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[EW, ABT] Tricuspid Coverage & Sales Trajectory

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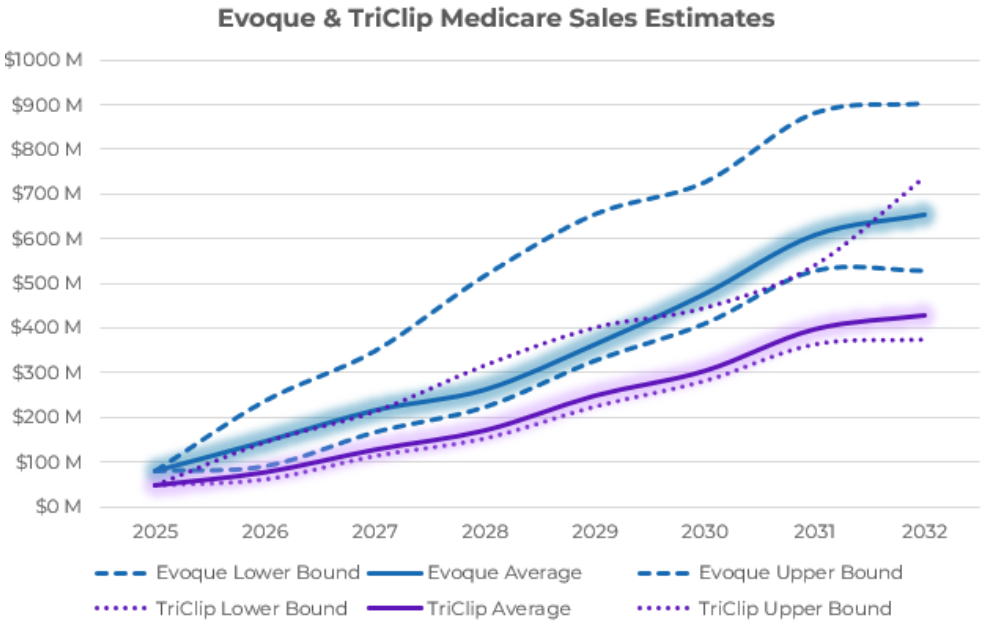
Key Takeaways: As investors look to model out sales of **Edwards Lifesciences' (EW)** Evoque tricuspid valve replacement in advance of CMS's draft National Coverage Determination (NCD), which is expected by ~Dec. 20 (final policy due March 20), we estimate Medicare sales of ~$80M in FY25, growing at a 30%-40% CAGR through 2032. This compares to ~$50M for **Abbott's (ABT)** TriClip following CMS's opening of a separate NCD last week for tricuspid *repair* devices, with comments due by Nov. 2, a draft policy targeted for Apr. 3, and the final decision likely by July 2.



CPP estimate based on Medicare FFS claims

Coverage Criteria: Volume & Registry Requirements

While we will reserve ultimate judgement on the specific contours of the tricuspid *repair* NCD [e.g., ABT's TriClip, EW's Pascal] until the full suite of comments are published early next month, we would at this point expect its criteria to be based on those of the 2014 policy for mitral valve transcatheter edge-to-edge repair (M-TEER), updated in 2021, given that both are TEER procedures [i.e., M-TEER vs T-TEER]. In such services, a clip device is used to pull together the leaflets of the native valve.

This is distinct from transcatheter tricuspid valve replacement (TTVR) in which, as CMS notes, "a bioprosthetic valve is inserted and implanted inside the native tricuspid valve," and also explains the agency's motivation in utilizing two separate NCDs. In contrast to T-TEER, however, the precedent NCD for TTVR is likely to be the previously established policy (2012) for transcatheter aortic valve replacement (TAVR), last updated in 2019.

Edwards Lifesciences Corp (EW)

Price:	$64.49
52-Week High:	$96.12
52-Week Low:	$58.93

Abbott Laboratories (ABT)

Price:	$113.07
52-Week High:	$121.64
52-Week Low:	$89.67

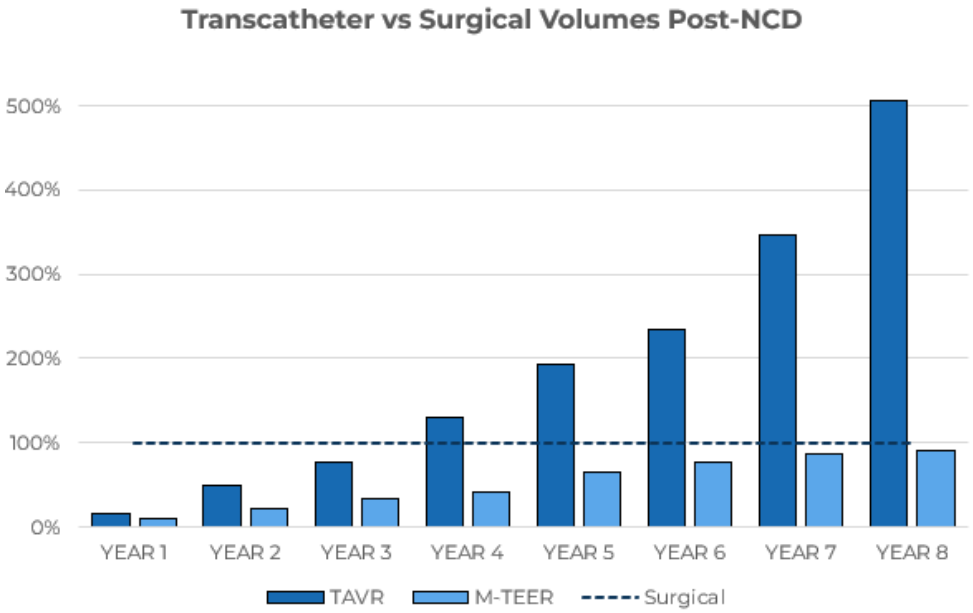
Medtronic PLC (MDT)

Price:	$87.45
52-Week High:	$91.49
52-Week Low:	$68.84

Boston Scientific Corp (BSX)

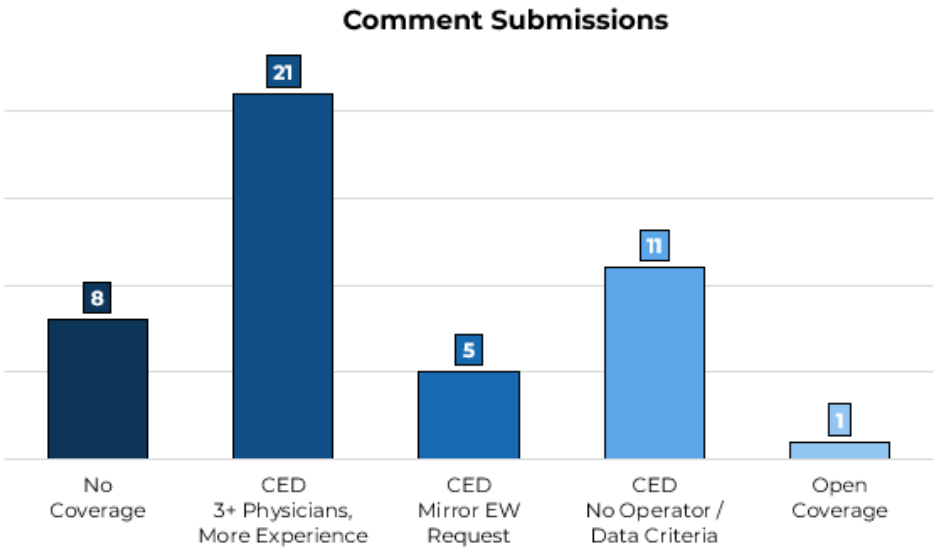
Price:	$84.44
52-Week High:	$84.89
52-Week Low:	$48.35

We briefly summarize the distinctions between these previous coverage policies in the table below, but a review of Medicare fee-for-service (FFS) claims also shows that, despite the earlier TAVR NCD having laid the groundwork for future cardiac device policies like M-TEER that rely on integrated care models, multi-disciplinary heart teams, and registry participation via Coverage with Evidence Development (CED), the utilization ramp has remained noticeably shallower for the latter, both in terms of YoY growth and its relative proportion of more traditional surgical approaches.



CPP estimate based on Medicare FFS claims data

Our expectations for the TTVR policy under review are informed by the public comments submitted in response to the June 20 request, most notably those of prominent medical societies [e.g., Society of Thoracic Surgeons (STS), American Association for Thoracic Surgery (AATS), American College of Cardiology (ACC), Heart Rhythm Society (HRS), Society for Cardiovascular Angiography & Interventions (SCAI), the American Society of Echocardiography (ASE)], with the key outstanding questions being the extent of facility / operator criteria needed for coverage. In our view, this will likely include the intra-procedural participation of 2-3 separate practitioners, including a cardiac surgeon, interventional cardiologist, and an interventional echocardiographer.



Source: Capital Policy Partners

More specifically, we suspect facilities wishing to initiate a TTVR program will be required to demonstrate their having performed at least: (1) 20 TEER *and* 100 TAVR procedures per year; (2) 20 tricuspid valve surgeries in the prior two years; (3) 200 transesophageal echocardiography (TEE) services each year; and (4) 50 open heart surgeries in the previous year. Based on the societies' recommendations, each operator must also have performed at least 50 career structural valve procedures, with 25 having been TEER.

CRITERIA	TAVR	M-TEER	TMVR – SOCIETIES
New Facility Program	▪ ≥ 20 aortic valve surgeries in prior 2 years ▪ ≥ 50 open heart surgeries in prior year ▪ ≥ 300 PCIs per year	▪ ≥ 20 mitral valve surgeries for severe MR per year, with 50%+ being mitral valve repair ▪ ≥ 300 PCIs per year	▪ ≥ 20 TEER per year ▪ ≥ 100 TAVR per year ▪ ≥ 20 tricuspid valve surgeries in prior 2 years ▪ ≥ 50 open heart surgeries in prior year ▪ ≥ 200 transesophagel echocardiography per year
Procedure Operators	▪ Interventional cardiologist ***and*** cardiac surgeon	▪ Interventional cardiologist ***or*** cardiac surgeon ▪ Interventional echocardiographer	▪ Interventional cardiologist ***and*** cardiac surgeon ▪ Interventional echocardiographer
OPERATOR EXPERIENCE			
Interventional Cardiologist	▪ ≥ 100 career structural heart disease procedures or ≥ 30 left-sided structural procedures per year	▪ ≥ 50 career structural heart disease surgeries or 30+ left-sided structural procedures per year ▪ Participation in ≥ 20 career transseptal interventions	▪ ≥ 50 career structural valve procedures, with ≥ 25 TEER
Cardiac Surgeon	▪ ≥ 100 career open heart surgeries, with ≥ 25 being aortic valve	▪ ≥ 20 mitral valve surgeries per year, with 50% repairs	▪ ≥ 50 career structural valve procedures, with ≥ 25 TEER
Interventional Echocardiographer	N/A	▪ ≥ 10 career transseptal guidance procedures ▪ ≥ 30 career structural heart procedures	▪ ≥ 50 career structural valve procedures, with ≥ 25 TEER

Source: Capital Policy Partners

In contrast, EW recommends that the procedure be performed by *either* a cardiac surgeon *or* interventional cardiologist, with facilities meeting just **one** of the following two volume criteria: (A) ≥ 20 mitral *or* tricuspid valve procedures per year, with ≥ 10 having been transcatheter; or (B) ≥ 5 tricuspid valve surgical procedures per year *and* ≥ 10 transcatheter services targeting any valve (e.g., tricuspid, mitral, aortic).

As outlined in EW's own comment submission, the threshold for such standards can have a meaningful impact on accessibility, and therefore sales of a company's device.

MEDICARE PATIENTS	≥ 20 TEER PER YEAR	EW REQUEST
% Without Access	27%	7%
% Low Income w/o Access	89%	78%

Source: Capital Policy Partners

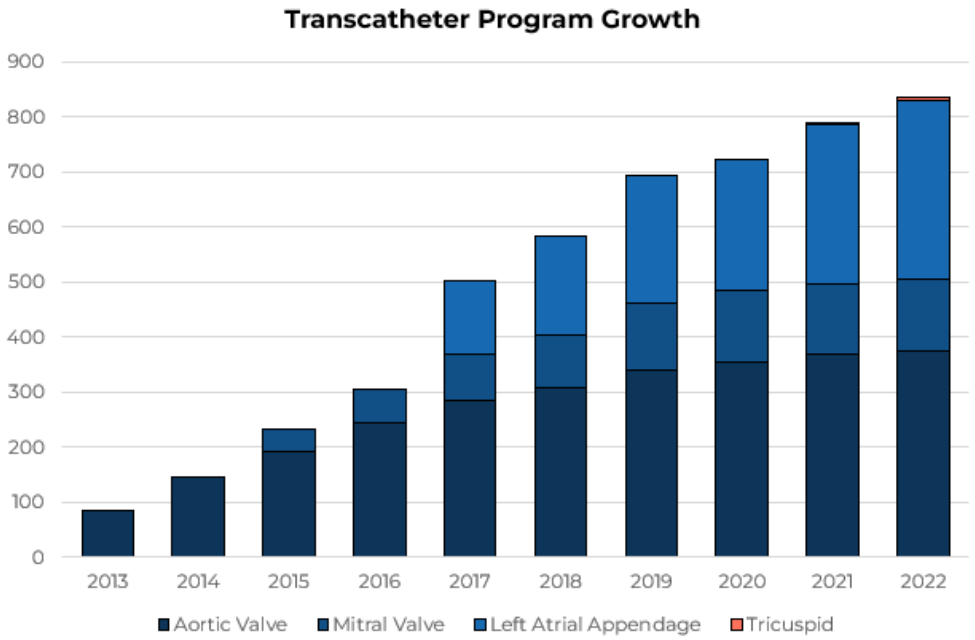
With EW estimating 7+ years before a likely required CED study can be completed and the NCD criteria reevaluated, how these criteria are applied will govern utilization for the foreseeable future.

It should therefore be noted that, of the 46 public comments submitted (excluding form letters), 21 (46%) called for facility / operator volume requirements more in keeping with the above medical societies (i.e., ≥ 20 TEER per year) than the EW recommendation, with another 8 (17%) suggesting CMS should delay coverage altogether, or at least until complete data from the TRISCEND II Pivotal Trial can be reviewed by the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC).

Conversely, we count 5 (11%) comments as largely mirroring EW's recommendations, with another 11 (24%) calling for CMS to omit the typical volume requirements altogether, and just 1 (2%) suggesting that an open-ended policy, without CED registry / study criteria, should be pursued.

Revenue Implications

While many investors have focused on the potential growth of facility-based transcatheter programs (e.g., TAVR, TEER) [*see below chart*] to glean insights into the potential sales trajectory, we have taken a more wholistic approach that we hope better allows for upper- and lower-bound estimates.



CPP estimate based on Medicare FFS claims

We start with EW and ABT's own projections of 800 and 150 Medicare fee-for-service (FFS) procedures in FY25, respectively, included in the most recent inpatient rule. With FFS representing 49.5% of total beneficiaries – the remaining 50.5% being enrolled in Medicare Advantage (MA) plans, which must use any NCD as its coverage baseline – this would imply ~1,600 Evoque services next year. At EW's price point of $49K per device, this would generate $79M in Medicare sales.

We suspect that ABT's TriClip projection of 150 FFS units (~300 for FFS + MA) in FY25 – equating to just $12M in Medicare sales at the company's $40K price point – is likely artificially low given the absence of a coverage policy review schedule at the time the rule was written. However, with CMS targeting completion of a T-TEER NCD by July 2, or 3/4 of the way through FY25, the 12-month run rate would be ~600 (~1,200 for FFS + MA), or ~$48M.

We next trended these two baselines forward using several precedent transcatheter metrics, including not only the number of *facilities* offering TAVR, M-TEER, and left atrial appendage closure (LAAC) [e.g., **Boston Scientific (BSX)**], but also YoY growth in the *volume* of services being done at each site and the proportion of each transcatheter approach relative to traditional *surgical* techniques in the years following their NCDs.

This results in the following estimates, which are reflected in the line chart on page one.

MEDICARE SALES	2025	2026	2027	2028	2029	2030	2031	2032
Evoque – Lower Bound	$79M	$90M	$166M	$222M	$326M	$409M	$528M	$528M
Evoque – Average	$79M	$146M	$215M	$261M	$362M	$475M	$607M	$652M
Evoque – Upper Bound	$79M	$237M	$348M	$517M	$654M	$726M	$881M	$903M
TriClip – Lower Bound	$48M	$62M	$114M	$153M	$224M	$281M	$363M	$373M
TriClip – Average	$48M	$78M	$128M	$172M	$249M	$305M	$399M	$430M
TriClip – Upper Bound	$48M	$145M	$213M	$316M	$401M	$444M	$539M	$737M

Source: Capital Policy Partners

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