

Budget Impact and Scenario-Based Analysis of an Adjustable Pulmonary Artery Band Versus Conventional Banding and Medical Management for Pediatric Congenital Heart Disease in the United States

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OBJECTIVES

Pulmonary artery banding (PAB) is a surgical intervention performed in approximately 840 pediatric patients annually in the United States for congenital heart defects requiring staged hemodynamic optimization. With conventional fixed PAB, the band is set intraoperatively and cannot be modified without reoperation. As pediatric patients grow rapidly in the months following implantation, the fixed band becomes either too tight or too loose relative to the evolving cardiac physiology, impeding normal heart function and growth.

Published data from the Society of Thoracic Surgeons Congenital Heart Surgery Database (STS-CHSD) indicate that up to 35% of patients require reoperation via sternotomy to adjust band tightness. Each reoperation exposes the child to repeated general anesthesia, cardiopulmonary bypass risk, extended ICU stays, and cumulative surgical morbidity.

A novel adjustable PAB is a hydraulic, battery-free, MRI-conditional device that enables post-procedural pressure titration via a subcutaneous port at the bedside, potentially eliminating repeat sternotomies for band adjustment. This study estimated the budget impact of adjustable PAB adoption compared with conventional fixed PAB and no-PAB management from US payer and societal perspectives over a 1-year time horizon.

METHODS

A budget impact model compared three management scenarios: (1) adjustable PAB with bedside titration via subcutaneous port, (2) conventional fixed PAB with surgical reoperation for band adjustment, and (3) no PAB (medical management or early primary repair).

Target population: pediatric patients across four congenital heart disease indications — multiple VSDs, borderline LV, pediatric DCM, and CCTGA (~840 PAB-eligible cases/year; Devlin et al., Ann Thorac Surg 2024; STS-CHSD 2016–2019).

Cost Input	Cost (2025 USD)	Source / Notes
Index PAB surgery	\$68,000/case	PHIS/KID 2012, inflation-adj.
Reoperation (sternotomy)	\$75,000–\$95,000	Incl. anesthesia, ICU 7–10d
Adj-PAB bedside adjustment	\$1,200/episode	Outpatient, no OR/anesthesia
No-PAB medical mgmt	\$15,000–\$25,000/yr	HF pharmacotherapy + monitoring
Early primary repair	\$85,000–\$140,000	No staged banding, higher risk

- Scenarios Modeled:
- Base case: 85% reduction in band-adjustment reoperations (accounting for non-band-related reoperations)
 - Optimistic: 100% elimination of band-adjustment reoperations

Sensitivity analyses: reoperation rate (25%–45%), per-case costs (±20%), device cost (±30%), Year 1 market penetration (10%–50%).

Perspective: US payer + societal. Time horizon: 1 year.

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Adjust. Adapt. Advance. | 調節。適応。前進。

RESULTS

250	\$4.7–5.9M	18%
Reoperations Avoided/Year (Base Case)	Net Direct Savings (25% Penetration) (Base Case)	Break-Even Threshold (Reoperation Reduction)

Adjustable PAB vs. Conventional Fixed PAB:
In the base case (35% reoperation rate, 85% reduction with adjustable PAB), an estimated 294 reoperations occur annually with conventional PAB (840 × 0.35). Adjustable PAB would prevent ~250 reoperations/year, yielding direct medical cost avoidance of \$18.7–\$23.8M annually. At 25% Year 1 market penetration (210 patients), net savings were \$4.7–\$5.9M in direct costs after incremental device costs. Societal savings from avoided hospitalizations (1,750–2,100 avoided hospital days) and reduced caregiver burden added \$1.8–\$2.5M. In the optimistic scenario (100% elimination), direct savings increased to \$5.5–\$7.0M at 25% penetration and \$22.1–\$27.9M at full adoption.

Scenario	Annual Reoperations	Direct Cost Savings (Full)	Net Savings (25% Pen.)
Conventional PAB (Status Quo)	294	—	—
Adj-PAB Base Case (85% Reduction)	44	\$18.7–23.8M	\$4.7–5.9M
Adj-PAB Optimistic (100% Reduction)	0	\$22.1–27.9M	\$5.5–7.0M

Adjustable PAB vs. No PAB (Medical Management / Early Primary Repair):
For patients deferring PAB in favor of medical management, annual costs of \$15,000–\$25,000/patient yielded inferior hemodynamic outcomes and delayed candidacy for definitive repair. For early primary repair without staged banding, published data indicate higher procedural mortality in low-weight neonates and mean costs of \$85,000–\$140,000/case. Adjustable PAB provided staged hemodynamic optimization at lower total episode cost (\$70,400–\$71,600 per patient including 2–3 adjustments) while preserving optimally timed definitive repair.
Sensitivity Analysis:
Results were robust across all tested parameter ranges. Net cost savings were most sensitive to assumed reoperation rate and per-case reoperation cost. Even at the lowest tested reoperation rate (25%) and highest device cost assumptions (+30%), the adjustable PAB remained cost-saving. Break-even for cost-neutrality versus conventional PAB occurred at ~18% reoperation reduction — well below the 85% base case assumption.

CONCLUSIONS

Adoption of an adjustable pulmonary artery band has the potential to generate substantial cost savings for the US healthcare system by eliminating costly repeat sternotomies in pediatric congenital heart disease patients.

The device enables bedside hemodynamic optimization as children grow and cardiac physiology evolves, directly addressing the fundamental limitation of conventional fixed banding — that a static device cannot accommodate the dynamic physiological changes inherent in a developing child.

Compared with no-PAB strategies, the adjustable PAB provides a cost-effective staged approach that avoids the higher risks and costs of early definitive repair in fragile neonates while maintaining hemodynamic control through non-invasive titration.

From both US payer and societal perspectives, adjustable PAB adoption is projected to be cost-saving even at conservative assumptions regarding market penetration and reoperation reduction.