PriorityHealth

MEDICAL POLICY
No. 91580-R1

DRUG-ELUTING STENTS FOR ISCHEMIC HEART DISEASE

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I. POLICY/CRITERIA

FDA approved drug eluting intracoronary stents (DES) using everolimus, paclitaxel, sirolimus, zotarolimus, and biolimus are considered medically appropriate when greater than 50% stenosis in one or more coronary arteries and the chance of vessel restenosis is high.

DES are a covered benefit for de novo coronary lesions when one of the following is present:

1. Vessel diameter <3.5 mm
2. Lesion length ≥15mm
3. Patient has diabetes mellitus requiring medication management

DES are contraindicated and are not a covered benefit if either of the following apply:

1. Patient is scheduled to have non-cardiac surgery within one year requiring interruption of dual antiplatelet therapy (DAPT)
2. Patient has one or more contraindications to, or is unable to take DAPT for any reason (e.g. medical, financial, non-compliance).

Priority Health considers biodegradable (bioresorbable, bioabsorbable) polymer drug eluting stents experimental and investigational because their effectiveness for these indications has not been established.

II. MEDICAL NECESSITY REVIEW

☐ Prior Authorization Required
☒ Retrospective Review (Plan Discretion)

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***

- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***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.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

IV. DESCRIPTION

Coronary artery disease (CAD) is the most common type of heart disease and the leading cause of death in the United States in both men and women, comprising more than 50% of all cardiovascular events in men and women younger than 75 years of age. Approximately 33% of CAD patients undergo percutaneous coronary intervention (PCI) and stenting of obstructed coronary arteries. In 2006, an estimated 1,313,000 PCI procedures were performed in the US (AHA Statistics Committee 2009). Currently, nearly 80% of all inserted stents in the United States are drug-eluting stents (DES).

DES are device/drug combination products consisting of a coronary stent system, coated with an antiproliferative or immunomodulatory drug that suppresses scar tissue formation within the stent and adjacent areas. Compared with bare-metal stents (BMS), DES reduce the incidence of in-stent restenosis, and thereby the need for repeat percutaneous or surgical revascularization. The overall mortality or incidence of myocardial infarction (MI) is not affected. However, reports of very late stent thrombosis, associated with possible increased mortality, in patients who have received DES have elicited concerns about long-term safety.

In the 2010 Cochrane Review, three review authors independently extracted data on more than 14,500 patients in 47 RCTs comparing DES with bare metal stents (BMS) used in conjunction with PTCA techniques. Participants were adults with

stable angina or acute coronary syndrome (ACS). Data extraction included composite event rates (major adverse cardiac event, target vessel failure); death; acute myocardial infarction (AMI); target lesion revascularisation (TLR); target vessel revascularisation (TVR) and thrombosis. Data synthesis included meta-analysis of composite event rate, death, AMI and revascularisation rates, presented as odds ratios with 95% confidence intervals (CI) using a fixed-effect model. Main results: There were no statistically significant differences in death, AMI or thrombosis between DES and BMS. For composite events, TLR and TVR reductions were evident with use of sirolimus, paclitaxel, everolimus, dexamethasone, zotarolimus and (to a limited extent) tacrolimus-eluting stents. Subgroup analyses (e.g. diabetics) largely mirrored these findings.

Cochrane authors' conclusions: Drug-eluting stents releasing sirolimus, paclitaxel, dexamethasone and zotarolimus reduce composite cardiac events. However, this reduction is due largely to reductions in repeat revascularisation rates as there is no evidence of a significant effect on rates of death, MI or thrombosis. The conclusion of their economic analysis was that all patients considered together, the calculated cost per QALY ratios are high ([pounds]183,000-562,000) and outside the normal range of acceptability. The use of DES would be best targeted at the subgroups of patients with the highest risks of requiring re-intervention, and could be considered cost-effective in only a small percentage of such patients.

UpToDate review on “Coronary artery stent types in development” (Cutlip and Abbott, 2014) states that “The coronary stents currently available are permanent implants composed of a metallic alloy. Drug-eluting stents (DES) have additional durable polymer and anti-restenotic drug components. While bare metal stents (BMS) and DES have improved outcomes for patients, they have several limitations. The development of stent thrombosis after placement of BMS or DES and the residual rate of restenosis after DES are two reasons for the development of newer coronary artery stents. This topic will present studies of coronary artery stent types that show promise for reduction in rates of these adverse outcomes, including DES with bioresorbable polymers vascular scaffolds. The terms bioresorbable (also called biodegradeable) and bioabsorbable are used in this topic. Bioresorbable refers to the complete breakdown and removal of a material over time and often by a known mechanism. Bioabsorbable refers to incomplete breakdown; the material may be partially digested and remain indefinitely in local tissue. Stent material and polymer may be bioresorbable or bioabsorbable …. A number of drug eluting stent models, including abciximab-coated, beta-estradiol, and dexamethasone stents, have been tested and not carried forward into regulatory approval clinical trials in the United States. The Combo stent combines sirolimus elution from an abluminal biodegradable polymer matrix with a CD34 antibody layer. The CD34 antibody is directed toward circulating endothelial progenitor cells with a goal of increasing the rate of cellular coverage and thus decreasing the rate of stent

thrombosis. In the first-in-man trial, the Combo stent was noninferior to a paclitaxel-eluting stent for outcomes of nine-month angiographic in-stent late lumen loss and 12-month major adverse cardiovascular events. Newer stent types are being developed to overcome some of the limitations of current stents, such as the development of stent thrombosis after placement of any intracoronary stent and the residual rate of restenosis after drug-eluting stent (DES). These newer stent types fall into three broad categories: stents with bioresorbable polymer; drug-eluting stents that are polymer free; or stents with a bioresorbable scaffold".

V. CODING INFORMATION

ICD-10 Codes that may *support medical necessity:*

I20.0 - I20.9	Angina pectoris
I21.01 – I21.4	ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
I22.0 – I22.9	Subsequent ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
I24.0 - I24.9	Other acute ischemic heart diseases
I25.10 – I25.119	Atherosclerotic heart disease of native coronary artery with or without angina pectoris
I25.5	Ischemic cardiomyopathy
I25.6	Silent myocardial ischemia
I25.700 – I25.799	Atherosclerosis of coronary artery bypass graft(s) and coronary artery of transplanted heart with angina pectoris
I25.810 – I25.89	Other forms of chronic ischemic heart disease
I25.9	Chronic ischemic heart disease, unspecified
T82.817A - T82.817S	Embolism due to cardiac prosthetic devices, implants and grafts
T82.827A - T82.827S	Fibrosis due to cardiac prosthetic devices, implants and grafts
T82.837A - T82.837S	Hemorrhage due to cardiac prosthetic devices, implants and grafts
T82.847A - T82.847S	Pain due to cardiac prosthetic devices, implants and grafts
T82.857A - T82.857S	Stenosis of other cardiac prosthetic devices, implants and grafts
T82.867A - T82.867S	Thrombosis due to cardiac prosthetic devices, implants and grafts
T82.897A - T82.897S	Other specified complication of cardiac prosthetic devices, implants and grafts
T82.9xxA - T82.9xxS	Unspecified complication of cardiac and vascular prosthetic device, implant and graft

CPT/HCPCS Codes:

92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch

92929 Percutaneous transcatheter placement of 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)

92933 Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch

92934 Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure)

92937 Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel

92938 Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of 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)

92941 Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel 1/01/2013

92943 Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel

92944 Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (List separately in addition to code for primary procedure)

OP Facility

C9600 Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch

C9601 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)

C9602 Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch

C9603 Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)

C9604 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

C9605 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)

C9606 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

C9607 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

C9608 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, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)

C1874 Stent, coated/covered, with delivery system
C1875 Stent, coated/covered, without delivery system

VI. REFERENCES

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