Clinical Policy: Alprostadil (Caverject, Edex, Muse)

Reference Number: CP.CPA.02
Effective Date: 00.16.16
Last Review Date: 08.24
Line of Business: Commercial

Coding Implications
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 (ED);
- As an adjunct to other diagnostic tests in the diagnosis of ED.

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

Muse is indicated for the treatment of ED. 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. Diagnosis of ED;
2. Age ≥ 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 (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the formulary (commercial), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
b. For drugs NOT on the formulary (commercial), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

II. Continued Therapy

A. Erectile Dysfunction (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
   b. For drugs NOT on the formulary (commercial), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: 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

ED: erectile dysfunction
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. The maximum recommended dosing frequency is ONCE per day.	100 mg/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), sickle cell anemia or trait, thrombocythemia, polycythemia, multiple myeloma: patients who are prone to venous thrombosis or who have a hyperviscosity syndrome and are therefore at increased risk of priapism (rigid erection lasting 6 or more hours), 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, hypersensitivity.

- 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 times weekly, with at least 24 hours between each dose.	40 mcg/dose, with at least 24 hours between doses, and no more than 3 doses weekly
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 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/020379s038lbl.pdf. Accessed May 2, 2024.
2. Caverject Impulse Prescribing Information. New York, NY: Pharmacia and Upjohn; December 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021212s018lbl.pdf. Accessed May 2, 2024.

3. Edex Prescribing Information. Malvern, PA: Endo Pharmaceuticals; March 2024. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e8b8ec8d-1318-43e4-a182-446e9f9579de. Accessed May 2, 2024.
4. Muse Prescribing Information. Somerset, NJ: Meda Pharmaceuticals; April 2018. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4c55f3f9-c4cf-11df-851a-0800200c9a66. Accessed May 2, 2024.
5. Burnett AL, Nehra A, Breau RH, et al. Erectile Dysfunction: American Urological Association Guideline 2018. Available at: https://www.auanet.org/guidelines-and-quality/guidelines/erectile-dysfunction-(ed)-guideline. Accessed May 8, 2024.
6. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 6, 2024.
7. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: https://www.clinicalkey.com/pharmacology/. Accessed May 6, 2024.
8. Kloner RA, Burnett AL, Miner M, et al. Princeton IV consensus guidelines: PDE5 inhibitors and cardiac health. The Journal of Sexual Medicine. February 2024; 21(2): 90–116.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0270	Injection, alprostadil, 1.25 mcg (Caverject, Edex)
J0275	Alprostadil urethral suppository (Muse)
J3490	Unclassified drugs (Caverject Impulse)

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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
3Q 2022 annual review: no significant changes; references reviewed and updated.	04.19.22	08.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.22.22	
3Q 2023 annual review: replaced requirement that member is male to require diagnosis of ED; references reviewed and updated.	04.14.23	08.23
3Q 2024 annual review: no significant changes; added Coding Implications with HCPCS codes; references reviewed and updated.	05.02.24	08.24

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.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.