>. Accessed April 6, 2021.
4. Muse Prescribing Information. Somerset, NJ: Meda Pharmaceuticals; February 2018. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4c55f3f9-c4cf-11df-851a-0800200c9a66>. Accessed April 6, 2021.
5. Burnett AL, Nehra A, Breau RH, et al. Erectile Dysfunction: American Urological Association Guideline 2018. Available at: [https://www.auanet.org/guidelines/erectile-dysfunction-\(ed\)-guideline](https://www.auanet.org/guidelines/erectile-dysfunction-(ed)-guideline). Accessed April 6, 2021.
6. Micromedex[®] Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed April 6, 2021.
7. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: www.clinicalpharmacology-ip.com. Accessed April 6, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template; added contraindications to “Coverage is Not Authorized For” section for 1) Patients who have conditions that might predispose them to priapism, such as sickle cell anemia or trait, multiple myeloma, or leukemia, 2) Patients with anatomical	1.13.17	08.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
deformation of the penis, such as angulation, cavernosal fibrosis, or Peyronie’s disease, 3) Patients with penile implants		
3Q 2018 annual review: added Muse to policy (previously CP.CPA.70); removed off-label use for severe peripheral arterial occlusive disease; removed contraindications in section III as these do not satisfy safety approach for objectively confirmed conditions the result in serious adverse reactions; references reviewed and updated.	05.08.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	04.16.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	04.22.20	08.20
3Q 2021 annual review: no significant changes; references reviewed and updated.	04.06.21	08.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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