







































































COR: class of recommendation; LOE: level of evidence; SAVR: surgical aortic valve replacement; STS: Society of Thoracic Surgeons; TAVI: transcatheter aortic valve implantation.

## U.S. Preventive Services Task Force Recommendations

Not applicable.

## Medicare National Coverage

The Centers for Medicare & Medicaid Services published a decision memo on the use of TAVR in 2012.<sup>84</sup> This memo indicated that the Centers for Medicare & Medicaid Services covers TAVI when used according to FDA indications when the following conditions are met:

- Device has FDA approval
- Two cardiac surgeons agree with indications for the procedure
- The patient is “under the care of a heart team,” and the hospital meets qualifications for performing TAVR.

The memo also stated that TAVR could be covered for non-FDA-approved indications under the Coverage with Evidence Development program. The following is a summary of the main conditions required for Coverage with Evidence Development:

- TAVI is performed within a clinical study that has the following characteristics:
- “The clinical study must adhere to the ... standards of scientific integrity and relevance to the Medicare population.”
- The study must address quality of life and adverse events at follow-up periods of 1 year or longer.

## Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 9.

**Table 9. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
NCT01586910 <sup>a</sup>	Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI)	2500	Oct 2017 (ongoing)
NCT02956915	Evaluation of Length of Stay and Predisposing Factors of Late Discharge After Transfemoral Transcatheter Aortic Valve Implantation Using the SAPIEN-3 Prosthesis: A French Multicenter Prospective Observational Trial	300	Dec 2017 (ongoing)
NCT01057173	Transcatheter Versus Surgical Aortic Valve Implantation in Patients With Severe Aortic Valve Stenosis (NOTION)	280	Apr 2018
NCT01645202	A Randomized Comparison of Transcatheter Heart Valves in High Risk Patients With Severe Aortic Stenosis: Medtronic CoreValve Versus Edwards SAPIEN XT (The CHOICE Trial)	240	Dec 2018

<b>NCT No.</b>	<b>Trial Name</b>	<b>Planned Enrollment</b>	<b>Completion Date</b>
NCT01240902 <sup>a</sup>	Medtronic CoreValve® U.S. Pivotal Trial	1650	Aug 2019
NCT02661451 <sup>a</sup>	Transcatheter Aortic Valve Replacement to UNload the Left Ventricle in Patients With ADvanced Heart Failure: A Randomized Trial (TAVR UNLOAD)	600	May 2020
NCT02436655	Aortic Valve Replacement Versus Conservative Treatment in Asymptomatic Severe Aortic Stenosis: (AVATAR Trial): A Multicentre Randomized Controlled Trial	312	Jun 2020
NCT01314313 <sup>a</sup>	The PARTNER II Trial "Placement of AoRTic TraNscathetER Valves Trial" (US) [Edwards Study 2010-12]	6650	Sep 2020
NCT02163850 <sup>a</sup>	SALUS Trial: TranScatheter Aortic Valve RePlacement System Pivotal Trial The Safety and Effectiveness of the Direct Flow Medical Transcatheter Aortic Valve System	878	Dec 2021
NCT01737528	Society of Thoracic Surgeons and American College of Cardiology Transcatheter Valve Therapy Registry (STS/ACC TVT Registry)	16,000	Jun 2022
NCT02249000	Safety and Clinical Performance of the Self-expanding Transcatheter BIOVALVE Prosthesis in Subjects With Severe Symptomatic Aortic Stenosis Suitable for Transfemoral Transcatheter Aortic Valve Implantation	86	Dec 2022
NCT03361046	Evaluation of Clinical Outcomes of Transcatheter Aortic Valve-in-Valve Implantation in Polish Population – Observational Multicenter Registry	150	May 2024

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

## References

- Freeman RV, Otto CM. Spectrum of calcific aortic valve disease: pathogenesis, disease progression, and treatment strategies. *Circulation*. Jun 21 2005;111(24):3316-3326. PMID 15967862
- Coeytaux RR, Williams JW, Jr., Gray RN, et al. Percutaneous heart valve replacement for aortic stenosis: state of the evidence. *Ann Intern Med*. Sep 7 2010;153(5):314-324. PMID 20679543
- Lindroos M, Kupari M, Heikkila J, et al. Prevalence of aortic valve abnormalities in the elderly: an echocardiographic study of a random population sample. *J Am Coll Cardiol*. Apr 1993;21(5):1220-1225. PMID 8459080
- Bonow RO, Carabello BA, Kanu C, et al. ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (writing committee to revise the 1998 Guidelines for the Management of Patients With Valvular Heart Disease): developed in collaboration with the Society of Cardiovascular Anesthesiologists: endorsed by the Society for Cardiovascular Angiography and Interventions and the Society of Thoracic Surgeons. *Circulation*. Aug 1 2006;114(5):e84-231. PMID 16880336
- Iung B, Cachier A, Baron G, et al. Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery? *Eur Heart J*. Dec 2005;26(24):2714-2720. PMID 16141261
- Lieberman EB, Bashore TM, Hermiller JB, et al. Balloon aortic valvuloplasty in adults: failure of procedure to improve long-term survival. *J Am Coll Cardiol*. Nov 15 1995;26(6):1522-1528. PMID 7594080
- Meredith IT, Walton A, Walters DL, et al. Mid-term outcomes in patients following transcatheter aortic valve implantation in the CoreValve Australia and New Zealand Study. *Heart Lung Circ*. Mar 2015;24(3):281-290. PMID 25456213

8. Figulla L, Neumann A, Figulla HR, et al. Transcatheter aortic valve implantation: evidence on safety and efficacy compared with medical therapy. A systematic review of current literature. *Clin Res Cardiol*. Apr 2011;100(4):265-276. PMID 21165626
9. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med*. Oct 21 2010;363(17):1597-1607. PMID 20961243
10. Reynolds MR, Magnuson EA, Lei Y, et al. Health-related quality of life after transcatheter aortic valve replacement in inoperable patients with severe aortic stenosis. *Circulation*. Nov 1 2011;124(18):1964-1972. PMID 21969017
11. Makkar RR, Fontana GP, Jilaihawi H, et al. Transcatheter aortic-valve replacement for inoperable severe aortic stenosis. *N Engl J Med*. May 3 2012;366(18):1696-1704. PMID 22443478
12. Svensson LG, Blackstone EH, Rajeswaran J, et al. Comprehensive analysis of mortality among patients undergoing TAVR: results of the PARTNER trial. *J Am Coll Cardiol*. Jul 15 2014;64(2):158-168. PMID 25011720
13. Kapadia SR, Tuzcu EM, Makkar RR, et al. Long-term outcomes of inoperable patients with aortic stenosis randomly assigned to transcatheter aortic valve replacement or standard therapy. *Circulation*. Oct 21 2014;130(17):1483-1492. PMID 25205802
14. Webb JG, Doshi D, Mack MJ, et al. A randomized evaluation of the SAPIEN XT transcatheter heart valve system in patients with aortic stenosis who are not candidates for surgery. *JACC Cardiovasc Interv*. Dec 21 2015;8(14):1797-1806. PMID 26718510
15. Popma JJ, Adams DH, Reardon MJ, et al. Transcatheter aortic valve replacement using a self-expanding bioprosthesis in patients with severe aortic stenosis at extreme risk for surgery. *J Am Coll Cardiol*. May 20 2014;63(19):1972-1981. PMID 24657695
16. Reardon MJ, Adams DH, Coselli JS, et al. Self-expanding transcatheter aortic valve replacement using alternative access sites in symptomatic patients with severe aortic stenosis deemed extreme risk of surgery. *J Thorac Cardiovasc Surg*. Dec 2014;148(6):2869-2876 e2861-2867. PMID 25152474
17. Mack MJ, Brennan JM, Brindis R, et al. Outcomes following transcatheter aortic valve replacement in the United States. *JAMA*. Nov 20 2013;310(19):2069-2077. PMID 24240934
18. Yakubov SJ, Adams DH, Watson DR, et al. 2-year outcomes after iliofemoral self-expanding transcatheter aortic valve replacement in patients with severe aortic stenosis deemed extreme risk for surgery. *J Am Coll Cardiol*. Sep 22 2015;66(12):1327-1334. PMID 26383718
19. Baron SJ, Arnold SV, Reynolds MR, et al. Durability of quality of life benefits of transcatheter aortic valve replacement: Long-term results from the CoreValve US extreme risk trial. *Am Heart J*. Dec 2017;194:39-48. PMID 29223434
20. Osnabrugge RL, Arnold SV, Reynolds MR, et al. Health status after transcatheter aortic valve replacement in patients at extreme surgical risk: results from the CoreValve U.S. trial. *JACC Cardiovasc Interv*. Feb 2015;8(2):315-323. PMID 25700755
21. Linke A, Wenaweser P, Gerckens U, et al. Treatment of aortic stenosis with a self-expanding transcatheter valve: the International Multi-centre ADVANCE Study. *Eur Heart J*. Oct 7 2014;35(38):2672-2684. PMID 24682842
22. Piazza N, Grube E, Gerckens U, et al. Procedural and 30-day outcomes following transcatheter aortic valve implantation using the third generation (18 Fr) corevalve revalving system: results from the multicentre, expanded evaluation registry 1-year following CE mark approval. *EuroIntervention*. Aug 2008;4(2):242-249. PMID 19110790
23. Rodes-Cabau J, Webb JG, Cheung A, et al. Transcatheter aortic valve implantation for the treatment of severe symptomatic aortic stenosis in patients at very high or prohibitive surgical risk: acute and late outcomes of the multicenter Canadian experience. *J Am Coll Cardiol*. Mar 16 2010;55(11):1080-1090. PMID 20096533
24. Zahn R, Gerckens U, Grube E, et al. Transcatheter aortic valve implantation: first results from a multi-centre real-world registry. *Eur Heart J*. Jan 2011;32(2):198-204. PMID 20864486
25. Tamburino C, Capodanno D, Ramondo A, et al. Incidence and predictors of early and late mortality after transcatheter aortic valve implantation in 663 patients with severe aortic stenosis. *Circulation*. Jan 25 2011;123(3):299-308. PMID 21220731
26. Panoulas VF, Francis DP, Ruparelina N, et al. Female-specific survival advantage from transcatheter aortic valve implantation over surgical aortic valve replacement: Meta-analysis of

- the gender subgroups of randomised controlled trials including 3758 patients. *Int J Cardiol.* Jan 1 2018;250:66-72. PMID 29169764
27. Villablanca PA, Mathew V, Thourani VH, et al. A meta-analysis and meta-regression of long-term outcomes of transcatheter versus surgical aortic valve replacement for severe aortic stenosis. *Int J Cardiol.* Dec 15 2016;225:234-243. PMID 27732927
  28. Villablanca P, Briceño D, Makkiya M, et al. Long-term outcomes of transcatheter versus surgical aortic valve replacement for severe aortic stenosis: a meta-analysis and meta-regression: PROSPERO 2016:CRD42016036772. PROSPERO International prospective register of systematic reviews 2016; [https://www.crd.york.ac.uk/PROSPERO/display\\_record.asp?ID=CRD42016036772](https://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42016036772). Accessed March 7, 2018.
  29. Mack MJ, Leon MB, Smith CR, et al. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. *Lancet.* Jun 20 2015;385(9986):2477-2484. PMID 25788234
  30. Reardon MJ, Adams DH, Kleiman NS, et al. 2-year outcomes in patients undergoing surgical or self-expanding transcatheter aortic valve replacement. *J Am Coll Cardiol.* Jul 14 2015;66(2):113-121. PMID 26055947
  31. Panchal HB, Ladia V, Desai S, et al. A meta-analysis of mortality and major adverse cardiovascular and cerebrovascular events following transcatheter aortic valve implantation versus surgical aortic valve replacement for severe aortic stenosis. *Am J Cardiol.* Sep 15 2013;112(6):850-860. PMID 23756547
  32. Takagi H, Niwa M, Mizuno Y, et al. A meta-analysis of transcatheter aortic valve implantation versus surgical aortic valve replacement. *Ann Thorac Surg.* Aug 2013;96(2):513-519. PMID 23816417
  33. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med.* Jun 9 2011;364(23):2187-2198. PMID 21639811
  34. Reynolds MR, Magnuson EA, Wang K, et al. Health-related quality of life after transcatheter or surgical aortic valve replacement in high-risk patients with severe aortic stenosis: results from the PARTNER (Placement of AoRTic TraNscathetER Valve) Trial (Cohort A). *J Am Coll Cardiol.* Aug 7 2012;60(6):548-558. PMID 22818074
  35. Genereux P, Cohen DJ, Williams MR, et al. Bleeding complications after surgical aortic valve replacement compared with transcatheter aortic valve replacement: insights from the PARTNER I Trial (Placement of Aortic Transcatheter Valve). *J Am Coll Cardiol.* Mar 25 2014;63(11):1100-1109. PMID 24291283
  36. Adams DH, Popma JJ, Reardon MJ, et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N Engl J Med.* May 8 2014;370(19):1790-1798. PMID 24678937
  37. Deeb GM, Reardon MJ, Chetcuti S, et al. 3-year outcomes in high-risk patients who underwent surgical or transcatheter aortic valve replacement. *J Am Coll Cardiol.* Jun 7 2016;67(22):2565-2574. PMID 27050187
  38. Zorn GL, 3rd, Little SH, Tadros P, et al. Prosthesis-patient mismatch in high-risk patients with severe aortic stenosis: A randomized trial of a self-expanding prosthesis. *J Thorac Cardiovasc Surg.* Apr 2016;151(4):1014-1022, 1023 e1011-1013. PMID 26614412
  39. Muneretto C, Bisleri G, Moggi A, et al. Treating the patients in the 'grey-zone' with aortic valve disease: a comparison among conventional surgery, sutureless valves and transcatheter aortic valve replacement. *Interact Cardiovasc Thorac Surg.* Jan 2015;20(1):90-95. PMID 25320140
  40. Minutello RM, Wong SC, Swaminathan RV, et al. Costs and in-hospital outcomes of transcatheter aortic valve implantation versus surgical aortic valve replacement in commercial cases using a propensity score matched model. *Am J Cardiol.* May 15 2015;115(10):1443-1447. PMID 25784513
  41. Sedaghat A, Al-Rashid F, Sinning JM, et al. Outcome in TAVI patients with symptomatic aortic stenosis not fulfilling PARTNER study inclusion criteria. *Catheter Cardiovasc Interv.* Nov 15 2015;86(6):1097-1104. PMID 26032437
  42. Arora S, Strassle PD, Ramm CJ, et al. Transcatheter versus surgical aortic valve replacement in patients with lower surgical risk scores: a systematic review and meta-analysis of early outcomes. *Heart Lung Circ.* Aug 2017;26(8):840-845. PMID 28169084
  43. Arora S, Vaidya SR, Strassle PD, et al. Meta-analysis of transfemoral TAVR versus surgical aortic valve replacement. *Catheter Cardiovasc Interv.* Oct 25 2017. PMID 29068166

44. Garg A, Rao SV, Visveswaran G, et al. Transcatheter aortic valve replacement versus surgical valve replacement in low-intermediate surgical risk patients: a systematic review and meta-analysis. *J Invasive Cardiol*. Jun 2017;29(6):209-216. PMID 28570236
45. Singh K, Carson K, Rashid MK, et al. Transcatheter aortic valve implantation in intermediate surgical risk patients with severe aortic stenosis: a systematic review and meta-analysis. *Heart Lung Circ*. Feb 2018;27(2):227-234. PMID 28473216
46. Ando T, Takagi H, Grines CL. Transfemoral, transapical and transcatheter aortic valve implantation and surgical aortic valve replacement: a meta-analysis of direct and adjusted indirect comparisons of early and mid-term deaths. *Interact Cardiovasc Thorac Surg*. Sep 1 2017;25(3):484-492. PMID 28549125
47. Gozdek M, Raffa GM, Suwalski P, et al. Comparative performance of transcatheter aortic valve-in-valve implantation versus conventional surgical redo aortic valve replacement in patients with degenerated aortic valve bioprostheses: systematic review and meta-analysis. *Eur J Cardiothorac Surg*. Mar 1 2018;53(3):495-504. PMID 29029105
48. Khan SU, Lone AN, Saleem MA, et al. Transcatheter vs surgical aortic-valve replacement in low-to intermediate-surgical-risk candidates: A meta-analysis and systematic review. *Clin Cardiol*. Nov 2017;40(11):974-981. PMID 29168984
49. Tam DY, Vo TX, Wijesundera HC, et al. Transcatheter vs surgical aortic valve replacement for aortic stenosis in low-intermediate risk patients: a meta-analysis. *Can J Cardiol*. Sep 2017;33(9):1171-1179. PMID 28843328
50. Witberg G, Lador A, Yahav D, et al. Transcatheter versus surgical aortic valve replacement in patients at low surgical risk: A meta-analysis of randomized trials and propensity score matched observational studies. *Catheter Cardiovasc Interv*. Feb 1 2018. PMID 29388308
51. Zhou Y, Wang Y, Wu Y, et al. Transcatheter versus surgical aortic valve replacement in low to intermediate risk patients: A meta-analysis of randomized and observational studies. *Int J Cardiol*. Nov 12 2016;228:723-728. PMID 27886617
52. Thyregod HG, Steinbruchel DA, Ihlemann N, et al. Transcatheter versus surgical aortic valve replacement in patients with severe aortic valve stenosis: 1-year results from the all-comers NOTION randomized clinical trial. *J Am Coll Cardiol*. May 26 2015;65(20):2184-2194. PMID 25787196
53. Nielsen HH, Klaaborg KE, Nissen H, et al. A prospective, randomised trial of transapical transcatheter aortic valve implantation vs. surgical aortic valve replacement in operable elderly patients with aortic stenosis: the STACCATO trial. *EuroIntervention*. Jul 20 2012;8(3):383-389. PMID 22581299
54. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med*. Apr 28 2016;374(17):1609-1620. PMID 27040324
55. Kondur A, Briasoulis A, Palla M, et al. Meta-Analysis of transcatheter aortic valve replacement versus surgical aortic valve replacement in patients with severe aortic valve stenosis. *Am J Cardiol*. Jan 15 2016;117(2):252-257. PMID 26639040
56. Tamburino C, Barbanti M, D'Errigo P, et al. 1-year outcomes after transfemoral transcatheter or surgical aortic valve replacement: results from the Italian OBSERVANT Study. *J Am Coll Cardiol*. Aug 18 2015;66(7):804-812. PMID 26271063
57. Siemieniuk RA, Agoritsas T, Manja V, et al. Transcatheter versus surgical aortic valve replacement in patients with severe aortic stenosis at low and intermediate risk: systematic review and meta-analysis. *BMJ*. Sep 28 2016;354:i5130. PMID 27683246
58. Søndergaard L, Steinbruchel DA, Ihlemann N, et al. Two-year outcomes in patients with severe aortic valve stenosis randomized to transcatheter versus surgical aortic valve replacement: the all-comers nordic aortic valve intervention randomized clinical trial. *Circ Cardiovasc Interv*. Jun 2016;9(6). PMID 27296202
59. Reardon MJ, Kleiman NS, Adams DH, et al. Outcomes in the randomized corevalve us pivotal high risk trial in patients with a Society of Thoracic Surgeons Risk Score of 7% or less. *JAMA Cardiol*. Nov 1 2016;1(8):945-949. PMID 27541162
60. Reardon MJ, Van Mieghem NM, Popma JJ, et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. *N Engl J Med*. Apr 6 2017;376(14):1321-1331. PMID 28304219
61. Fanning JP, Wesley AJ, Walters DL, et al. Neurological injury in intermediate-risk transcatheter aortic valve implantation. *J Am Heart Assoc*. Nov 15 2016;5(11). PMID 27849158

62. Dvir D, Webb JG, Bleiziffer S, et al. Transcatheter aortic valve implantation in failed bioprosthetic surgical valves. *JAMA*. Jul 2014;312(2):162-170. PMID 25005653
63. Linke A, Woitek F, Merx MW, et al. Valve-in-valve implantation of Medtronic CoreValve prosthesis in patients with failing bioprosthetic aortic valves. *Circ Cardiovasc Interv*. Oct 1 2012;5(5):689-697. PMID 23048050
64. Latib A, Ielasi A, Montorfano M, et al. Transcatheter valve-in-valve implantation with the Edwards SAPIEN in patients with bioprosthetic heart valve failure: the Milan experience. *EuroIntervention*. Mar 2012;7(11):1275-1284. PMID 22278193
65. Subban V, Savage M, Crowhurst J, et al. Transcatheter valve-in-valve replacement of degenerated bioprosthetic aortic valves: a single Australian Centre experience. *Cardiovasc Revasc Med*. Nov-Dec 2014;15(8):388-392. PMID 25456416
66. Toggweiler S, Wood DA, Rodes-Cabau J, et al. Transcatheter valve-in-valve implantation for failed balloon-expandable transcatheter aortic valves. *JACC Cardiovasc Interv*. May 2012;5(5):571-577. PMID 22625197
67. Raval J, Nagaraja V, Eslick GD, et al. Transcatheter valve-in-valve implantation: a systematic review of literature. *Heart Lung Circ*. Nov 2014;23(11):1020-1028. PMID 25038030
68. Conte JV, Hermiller J, Jr., Resar JR, et al. Complications after self-expanding transcatheter or surgical aortic valve replacement. *Semin Thorac Cardiovasc Surg*. Autumn 2017;29(3):321-330. PMID 29195573
69. Khatri PJ, Webb JG, Rodes-Cabau J, et al. Adverse effects associated with transcatheter aortic valve implantation: a meta-analysis of contemporary studies. *Ann Intern Med*. Jan 1 2013;158(1):35-46. PMID 23277899
70. Giordana F, D'Ascenzo F, Nijhoff F, et al. Meta-analysis of predictors of all-cause mortality after transcatheter aortic valve implantation. *Am J Cardiol*. Nov 1 2014;114(9):1447-1455. PMID 25217456
71. Van Mieghem NM, Tchetché D, Chieffo A, et al. Incidence, predictors, and implications of access site complications with transfemoral transcatheter aortic valve implantation. *Am J Cardiol*. Nov 1 2012;110(9):1361-1367. PMID 22819428
72. Czerwinska-Jelonkiewicz K, Michalowska I, Witkowski A, et al. Vascular complications after transcatheter aortic valve implantation (TAVI): risk and long-term results. *J Thromb Thrombolysis*. May 2014;37(4):490-498. PMID 24132402
73. Genereux P, Kodali SK, Green P, et al. Incidence and effect of acute kidney injury after transcatheter aortic valve replacement using the new valve academic research consortium criteria. *Am J Cardiol*. Jan 1 2013;111(1):100-105. PMID 23040657
74. Khawaja MZ, Thomas M, Joshi A, et al. The effects of VARC-defined acute kidney injury after transcatheter aortic valve implantation (TAVI) using the Edwards bioprosthesis. *EuroIntervention*. Sep 2012;8(5):563-570. PMID 22995082
75. Siontis GC, Juni P, Pilgrim T, et al. Predictors of permanent pacemaker implantation in patients with severe aortic stenosis undergoing TAVR: a meta-analysis. *J Am Coll Cardiol*. Jul 15 2014;64(2):129-140. PMID 25011716
76. Gensas CS, Caixeta A, Siqueira D, et al. Predictors of permanent pacemaker requirement after transcatheter aortic valve implantation: insights from a Brazilian registry. *Int J Cardiol*. Aug 1 2014;175(2):248-252. PMID 24880480
77. Abdel-Wahab M, Mehilli J, Frerker C, et al. Comparison of balloon-expandable vs self-expandable valves in patients undergoing transcatheter aortic valve replacement: the CHOICE randomized clinical trial. *JAMA*. Apr 16 2014;311(15):1503-1514. PMID 24682026
78. Lenders GD, Collas V, Hernandez JM, et al. Depth of valve implantation, conduction disturbances and pacemaker implantation with CoreValve and CoreValve Accutrak system for Transcatheter Aortic Valve Implantation, a multi-center study. *Int J Cardiol*. Oct 20 2014;176(3):771-775. PMID 25147076
79. Boerlage-Van Dijk K, Kooiman KM, Yong ZY, et al. Predictors and permanency of cardiac conduction disorders and necessity of pacing after transcatheter aortic valve implantation. *Pacing Clin Electrophysiol*. Nov 2014;37(11):1520-1529. PMID 25040838
80. Kim WJ, Ko YG, Han S, et al. Predictors of permanent pacemaker insertion following transcatheter aortic valve replacement with the CoreValve revalving system based on computed tomography analysis: an Asian multicenter registry study. *J Invasive Cardiol*. Jul 2015;27(7):334-340. PMID 26136283

81. Nishimura RA, Otto CM, Bonow RO, et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. Jun 10 2014;63(22):2438-2488. PMID 24603192
82. Nishimura RA, O'Gara PT, Bonow RO. Guidelines update on indications for transcatheter aortic valve replacement. JAMA Cardiol. Sep 1 2017;2(9):1036-1037. PMID 28768333
83. Baumgartner H, Falk V, Bax JJ, et al. 2017 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J. Sep 21 2017;38(36):2739-2791. PMID 28886619
84. Center for Medicare & Medicaid Services. Decision Memo for transcatheter aortic valve replacement (TAVR) (CAG-00430N). 2012; [https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=257&ver=4&NcaName=Transcatheter+Aortic+Valve+Replacement+\(TAVR\)&bc=ACAAAAAAAgAAAA%3d%3d&](https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=257&ver=4&NcaName=Transcatheter+Aortic+Valve+Replacement+(TAVR)&bc=ACAAAAAAAgAAAA%3d%3d&). Accessed March 2, 2018.

## **Billing Coding/Physician Documentation Information**

---

- |              |  |
|--------------|--|
| <b>33361</b> | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach   |
| <b>33362</b> | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach   |
| <b>33363</b> | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach  |
| <b>33364</b> | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach   |
| <b>33365</b> | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)   |
| <b>33366</b> | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)  |
| <b>33367</b> | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (eg, femoral vessels) (List separately in addition to code for primary procedure)          |
| <b>33368</b> | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (eg, femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure) |
| <b>33369</b> | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)    |
| <b>93591</b> | Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve (new code 1/1/2017)  |
| <b>93592</b> | Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure) (new code 1/1/2017)  |

### **ICD-10 Codes**

- |               |  |
|---------------|--|
| <b>I06.0-</b> | Rheumatic aortic valve diseases                |
| <b>I06.9</b>  |  |
| <b>I08.0;</b> | Multiple valve diseases involving aortic valve |
| <b>I08.2-</b> |  |

**I08.9**

**I35.0-** Nonrheumatic aortic valve disorders (I35.0 is nonrheumatic aortic valve stenosis and I35.2 is nonrheumatic aortic valve stenosis with insufficiency)  
**I35.9**

**T82.01xA-** Mechanical complication of heart valve prosthesis code range

**T82.09xS**

**T82.857A;** Stenosis of other cardiac prosthetic devices, implants and grafts code

**T82.857D;** list

**T82.857S**

Prior to 2013, there were category III CPT codes for this procedure: 0256T, 0257T, 0258T, 0259T.

0318T was deleted 1/1/2014

**Additional Policy Key Words**

N/A

**Policy Implementation/Update Information**

- 2/1/12 New policy; considered medically necessary for patients who are not surgical candidates; investigational for all other indications
- 2/1/13 Medically necessary indications added for patients who are at high risk for open surgery using the transfemoral approach, and patients who are at high risk for open surgery using the transapical approach. Investigational statement added for treatment of degenerated bio-prosthetic valve or failed TAVI (Valve-in-Valve approach), and for vascular approaches other than transfemoral or transapical
- 2/1/14 Policy statement revised to include medically necessary indication for TAVI by the transapical approach for patients who are not suitable candidates for open surgery.
- 12/1/14 Policy statement revised to remove statement that "procedures performed via the transaxillary, transiliac, transaortic, or other approaches" are investigational, to reflect the approval of the CoreValve device that is labeled for use via transaxillary, transfemoral, and transaortic approaches. A statement was added to the policy statement that devices should be used according to their FDA approved indication. Clinical input supported proposed policy statements.
- 2/1/15 No policy statement changes.
- 2/1/16 No policy statement changes.
- 10/1/16 Medically necessary policy statement added for valve-in-valve implantation in patients at high or prohibitive risk for open surgery.
- 2/1/17 No policy statement changes.
- 2/1/18 No policy statement changes.
- 6/1/18 Policy statements changed to add patients at intermediate surgical risk to first medically necessary statement.
- 2/1/19 No policy statement changes.

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.