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Coverage Policy Number **IP0425**

Alprostadil for Individual and Family Plans (IFP)

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Related Coverage Resources

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.

Overview

This policy supports medical necessity review for alprostadil intracavernous injection (Edex®).

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.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Initial Approval Criteria

Alprostadil intracavernous injection (Edex) is considered medically necessary for the treatment of Erectile Dysfunction when the medication is prescribed by or in consultation with a urologist.

Alprostadil (Edex) for Erectile Dysfunction
Where covered, a maximum quantity limitation of 6 cartridge kits per 30 days is allowed.

Alprostadil intracavernous injection (Edex) is considered medically necessary for prophylaxis after Radical Prostatectomy (Early Penile Rehabilitation) in treatment-naïve individuals when the individual meets ALL of the following criteria:

1. Therapy will be started within 6 months of surgery
2. Medication is prescribed by or in consultation with a urologist

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Alprostadil intracavernous injection (Edex) is considered medically necessary for the treatment of individuals with a History of Radical Prostatectomy when the individual meets ALL of the following criteria:

1. Individual was started on alprostadil therapy post-operatively and is continuing therapy.
2. Individual has not received 6 months of therapy.
3. 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.

Continuation of Therapy

Continuation of alprostadil intracavernous injection (Edex) is considered medically necessary for **ALL** covered diagnoses when initial criteria are met AND beneficial response is demonstrated.

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.[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]

References

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