Enhanced external counterpulsation is considered investigational for all indications, including but not limited to:

- Erectile dysfunction
- Heart failure
- Ischemic stroke
- Treatment of chronic stable angina pectoris

This policy only addresses outpatient uses of enhanced external counterpulsation (EECP), such as for the treatment of chronic stable angina or heart failure. This policy does not address its use for unstable angina pectoris, acute myocardial infarction, or cardiogenic shock.

**Coding**

EECP may be coded using a series of CPT codes describing the individual components of the procedure (see the Coding section).

The following HCPCS code is specific to EECP:

- G0166: External counterpulsation, per treatment session

Enhanced external counterpulsation (EECP) is a noninvasive treatment used to augment diastolic pressure, decrease left ventricular afterload, and increase venous return. EECP has been studied primarily as a treatment for patients with refractory angina and heart failure.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

A variety of EECP devices have been cleared for marketing by the Food and Drug Administration (FDA) through the 510(k) process. Examples of EECP devices with the FDA clearance are outlined in Table 1. FDA product code: DRN.
Table 1. FDA-Cleared Enhanced External Counterpulsation Devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Clearance Date</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renew® NCP-5 External Counterpulsation System</td>
<td>Renew Group (Rockville, MD)</td>
<td>Dec 2015</td>
<td>Treatment of chronic stable angina refractory to optimal anti-anginal medical therapy and without options for revascularization. In healthy patients to improve vasodilation, increase VO₂, and increase blood flow.</td>
</tr>
<tr>
<td>CardiAssist™ Counterpulsation System</td>
<td>Cardiomedics (Irvine, CA)</td>
<td>Mar 2005</td>
<td>Treatment of ischemic heart disease by increasing perfusion during diastole in people with chronic angina pectoris, congestive heart failure, myocardial infarction, and cardiogenic shock.</td>
</tr>
</tbody>
</table>

EECP: enhanced external counterpulsation; FDA: Food and Drug Administration; VO₂: oxygen consumption.

**Rationale**

**Background**
Enhanced external counterpulsation (EECP) uses timed, sequential inflation of pressure cuffs on the calves, thighs, and buttocks to augment diastolic pressure, decrease left ventricular afterload, and increase venous return. Augmenting diastolic pressure displaces a volume of blood backward into the coronary arteries during diastole when the heart is in a state of relaxation and resistance in the coronary arteries is at a minimum. The resulting increase in coronary artery perfusion pressure may enhance coronary collateral development or increase flow through existing collaterals. In addition, when the left ventricular contracts, it faces reduced aortic counterpressure, because the counterpulsation has somewhat emptied the aorta. EECP has been primarily investigated as a treatment for chronic stable angina.

Intra-aortic balloon counterpulsation is a more familiar, invasive form of counterpulsation that is used as a method of temporary circulatory assistance for the ischemic heart, often after an acute myocardial infarction. In contrast, EECP is thought to provide a permanent effect on the heart by enhancing the coronary collateral development. A full course of therapy usually consists of 35 one-hour treatments, which may be offered once or twice daily, usually 5 days a week. The multiple components of the procedure include the use of the device itself, finger plethysmography to follow the blood flow, continuous electrocardiograms to trigger inflation and deflation, and optional use of pulse oximetry to measure oxygen saturation before and after treatment.

**Literature Review**
Randomized controlled trials (RCTs) that report on relevant clinical outcomes are required to determine whether enhanced external counterpulsation (EECP) is efficacious and whether it is at least as good as alternative treatments. Observational data are of limited utility given the variable natural history of disorders (e.g., angina, heart failure), the presence of many potential confounders of cardiac outcomes, and the potential for a placebo effect.
The literature base consists of a low number of RCTs, some of which have reported relevant clinical outcomes, and others that have reported intermediate or physiologic outcome measures. In addition, there are a large number of observational studies, including publications from EECP registries and case series, that have generally reported pre- and posttreatment measures of EECP effectiveness.

**Chronic Stable Angina**

**Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessments**

The original literature update for this evidence review was based on a 1999 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment on EECP for chronic stable angina, which was updated in 2002 and again in 2005. These Assessments concluded that the evidence was insufficient to determine whether EECP improved the net health outcome or was as beneficial as any established alternatives in patients with chronic stable angina.

Specifically, the 2005 Blue Cross Blue Shield Association TEC Assessment offered the following observations and conclusions regarding EECP for chronic stable angina:

- There was insufficient evidence to draw conclusions about the benefits of EECP.
- The results of the single RCT, the Multicenter Study of Enhanced External Counterpulsation (MUST-EECP), must be interpreted with caution given the following factors: (1) the high subject dropout rate; and (2) the uncertain clinical significance of the reported improvement in physiologic measures, especially when intention-to-treat analysis is applied.
- Comparative studies of EECP did not address the hard outcomes of cardiac death or recurrent cardiac events, such as myocardial infarction and revascularization procedures.
- Several case series and registry-based studies have reported the outcomes of large numbers of patients treated in a number of different institutions. There were several problems with this kind of evidence: first, these studies, while contributing to the body of knowledge of EECP, did little to address the efficacy or durability of EECP treatment; second, the lack of comparison groups made it impossible to rule out either placebo effect or spontaneous recovery among patients with milder disease.

**Randomized Controlled Trials**

In 1999, Arora et al presented results of the MUST-EECP trial. The MUST-EECP trial applied a randomized controlled, double-blinded protocol that compared active treatment with placebo (inactive counterpulsation sham treatment) among 139 patients with Canadian Cardiovascular Society (CCS) Classification Scales (a functional assessment tool based on the level of exertion that elicits symptoms) class I, II, or III chronic, stable angina. Four outcomes were examined: (1) self-reported frequency of angina, analyzed 2 ways; (2) self-reported use of on-demand nitroglycerin; (3) exercise duration tolerance testing; and (4) time to exercise-induced ischemia (defined as time to depression of ≥1 mm in the ST segment on electrocardiogram).

All patients underwent the same 35-hour protocol, followed by an exercise tolerance test within 1 week of completing therapy. Follow-up beyond the treatment period was not conducted. Intention-to-treat analyses were reported for the angina count and nitroglycerin usage outcomes only. There was a statistically significant difference (p=0.01) between groups in the change in time to 1 mm or greater ST segment depression. Patients in the EECP group had an average difference of 37 seconds longer time to ST segment depression compared with the sham-treated group. There was no significant difference between treatment groups in the change in exercise duration from baseline to the posttreatment period (p<0.31). In addition, there were no statistically significant differences between groups with respect to angina counts (p<0.09) or nitroglycerin use (p>0.1).

In addition to methodologic limitations found in the design, execution, and reporting of this study, the magnitude of the benefit reported is not large. Of the 4 endpoints of interest, only time to ST segment depression differed statistically in the EECP group compared with the sham.
group. The clinical significance of a 37-second improvement in time to ST segment depression is unknown, but because it occurred while the other 3 end points were statistically unchanged with therapy should not suggest that this anomaly marks improvement. That both groups showed increased exercise duration suggests a degree of placebo effect; exercise duration possesses a motivational component that time to ST segment depression does not.

In 2002, Arora et al published a 12-month follow-up study to the MUST-EECP trial. Only 71 (54%) of the original 139 subjects were included in the study. Subjects treated with EECP reported greater improvement in several quality-of-life (QOL) scales. However, such findings could not be correlated with treatment response reported in the first study (because of data limitations). The findings were further limited by the small sample size and potentially biased sample of the original subject pool.

A small unblinded RCT published in 2011 addressed a single health outcome (change after 7 weeks in CCS angina class), along with multiple intermediate outcomes. Twenty patients with refractory angina (CCS class III) were randomized to EECP or no EECP. Mean CCS class was significantly improved in the EECP group but not in the no-EECP group. At 7-week follow-up, soluble interleukin-2 receptor measurements significantly increased in the EECP group and significantly decreased in the no-EECP group. There were no differences between groups at 7 weeks in resting cutaneous microvascular blood flow or response to acetylcholine, sodium nitroprusside, or local heating.

Additional RCTs have reported on intermediate, or physiologic, outcomes. One such RCT (N=20), published in 2010, compared intracoronary blood flows in patients treated using EECP with those treated using a sham procedure. This trial was designed to detect statistically significant differences in collateral flow rates by angiography, not anginal symptoms. After 7 weeks of treatment, collateral flow index increased significantly in the EECP group compared with sham treatment. Similar findings were noted in a 2009 comparative study by Buschmann et al of 23 patients.

Two publications from a single trial reported on blood flow and other measures of arterial function. This study randomized 42 patients with coronary artery disease and chronic angina to EECP or sham EECP. EECP improved flow-mediated dilation in the brachial and femoral arteries and improved numerous serum markers of blood flow and inflammation. The same study also reported that measures of arterial stiffness were improved in the EECP group.

In a 2015 randomized pilot study, Shakouri et al reported on intermediate outcome measures, including plasma nitric oxide, endothelin 1, high-sensitivity C-reactive protein, and QOL, in patients with coronary artery disease allocated to 20 sessions of EECP (n=21) or cardiac rehabilitation (n=21). There were no statistically significant improvements in physiologic markers and QOL over time in either group and no statistically significant between-group differences in change in any of the parameters evaluated.

**Systematic Reviews**

Systematic reviews of the literature have evaluated EECP for chronic stable angina. In 2010, Amin et al published a Cochrane review of major databases through 2008 on evidence of the effectiveness of EECP for chronic angina pectoris. The solitary RCT identified was the MUST-EECP trial. Reviewers highlighted patient selection for this study. They noted that limiting the study population to patients with CCS class below IV diminished the trial’s generalizability to patients of interest, i.e., patients with the most severe symptoms of chronic angina pectoris.

Also in 2010, Shah et al published a meta-analysis of prospective studies, not limited to RCTs, of EECP in stable angina in which CCS class was adequately reported before and after treatment. The MUST-EECP RCT was not included because change in CCS class was not a reported outcome. Thirteen studies met these inclusion criteria (total N=949 patients). Overall, improvement of at least 1 level of angina class occurred in 86% of patients (95% confidence
interval [CI], 82% to 90%, p=0.008). No conclusions can be drawn from this analysis given the lack of randomization (comparison group) for most studies analyzed.

In 2009, McKenna et al report on a systematic review and economic analysis of EECP for the treatment of stable angina and heart failure. Four studies (1 RCT, 3 nonrandomized comparative studies) comparing EECP treatment with no treatment in adults with chronic stable angina were selected. The systematic review also included a 2008 study by Barsheshet et al in which 25 patients (15 EECP, 10 controls) were evaluated at the end of treatment. Similar to the Schechter et al (2003) study, “CCS classification improved with EECP but not with usual care, however statistical analysis of between-group differences was not reported and, for CCS classification, the data were treated as continuous data which is inappropriate for this four-category classification.”

A 2016 systematic review and meta-analysis focused on the effect of EECP on the intermediate measure of myocardial perfusion in patients with coronary artery disease. Reviewers included 6 studies reporting on myocardial perfusion or coronary flow outcomes published from 1992 to 2007, including 5 RCTs and 1 prospective, observational, blinded study. In pooled analysis, EECP was associated with increased myocardial perfusion in patients with coronary artery disease (pooled weighted mean difference, -0.19; 95% CI, -0.38 to 0.00; p=0.049).

Registry Studies
Registry-based studies have reported on relatively large numbers of patients. In 1 registry-based study (2007), 450 patients with left ventricular dysfunction (ejection fraction, ≤40%) and refractory angina had 0.7 fewer emergency department visits and 0.8 fewer hospitalizations 6 months after treatment with EECP compared with the 6 months before EECP; 6-month data were available on only 81 patients. Drawing conclusions from this study is not possible due to lack of a comparison group.

Another registry-based study (the International Enhanced External Counterpulsation Patient Registry) reported 3-year results for patients with chronic refractory angina. The registry enrolled 5000 patients from 99 U.S. and 9 international centers between 1999 and 2001. However, this 2008 analysis was completed only for those centers that had at least 80% compliance with follow-up data submission; the study reported results on 1427 patients. In this select group, 220 (15.4%) patients died, while 1061 (74.4%) patients completed their follow-up. Immediately post-EECP, the proportion of patients with severe angina (CCS class III/IV) were reduced from 89% to 25% (p<0.001). This improvement was sustained in 74% of the patients during follow-up. More severe baseline angina and a history of heart failure or diabetes were independent predictors of unfavorable outcome. Again, the lack of a control group in this study precludes drawing conclusions about this technology.

The International Enhanced External Counterpulsation Patient Registry data have also been examined to determine the safety and efficacy of this device in patients with peripheral arterial disease (PAD). PAD, while a common comorbidity of coronary artery disease, has been regarded as a contraindication to EECP due to concerns about compression on peripheral blood flow and a potentially greater risk of aortic rupture. Thakkar et al (2010) compared registry data in patients with PAD against those without. Based on a reduction of one or more CCS angina classes, patients with PAD had a similar rate of improvement as did the group without PAD (76.6% vs 79.0%, respectively; p=0.27). Rates of hospitalization for all cardiac causes (6.1% vs 4.4%, respectively; p=0.17) and for unstable angina (5.4% vs 3.5%, respectively; p=0.25) were also similar between groups.

Other Observational Studies
Numerous individual observational studies have been detailed in previous reviews and are included in systematic reviews previously described. For example, 2 prospective cohort studies (N=55 and N=61) with 1-year outcomes have been reported. Improved CCS classification was the main reported outcome, which was maintained for 1 year in 79% and 78%
of patients in the respective studies. Both studies had higher rates of treatment completion and follow-up than the previously reported (registry) studies of long-term outcomes. These studies addressed the need for data on treatment durability.

Section Summary: Chronic Stable Angina
Data on use of EECP in chronic stable angina are insufficient to form conclusions about the efficacy of this treatment. The single randomized trial (MUST-EECP) that included relevant clinical outcomes reported a benefit on 1 of 4 main angina-related outcomes, and the magnitude of this benefit was of uncertain clinical significance. RCTs that have reported on intermediate outcomes offer evidence on possible physiologic mechanisms underlying EECP treatment but do not themselves provide evidence of health outcome benefits. Observational studies (e.g., registry data, case series) offer little evidence on the efficacy of this procedure due to the variable natural history of angina, the multiple confounders of cardiac outcomes, and the potential for a placebo effect.

Heart Failure
The 510(k) approval of the Vasomedical devices stated that objective measures, such as peak oxygen consumption (VO2peak), exercise duration, and preload-adjusted maximal left ventricular power, are improved following EECP therapy, as are subjective measures of patient response to therapy, such as QOL and functional ability. However, no clinical details of these studies were provided in the Food and Drug Administration summary, and these data were not from controlled trials.

The 2005 Blue Cross Blue Shield Association Technology Evaluation Center TEC Assessment included heart failure in its analysis and concluded the evidence supporting the role of EECP as an effective treatment for heart failure was lacking in both quantity and quality. A single randomized, multicenter study compared EECP with usual care in 187 optimally medically managed patients with New York Heart Association (NYHA) functional class II or III heart failure with an ejection fraction of 35% or less of ischemic or idiopathic etiology. This study, the Prospective Evaluation of EECP in Congestive Heart Failure (PEECH trial), was mostly inconclusive. The design and methods of the PEECH trial were published by Feldman et al (2005). PEECH trial (2006) results found statistically improved, but modest, changes in exercise duration and improved functional class but not in QOL or VO2peak.

A subgroup analysis of the PEECH trial showed that subjects ages 65 years and older treated with EECP (n=41) were more likely to meet the exercise duration (35% vs 25% increased by ≥60 seconds) and VO2peak (30% vs 11% increased by ≥1.25 mL/kg/min) improvement thresholds compared with those undergoing sham treatment (n=45); there was no difference at 6 months in NYHA class.

In 2015, Rampengan et al reported on a double-blinded RCT evaluating EECP in patients with congestive heart failure treated in Indonesia. Patients with NYHA functional class I or II symptomatic heart failure from various causes were included. Patients were randomized to active EECP (n=56) or sham EECP (n=56), which involved the use of the EECP device at only 77 mm Hg of pressure vs the standard 300 mm Hg. Analysis was per protocol, excluding 6 and 7 patients who dropped out of the active and sham groups, respectively. Postintervention, active EECP group patients were more likely to have a 6-minute walk test (6MWT) distance of 300 meters or greater (98.0% vs 32.7%, p<0.01). The change in 6MWT distance was greater (improved) for the active EECP patients (192.6 meters) than for the sham control patients (-9 meters; p<0.05).

Similar to the registry evidence for EECP for angina, registry studies for heart failure have provided relatively little insight into the comparative efficacy of EECP. The single-arm study by Soran et al (2002) indicated that patients showed some improvements, but the lack of a comparison arm precluded inferences about the true effects of therapy.
The previously described 2009 review by McKenna et al. included the single trial of EECP for heart failure available at that time, the 2006 PEECH study. Reviewers concluded that the studies did not provide firm evidence of the clinical effectiveness of EECP in refractory stable angina or in heart failure and that high-quality studies are required to investigate the benefits of EECP and whether they outweigh the common adverse effects.

**Section Summary: Heart Failure**

The evidence for the use of EECP in heart failure includes 2 RCTs that reported on clinical outcomes. One study reported modest improvements for some outcomes and no improvement on others. A second study reported improvements in the 6MWT but had methodologic limitations that, in turn, limit the conclusions that could be drawn from the study. The observational studies added little to the evaluation of efficacy due to the variable natural history of heart failure, the multiple confounding variables for cardiac outcomes, and the potential for a placebo effect. Further high-quality RCTs are needed to determine whether EECP is a useful treatment for heart failure.

**Other Indications**

The use of EECP for other conditions associated with ischemia or vascular dysfunction has been investigated. In 2009, Fraser and Adams produced a Cochrane review on interventions for central retinal artery occlusion. One of the 2 RCTs identified compared hemodilution with EECP against hemodilution without further intervention. In this case, the EECP intervention was a single, 2-hour treatment. According to reviewers, in this study, 20 patients were randomized but not blinded; no sham treatment was given. Primary outcomes were Doppler flowmetry of retinal perfusion and visual acuity.

Published registry studies have also demonstrated improvements in erectile function. Erectile function was improved in a study of 120 men prospectively enrolled from 16 centers. Three of 5 domains of the International Index of Erectile Function were statistically improved with EECP treatment (erectile function, intercourse satisfaction, overall satisfaction), and the total score improved from 28 to 32, a statistically significant improvement. The noncomparative design of this study makes it difficult to draw conclusions on treatment efficacy. Preliminary studies from Asia are also reporting early results on use of EECP to the lower extremities in the treatment of acute ischemic stroke. A 2012 Cochrane review of 2 RCTs of EECP in acute ischemic stroke concluded that the methodologic quality of the studies was poor and reliable conclusions could not be reached from this evidence.

In 2016, Sardina et al. reported on an RCT that allocated 30 patients with type 2 diabetes in a 2:1 ratio to EECP (n=20) or standard care for diabetes (n=10), and reported results out to 37 and 6 months. At 6-month follow-up, patients in the EECP group had significant decreases over time in variety of biomarkers of advanced glycation end products, inflammation, and oxidative stress. At 6-month follow-up, the percent change in advanced glycation end products and receptor of advanced glycation end products differed significantly between groups (p<0.05).

**Summary of Evidence**

For individuals who have chronic stable angina who receive EECP, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and functional outcomes. There is a single blinded RCT that includes clinical outcomes, and it reported benefit on only one of four main angina outcomes. Additional small RCTs have reported changes in physiologic measures associated with EECP but did not provide relevant evidence on clinical efficacy. Because of the variable natural history of angina, the multiple confounding variables for cardiac outcomes, and the potential for a placebo effect, more RCT evidence is needed. Therefore, observational studies, including registry studies with large numbers of patients, add little to determinations of efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who have heart failure who receive EECP, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and functional outcomes. One RCT that reported on clinical outcomes found a modest benefit with EECP on some outcomes and no benefit on others. A second RCT reported improvements on the 6-minute walk test with EECP but had methodologic limitations; RCT findings ultimately proved inconclusive. The observational studies on EECP in heart failure have limited ability to inform the evidence on EECP due to the multiple confounding variables for cardiac outcomes and the potential for a placebo effect. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Supplemental Information**

**Clinical Input from Physician Specialty Societies and Academic Medical Centers**
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests from Blue Cross Blue Shield Association, input was received from 3 academic medical centers in April 2008, one during review in October 2008, and one during review in 2009. Reviewers agreed with the conclusion that enhanced external counterpulsation was investigational. Some reviewers commented about the potential use of enhanced external counterpulsation in those with angina not amenable to surgical interventions.

**Practice Guidelines and Position Statements**
The American College of Cardiology Foundation (ACCF), American Heart Association (AHA), and five other medical societies stated in their 2012 guidelines that “patients with stable ischemic heart disease who indicate for enhanced external counterpulsation (EECP) may be considered for relief of refractory angina.” This recommendation was based on class IIb, level of evidence: B, which indicates the efficacy of the intervention is not well established and further studies would be helpful.39

The 2013 ACCF and AHA guidelines on the management of heart failure did not address EECP.40

In 2014, ACCF and AHA updated to their 2012 guidelines on the diagnosis and management of patients with stable ischemic heart disease in which the associations specifically reviewed their recommendation on EECP. Based on this review, ACCF and AHA did not change their recommendation on EECP from the 2012 guidelines.41

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Medicare National Coverage**
Medicare has published a national coverage decision on EECP that mandates coverage for the following indications:

“Coverage is provided for the use of EECP for patients who have been diagnosed with disabling angina who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as percutaneous transluminal coronary angioplasty or cardiac bypass because: 1) Their condition is inoperable, or at high risk of operative complications or post-operative failure; 2) Their coronary anatomy is not readily amenable to such procedures; or 3) They have co-morbid states which create excessive risk.”

Medicare’s coverage decision also noted that while the U.S. Food and Drug Administration has cleared EECP “for use in treating a variety of cardiac conditions, including stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock, the use of this device to treat cardiac conditions other than stable angina pectoris is not covered....”
Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in July 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

References


**Documentation for Clinical Review**

- No records required
This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

### IE

The following services may be considered investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>92971</td>
<td>Cardioassist-method of circulatory assist; external</td>
</tr>
<tr>
<td></td>
<td>93041</td>
<td>Rhythm ECG, 1-3 leads; tracing only without interpretation and report</td>
</tr>
<tr>
<td></td>
<td>93922</td>
<td>Limited bilateral noninvasive physiologic studies of upper or lower extremity arteries, (e.g., for lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus bidirectional, Doppler waveform recording and analysis at 1-2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus volume plethysmography at 1-2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries with, transcutaneous oxygen tension measurement at 1-2 levels)</td>
</tr>
<tr>
<td></td>
<td>94761</td>
<td>Noninvasive ear or pulse oximetry for oxygen saturation; multiple determinations (e.g., during exercise)</td>
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<tr>
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<td>99211</td>
<td>Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services.</td>
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<td>99354</td>
<td>Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; first hour (List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service)</td>
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<td>99355</td>
<td>Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (List separately in addition to code for prolonged service)</td>
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<td>99356</td>
<td>Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour (List separately in addition to code for inpatient Evaluation and Management service)</td>
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<td>99358</td>
<td>Prolonged evaluation and management service before and/or after direct patient care; first hour</td>
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<td>99359</td>
<td>Prolonged evaluation and management service before and/or after direct patient care; each additional 30 minutes (List separately in addition to code for prolonged service)</td>
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<td>HCPCS</td>
<td>G0166</td>
<td>External counterpulsation, per treatment session</td>
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<td>ICD-10</td>
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</table>
## Policy History

This section provides a chronological history of the activities, updates, and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
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<tbody>
<tr>
<td>10/14/1998</td>
<td>New Policy Adoption</td>
<td>Medical Policy Committee</td>
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<tr>
<td>10/22/1999</td>
<td>Policy Review</td>
<td>Medical Policy Committee</td>
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<tr>
<td>08/01/2002</td>
<td>Coding Update</td>
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<td>10/16/2002</td>
<td>Policy Title Revision, criteria revised</td>
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<td>03/01/2006</td>
<td>Policy Name Change</td>
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<td>06/28/2007</td>
<td>Policy Revision</td>
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<td>06/26/2009</td>
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<td>07/02/2010</td>
<td>Policy revision with position change</td>
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<td>Policy revision without position change</td>
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<td>02/01/2018</td>
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## Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.
Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.