

Health-Economic Value of a Novel Anastomosis Protection Device After Colorectal Resection: An Analysis Based on the SAFE-2025 Study and U.S. Claims Data

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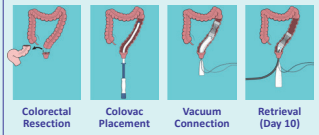
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OBJECTIVE

- Diverting ostomy after colorectal resection is associated with substantial costs, including an inpatient stoma reversal procedure, complication-related hospitalizations, and, when necessary, long-term stoma maintenance.
- Colovac (SafeHeal SAS) is a temporary, intraluminal bypass device designed as an alternative to the standard of care (SoC) of diverting ostomy (Figure 1).
- This analysis compares the lifetime, per-patient costs of Colovac versus SoC in the U.S.

FIGURE 1: COLOVAC PROCEDURE OVERVIEW



METHODS

- Model:** Decision-analytic model projecting strategy-specific lifetime costs from the payer perspective (Figure 2).
- Data:** Base-case inputs informed by SAFE-2025 study data (mean age 61 years, 51% male, 85.7% of patients avoided an ostomy at ten days), Medicare claims, and published literature (Table 1).
- Analysis:**
 - Survival was assumed not to differ between the two strategies, with survival calibrated to U.S.-specific outcomes after rectal resection.
 - Costs were discounted 3% per US guidelines.
 - Extensive sensitivity analyses were performed.

FIGURE 2: DECISION TREE WITH STRATEGIES AND KEY ASSUMPTIONS

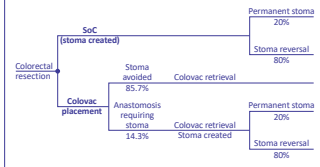


TABLE 1: KEY MODEL INPUTS

Clinical Parameter (mean)	Colovac		SoC	Source
Patient age (yrs)	60.9			SAFE-2025
Gender (% male)	51.0%			
Ostomy avoidance	85.7%		0%	
Stoma reversal	80%			Estimate based on Lemini et al. 2021
Stoma 30-day complications after index w/ stoma	14.0%			Estimate based on Vogel et al., 2022
30-day complications after stoma reversal	12.4%			Keller et al., 2014
30-day complications w/o stoma	5.0%		N/A	Exploratory assumption
Cost Parameter	Value		Source	
LAR with ileostomy	\$22,155		MedPAR 2023 mean amounts for primary diagnosis of C20, rectal cancer	
LAR without ileostomy	\$22,042			
Cost of ileostomy reversal	\$22,042			
LAR with Colovac placement, no stoma (excl. device cost)	\$22,155			
LAR with Colovac placement, stoma (excl. device add-on cost)	\$17,927			
Cost of readmission	\$5,511		US health-economic guidelines	
Discounting (costs)	3.0%			

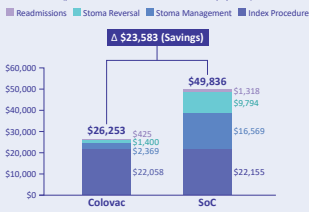
Legend: LAR: Low anterior resection.

RESULTS

\$23,583 Lifetime Savings Per Patient

with Colovac vs. SoC (prior to device add-on payment; Figure 3)

FIGURE 3: LIFETIME COSTS PER PATIENT (COLOVAC VS. SOC) (prior to consideration of device add-on payment)



- 67% of the savings realized in Year 1
- Cost savings positively correlated with stoma avoidance rate.
- Estimates are likely conservative, as only 30-day stoma-related complications included.

CONCLUSION

Colovac may deliver meaningful cost savings to U.S. payers by reducing the need for stomas, reversal procedures, and related stoma management and complication costs. These data provide important perspective as U.S. payers consider add-on payments for this novel therapy.

Disclosures: Funding support by SafeHeal SAS. Colovac and SmartVac are investigational devices limited by Federal (United States) law to investigational use.