Coverage Guidelines

Drug-Eluting Coronary Stents

Disclaimer:

Please note that Baptist Health Plan updates Coverage Guidelines throughout the year. A printed version may not be most up to date version available. The health plan reserves the right to review and update this policy as needed. Refer to the website to ascertain that you are utilizing the most current available version. Clinical guideline policies are not intended to serve as treatment guidelines or treatment recommendation. Treating providers must use their own clinical judgment in rendering care to their patient population.

For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern. In addition, coverage for Medicare Advantage members may differ. This is a result of applicable coverage statements by the Center for Medicare and Medicaid Services (CMS). The National Coverage Determinations, Local Coverage Determinations, and Local Medical Review Policies may be found at the CMS website, http://www.cms.gov. Please note that for all plans, the member’s health plan benefits that are in effect on the rendered date of service must be used in coverage determinations.

DEFINITION

Drug-eluting stents are a combination product including both a drug and device used for the treatment of symptomatic coronary artery disease (CAD). The device mimics the scaffolding properties of cardiac stents, but also includes either a coating of drug directly on the stent or a thin polymer coating of antiproliferative drug intended to inhibit vascular responses to arterial injury and reduce restenosis. DES is a minimally invasive treatment option when percutaneous coronary angioplasty or stenting is required.¹

COVERAGE CRITERIA

Drug-eluting coronary stents using agents such as paclitaxel, sirolimus, or everolimus may be medically necessary only for FDA approved indications of coronary artery disease (CAD) such as:

- Symptomatic CAD associated with stable or unstable angina pectoris (AP), or
- Silent ischemia caused by a single de novo stenosis of a native coronary artery measuring approximately 2.5 to 3.75 mm in diameter and less than 28 mm in length that can be covered with one or two stents.² ³ ⁴

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Drug-eluting stents are not medically necessary and/or may be considered experimental/investigational if not FDA approved and/or when an FDA approved stent is not used for the FDA approved indication. Examples include but are not limited to the following:

- Off-label use in members with complex coronary disease such as symptomatic CAD with a high-risk profile for restenosis
- Allergy to aspirin or other antiplatelet medication including but not limited to clopidogrel, ticlopidine, or heparin
- Allergy to contrast agents
- Allergy to stainless steel
- Drug allergy or hypersensitivity to agent used to coat the stent
- Complex lesions such as long lesions, lesions in small vessels, lesions in multiple vessels, bifurcation lesions, ostial lesions, chronic total lesions, chronic total occlusions, or unprotected left main CAD
- Acute coronary symptoms
- Saphenous vein graft disease
- In-stent restenosis following previous percutaneous coronary intervention and stenting

**MEDICAL BACKGROUND**

Coronary artery disease (CAD) describes the common condition in which the coronary arteries become hardened and narrow due to atherosclerosis. CAD represents the leading cause of death in the US and makes up over 50% of cardiovascular events in both men and women under 75 years of age. The prevalence of CAD in the US is exacerbated by common behavioral risk factors such as tobacco use, lack of exercise and overweight, and type II Diabetes Mellitus (DM). Common contributing comorbidities associated with behavioral risk factors as well as advanced age are hypertension and hypercholesterolemia.\(^5\) The aging population in the US coupled with the epidemic of obesity and type II DM has contributed to the growing importance of the management and treatment of CAD.

The treatment goal for CAD is the restoration of blood supply through the coronary arteries leading to the heart muscle. CAD treatment options vary depending on the severity of disease, anatomy of the heart in relation to disease, left ventricular function, severity of symptoms, comorbidities, prior treatment history, and the degree to which treatment plans would be tolerated by the patient. Primary treatment plans include an augmentation of lifestyle and behavioral choices, which may include weight loss and exercise or smoking cessation. In more severe cases, medication may be warranted in addition to primary treatment, such as cholesterol lowering agents, vasodilators, beta-blockers, and anticoagulants. In the most severe cases, surgical inventions including percutaneous coronary interventions (PCI) or a coronary artery bypass (CABG) may be a consideration. PCI is considered a minimally invasive procedure in which revascularization occurs through the insertion of a balloon stent in order to physically remove the obstruction and thus restore blood flow.

The development of drug-eluting stents (DES) represents advancement in CAD treatment options in which the obstruction is both physically and medically addressed. In addition to manually removing the obstruction, drug therapy delivered by the stent over time limits cell
growth around the stent in order to preserve the blood flow into the heart. Early studies of DES demonstrated promising results for DES in both safety and efficacy.

Currently used therapeutic agents in drug-eluting stents include paclitaxel, sirolimus, everolimus, biolimus, tacrolimus, and zotarolimus. Paclitaxel is an antineoplastic drug, which undermines vascular smooth muscle cell proliferation by interfering with cell division. Sirolimus is an immunosuppressant that also undermines the proliferation of vascular smooth muscle cells by interrupting the cell cycle. Several drugs function in a similar mechanism as sirolimus, including everolimus, biolimus, tacrolimus, and zotarolimus. Three updated Hayes, Inc. technology reports found sufficient evidence to recommend paclitaxel, sirolimus, and everolimus in select patients with CAD with a B rating. However, more research needs to be done on remaining agents biolimus, tacrolimus, and zotarolimus before a similar recommendation can be made.

The SIRIUS study was the pinnacle study of DES published in The New England Journal of Medicine in 2003. This randomized, double-blind trial compared the sirolimus-eluting stent with the bare metal stent in 1058 patients at 53 centers in the United States. Results were similar for the two stents in the weeks immediately following the implantation, but after nine months patients who received the DES demonstrated a much lower rate of repeat procedures than those patients who received the uncoated stent (4.2% versus 16.8%). Patients who received DES had a restenosis rate of 8.9% compared to 36.3% of patients with the uncoated stent. CYPHER™ was given FDA approval in 2003.

In 2004, TAXUS™ was approved by the FDA. Approval of TAXUS was based on the next pivotal study of DES in which 1314 patients were evaluated at 73 American centers in a prospective, randomized double-blind clinical trial. This study demonstrated safety as well as a reduction in the rate of clinical and angiographic restenosis at a 9 month follow up.

In February 2008, Endeavor® Zotarolimus-Eluting Coronary Stent received FDA approval on the Over-the-Wire, Rapid Exchange, or Multi-Exchange II Stent Delivery Systems. This device, manufactured by Medtronic, is indicated for improving coronary luminal diameter in patients with ischemic heart disease due to de novo lesions of length ≤ 27 mm in native coronary arteries with reference vessel diameters of 2.5 mm to 3.75 mm.

In July 2008, XIENCE™ V Everolimus-Eluting Coronary Stent Over-the-Wire or Rapid Exchange Stent Delivery Systems, manufactured by Abbott Vascular, received FDA approval. This device/drug combination product is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to de-novo native coronary artery, lesions (length < 28 mm) with reference vessel diameters of 2.5 mm to 4.25 mm.

In 2012, the FDA approved Zilver PTX Drug-Eluting Peripheral Stent. Zilver is the first drug-eluting stent indicated to re-open a particular artery in the thigh, the femoropopliteal artery, when narrowed or blocked as a result of peripheral artery disease (PAD). The approval was largely based on the publication of two important studies. The first was a prospective, multination, randomized study evaluating both safety and efficacy of DES in 479 patients. At the 12 month follow up, 83% of patients in the DES arm remained open as opposed to 33% in the bare metal arm. PTX failures were also randomized into the same two groups in which 90% remained open in the DES arm versus 73% in the bare metal arm. The next study was a prospective, single arm, multicenter analysis of 787 patients with de novo or restenotic lesions of the femoropopliteal segment, in which the use of DES proved effective and safe. As a result of this study, DES was awarded approval for use in the thigh. This study also alludes to a future role of DES in vascular therapy.
Looming safety concerns began immediately in 2003 following the FDA’s receipt of 290 reports of stent thrombosis, including 60 cases in which the outcome was death. The following month the FDA issued a public notification stating that safety concerns can be mitigated with proper patient selection and appropriate peril-procedural medications.\textsuperscript{24} Over the next three years, the FDA continued to monitor cases and maintain the advisory until their 2006 announcement that upon the analysis of the data, DES represents “a small but significant increased risk of stent thrombosis.”\textsuperscript{25} Later that year the FDA announced that both currently approved DES devices, (CYPHER and TAXUS) are associated with a small increase in stent thrombosis when compared to bare-metal stents at one year post-stent implantation, however, this risk does not outweigh the benefits of DES when implanted following the FDA approved indications. Later that year, the FDA announced that both currently approved DES devices, CYPHER and TAXUS, are associated with a small increase in stent thrombosis when compared to bare metal stents at one year post-stent implantation.

In 2008, the FDA announced that adverse events were similar in those implanted with bare metal stents and the Endeavor-Zotarolimus stent.\textsuperscript{26} As a result, much of the subsequent literature has focused on safety. In 2006, nearly 1200 patients were evaluated in a prospective, randomized, double-blind study of which 598 received DES and 599 received bare metal stents. With endpoints of clinical and angiographic restenosis, DES was found safe and superior at 9, 12, and 24 month follow ups.\textsuperscript{27} Several safety studies have followed. In 2008, a large study looked at both safety and efficacy in which 38,917 patients receiving bare-metal stents were compared to 28,086 who received DES. An 18\% improvement in revascularization rates was found in the DES group over the control. A large prospective trial of patients (n=6471) undergoing percutaneous coronary intervention with stenting between April 1, 2003 and March 31, 2006 was conducted in Canada. There were 1120 patients who received drug-eluting stents, 5320 who received bare-metal stents and another 31 who were excluded because of undeployed stents. Safety was confirmed at one year follow up.\textsuperscript{28}

In an observational analysis of 5,745 patients from the Assessment of Pexelizumab in Acute Myocardial Infarction (APEX-AMI) trial, drug-eluting stents appeared to be as safe as bare-metal stents. The observational analysis focused on rates of death and recurrent myocardial infarction six-months after revascularization. Longer-term analysis is required to determine the effects of stent choice on very late stent thrombosis, overall death, and MI.\textsuperscript{29} A small, prospective, multicenter randomized control trial of 474 patients divided into 2 arms, along with a complementary single arm DES study of 787 DES patients demonstrates both superiority and safety in outcomes at 2 years.\textsuperscript{30}

<table>
<thead>
<tr>
<th>REGULATORY INFORMATION</th>
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<tbody>
<tr>
<td>Kentucky – No legislative mandates for coverage of drug eluting stents were found.</td>
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<tr>
<td>Indiana – No legislative mandates for coverage of drug eluting stents were found.</td>
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<tr>
<td>Tennessee – No legislative mandates for coverage of drug eluting stents were found.</td>
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The FDA granted new device approval to the CYPHER Sirolimus-eluting coronary stent on April 24, 2003.\textsuperscript{31}

The FDA is requiring the maker of the CYPHER stent to conduct a 2000-patient post-approval study. The study is to continue evaluation of patients from ongoing clinical trials to assess the long-term safety and effectiveness of the CYPHER stent and to look for rare adverse events that may result from the use of their stent.\textsuperscript{32}

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The FDA granted premarket approval (PMA) to the TAXUS™ Express™ Paclitaxel-Eluting Coronary Stent System (Monorail and Over-the-Wire) on March 4, 2004. On July 1, 2004 the FDA issued a Class 1 Recall for the TAXUS™ Express™ Paclitaxel-Eluting Coronary Stent System (Monorail and Over-the-Wire) lot numbers 6294706 and 6365192. These two lot numbers were recalled because “characteristics in the design of these two lots resulted in failure of the balloon to deflate and impeded removal of the balloon after stent placement.” Then on July 16, 2004 a Class I Recall was issued for the bare metal version of the same stent for the same reason. On February 1, 2008 the FDA approved the Endeavor Zotarolimus-Eluting Coronary Stent for use in treating narrowed coronary arteries. The Endeavor was the first drug-eluting stent approved since 2004.

COVERAGE DETAIL

Both CPT and HCPC codes may be billed when both bare-metal stents and drug-eluting stents are used.

CODES INCLUDE BUT MAY NOT BE LIMITED TO THE FOLLOWING

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
<th>Coverage Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>92980</td>
<td>Transcatheter placement of an intracoronary stent(s), percutaneous with or without other therapeutic intervention, any method; single vessel</td>
<td>Medically necessary when criteria are met</td>
</tr>
<tr>
<td>+92981</td>
<td>Transcatheter placement of an intracoronary stent(s), percutaneous with or without other therapeutic intervention, any method; each additional vessel (List separately in addition to code for primary procedure)</td>
<td>Medically necessary when criteria are met</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPC® Codes</th>
<th>Description</th>
<th>Coverage Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1874</td>
<td>Stent, coated/covered, with delivery system</td>
<td>Medically necessary when criteria are met</td>
</tr>
<tr>
<td>C1875</td>
<td>Stent, coated/covered, without delivery system</td>
<td>Medically necessary when criteria are met</td>
</tr>
<tr>
<td>C9600</td>
<td>Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; singly major coronary artery or branch</td>
<td>Medically necessary when criteria are met</td>
</tr>
<tr>
<td>C9601</td>
<td>Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)</td>
<td>Medically necessary when criteria are met</td>
</tr>
<tr>
<td>C9602</td>
<td>Percutaneous transluminal coronary atherectomy, with</td>
<td>Medically necessary</td>
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<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Criteria</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9603</td>
<td>Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronal stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)</td>
<td>Medically necessary when criteria are met</td>
<td></td>
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<tr>
<td>C9604</td>
<td>Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel</td>
<td>Medically necessary when criteria are met</td>
<td></td>
</tr>
<tr>
<td>C9605</td>
<td>Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)</td>
<td>Medically necessary when criteria are met</td>
<td></td>
</tr>
<tr>
<td>C9606</td>
<td>Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel.</td>
<td>Medically necessary when criteria are met</td>
<td></td>
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<tr>
<td>C9607</td>
<td>Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel</td>
<td>Medically necessary when criteria are met</td>
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<tr>
<td>C9608</td>
<td>Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)</td>
<td>Medically necessary when criteria are met</td>
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<tr>
<td>G0290</td>
<td>Transcatheter placement of a drug eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; single vessel. This code is to be utilized specifically for drug-eluting stents</td>
<td>Medically necessary when criteria are met</td>
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<tr>
<td>G0291</td>
<td>Transcatheter placement of a drug eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; each additional vessel. This code is to be utilized specifically for drug-eluting stents</td>
<td>Medically necessary when criteria are met</td>
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</tbody>
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ICD-9© Codes | Description | Coverage Information
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36.07 | Operations on vessels of heart; Insertion of drug-eluting coronary artery stent(s) | Medically necessary when criteria are met
38.24 | Intravascular imaging of coronary vessel(s) by optical coherence tomography [OCT] | No additional reimbursement when performed during diagnostic evaluation and/or therapeutic intervention

Both CPT and HCPC codes may be billed when both bare-metal stents and drug-eluting stents are used.

REFERENCES


