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EW: Tricuspid Coverage Positive, With Some Caveats

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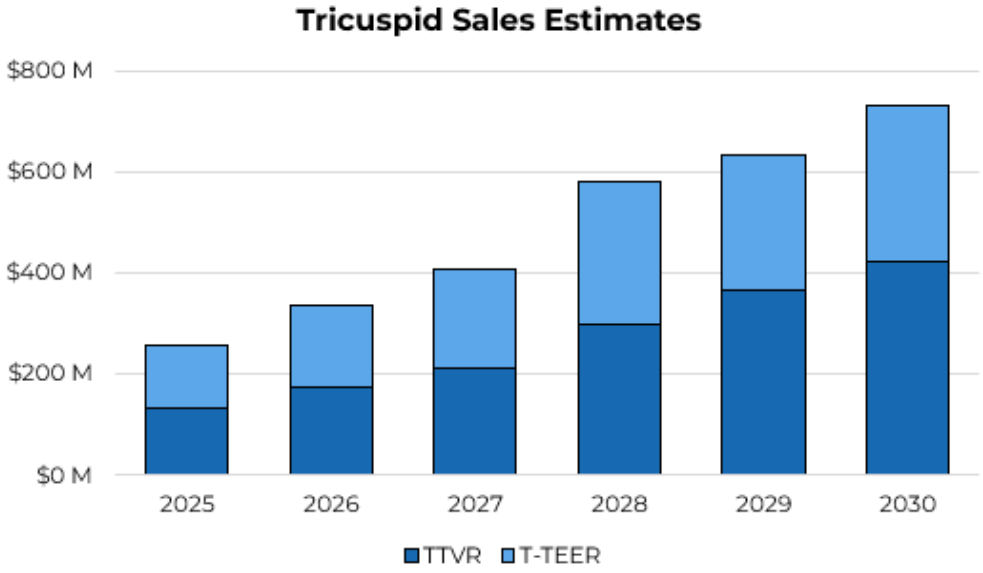
Edwards Lifesciences Corp (EW)

Price:	$73.93
52-Week High:	$96.12
52-Week Low:	$58.93

Abbott Laboratories (ABT)

Price:	$112.42
52-Week High:	$121.64
52-Week Low:	$99.71

We view CMS's draft coverage policy for transcatheter tricuspid valve replacement (TTVR) as incrementally more positive for **EW**'s Evoque relative to our initial expectations. The lack of facility / operator volume thresholds will likely allow for broader utilization and make it easier to meet or exceed the ~25% CAGR observed with mitral valve procedures. The counterweight to this, however, is the agency's clear focus on clinically meaningful endpoints and use of an active comparator in the mandatory two-year evidence development study. With TTVR having a superior reimbursement profile to ABT's TriClip transcatheter tricuspid edge-to-edge repair (T-TEER), a draft NCD for which will be out in early April, we suspect EW has the edge on the adoption curve.



Source: Capitol Policy Partners

Coverage Criteria Breaks Precedent

CMS proposes to cover TTVR under Coverage with Evidence Development (CED) "for the treatment of symptomatic tricuspid regurgitation (TR) graded as at least severe."

- While this is consistent with EW's labeling, we note that its specificity is a departure from prior structural heart NCDs (e.g., TAVR, M-TEER) that provide coverage for use that is consistent with an FDA-approved indication.
- In other words, any supplemental approvals into lower acuity patients would require a full NCD reconsideration, with the policy unable to accommodate such use organically.

The CED study should have "primary outcomes of all-cause mortality, hospitalizations, or a composite of these, through a minimum of 24 months," along with the use of optimal medical therapy (OMT) as an active comparator. Patient reported outcome measures must also be reported independently to avoid confounding the overall clinical utility picture.

- The use of an active comparator also represents a deviation from relevant prior NCDs, as well as the five-year post-approval study EW is already running for Evoque, which relies merely on reporting into an established registry. Such a design will therefore make utilization beyond integrated medical systems challenging.
- We suspect that a key consideration in this decision is the significance of patient-reported quality-of-life measures in driving device arm performance in the pivotal trials, which CMS notes makes it "impossible to assess the true benefit against OTM alone, and treatment benefit for hospitalizations…and survival have not been shown."

More positively, while CMS strongly insinuates that this TTVR procedures should involve three separate participants – an interventional cardiologist, cardiac surgeon, and interventional echocardiographer – it stops short of an explicit requirement, as it has previously. The same is true of the facility / provider volume criteria it has often relied on as a proxy for quality, the need for which was echoed by key medical societies.

- EW had noted in its public comment that the requirements put forward by these stakeholders would leave nearly ~30% of Medicare beneficiaries without access to qualifying facilities, making its omission a clear victory.
- That said, the *reason* for the omission appears to stem from what the agency views as a lack of consistency / data within the relevant pivotal studies, which it notes took place only at highly selective sites with rigorous inclusion / exclusion criteria.
- CMS therefore concludes that "active data collection on treatment conditions, including operator, facility, and procedure team characteristics is needed in CED studies to understand conditions that can replicate or exceed those trial results."

This sets up the bar for what a "successful" CED study must demonstrate, with failure to do so likely to result in more restrictive conditions being imposed. As outlined by CMS, this would include clinically meaningful improvements in health outcomes and a satisfactory risk / benefit profile when compared with tricuspid surgical interventions.

Read-Through to ABT's TriClip

As noted, the draft NCD for T-TEER is scheduled for release on or before April 3, and with ABT's TriClip having a stronger safety profile than EW's Evoque, we would expect the release to be similarly non-specific in terms of explicit facility / operator requirements.

However, in light of similar concerns over the product's clinical utility, with trial performance driven more by significant – but potentially biased – patient-reported outcomes rather than "hard" data points like improved mortality / hospitalizations, we suspect the CED study requirements will be similar to TTVR as well.

From a policy standpoint, this would seem to leave *reimbursement* as the outstanding distinguishing factor for provider adoption. As we have previously noted, ABT maintains a nominal advantage in that regard, but its longer procedural time (2-3 hours) relative to Evoque (60-90 minutes) and meaningfully higher imaging requirements / costs likely make TTVR the more attractive option.

As shown below, nominal physician payments are likely ~20% higher for the typical T-TEER service, but more than 15% *less* than TTVR on a per minute basis, which speaks to provider opportunity costs for selecting a given intervention. Facilities, meanwhile, would collect nearly 40% less by this measure, which includes an accounting for the New Technology Add-On Payments (NTAPs) that took effect Oct. 1.

ENTITY	TTVR	T-TEER	%Δ
Procedure Time (Mins)	**90**	**130**	**44%**
Physician Rate	$1,610	$1,948	21%
Rate Per Minute	$17.88	$14.99	-16%
Facility Rate*	$68,559	$62,709	-9%
Rate Per Minute	$762	$482	-37%

** Includes weighted average base rate ($36,706) plus Evoque ($31,850) and TriClip ($26,000) NTAPs*

Source: CMS, BMC Cardiovascular Disorders, Capitol Policy Partners

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