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[EW, ABT] Tricuspid Coverage Expectations

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Edwards Lifesciences Corp (EW)

Price:	$73.30
52-Week High:	$96.12
52-Week Low:	$58.93

Abbott Laboratories (ABT)

Price:	$115.40
52-Week High:	$121.64
52-Week Low:	$99.71

With CMS due to publish its draft National Coverage Determinations (NCD) for **EW's** Evoque transcatheter tricuspid valve replacement (TTVR) by Dec. 20, followed by **ABT's** TriClip edge-to-edge repair (T-TEER) by Apr. 3, we view EW as incrementally better positioned than ABT. This is due to the shorter procedure time and marginally more attractive physician reimbursement associated with Evoque TTVR. However, those benefits are likely to be somewhat offset by additional operator requirements and TriClip's more attractive safety profile. In short, while neither policy is likely to be as flexible as either company is requesting, we suspect additional considerations will inform adoption and – ultimately – market share between TTVR and T-TEER.

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

Coverage Request Comparisons

In contrast to what we view as more substantive coverage recommendations from EW and others regarding the TTVR National Coverage Analysis (NCA) [*see Oct. 8 report*], ABT's T-TEER submission leaves the specifics of its request far more ambiguous.

While this may be an intentional effort to avoid endorsement of any facility / operator criteria that – as ABT puts it – "can reduce the availability…and unintentionally hinder equitable patient access," the agency has a demonstrated preference over many years for unambiguous standards regarding provider infrastructure and experience coverage conditions [*Transcatheter Aortic Valve Replacement (TAVR) (2012, 2019)*, *Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (2014, 2021)*].

Perhaps the most important stakeholders in setting such standards are the relevant medical societies, most notably the Society of Thoracic Surgeons (STS), American College of Cardiology (ACC), Heart Rhythm Society (HRS), American Society of Echocardiography (ASE), and Society for Cardiovascular Angiography & Interventions (SCAI). Indeed, with any coverage policy likely to adopt a Coverage with Evidence Development (CED) approach that requires participation in the STS / ACC Transcatheter Valve Therapy (TVT) Registry – as is the case for both TAVR and M-TEER – we suspect the draft policies for TTVR and T-TEER will hew closely to their joint recommendations [*TTVR*, *T-TEER*].

For ease of comparison, we have included a summary of those recommendations below, side-by-side with those from EW and ABT, which build upon their initial coverage requests submitted in Feb. 2024 and Mar. 2023, respectively. In the appendix below there is also a side-by-side comparison with the current standards for TAVR and M-TEER.

We should nevertheless note that EW's comment submission explains that, if CMS were to endorse the societies' proposed requirement that facilities have a demonstrated track record of at least 20 TEER procedures per year, nearly 30% of beneficiaries would live more than 50 miles from a qualifying hospital, posing an additional barrier to access. In comparison, following EW's recommendation would put this number at just 7% of beneficiaries.

	TRICUSPID REPLACEMENT		TRICUSPID REPAIR	
CRITERIA	**EW**	**SOCIETIES**	**ABT**	**SOCIETIES**
New Facility Program	▪ ≥ 20 mitral or tricuspid procedures per year, with 50%+ being transcatheter; ***or*** ▪ ≥ 5 tricuspid valve procedures per year; ***and*** ≥ 10 transcatheter valve (any) procedures	▪ ≥ 20 TEER ***and*** ≥ 100 TAVR per year; ***and*** ▪ ≥ 20 tricuspid cases in prior 2 years; ***and*** ▪ ≥ 50 open heart cases in prior year; ***and*** ▪ ≥ 200 transesophagel echocardiography per year	Prioritize TEER infrastructure (multidisciplinary heart team, imaging training, TEER experience) over surgical volumes	▪ ≥ 20 TEER ***and*** ≥ 100 TAVR per year; ***and*** ▪ ≥ 20 tricuspid cases in prior 2 years; ***and*** ▪ ≥ 50 open heart cases in prior year; ***and*** ▪ ≥ 200 transesophagel echocardiography per year
Procedure Operators	Interventional cardiologist ***or*** cardiac surgeon	Interventional cardiologist ***and*** cardiac surgeon, ***and*** interventional echocardiographer	Permit, not require, co-implanters, and embrace diverse / emerging imaging modalities	Interventional cardiologist ***or*** cardiac surgeon, ***and*** interventional echocardiographer
OPERATOR EXPERIENCE				
Interventional Cardiologist	≥ 30 structural heart disease procedures	≥ 50 structural valve cases, with 50%+ being TEER	None Listed	≥ 50 structural valve cases, with 50%+ being TEER
Cardiac Surgeon	≥ 20 mitral valve surgical procedures per year	≥ 50 structural valve cases, with 50%+ being TEER	None Listed	≥ 50 structural valve cases, with 50%+ being TEER
Interventional Echocardiographer	≥ 30 structural heart disease procedures	≥ 50 structural valve cases, with 50%+ being TEER	None Listed	≥ 50 structural valve cases, with 50%+ being TEER

Source: NCD comment letter submissions

Show Me the Money

Perhaps more interesting, however, is the repeated calls for additional *payment* for T-TEER services among practicing physicians, which are nearly entirely absent from comment letters submitted for the TTVR review. Despite the fact that CMS *reimbursement* decisions are entirely distinct from their *coverage* analyses, fully 25% of commenters in the T-TEER NCD highlight the insufficiency of current payments to drive adoption and ensure program viability.

With T-TEER cases (2-3 hours) taking 45%-150% longer than TTVR, TAVR, or even M-TEER (60-90 minutes), along with meaningfully higher imaging requirements / costs, numerous stakeholders highlight payment (in addition to coverage) as an obstacle to adoption. The agency is nevertheless likely to deem such issues "beyond the scope" of its current coverage review. In fact, physician payments for temporary Category III codes – such as those for TTVR (0646T) and T-TEER (0569T / 0570T) – are likely beyond CMS auspices altogether, as their payment rates are typically set by each Medicare Administrative Contractor (MAC).

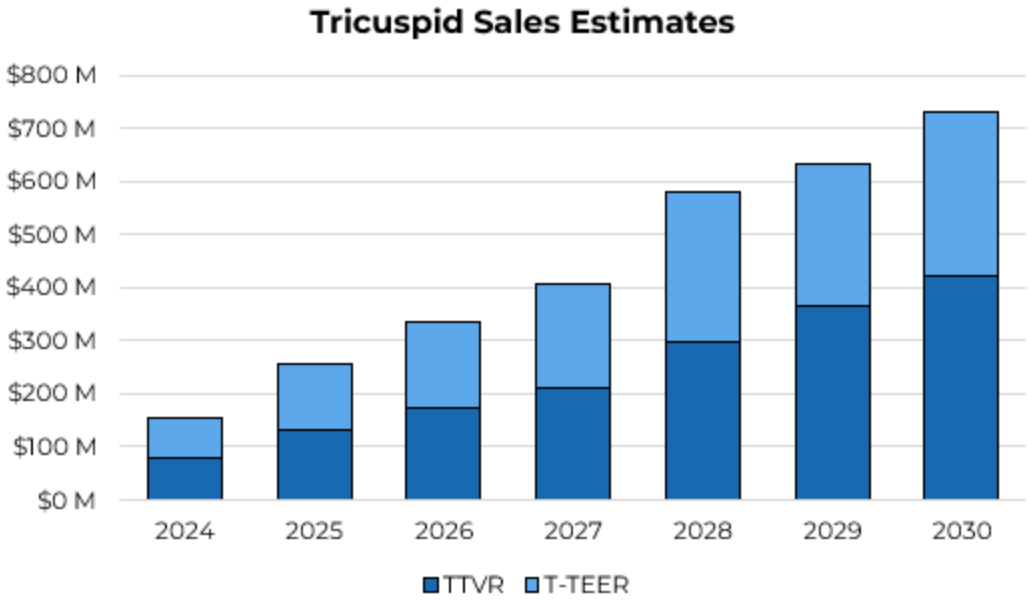
- ***Medical Center Director, Transcatheter Valve Interventions:*** *"These procedures are more complex and take longer compared with M-TEER…CMS should consider creating a new DRG and CPT for T-TEER, which reimburses hospitals and physicians at a higher rate than for M-TEER."*
- ***Large Medical Center:*** *"Given the high level of experience and expertise required, and the significant procedural time involved (greater than that of TAVR or M-TEER on average), it is critical that appropriate reimbursement reflect this."*
- ***Director, Structural Heart Program:*** *"Adequate reimbursement is needed to make this procedure viable for institutions and providers…This would reflect the significant increase in time, effort, and expertise for the population with longer lengths of stay and more expensive equipment requirements, along with associated opportunity costs."*

We find the opportunity cost argument interesting, in that despite the nominally greater dollar amount paid for T-TEER services ($1,948) compared to TTVR ($1,610), practitioners actually stand to make *~15% less* on a per minute basis ($14.99 vs $17.88). Facilities themselves, meanwhile, would collect nearly 40% less by this measure, which includes an accounting for Medicare's New Technology Add-On Payments (NTAPs) that took effect Oct. 1.

Gauging The Potential Sales Trajectory

Given likely similarities to the M-TEER coverage policy, along with survey data suggesting clinicians expect the tricuspid space to evolve at a similar pace to what we saw with mitral products following their own FDA approval and NCD, we have used that as a proxy to estimate the potential growth rate for TTVR / T-TEER.

Starting with disclosed sales figures from EW and ABT, we then trended this forward via the YoY growth rate for M-TEER observed in Medicare claims data in the years following its initial NCD in 2014, which would imply a ~25% CAGR.



Source: Capitol Policy Partners

APPENDIX

TAVR & M-TEER COVERAGE vs TTVR & T-TEER RECOMMENDATIONS

			SOCIETY RECOMMENDATIONS	
CRITERIA	**TAVR**	**M-TEER**	**TTVR**	**T-TEER**
New Facility Program	▪ ≥ 20 aortic valve surgeries in prior 2 years; ***and*** ▪ ≥ 50 open heart surgeries in prior year; ***and*** ▪ ≥ 300 PCIs per year	▪ ≥ 20 mitral valve cases for severe MR per year, with 50%+ being mitral valve repair; ***and*** ▪ ≥ 300 PCIs per year	▪ ≥ 20 TEER ***and*** ≥ 100 TAVR per year; ***and*** ▪ ≥ 20 tricuspid cases in prior 2 years; ***and*** ▪ ≥ 50 open heart cases in prior year; ***and*** ▪ ≥ 200 TEE per year	▪ ≥ 20 TEER ***and*** ≥ 100 TAVR per year; ***and*** ▪ ≥ 20 tricuspid cases in prior 2 years; ***and*** ▪ ≥ 50 open heart cases in prior year; ***and*** ▪ ≥ 200 TEE per year
Procedure Operators	Interventional cardiologist ***and*** cardiac surgeon	Interventional cardiologist ***or*** cardiac surgeon, ***and*** interventional echocardiographer	Interventional cardiologist ***and*** cardiac surgeon, ***and*** interventional echocardiographer	Interventional cardiologist ***or*** cardiac surgeon, ***and*** interventional echocardiographer
OPERATOR EXPERIENCE				
Interventional Cardiologist	≥ 100 structural heart cases ***or*** ≥ 30 left-sided structural cases per year	▪ ≥ 50 structural heart cases ***or*** ≥ 30 left-sided structural cases per year; ***and*** ▪ ≥ 20 transseptal cases	≥ 50 structural valve cases, with 50%+ being TEER	≥ 50 structural valve cases, with 50%+ being TEER
Cardiac Surgeon	≥ 100 open heart surgeries, with ≥ 25 being aortic valve	≥ 20 mitral valve cases per year, with 50% being repairs	≥ 50 structural valve cases, with 50%+ being TEER	≥ 50 structural valve cases, with 50%+ being TEER
Interventional Echocardiographer	N/A	▪ ≥ 10 transseptal guidance cases; ***and*** ▪ ≥ 30 structural heart cases	≥ 50 structural valve cases, with 50%+ being TEER	≥ 50 structural valve cases, with 50%+ being TEER

Source: CMS NCDs 20.32 and 20.33, Company Comment Letters, Capitol Policy Partners

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