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Transcatheter Closure of Septal Defects

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Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for transcatheter closure of septal defects when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Transcatheter closure of secundum atrial septal defects may be considered **medically necessary** when using a device that has been FDA approved for that purpose and used according to the labeled indications.

Transcatheter closure of patent foramen ovale (PFO) using atrial septal closure devices may be considered **medically necessary** for patients who have had an embolic event related to the PFO.

When Policy Topic is not covered

Transcatheter closure of ventricular septal defects is considered **investigational.**

Transcatheter closure of patent foramen ovale (PFO) for the treatment of migraine headaches is considered **investigational**.

Considerations

At present, no PFO closure devices are FDA approved for patients with cryptogenic stroke. All uses of these PFO closure devices are currently off-label.

There are 2 FDA-approved devices for ASD closure: the AMPLATZER™ Septal Occluder, and the GORE HELEX™ Septal Occluder.

The labeled indications for these devices are similar and include:

- Those with echocardiographic evidence of ostium secundum atrial septal defect; AND
- Clinical evidence of right ventricular volume overload (i.e., 1.5:1 degree of left to right shunt or right ventricular enlargement.

In 2003, CPT established a code for percutaneous transcatheter closure of congenital interatrial communication (i.e., fontan fenestration, atrial septal defect) with implant (93580). CPT notes that 93580 includes a right heart catheterization procedure. Other heart catheterization procedures should not be reported separately in addition to 93580.

Description of Procedure or Service

“Closure” devices are intended as less-invasive, catheter-based approaches of repairing patent foramen ovale or atrial septal defects.

Patent Foramen Ovale

The foramen ovale, a component of fetal cardiovascular circulation, consists of a communication between the right and left atrium that functions as a vascular bypass of the uninflated lungs. The ductus arteriosus is another feature of the fetal cardiovascular circulation, consisting of a connection between the pulmonary artery and the distal aorta. Prior to birth, the foramen ovale is held open by the large flow of blood into the left atrium from the inferior vena cava. Over a course of months after birth, an increase in left atrial pressure and a decrease in right atrial pressure result in the permanent closure of the foramen ovale in most individuals. However, a patent foramen ovale (PFO) is a common finding in normal adults, detected in up to 25% of adults. (1) In some epidemiologic studies, PFO has been associated with cryptogenic stroke, a type of stroke defined as an ischemic stroke occurring in the absence of potential cardiac, pulmonary, vascular, or neurological sources. Studies also show an association of PFO and migraine headache. There has been interest in either open surgery or transcatheter approaches to close the PFO in patients with a history of cryptogenic stroke in order to prevent recurrent stroke.

Two transcatheter devices received approval for marketing from the U.S. Food and Drug Administration (FDA) in 2002 as a treatment for patients with cryptogenic stroke and patent foramen ovale: the CardioSeal Septal Occlusion System and the Amplatzer Patent Foramen Ovale occluder. Both received approval by the FDA through a Humanitarian Device Exemption (HDE), a category of FDA approval that is applicable to devices that are designed to treat a patient population of fewer than 4,000 patients per year. This approval process requires the manufacturer to submit data on the safety and the probable clinical benefit. Clinical trials validating the device effectiveness are not required. The labeled indications of both limited the use of these devices to closure of PFO in patients with recurrent cryptogenic stroke due to presumed paradoxical embolism through a patent foramen ovale and who have failed conventional drug therapy.

Following this limited FDA approval, the use of PFO closure devices increased by over 50-fold, well in excess of the 4,000 per year threshold intended under the HDE. (2) As a result, in 2006, the FDA withdrew the HDE approval for these devices. At this time, the FDA also reiterated the importance of randomized, controlled trials of PFO closure devices versus medical therapy, but noted that ongoing trials were hampered by slow enrollment. Withdrawal of the HDE approval was, in part, intended to spur greater enrollment in ongoing randomized, controlled trials of these devices. (2) Currently, all uses of closure devices to treat PFO are off-label uses.

Atrial Septal Defect

In contrast to patent foramen ovale, which represents the persistence of normal fetal cardiovascular physiology, atrial septal defects (ASDs) represent an abnormality in the development of the heart that results in free communication between the atria. ASDs are categorized according to their anatomy. For example, ostium secundum ASDs are the third most common form of congenital heart disorder and one of the most common congenital cardiac malformations in adults, accounting for 30–40% of these patients over the age of 40. Ostium secundum describes defects that are located midseptally and are typically near the fossa ovalis. Ostium primum defects lie immediately adjacent to the atrioventricular valves and occur commonly in patients with Down's syndrome. Sinus venous defects occur high in the atrial septum and are frequently associated with anomalies of the pulmonary veins. The ASD often goes unnoticed for decades, because the physical signs are subtle and the clinical sequelae are mild. However, virtually all patients who survive into their sixth decade are symptomatic; fewer than 50% of patients survive beyond 40 to 50 years due to heart failure or pulmonary hypertension related to the left-to-right shunt. Patients with ASDs are also at risk for paradoxical emboli.

Repair of ASDs is recommended for those with pulmonary systemic flows exceeding 1.5:1.0. Despite the success of operative repair, there has been interest in developing a catheter-based approach to ASD repair to avoid the risks and morbidity of open heart surgery. A variety of devices has been researched over the past 20 years; technical challenges include minimizing the size of device so that smaller catheters can be used; developing techniques to properly center the device across the ASD, and ensuring that the device can be easily retrieved or repositioned, if necessary. At present, 2 devices

are FDA approved for ASD closure: the AMPLATZER™ Septal Occluder, and the GORE HELEX™ Septal Occluder.

There are several types of atrial and ventricular septal wall defects; these can be congenital or can occur as the result of increased intrathoracic pressure or following a myocardial infarction (MI). Conventional open-heart surgical repair of septal defects carries some risk, especially in patients in whom heart or pulmonary function may be compromised. In addition, there is considerable morbidity associated with open-heart surgery. Moreover, some types of ventricular septal defects (VSDs) are difficult to repair surgically due to their location or orientation. Consequently, there has been considerable interest in the development of a transcatheter method of repairing septal lesions. Access to the defect is achieved through the venous system via the internal jugular or groin. The CardioSEAL® Septal Occlusion System (NMT Medical, Boston, MA) has been approved for use in the United States by the Food and Drug Administration (FDA) for use in patients with complex VSDs of significant size to warrant closure, and who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or overall medical condition. The CardioSEAL was previously approved for limited marketing as a Humanitarian Use Device (HUD) for treatment of patients with complex single ventricle physiology who have undergone a fenestrated Fontan palliation procedure and require closure of the fenestration, and for treatment of patients with a patent foramen ovale (PFO) with recurrent cryptogenic stroke due to presumed paradoxical embolism through a PFO and who have failed conventional drug therapy.

Rationale

Patent Foramen Ovale

Conventional therapy for cryptogenic stroke consists of either antiplatelet therapy (aspirin, clopidogrel, or dipyridamole given alone or in combination) or oral anticoagulation with warfarin. In general, patients with a known clotting disorder or evidence of pre-existing thromboembolism are treated with warfarin, and patients without these risk factors are treated with antiplatelet agents.

Evidence on the efficacy of PFO closure devices consists of a small number of nonrandomized, comparative studies, numerous case series, and meta-analyses of the published studies. Two nonrandomized comparative studies were identified for this policy review. Windecker et al. (3) compared 150 patients who underwent PFO closure between 1994 and 2000 with 158 medically treated patients over the same time period. The choice of therapy was based on clinician and/or patient preference. The patients who received closure differed from the medically treated patients on key clinical variables, including the percentage with more than one cerebrovascular event and the size of the PFO. At 4 years' follow-up, there was a trend toward lower recurrence of stroke or TIA in the PFO group that did not reach statistical significance (7.8% vs. 22.2%, p=0.08). Harrer et al. (4) reported on 124 patients with cryptogenic stroke and PFO treated over a 10-year period. Eighty-three patients were treated with medical therapy, 34 were treated with percutaneous PFO closure, and 7 were treated with surgical closure. After a mean follow-up of 52 +/- 32 months, annual recurrence rates of stroke were not different between medical therapy and PFO closure (2.1% vs. 2.9%, p=NS).

Many case series report on outcomes of PFO closure in an uncontrolled fashion; some examples of these series are as follows. Onorato et al. (5) reported on 256 patients with paradoxical embolism who received transcatheter closure of PFO. The authors reported a 98.1% full closure rate of the PFO and no neurological events at a mean follow-up of 19 months. Martin and colleagues (6) also reported on a study of 110 patients with paradoxical embolism who received transcatheter closure of PFO. While the full closure rate of PFO was 71% at 2 years, only 2 patients had experienced a recurrent neurological event. Windecker and colleagues (7) reported on a case series of 80 patients with a history of at least 1 paradoxical embolic event and who underwent closure of a PFO with a variety of transcatheter devices. Patients were followed up for a mean of 1.6 years. During 5 years of follow-up, the risk of an embolic event (either transient ischemic attack [TIA], stroke, or peripheral embolism) was 3.4%, considered comparable to either medical therapy with anticoagulation or open surgical approaches. The presence of a postprocedural shunt was a predictor of recurrent thromboembolic events, emphasizing the importance of complete closure.

Two systematic reviews of the observational studies have compared outcomes of PFO closure with medical therapy. (8, 9) Worhle (8) compared the results of 12 series of PFO closure (n=2,016) with 8 series (n=998 patients) of medical therapy. At 2 years of follow-up, the range of recurrent stroke was 0–1.6% for PFO closure and 1.8–9.0% for medical therapy. The combined annual incidence of stroke or TIA was 1.3% (95% CI: 1.0–1.8%) following PFO closure compared with 5.2% (95% CI: 4.4–6.2) for medical therapy. In an earlier review, Khairy et al. (9) analyzed 6 series of medical therapy (n=895 patients) and 10 series of PFO closure (n=1,355 patients). These authors noted differences in key clinical characteristics among patients in the two treatment groups. Patients treated with medical therapy were older, had a greater proportion of men, and higher rates of smoking and diabetes. Patients treated with PFO closure were more likely to have had more than one cerebrovascular event. The recurrence rate at 1 year ranged from 0–4.9% with PFO closure, compared with 3.8–12.0% with medical therapy. There was a estimated major complication rate (death, hemorrhage requiring transfusion, tamponade, need for surgical intervention, and pulmonary embolus) for PFO closure of 1.5%, and a minor complication rate of 7.9%.

Guidelines for treatment of patients with PFO and cryptogenic stroke have been published by 3 major medical societies. (10–13) Guidelines from the American College of Chest Physicians (10) and the American Academy of Neurology (11), both published in 2004, state that the evidence is inconclusive regarding the comparative efficacy of PFO closure devices and medical therapy. Neither of these guidelines offers specific recommendations as to when PFO closure devices should be used. The American College of Chest Physicians published newer guidelines on antiplatelet and antithrombotic therapy in 2008. (12) These guidelines state, "In patients with cryptogenic ischemic stroke and a PFO, we recommend antiplatelet therapy over no therapy (Grade 1A) and suggest antiplatelet therapy over warfarin (Grade 2A). For patients with evidence of a DVT, we recommend anticoagulation." These 2008 guidelines do not specifically make recommendations on the use of PFO closure devices. The American Heart Association (AHA)/American Stroke Association guidelines (13) published in 2006 offer somewhat more specific recommendations. These guidelines do not recommend PFO closure as initial therapy for patients with a first ischemic stroke and PFO, stating that, “Insufficient data exist to make a recommendation about PFO closure in patients with a first stroke and a PFO.” They also state that “…aspirin (50-325mg/d), aspirin and extended-release dipyridamole in combination, and clopidrogel are all acceptable options for initial therapy (class IIa, level of evidence A),” and that “Warfarin is reasonable for high-risk patients who have other indications for oral anticoagulation, such as underlying hypercoagulable state or evidence of venous thrombosis (class IIa, level of evidence C).” For patients with stroke or TIA while on medical therapy, they state that, “PFO closure may be considered for patients with recurrent cryptogenic stroke despite optimal medical therapy (class IIB, level of evidence C).”

There are at least 5 ongoing randomized, controlled trials comparing PFO closure with medical therapy. (14) These trials have been hampered by slow enrollment and one of the trials is no longer recruiting participants. Two of the trials, the “PC” trial (NCT 00166257) and the “RESPECT PFO” trial (NCT 00465270) have enrolled a majority of patients and should be completed successfully, although the publication date for both remains uncertain.

No clinical trials focus specifically on patients who have failed medical therapy, as defined by recurrent stroke or TIA while on therapy. Many of the published studies include both patients with first cryptogenic stroke, as well as patients with recurrent stroke or TIA, and generally do not analyze these patient populations separately. As a result, it is not possible to determine from the evidence whether PFO closure in patients who have failed medical therapy reduces the risk of subsequent recurrences.

A sham-controlled randomized clinical trial of PFO closure for the indication of refractory migraine headache was published in 2008. (15) Migraine headache is another condition that has been associated with PFO in epidemiologic studies. In this study, there was no significant difference observed in the primary end point of migraine headache cessation (3 of 74 in the implant group, 3 of

73 in the sham group, p=0.051). The results of this study cast some doubt on the causal relationship between PFO and migraine.

In summary, the evidence does not permit conclusions as to whether PFO closure improves outcomes for patients with cryptogenic stroke and PFO. The causal link between cryptogenic stroke and PFO is not strong enough that success in closure of the PFO alone can be considered a clinical outcome. Two nonrandomized comparative studies do not show significant differences in recurrence rate of stroke or TIA between PFO closure and medical therapy. While the observational data suggest that recurrence of stroke or TIA may be lower following PFO closure, these data are prone to bias and are not definitive. Ongoing randomized, controlled trials, which have been slow in accruing patients, will provide higher quality evidence on this question when they are completed. Some expert groups recommend that PFO closure should be considered for patients who have failed medical therapy. However, since closure devices do not have FDA approval, other options may be explored, including surgical repair.

Atrial Septal Defect
At present there are 2 FDA-approved devices for ASD closure: the AMPLATZER™ Septal Occluder, and the GORE HELEX™ Septal Occluder.

Evidence supporting the efficacy of devices for closure of ASD consists of nonrandomized comparison studies and case series studies. However, in contrast to the situation of PFO and cryptogenic stroke, the relationship of closure of the ASD and improved clinical outcomes is direct and convincing. Results generally show a high success rate in achieving closure and low complication rates. The FDA approval of the AMPLATZER Septal Occluder was based on the results of a multicenter, nonrandomized study comparing the device to surgical closure of ASDs; 423 patients received 433 devices. (16) This study was subsequently published with slightly different numbers, but similar quantitative findings. (17) All patients had an ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload. The results for the septal occluder group, showed comparably high success rates to surgery; the 24-month closure success rate was 96.7% in the septal occluder group compared to 100% in the surgical group. While the pattern of adverse events was different in the 2 groups, overall, those receiving a septal occluder had a significantly lower incidence of major adverse events (p=0.03). Similarly, there was a significantly lower incidence of minor adverse events in the septal occluder group (p<0.001). It should be noted that the mean age of patients of the 2 groups was significantly different; in the septal occluder group the mean age was 18 years, compared to 6 years in the surgically treated group.

Other nonrandomized studies comparing transcatheter closure to surgery show similar success rates. Suchon et al., in a study of 100 patients, had a 94% success rate in the transcatheter closure group compared to a 100% success rate in the surgical group. (18) A study by Berger et al. showed identical 98% success rate in both treatment groups. (19)

Single-arm studies show high success rates of ASD closure. Fischer and colleagues reported on use of the AMPLATZER device in 236 patients with secundum ASD. (20) In this evaluation study, closure was achieved in 84.7% of patients, and intermediate results were reported as excellent. Other smaller studies have reported favorable results for transcatheter closure of ASD. In Du et al., transcatheter closure of ASD in 23 patients with deficient ASD rims was compared to transcatheter closure of 48 patients with sufficient ASD rims. (21) The authors reported no significant differences in closure rates between the groups (91% for deficient rims and 94% for sufficient rims) along with no major complications at 24 hours and 6-month follow-up. Oho and colleagues also reported a successful closure rate of 97% at 1-year follow-up in 35 patients receiving transcatheter closure of ASD, while only 1 patient complication of second-degree atrioventricular block was noted. (22) Finally, Brochu and colleagues evaluated 37 New York Heart Association (NYHA) class I or II patients who underwent transcatheter closure of ASD. (23) At 6-month follow-up, maximal oxygen uptake improved significantly and the dimensions of the right ventricle decreased significantly while 20 patients moved from NYHA class II to class I and improved exercise capacity.

Guidelines issued by the ACC/AHA in 2008 on the management of congenital heart disease recommend closure of an ASD by either percutaneous or surgical methods for several indications. (24) For sinus venosus, coronary sinus, or primum ASD, however, surgical rather than percutaneous closure is recommended.

In summary, nonrandomized comparison studies and single arm case series show high success rates of closure using closure devices approaching the high success rates of surgery. The percutaneous approach has a low complication rate, and avoids the morbidity and complications of open surgery. If the percutaneous approach is unsuccessful, ASD closure can be achieved using surgery.

Ongoing Clinical Trials

There have been numerous randomized, controlled trials comparing PFO closure with medical therapy planned in the last two decades. (27-29) However, these trials have been hampered by slow enrollment and some of the trials have been terminated due to low enrollment. A search of online site ClinicalTrials.gov using the keywords patent foramen ovale returned 38 studies. Four of these studies were RCTs that are listed as still ongoing:

- NCT00562289. Patent Foramen Ovale Closure or Anticoagulants versus Antiplatelet Therapy to Prevent Stroke Recurrence. This is an RCT comparing PFO closure with medical therapy in patients with PFO and cryptogenic stroke. The primary endpoints are fatal and nonfatal stroke, all-cause mortality, and vascular death. Planned enrollment is for 900 patients with completion date estimated to be December 2012.
- NCT00166257 The PC trial. Patent Foramen Ovale and Cryptogenic Embolism. This is an RCT comparing PFO closure to medical therapy in patients with cryptogenic stroke and PFO. The primary endpoints are time to death, non-fatal stroke, and peripheral embolism. Planned enrollment is for 414 patients. The status of this trial is listed as “unknown” on ClinicalTrials.gov, with no updates in the last 2 years, and a stated estimated completion date of May 2011.
- NCT01550588 Defense-PFO study. Device Closure Versus Medical Therapy for Cryptogenic Stroke Patients with High-Risk Patent Foramen Ovale**.** This is an RCT comparing PFO closure with medical therapy. Primary endpoints are non-fatal stroke, vascular death, and major bleeding. Planned enrollment is for 210 patients with an estimated completion date of February 2017.
- NCT00738894 Gore REDUCE study. GORE HELEX™ Septal Occluder for Patent Foramen Ovale (PFO) Closure in Stroke Patients. This is an RCT of PFO closure compared to medical therapy in patients with cryptogenic stroke. The primary endpoint is freedom from recurrent stroke/TIA at 2 years. Planned enrollment is for 664 patients, with an estimated completion date of August 2015.

Summary

The evidence on the efficacy of closure devices for patients with PFO and cryptogenic stroke is insufficient to draw conclusions. One RCT of 909 patients reported that PFO closure does not reduce recurrent stroke or TIA compared to medical therapy. The results of this RCT contrast with the results of nonrandomized, comparative studies and systematic reviews of observational studies, which report lower rates of recurrent events following closure of PFO compared to medical therapy. The discrepancy in these results may arise from selection bias, since the non-randomized populations may differ on important clinical and demographic confounding variables. It is also possible that the rates of recurrent stroke following PFO closure are biased in the observational studies, since the RCT reported a rate of stroke following PFO closure that was much higher than the rates reported in the observational studies. Because the evidence does not support a benefit for percutaneous PFO closure, PFO closure devices are considered investigational for patients with cryptogenic stroke and PFO.

For patients with ASD that require closure, nonrandomized comparative studies and single-arm case series show high success rates of closure using closure devices, approaching the high success rates

of surgery. The percutaneous approach has a low complication rate and avoids the morbidity and complications of open surgery. Since the main alternative to percutaneous closure is open surgery, this evidence is sufficient to conclude that percutaneous closure achieves similar outcomes with less risk compared to the alternative. If the percutaneous approach is unsuccessful, ASD closure can be achieved using surgery. Because of the advantages of percutaneous closure over open surgery, the use of percutaneous ASD closure devices can be considered medically necessary for this purpose.

Practice Guidelines and Position Statements
The American College of Chest Physicians published guidelines on antiplatelet and antithrombotic therapy in 2012, (30) which were an update to previous guidelines published in 2008. (31) These guidelines contained the following statements about the treatment of patients with a PFO:

- In patients with asymptomatic patent foramen ovale (PFO) or atrial septal aneurysm, we suggest against antithrombotic therapy (Grade 2C)
- In patients with cryptogenic stroke and PFO or atrial septal aneurysm, we recommend aspirin (50-100 mg/d) over no aspirin (Grade 1A).
- In patients with cryptogenic stroke and PFO or atrial septal aneurysm, who experience recurrent events despite aspirin therapy, we suggest treatment with (VKA [vitamin K antagonists] therapy (target INR, 2.5; range, 2.0-3.0) and consideration of device closure over aspirin therapy (Grade 2C).
- In patients with cryptogenic stroke and PFO, with evidence of DVT [deep vein thrombosis], we recommend VKA therapy for 3 months (target INR, 2.5; range, 2.0-3.0) (Grade 1B) and consideration of device closure over no VKA therapy or aspirin therapy (Grade 2C).

Guidelines from the American College of Chest Physicians (27) and the American Academy of Neurology, (32) both published in 2004, state that the evidence is inconclusive regarding the comparative efficacy of PFO closure devices and medical therapy. Neither of these guidelines offers specific recommendations as to when PFO closure devices should be used.

The American Heart Association (AHA)/American Stroke Association guidelines (33) published in 2006 offer somewhat more specific recommendations. These guidelines do not recommend PFO closure as initial therapy for patients with a first ischemic stroke and PFO, stating that, “Insufficient data exist to make a recommendation about PFO closure in patients with a first stroke and a PFO.” They also state that “…aspirin (50-325mg/d), aspirin and extended-release dipyridamole in combination, and clopidrogel are all acceptable options for initial therapy (class IIa, level of evidence A),” and that “Warfarin is reasonable for high-risk patients who have other indications for oral anticoagulation, such as underlying hypercoagulable state or evidence of venous thrombosis (class IIa, level of evidence C).” For patients with stroke or TIA while on medical therapy, they state that, “PFO closure may be considered for patients with recurrent cryptogenic stroke despite optimal medical therapy (class IIB, level of evidence C).”

Guidelines issued by the ACC/AHA in 2008 on the management of congenital heart disease recommend closure of an ASD by either percutaneous or surgical methods for several indications. (34) For sinus venosus, coronary sinus, or primum ASD, however, surgical rather than percutaneous closure is recommended.

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Billing Coding/Physician Documentation Information

93580 Percutaneous transcatheter closure of congenital interatrial communication (ie, Fontan fenestration, atrial septal defect) with implant
93581 Percutaneous transcatheter closure of a congenital ventricular septal defect with implant
0166T Transmyocardial transcatheter closure of ventricular septal defect, with implant; without cardiopulmonary bypass
0167T Transmyocardial transcatheter closure of ventricular septal defect, with implant; with cardiopulmonary bypass

In 2003, CPT established a code for percutaneous transcatheter closure of congenital interatrial communication (i.e., fontan fenestration, atrial septal defect) with implant (93580). CPT notes that 93580 includes a right heart catheterization procedure. Other heart catheterization procedures should not be reported separately in addition to 93580.

Additional Policy Key Words

N/A

Policy Implementation/Update Information

3/1/07	New policy; considered investigational.
9/1/07	Policy language revised to be consistent with the BCBS Association statement regarding atrial septal defects. It remains medically necessary. The statement regarding ventricular septal defects is not addressed in the Association policy. It remains investigational.
9/1/08	No policy statement changes.
7/15/09	Information on FDA status of devices updated. Policy statement for patent foramen ovale changed to investigational due to the FDA's withdrawal of the devices' humanitarian device exemption approval.
9/1/09	No policy statement changes.
12/1/09	Policy statement revised to indicate transcatheter closure of PFO may be medically necessary with criteria.
9/1/10	No policy statement changes.
3/1/11	Policy statement added regarding transcatheter closure of patent foramen ovale for the treatment of migraine headaches; considered investigational.
9/1/11	No policy statement changes.
11/1/13	No policy statement changes.