INTRACORONARY BRACHYTHERAPY FOR THE PREVENTION AND MANAGEMENT OF 
RESTENOSIS 
MED202.055

COVERAGE:

Intracoronary brachytherapy with gamma or beta radioactive ribbons for 
the management of in-stent restenosis in native coronary vessels IS 
MEDICALLY NECESSARY.

Intracoronary brachytherapy with gamma or beta radioactive ribbons for 
the management of de novo (initial) lesions to prevent restenosis is 
considered experimental and investigational.

Intracoronary brachytherapy utilizing any other radioactive source 
(e.g., alpha source) or delivered via any other method (e.g., with 
radioactive stents or catheter balloons filled with radioactive 
material) is considered experimental and/or investigational.

DESCRIPTION:

Patients who undergo percutaneous transluminal coronary angioplasty 
(PTCA) for coronary artery disease are at risk for recurrence at the 
site of the procedure. Placement of stents as an adjunct to PTCA is 
one strategy to reduce recurrence. The use of various techniques to 
apply intracoronary radiation through local application of catheters 
or placement of radioactive stents (also known as intracoronary 
brachytherapy) may reduce the rate of restenosis and improve overall 
health outcomes.

The three types of radioactive emissions are alpha, beta and gamma. 
To date, intracoronary brachytherapy has utilized beta and gamma 
emissions.

Currently there are many clinical trials involving different devices, 
all of which deliver radiation to the PTCA site. Radiation is 
delivered by threading the radiation source into the stenosis until 
the correct dose is given, or a radioactive stent is placed 
permanently across the stenosis. The dosages of radiation, methods to 
measure dosage, type of radiation, and delivery system, all vary among 
these clinical trials.

Two of the better-studied devices are the Novoste Beta-Cath and the 
Cordis Checkmate system. The Beta-Cath system utilizes strontium-90 
seeds embedded on a catheter tip (beta radiation). After angioplasty 
of a stenosis, the Beta-Cath ribbon is threaded into the stenotic site 
through the same introducer as the angioplasty balloon. The catheter 
tip is allowed to dwell in the lesion for 2 to 5 minutes and then is 
removed. The Checkmate system utilizes iridium-192 seeds embedded on 
a catheter tip (gamma radiation). This procedure is the same as the 
Beta-Cath procedure, however, the dwell time is 15 to 25 minutes. 
Both devices can alter the number of seeds at the catheter tip, thus 
changing the length of the radioactive ribbon.
On November 6, 2000, the Cordis’s Checkmate and the Novoste’s Beta-Cath systems both received final FDA approval through the premarket application (PMA) approval process. The devices have been approved for treatment of native coronary arteries, with in stent restenosis, following percutaneous revascularization using current interventional techniques.

RATIONALE:

Based on an 11/2000 TEC evaluation there is good evidence from four randomized controlled trials to support the effectiveness of beta and gamma radioactive ribbons for the management of in-stent restenosis in native coronary vessels. There is insufficient evidence; however, to recommend the use of other devices such as radioactive stents or radioactive filled catheter balloons.

The outcomes of the GAMMA-1, beta-WRIST, SCRIPPS, and START trials indicate that patients with in-stent restenosis treated with brachytherapy do better than patients treated with PTCA alone or PTCA and stenting.

DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically. HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.

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Posted Jan. 7, 2003