A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

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<th>Plan: Aetna Better Health</th>
<th>Submission Date: 05/01/2019</th>
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<td>Policy Number: 0163</td>
<td>Effective Date:</td>
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<tr>
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<td>Revision Date: 02/14/2019</td>
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<td>Policy Name: Transmyocardial and Endovascular Laser Revascularization</td>
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Type of Submission – Check all that apply:
- [ ] New Policy
- [X] Revised Policy*
- [ ] Annual Review – No Revisions

*All revisions to the policy must be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below:

**CPB 163 Transmyocardial and Endovascular Laser Revascularization**

This CPB has been revised to state that the following are considered experimental and investigational: (i) the use transmyocardial laser revascularization plus cell therapy with adipose derived stromal cells for the treatment of ischemic heart disease; and (ii) excimer laser coronary angioplasty for acute coronary syndrome.

Name of Authorized Individual (Please type or print): Dr. Bernard Lewin, M.D.

Signature of Authorized Individual:

[Signature]
Transmyocardial and Endovascular Laser Revascularization

Number: 0163

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*

I. Aetna considers open chest, and thoracoscopic approaches to transmyocardial laser revascularization (TMLR) medically necessary for the treatment of medically refractory, severe intractable angina (see Appendix for selection criteria).

Aetna considers open chest and thoracoscopic approaches to TMLR experimental and investigational for all other indications because its effectiveness for indications other than the one listed above has not been established.

II. Aetna considers the use TMLR plus cell therapy with adipose derived stromal cells or autologous bone marrow cells for the treatment of ischemic heart disease experimental and investigational because of insufficient evidence of this approach.
III. Aetna considers percutaneous TMLR experimental and investigational for the treatment of refractory angina and all other indications because its effectiveness has not been established.

IV. Aetna considers excimer laser coronary angioplasty experimental and investigational for all indications including treatment of individuals with acute coronary syndrome, acute myocardial infarction, and persons with depressed left ventricular ejection fraction, as well as treatment of atherosclerotic lesions that are causing stenosis or occlusion of native coronary arteries, vein grafts placed at coronary artery bypass surgery, or stainless steel intra-coronary stents.

See

CPB 0599 - Autologous Skeletal Myoblast/Mononuclear Bone Marrow Cell
also, Transplantation (../500_599/0599.html)

Background

Refractory angina in coronary artery disease is defined as the persistence of severe anginal symptoms despite maximal conventional anti-anginal combination therapy. Furthermore, the option to use an invasive revascularization procedure such as percutaneous coronary balloon angioplasty or aorto-coronary bypass grafting must be excluded on the basis of a recent coronary angiogram. This coronary syndrome, which represents end-stage coronary artery disease, is characterized by severe coronary insufficiency but only moderately impaired left ventricular function. About 70% of the cases demonstrate severe coronary triple-vessel disease with diffuse coronary atherosclerosis, have had 1 or more myocardial infarctions, and have undergone aorto-coronary bypass grafting.

Transmyocardial laser revascularization (TMLR) has emerged as a promising therapy for patients with end-stage coronary artery disease not amenable to other forms of therapy. It is a surgical technique typically performed through a left thoracotomy, which uses a laser to bore 15 to 30 transmural channels from the epicardial to the endocardial surfaces through the left ventricular myocardium of the beating heart in an attempt to improve local perfusion to ischemic myocardial territories not being reached by diseased arteries. The precise workings of this
technique are not certain. The original theory upon which the technique was based, that the open channels would result in increased perfusion of the myocardium, does not appear to be the major or only action at work. Several theories have been proposed, including partial denervation of the myocardium, or the triggering of the cascade of biological reactions that encourage increased development of blood vessels. There are reports in the medical literature of TMLR being performed through a thoracoscopic approach, and pilot studies are underway using a percutaneous, catheter-based system, which allows creation of channels from the endocardial surface of the left ventricle into the myocardium.

Medicare began covering TMLR as of July 1, 1999 based on research at several medical centers indicating that this technique does offer relief of angina symptoms for a period of time in patients for whom no other treatment offering relief is available. Early results from non-randomized and randomized controlled trials of TMLR show both a significant reduction in pain, a reduction in hospitalizations, and a resumption of some normal activities of daily living for most patients treated. HCFA concluded, therefore, that such studies offer sufficient evidence of medical effectiveness for TMLR as a late or last resort treatment of the symptomatology. It is important to note that this technique has not been shown to increase life expectancy, nor is it proven to affect the underlying cause of the angina. With appropriate patient selection and peri-operative management, TMLR is associated with a very low operative risk.

Dallan and colleagues (2008) tested the hypothesis that TMLR combined with intra-myocardial injection of autologous bone marrow cells (BMC) is safe and may help increase the functional capacity of patient with refractory angina. A total of 9 patients (8 men, 1-woman, mean age of 6 +/- 5 years) with refractory angina for multi-vessel disease and previous myocardial re-vascularization procedures such as coronary artery bypass grafting (CABG)/percutaneous coronary intervention, and who not further surgical candidates due to the extension of the disease were enrolled. Transmyocardial laser revascularization (11 +/- 3 laser drills) was performed via a limited thoracotomy using a CO2 Heart Laser System. Autologous bone marrow cells were obtained immediately prior to surgery, and the lymphomonocytic fraction separated by density gradient centrifugation. During surgery, 5 ml containing approximately 1.9 +/- 0.3 x 10^8 BMC were delivered by multiple injections in the ischemic myocardium. Before (B) and 6 months (6M) after the procedure, patient underwent clinical evaluation and myocardial perfusion assessment by cardiac magnetic resonance imaging (MRI) during pharmacological
stress with dipyridamole. No major complications or deaths occurred during the procedure. One patient died after 2 years (non-cardiac cause). There was a reduction in the ischemic score as assessed by MRI from 1.64 +/- 0.10 (B) to 0.88 +/- 0.09 (6M) (p = 0.01). Clinically, there was a reduction in functional class of angina from 3.7 +/- 0.2 (B) to 1.3 +/- 0.2 (6M) (p < 0.0001). The authors concluded that in this initial experience, the combined strategy of TMLR plus cell therapy appeared to be safe, and may have synergistically acted to reduce myocardial ischemia, with clinically relevant improvement in functional capacity. Provided these data are confirmed in a larger, randomized, controlled trial with longer follow-up, this strategy could be used as a novel therapeutic option for treating patients with refractory angina. In this regard, Horvath (2008) stated that TMLR has been used as an adjunct to CABG. Combination CABG plus TMLR has resulted in symptomatic improvement without additional risk. Additional therapies to enhance the angiogenic response include combining TMLR with stem cell-based treatments, which appear to be promising future endeavors.

Oesterle and colleagues (2000) reported their finding of percutaneous transmyocardial laser revascularization (PTMR), a catheter-based technique of TMLR, for refractory angina pectoris when bypass surgery or angioplasty is not possible. They concluded that PTMR was associated with increased exercise tolerance time, low morbidity, lower angina scores assessed by masked reviewers, and improved quality of life. Although there is controversy about the mechanism of action, and the contribution of the placebo effect cannot be quantified, this unmasked study suggests that PTMR provides some clinical benefits in the defined population of patients. Commenting on the study by Oesterle et al (2000), Harbison and Kenny (2001) stated that PTMR is associated with a non-significant increase in mortality and a significant increase in non-anginal serious adverse events.

Moreover, recent reports indicated that PTMR is ineffective in treating patients with refractory angina. Stone and associates (2001) reported that in a patient population at high risk for restenosis (n = 26), recently created PTMR channels are not protective against severe ischemia caused by acute vessel closure and that late symptomatic restenosis after percutaneous intervention (angioplasty) may still frequently occur despite PTMR in the same region.

In a review on TMLR, Horvath (2002) noted that recent studies showed that PTMR failed to provide angina relief greater than that observed in placebo groups. In a prospective, multi-center, randomized trial of PTMR in patients with class III or IV
angina caused by non-recanalizable chronic total occlusions, Stone and colleagues (2002) reported that the performance of PTMR in addition to maximal medical therapy (n = 71) does not result in a greater reduction in angina, improvement in exercise duration or survival free of adverse cardiac events, as compared with maximal medical therapy only (n = 70).

Gatterer et al (2004) evaluated the short-term as well as long-term results of PTMR for patients with therapy refractory angina pectoris who are not amenable for angioplasty or bypass surgery. The authors concluded that while the angina class of the patients improved significantly, there was no significant change of myocardial perfusion but a trend to deterioration of left ventricular function after an average follow-up period of 7.7 months.

Leon et al (2005) reported the findings of a randomized, patient- and evaluator-blinded, placebo-controlled study in patients treated using PTMR. A total of 298 patients with severe angina were randomly assigned to receive low-dose or high-dose myocardial laser channels or no laser channels, blinded as a sham procedure. The primary end point was the change in exercise duration from baseline examination to 6 months. The incidence of 30-day death, stroke, myocardial infarction, coronary re-vascularization, or left ventricular perforation occurred in 2 patients in the placebo, 8 patients in the low-dose, and 4 patients in the high-dose groups (p = 0.12); 30-day myocardial infarction incidence was higher in patients receiving either low-dose or high-dose laser (9 patients) compared with placebo (no patients, p = 0.03). At 6 months, there were no differences in the change in exercise duration between those receiving a sham (28.0 s, n = 100), low-dose laser (33.2 s, n = 98), or high-dose laser (28.0 s, n = 98, p = 0.94) procedure. There were also no differences in the proportion of patients improving to better than Canadian Cardiovascular Society class III angina symptoms at 6 months. The follow-up visual summed stress single-photon-emission computed tomography scores were not significantly different from baseline in any group and were no different between groups. The modest improvement in angina symptoms assessed by the Seattle Angina Questionnaire also was not statistically different among the arms. The authors concluded that treatment with PTMR provides no benefit beyond that of a similar sham procedure in patients blinded to their treatment status.
An interventional procedure consultation document prepared for the National Institute for Health and Clinical Excellence (NICE, 2008) included the following provisional recommendations: "Current evidence on percutaneous laser revascularisation (PLR) for refractory angina pectoris shows no efficacy and suggests that the procedure may pose unacceptable safety risks. Therefore, this procedure should not be used." An interventional procedure consultation document by NICE on laser transmyocardial revascularization reached similar conclusions. The assessments noted that these procedures have not been shown to reduce mortality, and reductions in pain and improvements in quality of life in unblinded studies are likely to be placebo effects.

Guidelines from the Society of Thoracic Surgeons (Bridges, et al., 2004) state that "transmyocardial laser revascularization may be an acceptable form of therapy for selected patients: as sole therapy for a subset of patients with refractory angina and as an adjunct to coronary artery bypass graft surgery for a subset of patients with angina who cannot be completely revascularized surgically."

In a meta-analysis, McGillion et al (2010) evaluated the effectiveness of PMLR versus optimal medical therapy for improving angina symptoms, health-related quality of life (HRQL), and exercise performance; the impact on all-cause mortality was also examined. A total of 7 trials (n = 1,213) were included. Primary analyses showed that at 12-month follow-up, those who had received PMLR had greater than or equal to 2 Canadian Cardiovascular Society class angina symptom reductions, odds ratio (OR) 2.13 (95% confidence interval [CI]: 1.22 to 3.73), as well as improvements in aspects of HRQL including angina frequency, SMD = 0.29 (95% CI: 0.05 to 0.52), disease perception, SMD = 0.37 (95% CI: 0.14 to 0.61), and physical limitations, SMD = 0.29 (95% CI: 0.05 to 0.53). Percutaneous transmyocardial laser revascularization had no significant impact on all-cause mortality. For secondary analyses, in which these researchers considered data from 1 trial that featured a higher-dose laser group, yielded no significant overall impact of PMLR across outcomes. The authors concluded that while PMLR may be effective for improving angina symptoms and related burden, further work is needed to clarify appropriate dose and impact on disease-specific mortality and adverse cardiac events.

Excimer laser coronary angioplasty (ELCA) is one of the methods that fall within the spectrum of percutaneous coronary intervention (PCI) techniques. Coronary laser angioplasty is an alternative to coronary artery bypass surgery but not a
replacement therapy for those patients considered unfit for surgery. In the majority of laser angioplasty cases, balloon angioplasty will also be required during the same procedure to achieve satisfactory results. Although the Spectranetics ELCA system is approved by the Food and Drug Administration (FDA) for moderately calcified lesions, studies indicated an increased complication rate and lower success rate for these lesions. Thus, available evidence does not support laser technology as the most appropriate intervention.

The American College of Cardiology/American Heart Association (ACC/AHA) 2005 guideline update for PCI (Smith et al, 2006) does not include ELCA in treatment recommendations. In a discussion of techniques associated with PCI, the authors stated that despite the improvement in acute results observed for rotational atherectomy and excimer laser, there is no evidence that these approaches improve long-term outcomes in lesions that can be safely treated with balloon angioplasty or stenting alone. Furthermore, ELCA is not mentioned in a 2007 focused update of the 2005 guidelines (King et al, 2008).

An assessment of ELCA by the Ludwig Boltzmann Institut (Johanssen, et al., 2010) found that the laser angioplasty has been reported as a debulking tool in highly calcified stenosis and in chronic total occlusions followed by a conventional balloon angioplasty/stenting. This systematic review included one randomized controlled trial with per randomization and per protocol analysis, and two case series without controls, reporting on a total of 444 patients. The assessment concluded that, due to limitations in the design of these studies, the evidence of effectiveness and safety is low. The report recommends against reimbursement for ELCA in Austrian hospitals.

Excimer laser coronary angioplasty has also been studied as a treatment for patients with acute myocardial infarction, and in patients with depressed left ventricular ejection fraction. However, there is currently insufficient evidence to demonstrate the safety and effectiveness of ELCA for these indications.

Niccoli et al (2013) stated that laser atherectomy might decrease procedural complications during PCI of degenerated saphenous vein grafts (SVGs) in case of unstable or thrombotic lesions because of its ability to de-bulk and vaporize thrombus. These investigators prospectively evaluated the safety and effectiveness of ELCA as a primary treatment strategy in consecutively unstable patients undergoing PCI of degenerated SVG lesions. A total of 71 consecutive
patients with non-ST elevation acute coronary syndrome (mean age of 69 ± 10 years, 66 men [89 %]) undergoing PCI of degenerated SVG were enrolled in a prospective case-control registry, using 2 different distal protection devices (DPDs; FilterWire EZ [Boston Scientific, Natick, MA; n = 24] and SpiderRX [Ev3, Plymouth, MN; n = 23]) or ELCA (n = 24) were included in this study. Primary end-points of the study were incidence of angiographic microvascular obstruction (Thrombolysis In Myocardial Infarction flow grade of less than 3 or Thrombolysis In Myocardial Infarction flow grade of 3 with myocardial blush grade 1 to 2) and incidence of type IVa myocardial infarction. Angiographic microvascular obstruction incidence tended to be less in ELCA-treated patients compared with DPD-treated patients (3 [13 %] versus 15 [32 %], p = 0.09). Type IVa myocardial infarction incidence was more in DPD-treated patients compared with ELCA-treated patients (23 [49 %] versus 5 [21 %], p = 0.04). The authors concluded that in patients with non-ST elevation acute coronary syndrome undergoing PCI of degenerated SVG, ELCA compared with DPD, is associated with a trend for better myocardial reperfusion and a lesser incidence of peri-procedural necrosis. Moreover, they stated that controlled randomized controlled trials (RCTs) are needed to confirm these early observations.

Fracassi et al (2013) noted that excimer laser utilization as an adjunctive device for PCI has increased in the last few years. Technical advancements have led to better results in terms of safety and effectiveness with a low complication rate. In particular, excimer laser for thrombus-containing lesions is able to achieve rapid thrombus removal and plaque de-bulking along with subsequent facilitation of stent angioplasty and a low rate of microvascular obstruction. Other indications for laser angioplasty embrace in-stent restenosis, chronic total occlusions, SVG lesions and new potential applications, such as stent expansion optimization and bi-furcation lesions. The authors concluded that as for other medical devices, however, excimer laser should be tested in future RCTs against current standard of therapy in order to better define its role for each of the indications summarized above.

Lam and colleagues (2014) reported the successful management of under-expansion of a newly deployed coronary stent refractory to balloon dilatations. Direct stenting was performed for a lesion in the mid left anterior descending artery (without angiographically apparent heavy coronary calcification). The stent remained under-expanded despite repeated balloon dilatations including with high-pressure inflations. Subsequently, an excimer laser catheter was used in an attempt to vaporize the plaque by the accousto-mechanical effect of the rapidly
exploding bubbles. The overall angiographic result was good after further balloon
dilatation with ordinary pressure and full stent expansion was achieved. The
authors concluded that management of under-expansion of a newly deployed stent
is a potential indication of laser angioplasty.

**Excimer Laser for Coronary Artery Restenosis In-Stent Treatment:**

Hirose and associates (2016) stated that treatment of in-stent restenosis (ISR) is
associated with a high incidence of recurrence. These investigators evaluated the
clinical safety and 6-month efficacy of ELCA before scoring balloon dilatation for the
treatment of ISR. A total of 23 patients with ISR were included and treatment
strategy of ISR was dependent on each operator; 12 patients among those were
treated with ELCA before scoring balloon dilatation (ELCA group); and 11 patients
were treated with scoring balloon alone (non-ELCA group). Acute procedural
results were evaluated by quantitative coronary angiography (QCA) and frequency
domain optical coherence tomography (FD-OCT). Follow-up angiography was
performed in all patients and the incidence of recurrent ISR and target lesion
revascularization (TLR) was determined at 6 months after initial ISR treatment.
Procedural success was achieved in all patients. Baseline clinical and angiographic
characteristics were similar between groups. Maximum dilatation pressure of scoring
balloon was significantly lower in the ELCA group than in the non-ELCA group
(9.0 ± 3.1 versus 14.9 ± 4.3 ATM, p = 0.001). In follow-up angiography, the
occurrence of TLR was similar between groups (16.7 versus 45.5
%, p = 0.09), but the late luminal loss was significantly lower in the ELCA group (0.7
± 0.6 versus 1.3 ± 0.7 mm, p = 0.03). The authors concluded that ELCA was a safe
and feasible technique for the treatment of ISR and associated with a relatively low
recurrent restenosis in comparison with scoring balloon dilatation alone. The long-
term effectiveness of this approach need to be established by well-designed
studies.

Ambrosini and colleagues (2017) noted that stents reduce angiographic restenosis
in comparison with balloon angioplasty. The rate of ISR, although less frequent
than post-angioplasty restenosis, is becoming increasingly prevalent due to the
recent exponential increase in the use of intracoronary stents. In a multi-centric,
case-control study, these researchers evaluated angiographic and clinical outcomes
of percutaneous transluminal coronary angioplasty (PTCA) in combination with the
use of ELCA and drug-eluting balloon (DEB) in treatment of patients with ISR (n =
80). All patients underwent 9 months of clinical and a
coronary angiography follow-up. This study showed clinical and angiographic long-term success in the 91% of the patients. The incidence of myocardial infarctions (MI) and deaths was lower than the rate after plain balloon angioplasty within the stent. The authors concluded that the findings of this study showed that ELCA and DEB may be an alternative treatment for ISR.

Lee and colleagues (2018) evaluated the effectiveness of ELCA to treat ISR due to peri-stent calcium-related stent under-expansion as assessed by OCT. These investigators studied 81 patients (81 lesions with ISR, stent under-expansion, and peri-stent calcium greater than 90°) who underwent OCT imaging both pre- and post-PCI and compared lesions treated with ELCA (n = 23) vs without ELCA (n = 58). The use of ELCA was associated with more calcium fracture (ELCA: 61%, non-ELCA: 12%, p < 0.01), larger final minimum lumen area (ELCA: 4.76 mm² [3.25, 5.57], non-ELCA: 3.46 mm² [2.80, 4.13], p < 0.01), and a larger previously implanted stent area (ELCA: 6.15 mm² [4.83, 7.09], non-ELCA: 4.65 mm² [3.84, 5.40], p < 0.01). In the multi-variable model, ELCA use was associated with peri-stent calcium fracture (OR 46.5; 95% CI: 6.8 to 315.9, p = 0.01) that, in turn, was associated with final larger lumen and stent dimensions. Finally, contrast injection during ELCA was associated with multiple calcium fractures and fractures even in thicker calcium. The authors concluded that ELCA was effective for treating ISR with under-expansion by disrupting peri-stent calcium, facilitating better expansion of the previously implanted stent. The drawbacks of this study included that this was a retrospective observation study, and the number of patients was relatively small (n = 23 for ELCA treated subjects) precluding sub-group analysis especially the number of lesion treated with ELCA, likely causing selection bias.

Ichimoto and co-workers (2018) noted that ELCA has been used for the treatment of complex PCI such as ISR. However, little information was provided about the clinical outcomes after treatment with ELCA for ISR of drug-eluting stents (DES). These investigators examined the long-term clinical outcomes after PCI with ELCA for ISR of DES. A total of 81 consecutive patients with 87 lesions who underwent PCI for ISR of DES were included. Patients were classified into a PCI with ELCA group (23 patients with 24 lesions) and a PCI without ELCA group (58 patients with 63 lesions). The major adverse cardiac events (MACE) were evaluated. The mean duration of clinical follow-up was 29.8 ± 11.6 months. The incidences of diffuse restenosis and AHA/ACC type B2 or C lesion in the PCI with ELCA group were higher than in the PCI without ELCA group. Quantitative coronary angiography showed the acute luminal gain in the PCI with ELCA group was greater than in the
PCI without ELCA group (1.64 ± 0.48 mm versus 1.26 ± 0.42 mm, p < 0.001). There were no significant differences in all-cause death, MI, or TLR between the 2 groups. Multi-variate analysis due to a Cox proportional-hazards model showed that multi-vessel disease was an independent predictor of MACE (hazard ratio [HR] 3.05, 95 % CI: 1.22 to 7.61, p = 0.02). The authors concluded that ELCA was effective as an atherectomy device for lumen enlargement and optimal lesion preparation. These researchers noted that even though ELCA was used for ISR of DES in significantly more complex lesions, the long-term clinical outcomes were favorable and similar.

In an editorial that accompanied the afore-mention study by Ichimoto et al (2018), Nakamura and associates (2018) stated that “Their findings suggest that ELCA is safe and effective at facilitating balloon or stent expansion by ablating in-stent intimal hyperplasia and improving optimal lesion preparation, especially in undilatable and under-expanded stents, although their study has several potential limitations, such as the absence of randomization to the treatment strategy, the small number of intravascular imaging used, and the retrospective nature of the study. We look forward to further studies in a larger number of patients and randomized trials”.

**Transmyocardial Laser Revascularization Plus Cell Therapy:**

Konstanty-Kalandyk (2018) noted that refractory angina has limited effective therapeutic options and often contributes to frequent hospitalizations, morbidity and impaired quality of life (QOL). These researchers examined mid-term results of a bio-interventional therapy combining TMLR and intra-myocardial injection of adipose derived stem cells (ADSC) in patients with refractory angina not amenable to percutaneous or surgical revascularization. This study included 15 patients with severe refractory angina and anterior wall ischemia who were ineligible for revascularization strategies. Adipose tissue was harvested and purified, giving the stem cell concentrate. All patients underwent left anterior thoracotomy and TMLR using a low-powered holmium: yttrium-aluminum-garnet laser and intra-myocardial injection of ADSC using a combined delivery system. No deaths or major adverse cardiovascular or cerebrovascular events were observed in the 6-month follow-up. Mean ejection fraction increased from 35 % to 38 %, and mean Canadian Cardiovascular Society Angina Score decreased from 3.2 to 1.4, with decreased necessity of nitrate usage; 73 % of patients reported health improvement particularly regarding general health and bodily pain. Improvement in endocardial
movement, myocardial thickening and stroke volume index (35.26 to 46.23 ml/m2) on cardiac MRI was observed in 3 patients who had repeat CMR imaging after 6 months. The authors concluded that the findings of this study suggested that interventional therapy combining TMLR with intra-myocardial implantation of ADSC may reduce symptoms and improve QOL in patients with refractory angina. Moreover, they stated that these early findings need further validation in large, multi-center RCTs.

The authors stated that the main drawbacks of this study were the small sample size (n = 15) and lack of a control group, which limited the statistical rigor of the findings and questioned the efficacy results. However, the improvement in symptoms was accompanied by an improvement in myocardial function. Despite these drawbacks, this study provided an important opportunity to explore a new therapeutic option that has a great potential to improve the QOL.

**Excimer Laser for Acute Coronary Syndrome:**

Harima and colleagues (2018) tested a novel stent-less re-vascularization strategy using a combination of ELCA and drug-coated balloon (DCB) for patients with acute coronary syndrome (ACS). Consecutive ACS patients were planned to receive either a DCB application following ELCA without a stent implantation or conventional re-vascularization with a coronary stent. The end-points were MACEs, defined as the composite of cardiac death, Mls, and TLR; target vessel revascularization (TVR); and angiographic outcome. Since a greater than expected number of patients allocated to the stent-less treatment arm eventually received a bailout stenting, the following 3 as-treated groups were compared; DCB with ELCA group (n = 60), stent with ELCA group (n = 23), and stent without ELCA group (n=85). During a mean follow-up period of 420 ± 137 days, and with angiographic 6- and 12-month-follow-up rates of 96.7 %, 87 %, and 81.2 %, and 50 %, 65.2 %, and 45.9 %, respectively, the MACE rate did not differ across the groups (10 %, 4.3 %, and 3.5 %; p = 0.22) while an incidence of TVR was more common (15 %, 0, and 4.7 %; p = 0.02) and the diameter stenosis at 6-months of follow-up was greater (25.7 ± 18.2, 14.9 ± 13.1 and 16.2 ± 15.4 %; p = 0.002) in the DCB with ELCA group. The authors concluded that the stent-less re-vascularization strategy with DCB and ELCA was associated with a higher occurrence of re-stenosis in ACS patients.
Appendix

Selection Criteria for Transmyocardial Laser Revascularization:

1. Anginal symptoms are caused by viable ischemic myocardium (as demonstrated by diagnostic study) not amenable to surgical revascularization therapies such as PTCA, stenting, coronary atherectomy or coronary bypass; and
2. Member has had maximal efforts to stabilize acute conditions such as severe ventricular arrhythmia, decompensated congestive heart failure or acute myocardial infarction; and
3. Severe New York Heart Association functional classification of angina pectoris -- Class III or IV (see note below); and
4. Symptoms of angina refractory to standard medical therapy, including drug therapy at the maximum tolerated or maximum safe dosages; and
5. The physician has been properly trained in the procedure and the laser used in performing the procedure has been approved by the FDA for the purpose for which it is being used.

The New York Heart Association (NYHA) functional classification of angina pectoris is as follows:

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<th>Class</th>
<th>Class Description</th>
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<tr>
<td>Class I</td>
<td>Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.</td>
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<td>Class II</td>
<td>Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.</td>
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<td>Class III</td>
<td>Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.</td>
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<td>Class IV</td>
<td>Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.</td>
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CPT Codes / HCPCS Codes / ICD-10 Codes
Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

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Transmyocardial laser revascularization plus cell therapy with autologous bone marrow cells:

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Excimer laser coronary angioplasty:

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<td>Other myocardial infarction type</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0161
Transmyocardial and Endovascular Laser Revascularization

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania  revised 02/14/2019