RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Alprostadil is 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.

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