

## Evidence Based Guideline

# Drug Eluting Coronary Stent

**File Name:** drug\_eluting\_coronary\_stent  
**Guideline Number:** EBG.SUR6215  
**Origination:** 06/2003  
**Last Review:** 03/2008  
**Next Review:** 03/2010

### Description of Procedure or Service

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A common treatment for angina is angioplasty with stent implantation. Angioplasty opens the partially blocked artery and the implanted stent keeps it open. However, in approximately 20% of treated patients, growth of tissue within the stent causes re-blockage of the artery (in-stent restenosis). Patients with co-morbid conditions such as diabetes have an even higher risk for in-stent restenosis.

Restenosis is caused by three mechanisms: the loss of vessel-lumen diameter from vessel collapse (elastic recoil), the shrinkage in vessel diameter caused by growth and subsequent pressure on the arterial wall (vessel remodeling), and a healing response triggered by vessel injury that occurs during the revascularization procedure (neointimal hyperplasia). Coronary stenting has successfully addressed elastic recoil and vessel remodeling. However, neointimal hyperplasia still occurs and investigators have been trying to develop stents that prevent neointimal hyperplasia.

Stents that elute drugs that block the proliferation of tissue within the stent are intended to prevent in-stent restenosis. Concentrations of the drug near the stent can be high enough to block local tissue proliferation without the drug being detectable systemically. Thus, there is little risk of whole-body adverse events from the powerful anti-proliferation drugs.

A wide variety of stents that elute antibiotics, anti-inflammatory agents, chemotherapeutic agents, hormones, or steroids are currently being investigated in clinical trials. Two drugs in particular have been investigated for the coronary arteries. Sirolimus, a potent immunosuppressive and anti-inflammatory agent often used to prevent rejection of transplanted kidneys, and paclitaxel, a chemotherapeutic agent used to treat cancer.

The implantation procedure for any coronary stent is similar to the procedure for balloon angioplasty, which involves inflating a balloon through a blocked artery to open the blockage. Placement of a coronary stent around an uninflated angioplasty balloon allows positioning across the coronary lesion. Inflating the balloon makes the stent expand and compress the inner lining of the artery, providing support to the artery wall. Covered with cells after two to three weeks, the stent becomes a permanent part of the blood vessel wall.

### Evidence Based Guideline for Drug Eluting Coronary Stent

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The CYPHER sirolimus and the Taxus Express paclitaxel-eluting coronary stents may be appropriate for improving coronary luminal diameter in patients with symptomatic ischemic disease due to discrete de novo lesions with 70-99% occlusion of length  $\leq 30$  mm in native coronary arteries with a reference vessel diameter of  $\geq 2.5$  to  $\leq 3.5$  mm.

## Policy: Drug Eluting Coronary Stent

### When a Drug Eluting Coronary Stent is not covered

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Drug eluting coronary stents are not covered in the following instances:

### Medical Evidence regarding Drug Eluting Coronary Stent indicates it is not recommended in the following situations:

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Drug eluting coronary stents are not recommended for:

- Patients with a hypersensitivity to sirolimus or its derivatives,
- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated,
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon,
- Patients with a known hypersensitivity to 316L stainless steel,
- Patients with known sensitivity to polymethacrylates or polyolefin copolymers,
- Non-coronary arteries,
- The use of any stent that is not FDA approved and not listed above as a covered stent is considered investigational.

### Benefits Application

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Please refer to certificate for availability of benefit. This guideline relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore certificate language should be reviewed before applying the terms of the policy.

### Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: G0290, G0291*

### Medical Term Definitions

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Not applicable.

### Scientific Background and Reference Sources

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ECRI Target Fact Sheet. Drug-eluting coronary stents for the treatment of coronary artery stenosis. TARGET Report #664. April 2003.

U.S. Food and Drug Administration. FDA approves drug-eluting stent for clogged heart arteries. FDA News. P03-31. Rockville, MD: FDA; April 24, 2003. Retrieved on 5/13/03 from <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00896.html>.

## Policy: Drug Eluting Coronary Stent

Specialty Matched Consultant Advisory Panel - 6/2003

ECRI Target Report #664 (2002, June) Drug-eluting coronary stents for the treatment of coronary artery stenosis. Retrieved on April 14, 2004 from [http://www.target.ecri.org/summary/detail.aspx?doc\\_id=569&q=drug-eluting+coronary+stents&anm](http://www.target.ecri.org/summary/detail.aspx?doc_id=569&q=drug-eluting+coronary+stents&anm).

ECRI Health Technology Assessment. (2003, July). Drug-eluting stents for treatment of coronary artery disease. Retrieved on April 14, 2004 from [http://www.ta.ecri.org/HTA\\_News/Prod/summary/detail.aspx?doc\\_id=6950&q=drug-eluting+coronary+stents&anm](http://www.ta.ecri.org/HTA_News/Prod/summary/detail.aspx?doc_id=6950&q=drug-eluting+coronary+stents&anm).

American College of Cardiology Foundation. (2004, April 7). Drug-coated stents safe for patients with complex artery disease. Retrieved on April 12, 2004 from <http://www.acc.org/media/releases/highlights/2004/apr04/stents.htm>.

Specialty Matched Consultant Advisory Panel - 6/2004

ECRI Target Report #664 (2004, July) Drug-eluting coronary stents for the treatment of coronary artery stenosis. Retrieved December 8, 2005 from [http://www.target.ecri.org/summary/detail.aspx?doc\\_id=569&q=drug%20eluting%20coronary%20stents&hl=1](http://www.target.ecri.org/summary/detail.aspx?doc_id=569&q=drug%20eluting%20coronary%20stents&hl=1)

Tu JV, Bowen J, Chiu M, Ko DT, Austin PC, He Y, et. al. (October 2007). Effectiveness and Safety of Drug-Eluting Stents in Ontario. *N Engl J Med* 2007;357:1393-402

## Policy Implementation/Update Information

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- 6/03 New policy issued.
- 4/04 Added Taxus Express paclitaxel-eluting coronary stent as covered.
- 7/15/04 Specialty Matched Consultant Advisory Panel review with no changes made to policy criteria. References added.
- 3/16/06 Specialty Matched Consultant Advisory Panel review 2/27/06. No changes made to policy criteria. Rationale added to Policy Guidelines. Policy number added to Key Words. References updated.
- 8/21/06 Medical Policy changed to Evidence Based Guideline.
- 4/21/08 Revised guideline to state that drug eluting stents may be appropriate for lesions with 70-99% occlusion. In the Not Recommended section, deleted the statements regarding left main coronary artery and non-native coronary vessels. Specialty Matched Consultant Advisory Panel review 3/12/08. No change to policy statement.

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.