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5.40.003

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Cardiovascular Agents	**Original Policy Date:**	January 1, 2014
Subject:	Alprostadil	**Page:**	1 of 4

Last Review Date: March 8, 2024

Alprostadil

Description

Alprostadil (prostaglandin E1)

Background
Alprostadil is a naturally occurring prostaglandin-E1 in pharmaceutical form that causes smooth-muscle relaxation, vasodilation, inhibition of platelet aggregation and other biological effects related to prostaglandins. Alprostadil is indicated for temporary, palliative maintenance of the ductal opening in patent ductus arteriosus in neonates (injectable / IV) (1).

Alprostadil for treatment of erectile dysfunction (ED) in any dosage form (topical, suppository, injection – cavernosal or otherwise) is **excluded** from coverage.

Regulatory Status
FDA-approved indication: Alprostadil injection is indicated for palliative, not definitive, therapy to temporarily maintain the patency of the ductus arteriosus until corrective or palliative surgery can be performed in neonates who have congenital heart defects and who depend upon the patent ductus for survival. Such congenital heart defects include pulmonary atresia, pulmonary stenosis, tricuspid atresia, tetralogy of Fallot, interruption of the aortic arch, coarctation of the aorta, or transposition of the great vessels with or without other defects (1).

Apnea is experienced by about 10 to 12% of neonates with congenital heart defects treated with Prostin VR Pediatric Sterile Solution. Apnea is most often seen in neonates weighing less than 2 kg at birth and usually appears during the first hour of drug infusion. Therefore, respiratory status should be monitored throughout treatment. Prostin VR Pediatric

should be administered only by trained personnel and used where ventilatory assistance and pediatric intensive care is immediately available (1).

Off-label (non-FDA approved) compounded topical preparations of alprostadil have not been proven to be safe or effective.

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Alprostadil may be considered **medically necessary** if the conditions indicated below are met.

Alprostadil may be considered **investigational** in patients with all other indications.

Prior-Approval is not required for members less than 1 year of age.

Prior-Approval Requirements

Age 1 year or older

Diagnosis

Patient must have the following:

Congenital heart defect with dependence on the patent ductus for survival

AND ALL of the following:

1. Need to maintain the patency of the ductus arteriosus
2. Pending corrective or palliative surgery

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre - PA Allowance

None

This is a covered benefit for members less than 1 year of age – PA not required**.**

Prior - Approval Limits

Duration 1 month

Prior – Approval *Renewal* Requirements

None

Rationale

Summary

Alprostadil is indicated for palliative therapy to temporarily maintain the patency of the ductus arteriosus in neonates with congenital heart defects until corrective or palliative surgery can be performed. Alprostadil used for this purpose should be administered only by trained personnel in facilities that provide pediatric intensive care (1).

Alprostadil for treatment of erectile dysfunction (ED) in any form (topical, suppository, injection – cavernosal or otherwise) is **excluded** from coverage.

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of alprostadil while maintaining optimal therapeutic outcomes.

References

1. Prostin VR [package insert]. New York, NY: Pfizer Inc.; April 2013.

Policy History

Date	Action
December 2013	New addition to PA
March 2014	Annual review
June 2015	Annual editorial review
December 2016	Annual editorial review and reference update Policy number change from 5.16.03 to 5.40.03
September 2017	Annual editorial review and reference update
September 2018	Annual review
September 2019	Annual review
September 2020	Annual review
March 2021	Annual review

March 2022	Annual review
March 2023	Annual review. Changed policy number to 5.40.003
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.