

# Financial Considerations for Single-Use and Conventional Duodenoscopes in ERCP Procedures

## Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is the dominant endoscopic intervention used to evaluate and/or treat disorders of the pancreatic and bile ducts. Recent studies estimated upwards of 500,000-600,000 ERCP procedures, which represent only 4% of all GI procedures, are performed in the United States.<sup>1,2,3</sup> Conventional duodenoscopes (CD) are considered the gold standard endoscopic tool to diagnose and treat gallbladder, biliary system, pancreas, and liver conditions. Single-use duodenoscopes (SD) have been introduced as a possible solution to mitigate the need for comprehensive microbiologic surveillance and infection control measures, and have been positioned by their manufacturers as a cost-effective alternative to CD with regard to reprocessing and other capital costs of ownership.

As the industry considers transitioning to disposable scopes to accommodate a limited volume of procedures, administrators should evaluate the financial implications of adopting disposable scopes. While there are many technical and clinical considerations that should be evaluated between the two types of scopes, this white paper focuses on understanding the economic differences of CD and SD used in ERCP procedures.

## Financial Considerations of Adopting Disposable Scopes

### Cost for ERCP

Given the majority of hospitals tend to contract a single company to supply their capital equipment, hospital administrators must consider both the capital investment and procedural costs associated with the utilization and maintenance of duodenoscopes and how each cost element drives the overall economic impact of each scope.

Using the current market-rate costs of CD and SD, benchmarks for per-procedure costs for each scope were generated (Table 1). The primary cost inputs for CD were the scope and all associated capital supplies, as well as scope service, reprocessing, and labor fees; SD cost inputs were scope capital, supplies, and disposable fees. ERCP data of a national CD manufacturer was used to estimate the average volume of procedures and CD scopes per hospital. The average hospital was estimated to have an annual volume of 144 ERCP procedures and utilize 2 conventional duodenoscopes.<sup>4</sup> The costs in the table below only represent ERCP device costs; costs associated with the procedure (e.g. operating room, anesthesia) are not included.

Annual ERCP /Scope Volume	Conventional Duodenoscope Costs		Single-use Duodenoscope Costs	
	144 Procedures/2 Scopes <sup>4</sup>	Per Procedure Cost	144 Procedures/144 Scopes <sup>4</sup>	Per Procedure Cost
Cost of duodenoscope <sup>5,6</sup>	\$25,400	\$176	\$360,000	\$2,500
Video processor <sup>7</sup>	--	\$0	\$7,000	\$49
Annual scope service fee <sup>8</sup>	\$2,400	\$17	--	\$0
ERCP medical supply cost <sup>9</sup>	\$49,968	\$347	\$49,968	\$347
Average reprocessing consumable supplies <sup>10</sup>	\$2,448	\$17	--	\$0
Average reprocessing labor cost <sup>10</sup>	\$720	\$5	--	\$0
Annual reprocessing service fee <sup>11</sup>	\$5,670	\$39	--	\$0
Scope disposal cost <sup>12</sup>	--	\$0	\$432	\$3
<b>Total</b>	<b>\$86,606</b>	<b>\$601</b>	<b>\$417,400</b>	<b>\$2,899</b>

Note: All costs were estimated from national conventional and single-use scope providers, as well as industry providers of reprocessing supplies, reprocessing labor, or scope disposal services. The annual costs of conventional duodenoscopes and SD video processors were amortized over 5 years

An average CD procedure was estimated to cost \$601, while SD procedures cost \$2,899 per procedure. Capital costs were amortized over a 5-year period consistent with standard financial practices. Cost savings of CD were largely driven by the minimal capital cost of the duodenoscope at a per-procedure level. The ability to reprocess and reuse a duodenoscope for daily procedures, rather than purchase a new single-use scope for each procedure, generates \$2,297 savings. The SD total cost per procedure is nearly 5 times greater than CD procedures. Additionally, the capital investments required to establish an additional video processor (\$35,000) to support the SD is significant, given the minimal volume of GI procedures (~3%) that would be impacted.<sup>3,7</sup>

Because hospitals will vary in ERCP procedure volume and number of CD, data from a national CD manufacturer was used to model the per procedure cost beyond the base case (~144 procedures/2 CD scopes).<sup>4</sup> As shown in Figure 1, a sensitivity analysis was performed using the median number of ERCP procedures of hospitals with a given number of CD scopes. The analysis demonstrated that hospitals with higher annual ERCP volumes continue to report ~\$2,900 costs per SD procedure while CD costs ranged from \$562-\$706 per procedure. Although CD procedures exhibit cost savings at every scale, the highest savings are present among hospitals with the greatest volumes of ERCP procedures.



Source: National conventional scope manufacturer data of these number of scope and median volume estimates adjusted for outliers. Due to low account data information, ERCP procedure volume for 5 CD scopes is projected based on the growth rate observed from the 3 CD to 4 CD scope level.<sup>4</sup>

### Reimbursement for ERCP

In 2019, 47% of the total ERCP procedure volume occurred in outpatient settings; commercial insurers accounted for 65% of these outpatient procedures.<sup>13</sup> Using the CMS 2021 final rule, estimated reimbursement amounts were generated for ERCP outpatient procedures; commercial outpatient procedure reimbursement was estimated using a multi-payer commercial claims dataset. Outpatient commercial reimbursement is 26% higher for similar outpatient Medicare procedures.<sup>14,15</sup>

	Volume (N/% of total)	Average Reimbursement (per procedure)
Medicare	80,163 (35%)	\$3,683
Commercial	146,964 (65%)	\$4,634

Note: The Medicare outpatient reimbursement rate was estimated using a weighted average, based on the volume and reimbursement rate associated with each ERCP procedure code (CPTs: 43260-43265; 43274-43278) outlined in the CMS 2021 final OPSS rule. The commercial outpatient reimbursement rate was estimated using a multi-payer commercial claims dataset. Source: Definitive<sup>13</sup>; CMS final rule<sup>14</sup>; IBM MarketScan Commercial Claims Dataset<sup>15</sup>

### Reimbursement Impact of TPT Code

CMS approved a new device temporary pass-through (TPT) code for select ERCP procedures using a SD. Over a 3-year period (July 1, 2020 - June 30, 2023), the TPT code temporarily adjusts reimbursement for select ERCPs (CPT codes 43260 - 43265 and 43274 - 43278) to account for SD costs. The estimated incremental single-use scope Medicare outpatient reimbursement associated with the TPT is the device cost, estimated to be \$2,500 (Table 3).<sup>6</sup> While the TPT does provide some additional reimbursement for SD, the supplemental reimbursement is specific to Medicare, which accounts for only 35% of all ERCP procedure volume in outpatient settings, and 17% of all ERCP procedures across all settings and payors.<sup>13</sup> Moreover, following the 3-year period, as with all TPT payments, the ERCP outpatient SD procedure reimbursement will be adjusted based on the utilization of SD compared to CD, and the resulting reimbursement will be equal regardless of whether CD or SD is used.

**Table 3: TPT Reimbursement Estimates for Medicare and ERCP Procedure Volume**

	Volume (N)		Medicare Outpatient SD Reimbursement (per procedure)	
	Total ERCPs Volume	TPT Eligible Medicare Outpatient ERCPS <sup>9</sup>	Without TPT	With TPT
National	473,403	80,163	<b>\$3,683</b>	<b>\$6,183</b>
Average Per Hospital	144	24		

Note: National ERCP procedure volumes were estimated by setting and payer using a multi-payer healthcare database. The reimbursement per procedure without TPT was estimated using a weighted average of reimbursement rates for CPT code 43260-43265; 43274-43278 outlined in the CMS 2021 final OPPS rule<sup>14</sup> and the corresponding CPT code Medicare procedure volume<sup>13</sup>. TPT reimbursement is the sum of the weighted average of procedure rates describe above plus the estimated device cost of \$2,500. Source: Definitive Data<sup>13</sup>; National conventional scope manufacturer<sup>4</sup>; CMS 2021 final rule<sup>15</sup>; CD manufacturer costs<sup>6</sup>

### Return on Investment

Using per-procedure scope costs and the estimated reimbursement amounts, the return on investment (ROI) was evaluated for both CD and SD. Profitability of each scope was estimated as the difference in scope reimbursement and scope costs (Table 4). Commercial outpatient procedures using SD had a return on investment of \$1,735 per procedure, while that of CD represented over a two-fold the ROI per procedure or \$4,033. For Medicare outpatient procedures, the incremental TPT payment for SD results in a ROI of \$3,284 compared to a \$3,082 ROI on ERCP procedures for CD. The weighted average return on investment of ERCP procedures using CD, based on 65% of outpatient procedures being commercial versus Medicare, is \$3,700 compared to \$2,277 for SD. The lower costs for CD are the key driver of these ROI findings.

**Table 4: ERCP Scope ROI Estimates during TPT period**

Commercial Outpatient CD Reimbursement (per procedure)			Commercial Outpatient SD Reimbursement (per procedure)		
Cost	Reimbursement	ROI	Cost	Reimbursement	ROI
\$601	\$4,634	<b>\$4,033</b>	\$2,899	\$4,634	<b>\$1,735</b>
Medicare Outpatient CD Reimbursement (per procedure)			Medicare Outpatient SD Reimbursement (per procedure)		
Cost	Reimbursement	ROI	Cost	Reimbursement	ROI
\$601	\$3,683	<b>\$3,082</b>	\$2,899	\$6,183	<b>\$3,284</b>

Note: Table 4 incorporates the estimated per procedure from Table 1 base case and the Medicare and Commercial reimbursement amounts from Tables 2 & 3. Table 4 ROI findings are based on base case estimates outlined in Table 2; actual customer reimbursement may differ. Source: CY2021 final rule<sup>15</sup>; IBM MarketScan Claims database<sup>14</sup>

Beyond June 2023, the ROI may change since the usual time period for a TPT rule is 3 years; after that time, hospitals will no longer benefit from the incremental SD outpatient Medicare device reimbursement. There would be in the future only one ERCP reimbursement amount per procedure for both CD and SD. If CD represent more of the procedure volume mix, TPT reimbursement for both scopes will be slightly above the current CD reimbursement but below the current SD reimbursement rate of \$6,183.

## Key Financial Considerations

Analysis of nationally representative hospital ERCP procedure volume and scope utilization demonstrated higher per-procedure costs with SD compared to CD (\$2,899 vs \$601). Given the high price of SD (\$2,899), the break-even point may be too high for many providers, making uniform industry adoption difficult. Hospitals should also take into account the payer and setting mix of its ERCP procedures. The TPT payment is only applicable for Medicare procedures occurring in outpatient settings, representing only 17% of annual ERCP procedure volume.<sup>13</sup> Given the majority of procedures are commercial, the incremental TPT payment for ERCP procedures for SD (\$2,500) is unlikely to meaningfully change a hospital's overall ERCP revenue.<sup>6</sup> Additionally, hospitals must consider the true impact of a SD investment within the larger gastroenterology department. High volume centers will experience slightly lower per-procedure SD costs, however, the adoption of SD requires significant investment in new technology and equipment, as well as the adoption of new labor and staff processes. Moreover, a high-volume center would continue to rely upon its existing CD reprocessing technology investment, across all its departments, and utilize its service contracts to ensure optimal service and repair of most GI products. In contrast, while centers with lower ERCP volumes may consider single-use scopes a solution for their limited procedures, the per-procedure cost of SD (\$2,899) may be too great an investment for centers with finite resources and a small number of ERCP procedures.

## Best Practices

Although this paper did not focus on the clinical considerations associated with SD, it is essential to consider the role of scope performance, patient outcomes, and the hospital's commitment to infection prevention and reprocessing policies. Prioritization of each, through comprehensive and ongoing staff education, not only ensures staff are properly trained and monitored but also helps support maintenance of optimal disinfection within institutional settings, lessening the risks of infection. Moreover, early, efficient, and consistent CD review and auditing of asset practices have been found to be key contributors to optimal scope performance.

## Conclusion

The entrance of single-use duodenoscopes into the market has prompted a discussion on the value in comparison to the mainstay conventional duodenoscope during ERCP procedures. While this may prompt some hospitals to reevaluate their duodenoscope needs, each scope's economic costs, including device, capital, and other costs, must be evaluated; similarly, as the body of evidence continues to grow, hospitals should continue to evaluate the technical and clinical scope differences. A review of the economic costs demonstrate that substantial fiscal investment is required for SD compared to CD. This suggests that shifting away from CD may not be worth the investment.

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8. Olympus offers a premium protection plan for the first 36 months. Years 4 and 5 have a service contract list price of \$3,000 per year. Cost of service amortized over 5 years. Service contracted amount may vary by provider.
9. Olympus estimate of ERCP medical supply costs includes medical supplies, medications and disposable use in procedure (e.g. guidewires, sphincterotomes) and other disposables used in the procedure.
10. Labor for reprocessing cost is based on hourly rate for a GI technician (\$16.86) divided by 60 minutes and multiplied by the technician time (17 minutes which consists of Pre-Cleaning 2 min, Leakage testing 4 min, Manual cleaning 3 min, AER processing 26 min, Post- AER processing 3 min and Transportation time 5 min). Hourly cost for technician from Source: Ofstead, C.L., Quick, M.R., Eiland, J.E., Adams, S.J. (2017). A Glimpse at the true cost of reprocessing endoscopes: results of a pilot project.
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