Clinical Policy Title: Transcatheter aortic and mitral valve replacement and repair

Clinical Policy Number: 04.03.01

Effective Date: January 1, 2016
Initial Review Date: September 16, 2015
Most Recent Review Date: September 21, 2017
Next Review Date: September 2018

Policy contains:
- SAPIAN Valve
- CoreValve
- MitraClip
- Transcatheter valve replacement

Related policies:
None.

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of transcatheter aortic valve replacement (TAVR) to be clinically proven and, therefore, medically necessary when any of the following criteria are met* (American Heart Association/American College of Cardiologists [AHA/ACC] 2014, Nishimura 2014, Ramlawi 2016, De Baker 2014, Chiam 2014, Adams 2014 Glower 2012):

- Severe aortic stenosis — aortic valve area less than 0.8cm².
- Technically or clinically inoperable patients at high risk for open surgery.

Select Health of South Carolina considers the use of transcatheter mitral valve replacement (TMVR) to be medically necessary when any of the following criteria are met*(DeBaker 2014, Foster 2013, Chaim 2011):

- Severe mitral stenosis — mitral valve area less than 2.0cm²
- Severe mitral valve calcification.
• Severe mitral regurgitation when regurgitated volume becomes equal to forward flow.
• Technically or clinically inoperable patients at high risk for open surgery.

Select Health of South Carolina considers the use of transcatheter mitral valve repair to be medically necessary when any of the following criteria are met*(Mant 2014):

• Severe degenerative mitral regurgitation.
• Technically or clinically inoperable patients at high risk for open surgery.

*Note: Procedure must occur in a hospital with a cardiac team capable of performing emergency surgical heart valve replacement.

Limitations:

All other uses of TAVR are considered to be investigational, and therefore not medically necessary.

All other uses of TMVR are considered to be investigational, and therefore not medically necessary.

All other uses of transcatheter mitral valve repair are considered to be investigational, and therefore not medically necessary.

Alternative covered services:

• Open surgical aortic valve replacement.
• Open surgical mitral valve replacement.
• Open surgical mitral valve repair.

Background

Aortic stenosis is the most common valvular heart disease in the western hemisphere. It is the abnormal narrowing of the aortic valve, which reduces blood flow to the rest of the body. Aortic stenosis is traditionally treated with surgical aortic valve replacement, which is considered the gold standard of care; but, many patients have an increased operative risk and are unsuitable candidates for open surgical valve replacement. Into this arena have stepped a number of less invasive techniques for valvular replacement and repair, namely methods and devices capable of implanting artificial aortic valves through a catheter, or TAVR. TAVR may be carried out transfemorally or transapically (antegrade) through the apex of the left ventricle. Two major TAVR devices are the Edwards SAPIEN heart valve and the Medtronic CoreValve heart valve.
The Edwards SAPIEN heart valve was studied in the Placement of Aortic Transcatheter Valve (PARTNER) Trial. One-year mortality rates showed that TAVR was superior to standard open valve therapies in high-risk patients (Glower 2012). Through the second year following valve replacement, there were no significant differences in all-cause mortality between the surgical and transcatheter groups (Conradi 2012, Kodali 2012). Valve performance in TAVR and surgery groups was also similar (Makkar 2012); however, aortic regurgitation after TAVR was associated with increased long-term mortality. Recent advances have further diminished 30-day mortality rates following TAVR with one-year and two-year morality rates similar to those of open surgical patients but with an increased risk of death from early and late stroke (Khatri 2013).

The Medtronic CoreValve heart valve is a self-expanding prosthesis for TAVR. All-cause mortality rates at one-year show the CoreValve significantly reduces mortality compared to surgical valve replacement from 19.1 percent to 14.2 percent (Adams 2014). A significant reduction in the rate of major adverse cardiovascular and cerebrovascular events at one-year and a lower risk of stroke at both 30-days and one-year time periods have also been demonstrated.

Mitral stenosis and mitral regurgitation may remain asymptomatic for more than 10 years, and both conditions may lead to chronic elevation of left atrial pressure and cardiomyopathy. Surgical mitral valve replacement and repair is the typical treatment for mitral stenosis and mitral regurgitation; however, many patients are older and present with comorbidities and left ventricular dysfunction. In these patients, TMVR has emerged as an alternative treatment (DeBaker 2014, Chiam 2011).

TMVR and transcatheter mitral valve repair are appropriate for patients with symptomatic, degenerative mitral valve regurgitation (grade 3+ or 4+) if the patient is inoperable or at a high risk for surgery (Foster 2013). Mitral valve repair with a prosthesis such as the MitraClip System (Feldman 2009) is associated with a 9 percent rate of complication by a major adverse event, such as partial clip detachment. Furthermore, at four-years of follow up, patients with the MitraClip require mitral valve surgery more frequently (Mauri 2013).

Searches:

Select Health of South Carolina searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality Guideline Clearinghouse and evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

Searches were conducted on August 1, 2017, using the terms “transcatheter,” “aortic,” “mitral,” “replacement,” “repair,” and “percutaneous.”

We included:
• **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

• **Guidelines based on systematic reviews.**

• **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Guidelines (Mant, 2014) for care of patients with valvular heart disease have been promulgated by National Institute for Health and Care Excellence (NICE) as follows:

All hospitals admitting those with suspected acute heart failure should provide a specialist heart failure team based on a cardiology ward and that provides outreach services.

New suspected acute heart failure should be evaluated with a single measurement of serum natriuretic peptides (B-type natriuretic peptide [BNP] or N-terminal pro-B-type natriuretic peptide [NT-proBNP]), and evaluated as per the following thresholds to diagnosis heart failure:

- **BNP > 100 ng/liter**
- **NT-proBNP > 300 ng/liter**

New suspected acute heart failure with raised natriuretic peptide levels: perform transthoracic Doppler two-dimensional (2-D) echocardiography to establish the presence or absence of cardiac abnormalities.

New suspected acute heart failure: consider performing transthoracic Doppler 2-D echocardiography within 48 hours of admission to guide early specialist management.

In patients presenting with acute heart failure who is already taking beta-blockers, continue the beta-blocker treatment unless they have a heart rate less than 50 beats per minute, second- or third-degree atrioventricular block or shock.

Start or restart beta-blocker treatment during hospital admission in individuals with acute heart failure due to left ventricular systolic dysfunction once their condition has been stabilized (e.g., when intravenous diuretics are no longer needed).

Ensure that the patient's condition is stable for typically 48 hours after starting or restarting beta-blockers and before discharging them from hospital.
Offer an angiotensin-converting enzyme inhibitor (or angiotensin receptor blocker if there are intolerable side effects) and an aldosterone antagonist during hospital admission to patients with acute heart failure and reduced left ventricular ejection fraction. If the angiotensin-converting enzyme inhibitor (or angiotensin receptor blocker) is not tolerated, an aldosterone antagonist should be offered.

In a narrative review Ramlawi (2016) noted that transcatheater technologies afford patients less-invasive durable mitral valve repair options. These image-guided technologies improve the quality and durability of repairs; but, it remains unclear if treatment in the functional mitral regurgitation population is of significant clinical benefit, given that the underlying problem is a ventricular rather than valvular one. The CoAPT trial, currently enrolling patients with functional ischemic mitral regurgitation into either therapy with a MitraClip or best medical therapy, suggests the value of the former in treating functional mitral regurgitation, albeit with a device that is not as effective as surgery at fixing functional mitral regurgitation. The authors emphasize that, for the time being, novel percutaneous devices used in the treatment of mitral regurgitation are not meant to replace surgical techniques in low-risk patient groups who are good candidates for surgery. Among all catheter-based mitral therapies, the leaflet repair MitraClip system has the largest clinical experience worldwide, with an established and reproducible safety profile and reasonably effective reduction of mitral regurgitation in high-risk surgical patients.

Policy updates:

The 2014 American Heart Association/American College of Cardiologists (AHA/ACC) guidelines established stages of severity for consideration of left heart valvular replacement and repair (Nishimura 2014). Stages A and B include patients at risk and asymptomatic patients with less than severe valve regurgitation. Stage C encompasses patients who meet criteria for severe mitral regurgitation but remain asymptomatic. The new definition of severe mitral regurgitation is based on integration of multiple parameters, including valve anatomy, regurgitant severity, ventricular size and systolic function and other consequences of chronic volume overload, such as pulmonary hypertension and atrial fibrillation. An effective orifice area of 0.4 cm² or greater was defined as severe mitral regurgitation because natural history studies have demonstrated poor clinical outcomes in patients with this degree of valve regurgitation.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Nishimura (2014)</td>
<td>Key points:</td>
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</table>
| AHA/ACC guideline for the management of patients with valvular heart disease | • AHA/ACC guidelines established stages of severity for consideration of left heart valvular replacement and repair.  
  o Stages A and B include patients at risk and asymptomatic patients with less than severe valve regurgitation. |
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|                          | Stage C encompasses patients who meet criteria for severe mitral regurgitation but remain asymptomatic.  
|                          | - The new definition of severe mitral regurgitation is based on integration of multiple parameters, including valve anatomy, regurgitant severity, ventricular size and systolic function and other consequences of chronic volume overload, such as pulmonary hypertension and atrial fibrillation.  
|                          | - An effective orifice area of 0.4 cm² or greater was defined as severe mitral regurgitation because natural history studies have demonstrated poor clinical outcomes in patients with this degree of valve regurgitation. |
| Ramlawi (2016) Mitral Valve Surgery: Current Minimally Invasive and Transcatheter Options. | **Key points:**  
|                          | - Repair is clearly superior to replacement for degenerative mitral valve disease (i.e., beating-heart/small incision and transcatheter techniques).  
|                          | - Image-guided technologies may improve the quality and durability of repairs.  
|                          | - Transapical or transcatheter replacement can be achieved in a safe and durable fashion.  
|                          | - Percutaneous devices are not meant to replace surgical techniques in low-risk patient groups who are good candidates for surgery.  
|                          | - MitraClip system has the largest clinical experience worldwide, with an established and reproducible safety profile and reasonably effective reduction of mitral regurgitation in high-risk surgical patients. |
| Mant (2014) Acute heart failure: diagnosing and managing acute heart failure in adults | **Key points:**  
|                          | - All hospitals admitting people with suspected acute heart failure should provide a specialist heart failure team that is based on a cardiology ward and provides outreach services.  
|                          | - New suspected acute heart failure: use a single measurement of serum natriuretic peptides (B-type natriuretic peptide [BNP] or N-terminal pro-B-type natriuretic peptide [NT-proBNP]) and the following thresholds to rule out the diagnosis of heart failure:  
|                          |   - BNP less than 100 ng/liter  
|                          |   - NT-proBNP less than 300 ng/liter  
|                          | - In a person presenting with acute heart failure who is already taking beta-blockers, continue the beta-blocker treatment unless they have a heart rate less than 50 beats per minute, second or third degree atrioventricular block, or shock.  
|                          | - Offer an angiotensin-converting enzyme inhibitor (or angiotensin receptor blocker if there are intolerable side effects) and an aldosterone antagonist during hospital admission to people with acute heart failure and reduced left ventricular ejection fraction. If the angiotensin-converting enzyme inhibitor (or angiotensin receptor blocker) is not tolerated an aldosterone antagonist should still be offered. |
| De Baker (2014) Percutaneous transcatheter mitral valve replacement: an overview of devices in preclinical and early clinical evaluation | **Key points:**  
|                          | - Prevalence of moderate–to-severe mitral regurgitation in people in the United States is two million to two-and-a-half million, which is expected to rise to five million by 2030.  
<p>|                          | - A decrease in the prevalence of rheumatic valve disease, in combination with an increased life expectancy, has led to a high prevalence of degenerative mitral regurgitation. |</p>
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| Adams (2014) Transcatheter aortic-valve replacement with a self-expanding prosthesis | **Key points:**
  - All-cause mortality was significantly lower in the TAVR group (14.2%) than the surgical aortic valve replacement group (19.1%) using Medtronic’s CoreValve self-expanding prosthesis.
  - Exploratory analysis suggested a reduction in the rate of adverse cardiovascular and cerebrovascular events and no increase in the risk of stroke.
  - The rate of major adverse cardiovascular and cerebrovascular events at one year was significantly lower in the TAVR group than the surgical aortic valve replacement group (20.4% and 27.3%, respectively).

| Khatri (2013) Adverse Effects Associated with Transcatheter Aortic Valve Implantation | **Key points:**
  - **Survival:**
    - Overall — 30-day survival rate was 91.9%.
    - Sapien valves — Transarterial replacement survival rates were significantly higher than transapical replacement at 30 days (93.7% vs. 90.0%), and higher at one year (80.2% vs. 74.7%).
  - **Stroke:**
    - Overall — Early stroke rate was 2.9%.
    - Sapien valves — Transarterial and transapical stroke rates were 3.5% and 2.8%, respectively.
    - CoreValve — Stroke rate was 3.6%.
    - Not significantly different.
  - **Vascular complications:**
    - Overall — Complication rate was 10.4%.
    - Method — Vascular complications occurred significantly more with transarterial procedures than with transapical procedures (14.2% vs. 3.4%).
    - Of the patients with transarterially inserted valves, those with the Sapien valve experienced a significantly higher incidence of vascular complications than those with CoreValves (22.3% vs. 10.8%).
  - **Permanent pacemaker implantation:**
    - Overall — Permanent pacemaker implantation rate was 13.1%, making it the most frequent complication among all the adverse effects.
    - Device — The pacemaker implantation rate was five times higher for patients receiving the CoreValve (25.2%) than for those receiving the Sapien valve (5.0%) via the transarterial route.
  - **Renal replacement therapy:**
    - Overall — Renal replacement therapy for acute renal failure rate was 4.9%.
    - Sapien valves — The need for renal replacement therapy was significantly higher with transapical procedures than transarterial procedures (8.2% vs. 2.8%).
  - **Aortic regurgitation:**
    - Overall — Moderate to severe aortic regurgitation rate post-procedure was 4.5%.
    - Sapien valves: Rates of aortic regurgitation were lower with the transapical approach (1.4%) than the transarterial approach (4.6%), but this difference is
### Citation

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<tr>
<td>not statistically significant.</td>
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<tr>
<td>• Valve embolism, myocardial infarction and coronary obstruction:</td>
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<tr>
<td>o Overall — Rates of valve embolization (1.3%), myocardial infarction (1.1%) and coronary obstruction (0.8%) were relatively low.</td>
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<tr>
<td>o Sapien valves — Myocardial infarction was more common transapically than transarterially (1.9% vs. 0.8%). No differences between valve types or routes of access were evident among cases involving valve embolization or coronary obstruction.</td>
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<td>• Valve-in-valve implantation and conversion to open-heart surgery:</td>
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<tr>
<td>o Overall — Rates of valve-in-valve implantation and conversion to open-heart valve replacement surgery were 2.2% and 1.2%.</td>
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<tr>
<td>o Devices — CoreValve had a larger rate of valve-in-valve implantation than the Sapien valve implanted via the transarterial route (3.3% vs. 1.1%).</td>
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<tr>
<td>o Sapien valves — Transapical delivery resulted in a higher valve-in-valve</td>
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#### Foster (2013)

**Percutaneous mitral valve repair in the initial EVEREST cohort**

**Key points:**

- In MitraClip patients with persistent mitral regurgitation and pre-existing left ventricular dysfunction, there was a reduction in left ventricular wall stress, reduced left ventricular end-diastolic volume, left ventricular end-systolic volume and increase in left ventricular ejection fraction, in contrast to those with normal baseline left ventricular function, who showed reduction in left ventricular end-diastolic volume, left ventricular wall stress, no change in left ventricular end-systolic volume and a fall in left ventricular ejection fraction.

#### Mauri (2013)

**4-Year results of a randomized controlled trial of percutaneous repair versus surgery for mitral regurgitation**

**Key points:**

- At four-year follow ups after MitraClip repair, the rate of the composite endpoint of freedom from death, surgery, or 3+ or 4+ mitral regurgitation in the intention-to-treat population was 39.8% vs. 53.4% in the percutaneous repair group and surgical groups, respectively (p = 0.070).
- Rates of death were 17.4% vs. 17.8% (p = 0.914), and 3+ or 4+ mitral regurgitation was present in 21.7% vs. 24.7% (p = 0.745) at four-year follow ups, respectively.
- Surgery for mitral valve dysfunction, however, occurred in 20.4% vs. 2.2% (p < 0.001) at 1 year and 24.8% vs. 5.5% (p < 0.001) at four years.

#### Glower (2012)

**EVEREST II randomized clinical trial: Predictors of mitral valve replacement in de novo surgery or after the MitraClip procedure**

**Key points:**

- Advantages of mitral valve repair over replacement include avoidance of mandatory anticoagulation, potentially better durability than bioprostheses, less impairment of left ventricular function, less risk of left ventricular posterior wall rupture (ventricular-annular disruption) and lower early and late mortality.

#### Kodali (2012)

**Key points:**
<table>
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</thead>
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| Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement | • Mortality after TAVR remained similar to that after surgical replacement.  
• Stroke frequency was similar in the surgery and TAVR groups after 30 days.  
• Periprocedural complications (strokes, major bleeding and major vascular events) affected mortality after TAVR or surgical replacement.  
• Aortic regurgitation (even mild) after TAVR was associated with increased long-term mortality.  
• Valve performance in the TAVR group was maintained during follow up and was similar to that in the surgery group. |
| Makkar (2012) Transcatheter Aortic-Valve Replacement for Inoperable Severe Aortic Stenosis | **Key points:**  
• Two-year death rates were 43.3% in TAVR patients and 68.0% in standard therapy patients (including balloon aortic valvuloplasty).  
• Cardiac death rates for TAVR and standard therapy were 31.0% and 62.4%, respectively.  
• Rate of stroke for TAVR and standard therapy were 13.8% and 5.5%, respectively, due to more ischemic events (6.7% and 1.7%).  
• Two-year rehospitalization rates for TAVR and standard therapy were 35.0% and 72.5%, respectively.  
• Patients with severe aortic stenosis undergoing TAVR had reduced rates of death and hospitalization, with a decrease in symptoms and an improvement in valve hemodynamics that were sustained at two years of follow up. |
| Conradi (2012) Transcatheter aortic valve implantation versus surgical aortic valve replacement: A propensity score analysis in patients at high surgical risk | **Key points:**  
• Mortality rates are similar for TAVR and surgical aortic valve replacement were similar at 30 days and 180 days, but TAVR resulted in short operative times, short ventilation times and shorter length of stay in the investigative care unit. |
| Chiam (2011) Percutaneous transcatheter mitral valve repair | **Key points:**  
• Surgical treatment of mitral regurgitation has evolved from replacement to mitral valve repair, because the latter produces superior long-term outcomes achieved through minimally invasive procedures. |

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


Wendler O, Dworakowski R. TAVI in Patients Unsuitable for Surgery: A Prognosis Benefit for All?

**CMS National Coverage Determinations:**

100.3 National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) (20.32) CMS Website: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=355&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=Valve+Replacement&KeyWordLookUp=Title&KeyWordSearchType=And&list_type=ncd&bc=gAAAAAABBBB%3d%3d& Accessed August 1, 2017.

**Local Coverage Determinations (LCDs):**

No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly with those manuals.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>33361</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach.</td>
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<td>33362</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach.</td>
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<tr>
<td>33363</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach.</td>
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<td>33364</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach.</td>
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<td>33365</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach.</td>
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<tr>
<td>33366</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure.</td>
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<tr>
<td>33418</td>
<td>Transcatheter mitral valve repair percutaneous approach including transseptal puncture when performed; initial prosthesis.</td>
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<td>+33419</td>
<td>Transcatheter mitral valve repair percutaneous approach including transseptal puncture when performed; additional prosthesis(es) during same session.</td>
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<td>0345T</td>
<td>Transcatheter mitral valve repair percutaneous approach via the coronary sinus.</td>
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<td>Rheumatic mitral stenosis</td>
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<td>I05.2</td>
<td>Rheumatic mitral stenosis with insufficiency</td>
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<td>I06.0</td>
<td>Rheumatic aortic stenosis</td>
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<td>I08.0</td>
<td>Rheumatic disorders of both mitral and aortic valves</td>
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<td>I35.0</td>
<td>Non-rheumatic aortic valve stenosis</td>
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<td>Non-rheumatic aortic valve stenosis with insufficiency</td>
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