Cigna Medical Coverage Policy

Subject **Excimer Laser Coronary Angioplasty (ELCA)**

Effective Date **5/15/2014**
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Coverage Policy

Cigna does not cover excimer laser coronary angioplasty (ELCA) for any indication because it is considered experimental, investigational or unproven.

General Background

Excimer laser coronary angioplasty (ELCA) was introduced in the 1980s as an alternative method of angioplasty intended to reduce the long- term complications and high restenosis rates associated with other angioplasty and stenting techniques. This procedure was introduced prior to the introduction and widespread use of drug-eluting stents, which have greatly reduced the incidence of restenosis and in-stent restenosis. ELCA removes atherosclerotic plaque by laser ablation. The excimer laser generates high-power ultraviolet pulses through a fiberoptic catheter. The pulses vaporize thin sections of tissue without causing significant damage to surrounding tissue. It was hypothesized that reduction of atherosclerotic tissue mass using laser ablation with or without balloon dilation could be more effective in enlarging the vessel lumen than balloon angioplasty alone. Early data from large observational registry studies published in the early 1990s provided evidence of the safety of ELCA for patients with coronary lesions suitable for treatment by conventional PTCA.

U.S. Food and Drug Administration (FDA)
The Spectranetics CVX-300® Excimer Laser Coronary Angioplasty (ELCA) system (Spectranetics Corporation, Colorado Springs, CO) was granted marketing approval by the FDA on March 24, 1993. The premarket approval states that the device is indicated for use in patients with single or multivessel coronary artery disease, as a stand-alone modality or in conjunction with PTCA. It was approved for patients who are acceptable candidates for CABG and have occluded saphenous vein bypass grafts, ostial lesions, long lesions (greater than 20 mm in length), moderately calcified stenoses, total occlusions traversable by a guide wire and lesions

that have previously failed balloon angioplasty. On October 10, 2001, treatment of restenosis in stainless steel stents prior to the administration of intravascular brachytherapy was added by the FDA as an approved indication for ELCA.

Literature Review

Coronary Artery Stenosis: Two randomized trials of ELCA were initiated in the 1990s based on early promising data. Appelman et al. (1996) conducted a randomized, controlled trial to compare ELCA with traditional balloon angioplasty. Patients with stable angina and coronary lesions larger than 10 mm on visual assessment were included. A total of 308 patients were randomized, with 151 patients (158 lesions) randomly assigned to ELCA and 157 patients (167 lesions) to balloon angioplasty. Because the majority of patients received balloon angioplasty following ELCA in order to achieve optimal vessel dilation, a true determination of ELCA alone compared to balloon angioplasty was not possible. The researchers reported that ELCA followed by balloon angioplasty provides no additional benefit than balloon angioplasty alone with respect to the initial and long-term clinical angiographic outcome in the treatment of obstructive coronary artery disease. A subsequent analysis of the same population (Appelman, et al., 2000) compared functional outcomes of ELCA and balloon angioplasty. The researchers reported that ELCA and balloon angioplasty yield similar long-term functional outcomes, as measured by anginal status, exercise tolerance and myocardial perfusion.

Reifart et al. (1997) published a randomized controlled trial to determine whether revascularization with ELCA or rotational atherectomy can improve initial angiographic and clinical outcomes compared to balloon angioplasty alone. A total of 685 patients with symptomatic coronary disease who required revascularization for complex lesions were randomly assigned to balloon angioplasty (n=222), ELCA (n=232) or rotational atherectomy (n=231). The primary endpoint was procedural success, defined as stenosis diameter less than 50% and absence of death, Q-wave myocardial infection or CABG. Overall, 93% of the ELCA group received adjunctive balloon dilatation to achieve the final angiographic result. Patients who underwent rotational atherectomy had higher rates of procedural success (89%) than those who underwent ELCA (77%) or balloon angioplasty (80%), but at six-month follow-up, revascularization of the original lesion was required more frequently in the atherectomy group (42%) and the ELCA group (46%) than in the balloon angioplasty group (32%). The authors reported that the role of plaque debulking prior to balloon dilatation in percutaneous revascularization remains to be fully defined.

Graft Stenosis: In the COronary graft Results following Atherectomy with Laser (CORAL) trial, Giugliano et al. (2012) evaluated the safety and efficacy of ELCA as a primary treatment strategy in patients presenting for percutaneous coronary intervention (PCI) of degenerated saphenous vein graft (SVG) lesions. This prospective multicenter registry study enrolled a total of 98 patients at 18 centers with greater than 50% stenosis of an SVG who presented for PCI due to angina pectoris or objective evidence of myocardial ischemia in a concordant myocardial distribution. Patients were excluded if the operator planned to utilize a distal protection device. Inclusion and exclusion criteria were aligned to those in the Saphenous vein graft Angioplasty Free of Emboli Randomized (SAFER) trial. The primary end point [30-day major adverse cardiac events (MACE)] occurred in 18/98 (18.4%) of the patients driven primarily by non-q-wave myocardial infarction. Major procedural complications included no reflow (n=5) and major dissection (n=1). There were no perforations. The authors reported that based on this registry, in the absence of embolic protection, ELCA-facilitated PCI of SVGs does not appear to convey a significant advantage over conventional PCI.

In-Stent Restenosis: ELCA has also been evaluated as a treatment for in-stent restenosis (ISR). In a small case series (n=98) conducted by Mehran et al. (1997), the clinical safety, mechanisms and six-month results of ELCA with adjunctive PTCA were compared to those of PTCA alone for the treatment of in-stent restenosis. This study was relatively small with a brief follow-up period. The researchers reported that ELCA+PTCA appeared to be superior to PTCA alone for in-stent restenosis but that a prospective, randomized trial comparing PTCA alone versus ELCA plus PTCA or other ablative techniques was warranted.

Köster et al. (1999) conducted a multi-center prospective study (n=440) to evaluate ELCA with adjunctive balloon angioplasty in the treatment of ISR. Device success was defined as less than 50% stenosis after ELCA, while procedure success was defined as ELCA success followed by less than 30% stenosis, with or without angioplasty. ELCA was combined with balloon angioplasty in 99% of patients. The device success rate was 92%, and the procedure success rate was 91%. The researchers reported that ELCA with balloon angioplasty is a safe and efficient technology to treat ISR. This was a nonrandomized uncontrolled study, however, with no comparison to balloon angioplasty alone and no follow-up beyond the initial period of hospitalization.

A subsequent study of 96 consecutive patients successfully treated with ELCA within 141 stents analyzed six-month clinical and angiographic data (Köster, et al., 2000). Mean diameter stenosis was 77 ± 12% prior to intervention and decreased to 41 ± 12% after ELCA and 11 ± 12% following adjunctive PTCA. Six months after ELCA, however, the mean diameter stenosis had increased to 60 ± 26%. Stenosis greater than 50% was present in 48 (54%) patients. The authors suggested that ELCA is unlikely to reduce recurrent ISR and that other approaches are necessary.

Mehran et al. (2000) conducted a retrospective clinical trial (n=249) to compare the mechanisms and clinical results of ELCA versus those of rotational atherectomy (RA), each followed by adjunct PTCA. ELCA+PTCA was performed on 119 patients (158 ISR lesions), and RA+PTCA was performed on 130 patients (161ISR lesions). There was no significant difference between the two groups in post-procedure luminal-dimension measurements, angiographic success or in-hospital complication rates. Target lesion revascularization rates at one year were comparable: 26% with ELCA+PTCA and 28% with RA+PTCA. The author stated that if atheroablation was a strong determinant of clinical outcome, then differences between atheroablative devices with respect to ablation efficiency and the amount of intimal hyperplasia removed should translate into improved long-term clinical benefit. ELCA+PTCA and RA+PTCA improved lumen dimension by tissue ablation, tissue extrusion and additional stent expansion. Although RA achieved greater intimal hyperplasia ablation, it did not result in improved one-year outcomes. The author reported that either combination of procedures could be used to treat ISR with similar clinical results.

Batyraliev et al. (2006) conducted a non-randomized experimental study (n=125) to evaluate angiographic and clinical outcomes of PTCA alone and in combination with ELCA in patients with in-stent restenosis. ELCA was performed prior to balloon dilation in 67 patients, and PTCA alone was performed in 58 patients. Immediate angiographic results were comparable in both groups, with success rates of 98.3% in the PTCA group and 98.5% in the ELCA + PTCA group. Follow-up at one year showed similar major adverse cardiac events (MACE) and target vessel revascularization rates.

Acute Coronary Syndrome and Acute Myocardial Infarction: ELCA has more recently been proposed as a treatment for patients with an evolving acute myocardial infarction (AMI) with thrombus-laden lesions. Current standard therapy involves either thrombolytic therapy or balloon angioplasty. Thrombolytic agents are limited by anterograde coronary flow, which is restored in only 50-60% of patients, and reocclusion of the infarcted artery occurs in 20-30% of treated vessels in patients who receive this therapy. Patients who experience ongoing chest pain after thrombolytic therapy or those with contraindications to thrombolytics often need PCI for removal of an occlusive thrombus and underlying atherosclerotic plaque. Treatment with ELCA has been explored as a possible alternative, since both atherosclerotic plaque and thrombi readily absorb laser energy.

In the CARMEL (Cohort of Acute Revascularization in Myocardial Infarction with Excimer Laser) multi-center trial, 151 patients with AMI underwent ELCA between 1997 and 2002 at eight participating medical centers (Topaz, et al., 2004). Eligibility for this non-randomized observational study included evolving MI within 24 hours of symptom onset necessitating urgent PCI for continuous chest pain and/or ischemia. The study included patients who failed to respond to thrombolytic agents or had contraindications to thrombolytics. Patients with cardiogenic shock and agents for whom an old saphenous vein graft was the infarct-related vessel were also included. Patients were selected for enrollment if angiographic characteristics known to increase the risk of balloon angioplasty (e.g., thrombus and complex morphology of the underlying plaque) were present in the target lesion. The primary endpoints of the study were device, angiographic success and procedural success, with secondary endpoints of documentation of major adverse cardiac events (MACE), emergent CABG, or target revascularization during the treatment and hospitalization period. The minimal lumen diameter increased from 0.5 ± 0.5 mm to 1.6 ± 0.5 mm after laser treatment and increased to 2.7 ± 0.6 mm after adjunctive balloon angioplasty and stenting, and the mean stenosis was reduced from 83 ± 17% to 52 ± 15% after ELCA and was reduced to 20 ± 16% after adjunctive stenting. Of the six patients who died (4%), all had presented in cardiogenic shock. The authors reported that ELCA is an effective and safe modality for treatment of AMI and that maximal thrombus dissolution in lesions with extensive thrombus burden, significant increase in minimal luminal diameter and adequate restoration of anterograde TIMI (thrombosis in myocardial infarction) flow to the infarct-related artery support successful debulking facilitated by ELCA. They also reported that, although the presence of cardiogenic shock does not affect the success of the technology, it remains a predictor of MACE during hospitalization. Although this study demonstrated that ELCA+PTCA is a promising technique that may be

beneficial for patients with AMI who are not candidates for thrombolytic therapy, the study did not compare ELCA+PTCA with PTCA alone in a comparable patient population.

In a similar case series, Topaz et al. (2003) reported success in ELCA followed by adjunct balloon angioplasty and stenting for patients with depressed left ventricular function (LVF). Depressed left ventricular ejection fraction (LVEF) is often seen in patients with multivessel CAD and a history of MI. Symptomatic patients with depressed LVEF are a potentially high-risk group for PCI, since the major complication rate is higher in this group. The study included 100 patients with acute coronary syndromes: 51 with unstable angina and 49 with AMI. There were 25 patients (group 1) with decreased LVEF and 75 (group 2) with preserved LVEF. Similar results were seen in both groups. Minimal lumen diameter in group 1 increased from 0.7 ± 0.5 mm to 1.4 ± 0.5 mm after ELCA and finally to 3.0 ± 0.4 mm. Minimal lumen diameter in group 2 increased from 0.7 ± 0.4 mm to 1.3 ± 0.5 mm after the procedure to a final diameter of 3.0 ± 0.5 mm. A comparable percentage of thrombus burden was ablated by ELCA in both groups. TIMI flow in group 1 improved from 1.4 ± 1.2 to 1.2 to 2.7 ± 0.7 after ELCA and finally to 2.9 ± 0.3. TIMI flow in group 2 improved from 2.0 ± 1.0 to 2.8 ± 0.6 after ELCA and finally to 2.9 ± 0.4. This small study demonstrates that ELCA as an adjunctive therapy may improve PCI success rates for patients with depressed LVEF, but additional well-designed studies are needed to support this conclusion.

Ilkay et al. (2005) conducted a non-randomized experimental study to compare the effects of PTCA and ELCA on ST resolution in patients with acute MI. A stent was inserted after ELCA in 36 patients (group I) and a stent was inserted after balloon angioplasty in 44 patients (group II). In group I, complete ST resolution was observed in 75% of patients, partial resolution in 22%, and resolution did not occur in 3% of patients. In group II, complete, partial and unsuccessful ST resolution rates were 41%, 45%, and 14%, respectively. The mean ST resolution, a good predictor of tissue perfusion, was 82.78 ± 11.89% in group I and 66.36 ± 10% in group II. The authors acknowledged that these findings should be supported by large randomized studies.

Dorr et al. (2006) conducted a randomized controlled trial to assess the feasibility and safety of ELCA in acute MI. A number of secondary endpoints were also evaluated, including final TIMI flow, minimal luminal diameter, and diameter stenosis. Patients who presented within 12 hours of symptom onset were randomly assigned to ELCA plus adjunctive PCI and stent implantation (n=14), or to PCI and stent implantation alone (n=13). There were no significant differences in main procedural results between the two groups. Successful laser device delivery was achieved in all patients, and the core laboratory observed no residual thrombus in any of the cases. Diameter stenosis decreased from 94.3 ± 9.6 to 20.7 ± 10.3% in the ELCA group and from 82.7 ± 16.8 to 18.9 ± 5.5% in the control group (p=ns). TIMI flow increased from 0.7 ± 1.2 to 2.8 ± 0.4 in the ELCA group and from 1.7 ± 1.5 to 3.0 ± 0 in the control group (p=ns). The corrected TIMI frame count (cTFC), a count of the number of angiographic frames elapsed until the contrast material arrives in the distal bed of the vessel, was also similar in both groups, but the cTFC gain was higher in the ELCA group than the control group (53 ± 14% compared to 35 ± 20%, $p<0.05$). The authors stated that laser angioplasty is feasible and safe, but further randomized trials are needed to assess the benefit of laser angioplasty in acute MI.

Professional Societies/Organizations
The American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI) 2011 Guideline Update for Percutaneous Coronary Intervention does not include ELCA in treatment recommendations (Levine, et al., 2011). There have been no updates to the guideline since 2011.

Use Outside of the US
No relevant information.

Summary
Excimer laser coronary angioplasty (ELCA) was introduced prior to the advent of drug-eluting stents, and showed early promise as an alternative method of angioplasty to reduce the long-term complications and high restenosis rates associated with other angioplasty and traditional stenting techniques. Results from clinical trials evaluating ELCA alone or as an adjunctive treatment for coronary artery stenosis and in-stent restenosis, however, did not demonstrate improved outcomes compared to established techniques. ELCA has also been proposed as a treatment for patients with acute MI, and in patients with depressed left ventricular ejection fraction. There is insufficient evidence in the published medical literature, however, to demonstrate the safety and efficacy of ELCA.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Experimental/Investigational/Unproven/Not Covered when used to report excimer laser coronary angioplasty (ELCA):

CPT* Codes	Description
33999	Unlisted procedure, cardiac surgery
37799	Unlisted procedure, vascular surgery
93799	Unlisted cardiovascular service or procedure

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