Aetna considers speech therapy for treatment of dysphagia, regardless of the presence of a communication disability, medically necessary for members who meet the criteria set forth below. Note: Some plans limit coverage of medically necessary speech therapy services. Members should check their benefit plan descriptions for any applicable benefit plan limitations and exclusions on coverage for speech therapy services.

Aetna considers therapy for the management of dysphagia medically necessary in members who meet any of the following criteria:

- Member exhibits weight loss or malnutrition because he/she has dysphagia and is unable to obtain adequate nutrition orally; or
- Member has a history of, or is at high-risk for, recurrent aspirations or choking; or
- Member is unable to swallow and has a nasogastric or gastrostomy tube for nutrition.

Policy

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

Policy History

Last Review 06/22/2017
Effective: 06/28/2002
Next Review: 06/21/2018

Review History

Definitions

Additional Information

Clinical Policy Bulletin Notes
Aetna considers dysphagia therapy experimental and investigational for all other indications because its effectiveness for indications other than the ones listed above has not been established.

Aetna considers esophageal dilation medically necessary for the treatment of symptomatic obstruction of the esophagus.

Aetna considers esophageal dilation for the treatment of non-obstructive esophageal dysphagia experimental and investigational because its effectiveness has not been established.

Aetna considers non-biodegradable stent placement medically necessary for refractory (cannot be dilated to an adequate diameter) malignant esophageal strictures. Aetna considers drug-eluting stents experimental and investigational for malignant esophageal strictures.

Aetna considers the following interventions (not an all-inclusive list) experimental and investigational for the treatment of dysphagia because their effectiveness for this indication has not been established:

- Acupuncture
- Biodegradable stent
- Botulinum toxin
- Electrical stimulation (including neuromuscular electrostimulation)
- ERBE electrocautery
- Per-oral endoscopic myotomy (POEM)
- Pharyngeal motor cortex stimulation
- Repetitive peripheral/transcranial magnetic stimulation
- Intensive dysphagia rehabilitation approach/program (e.g., the Swallow STRONG multi-disciplinary oropharyngeal strengthening program)

See also CPB 0135 - Acupuncture, and CPB 0243 - Speech Therapy.

Background
People with dysphagia have difficulty swallowing and may also experience pain while swallowing. Some people may be completely unable to swallow or may have trouble swallowing
liquids, foods, or saliva.

Dysphagia occurs when there is a problem with any part of the swallowing process. Weak tongue or cheek muscles may make it hard to move food around in the mouth for chewing. Food pieces that are too large for swallowing may enter the throat and block the passage of air.

Other problems include not being able to start the swallowing reflex (a stimulus that allows food and liquids to move safely through the pharynx) because of a stroke or other nervous system disorder. People with these kinds of problems are unable to begin the muscle movements that allow food to move from the mouth to the stomach. Another difficulty can occur when weak throat muscles cannot move all of the food toward the stomach. Bits of food can fall or be pulled into the trachea, which may result in aspiration pneumonia.

Dysphagia may be caused by any condition that weakens or damages the muscles and nerves used for swallowing. For example, people with nervous system diseases, such as cerebral palsy or Parkinson's disease, often have problems swallowing. Additionally, cerebrovascular accident or traumatic brain injury may affect the coordination of the swallowing muscles or limit sensation in the mouth and throat. An infection or irritation can cause narrowing of the esophagus. People born with abnormalities of the swallowing mechanism may not be able to swallow normally. Infants who are born with a cleft palate are unable to suck properly, which complicates breast-feeding and drinking from a regular baby bottle. In addition, cancers of the head, neck, or esophagus may cause dysphagia. Sometimes the treatment for these types of cancers can cause dysphagia. Injuries of the head, neck, and chest may also create swallowing problems.

Physicians and speech-language pathologists who test for and treat swallowing disorders use a variety of tests that allow them to look at the parts of the swallowing mechanism, including fiber optic laryngoscopy, video fluoroscopy, and ultrasound.
Once the cause of the dysphagia is found, surgery or medication may help. If treating the cause of the dysphagia does not help, the patient may refer the patient to a speech-language pathologist who is trained in testing and treating swallowing disorders. The speech-language pathologist will test the person's ability to eat and drink and may teach the person new ways to swallow.

Oral-motor therapy is directed at correcting abnormal oral muscle behaviors that interfere with feeding. Oral-motor therapy may be focused upon inducing active suckle movements, coordinating tongue movements, or facilitating normal oral movement patterns such as lip closure.

Oral-motor therapy has also been used in developmentally delayed children to stop drooling, correct abnormal tongue thrust, and improve speech. Speech management of the developmentally delayed child has included training to improve the functioning of oral and pharyngeal muscles. This oral-motor training is usually introduced before the emergence of speech. Most Aetna plans exclude treatment of developmental delay. Please check benefit plan descriptions for details.

**Non-Biodegradable Stent for Malignant Esophageal Strictures:**

Verschuur and associates (2007) compared small- and large-diameter stents for improvement of dysphagia, complications, and recurrent dysphagia. These investigators prospectively followed 338 patients with dysphagia from obstructing esophageal or gastric cardia cancer who were treated with an Ultraflex stent (n = 153), a Gianturco Z-stent (n = 89), or a Flamingo Wallstent (n = 96) of either a small diameter (n = 265) or a large diameter (n = 73). Major outcome measurements included dysphagia score (on a scale from 0 [no dysphagia] to 4 [complete dysphagia]), complications, and recurrent dysphagia. Analysis was by Chi-2 test, log-rank test, and Cox regression analysis. Improvement in dysphagia was similar between patients with a small- or a large-diameter stent (p = 0.35). The occurrence of major complications, such as hemorrhage, perforation, fistula, and fever, was increased in patients with a large-diameter
Gianturco Z-stent compared with those treated with a small-diameter stent (4 [40 %] versus 16 [20 %]; adjusted hazard ratio [HR] 5.03, 95 % confidence interval [CI]: 1.33 to 19.11) but not in patients with a large-diameter Ultraflex stent or a Flamingo Wallstent. Moreover, minor complications, particularly pain, were associated with prior radiation and/or chemotherapy in patients with a large- or a small-diameter Gianturco Z-stent (HR 4.27, 95 % CI: 1.44 to 12.71) but not in those with an Ultraflex stent or a Flamingo Wallstent. Dysphagia from stent migration, tissue overgrowth, and food bolus obstruction recurred more frequently in patients with a small-diameter stent than in those with a large-diameter stent (Ultraflex stent: 54 [42 %] versus 3 [13 %], adjusted HR 0.16, 95 % CI: 0.04 to 0.74; Gianturco Z-stent: 21 [27 %] versus 1 [10 %], adjusted HR 0.97, 95 % CI: 0.11 to 8.67; and Flamingo Wallstent: 21 [37 %] versus 6 [15 %], adjusted HR 0.40, 95 % CI: 0.03 to 4.79). The authors concluded that large-diameter stents reduce the risk of recurrent dysphagia from stent migration, tissue overgrowth, or food obstruction. Increasing the diameter in some stent types may, however, increase the risk of stent-related complications to the esophagus.

Conio et al (2007) stated that self-expanding metal stents (SEMS) provide effective palliation in patients with malignant dysphagia, although severe complications and mortality may result. These researchers performed a prospective controlled trial to compare a new self-expanding polyester mesh stent (Polyflex) with SEMS (Ultraflex). A total of 101 patients with unresectable esophageal carcinoma were randomized to placement of a Polyflex (n = 47) or a partially covered Ultraflex (n = 54) stent. Patients with esophagogastric junction malignancy were excluded. Placement was successful in 46 (98 %) patients with the Polyflex and 54 (100 %) patients with the Ultraflex stent. In 1 patient, the Polyflex stent could not be placed. After 1 week, dysphagia was improved by at least 1 grade in 100 % of the Polyflex group and in 94 % of the Ultraflex group. Major complications were observed in 48 % of the Polyflex group and 33 % of the Ultraflex group. Intra-procedural perforation occurred in 1 Polyflex and 1 Ultraflex patient; 2 Polyflex patients had post-procedural hemorrhage. Twenty (44 %) patients with a Polyflex stent and 18 (33 %) with an Ultraflex stent had recurrent dysphagia because of tumor
overgrowth, stent migration, hyperplastic granulomatous
reaction, or food bolus impaction. Multi-variate analyses showed
a significantly higher complication rate with Polyflex than with
Ultraflex stents (odds ratio 2.3, 95 % CI: 1.2 to 4.4). However,
median survival was 134 days with Polyflex and 122 days with
Ultraflex stents (p = NS). The authors concluded that no
difference was seen in palliation of dysphagia between the 2
stents. Significantly more complications, especially late stent
migration, were observed in the Polyflex group.

Verschuur and colleagues (2008) noted that stents are often used
for the palliation of inoperable esophageal or gastric cardia
cancer. One of the drawbacks of the currently used stents is the
high percentage of recurrent dysphagia due to stent migration
and tissue growth. New stents have been designed to overcome
this unwanted sequela of stent placement. In this randomized
trial, these investigators examined if results of stent placement
could be improved with newer stent designs. A total of 125
patients with dysphagia from inoperable carcinoma of the
esophagus or gastric cardia were randomized to placement of an
Ultraflex stent (n = 42), Polyflex stent (n = 41), or Niti-S stent (n =
42). Patients were followed by scheduled telephone calls at 14
days after treatment, and then monthly for 6 months or until
death. Technical and functional outcome, complications,
recurrent dysphagia, and survival were analyzed with Chi(2) tests,
Kaplan-Meier curves, and log-rank tests. Stent placement was
technically successful in all patients with an Ultraflex stent, in
34/41 (83 %) patients with a Polyflex stent, and in 40/42 (95 %)
patients treated with a Niti-S stent (p = 0.008). Dysphagia score
improved from a median of 3 (liquids only) to 1 (ability to eat
some solid food) in all patients. There were no differences in
complications among the 3 stent types. Recurrent dysphagia,
caused by tissue ingrowth or overgrowth, migration, or food
obstruction, was significantly different between patients with an
Ultraflex stent and patients with a Polyflex stent or Niti-S stent (22
[52 %] versus 15 [37 %] versus 13 [31 %], p = 0.03). Stent
migration occurred more frequently with Polyflex stents, whereas
tissue ingrowth or overgrowth was more frequently seen with
Ultraflex stents, and to a lesser degree, Niti-S stents. No
differences were found in survival (median survival: Ultraflex
stent 132 days versus Polyflex stent 102 days versus Niti-S stent 159 days) among the 3 stent types. The authors concluded that all 3 stents are safe and offer adequate palliation of dysphagia from esophageal or gastric cardia cancer. Nonetheless, Polyflex stents seem the least preferable in this patient group, as placement of this device is technically demanding and associated with a high rate of stent migrations.

**Esophageal Dilation:**

Guidelines on the use of esophageal dilation (Riley and Attwood, 2004) stated that esophageal dilation is indicated in the treatment of symptomatic obstruction of the esophagus. The guidelines explained that obstruction may develop as a consequence of a wide range of anatomical and functional esophageal disorders. Reflux-induced strictures, malignant strictures, and achalasia are the most frequent indications but patients with anastomotic, sclerotherapy, radiation, medication, and corrosive induced strictures, and those with rings and webs frequently require dilatation. The guidelines stated that patients with diffuse esophageal spasm and other motility disorders may occasionally require dilatation of the lower esophageal sphincter when conservative measures fail.

There is inadequate evidence of the clinical utility of esophageal dilation in dysphagia not associated with obstruction. In a randomized controlled trial (n = 96), Lavu et al (2004) examined the impact of esophageal dilation with a large-diameter dilator on dysphagia and quality of life in such patients. These investigators found that most patients with esophageal dysphagia have a non-obstructing esophageal lumen. Their findings did not support the practice of empiric esophageal dilation for patients with non-obstructive esophageal dysphagia. Improvement in both treatment and control groups suggests that it occurred due to proton pump inhibitor therapy, lending credence to the hypothesis that esophageal hypersensitivity to acid contributes to symptoms in most patients with non-obstructive esophageal dysphagia, which is the predominant category of dysphagia.

Siersema (2008) stated that esophageal strictures are frequently
encountered by gastroenterologists and can be caused by benign or malignant lesions. Dysphagia is the symptom experienced by all patients, regardless of the cause of their strictures. The methods most commonly employed for palliation of malignant esophageal strictures are stent placement (particularly in patients with an expected survival of 3 months or less) and brachytherapy (in patients with a life expectancy of more than 3 months). Brachytherapy has been shown to be beneficial in patients with an expected survival of longer than 3 months with regard to (prolonged) dysphagia improvement, complications and quality of life. The mainstay of benign esophageal stricture treatment is dilation. Although dilation usually results in symptomatic relief, strictures do recur. In order to predict which types of strictures are most likely to recur, it is important to differentiate between esophageal strictures that are simple (i.e., focal, straight strictures with a diameter that allows endoscope passage) and those that are more complex (i.e., over 2 cm in length, tortuous strictures with a narrow diameter). These complex strictures are considered refractory when they can not be dilated to an adequate diameter.

**Acupuncture:**

In a meta-analysis, Long and Wu (2012) examined the effect of acupuncture for treatment of dysphagia in patients affected by a stroke. Randomized controlled trials (RCTs) comparing acupuncture treatment with non-acupuncture treatment of dysphagia in patients with a stroke were identified from the databases of PubMed, Embase, Cochrane Library and CBM disc (China Biological Medicine Database). Eligible investigations were included and data on the effectiveness of acupuncture were extracted and synthesized by meta-analysis using RevMan 5.1.4. Results were expressed as odds ratio (OR) for dichotomous data; 95 % CIs were also calculated. A total of 72 RCTs (3,208 patients in the treatment group and 2,926 patients in the control group) were identified. Details of randomization and blinding were not reported and information on withdrawals and drop-outs was missing in most of included reports. Meta-analysis showed that the effectiveness of treatment in the group receiving acupuncture was higher than that in the non-acupuncture group (OR = 5.17, 95
% CI: 4.18 to 6.38; p < 0.00001). However, the study quality was generally low and of insufficient quality to make recommendations about using acupuncture in the rehabilitation of patients with dysphagia due to stroke. The authors concluded that acupuncture might be beneficial in the rehabilitation of patients with dysphagia caused by stroke, and the evidence justifies future high-quality studies.

**Biodegradable Stent:**

Griffiths et al (2012) noted that biodegradable (BD) esophageal stents have been available commercially only since 2008 and previous published research is limited. These researchers reviewed the use of BD stents to treat dysphagia in benign or malignant esophageal strictures. Patients were identified from a prospective interventional radiological database. Biodegradable stents were inserted radiologically under fluoroscopic control. Between July 2008 and February 2011, a total of 25 attempts at placing SX-ELLA BD esophageal stents were made in 17 males and 5 females, with a median age of 69 (range of 54 to 80) years. Two patients required more than 1 BD stent. Indications were benign strictures (n = 7) and esophageal cancer (n = 17). One attempt was unsuccessful for a technical success rate of 96 % with no immediate complications. Clinical success rate was 76 %. Median dysphagia score before stent insertion was 3 (range of 2 to 4) compared to 2 (range of 0 to 3) after stent insertion (p = 0.0001). The authors concluded that BD stents provide good dysphagia relief for the life time of the stent. They may help avoid the use of feeding tubes in patients having radical chemoradiotherapy or awaiting esophagectomy. They do not require removal or interfere with radiotherapy planning via imaging. However, the re-intervention rate was high after the stent dissolves.

Krokidis et al (2013) evaluated the clinical results of the use of BD esophageal stents in malignant strictures. A total of 11 patients were included in this prospective analysis in which a woven polydioxanone BD esophageal stent was used. The inclusion criterion was that the patient underwent neoadjuvant treatment or radical radiotherapy after the stent insertion. Primary end points were dysphagia score at discharge, stent patency, and
complication rate. Secondary end points were overall survival and surgical outcome of surgery. There was a 100 % procedure technical success rate. Early complications occurred in 3 patients resulting in failure to restore oral nutrition. In the remaining 8 patients, dysphagia was significantly improved at discharge. Mean stent patency rate in this group was 71.5 days. Stent dysfunction occurred in 5 of 8 patients (62.5 %); in 2 of 5 patients this was due to local inflammatory reaction, and in 3 of 5 patients it was due to tumor growth after a mean time of 97.8 days, and a new metallic stent was consequently placed in 4 of 5 patients. One patient was successfully treated with esophagectomy. At the end of follow‐up (mean time of 102.1 days), 3 of 8 stents were patent. The overall patient survival rate was 81.8 %. The authors concluded that although short‐term dysphagia scores improved, BD stents do not appear to offer a clear beneficial effect in most cases of malignant strictures, particularly due to a local inflammatory reaction that may be induced. Technical improvement of the device and delineation of the patient group that would benefit from its use is necessary if further studies are to be conducted in the future.

**Botulinum Toxin Injection:**

In a pilot study, Terre et al (2008) evaluated the effectiveness of botulinum toxin (BTX‐A) injection in the cricopharyngeus muscle in patients with neurological dysphagia caused by alteration in the upper esophageal sphincter (UES) opening and with preserved pharyngeal contraction. A total of 10 patients (7 brain lesions and 3 cervical spinal cord injuries), with a minimum time lapse of 6 months from neurological lesion received BTX‐A injection. Dysfunction of the UES opening and the presence of pharyngeal contraction were diagnosed by videofluoroscopy (VDF) and esophageal manometry (EM). The BTX‐A (100 U) injection was guided by endoscopy. Clinical, VDF, and EM follow ups were carried out at 3 weeks, 3 and 6 months, and at 1 year post‐injection. Prior to treatment, 6 patients were fed by nasogastric tube; VDF showed impairment of the UES opening, residue in pyriform sinuses, and aspiration in all cases. During follow‐up, there was a decrease in the number of patients who had aspiration: 3 patients at 1 year. During swallowing, EM showed a
mean UES relaxation of 90 % (range of 74.5 to 100 %), residual pressure 3.2 mm Hg (range of 0 to 13 mm Hg) and pharyngeal amplitude 52 mm Hg (range of 25 to 80 mm Hg). At follow-up, a significant improvement in UES relaxation (98 % [89 % to 100 %]) and pharyngeal contraction (97 mm Hg [35 mm Hg to 165 mm Hg]) was observed. At 3 months, 6 patients were eating exclusively by mouth. The authors concluded that 1 single injection of BTX-A in the UES has long-lasting effectiveness in patients with neurological dysphagia caused by alteration in the UES opening and with pharyngeal contraction. Nevertheless, they stated that a randomized control trial should be done to confirm these results and rule out the effect of potential spontaneous improvement of neurological injury.

*Electrical Stimulation (Including Neuromuscular Electrostimulation):*

Electrical stimulation (ES) has been examined for the treatment of dysphagia. However, there is currently insufficient evidence to support the effectiveness of ES in treating this condition. Park et al (1997) reported a pilot study of oral ES on swallow function in post-stroke patients. They found that oral ES resulted in an improvement in swallow function in 2 of the 4 patients. The authors concluded that these early results are promising, but further research is needed. In a controlled study, Freed et al (2001) compared the effectiveness of transcutaneous ES to thermal-tactile stimulation (TS) in patients with dysphagia caused by stroke. The investigators concluded that transcutaneous ES appears to be a safe and effective treatment for dysphagia due to stroke and results in better swallow function than conventional TS treatment. However, there were no follow-up data in this study. Grill et al (2001) reviewed emerging clinical applications of ES, and concluded that functional ES has great potential for increasing life support as well as for quality of life in chronic ailments, particularly obstructive sleep apnea and dysphagia.

In a non-concurrent cohort study, Blumenfeld et al (2006) assessed the effectiveness of ES in treating persons with dysphagia and aspiration. The charts of 40 consecutive subjects undergoing ES and 40 consecutive persons undergoing traditional
dysphagia therapy (TDT) were reviewed. Pre- and post-therapy treatment success was compared utilizing a previously described swallow severity scale. A linear regression analysis was employed to adjust for potential confounding variables. The swallow severity scale improved from 0.50 to 1.48 in the TDT group (p < 0.05) and from 0.28 to 3.23 in the ES group (p < 0.001). After adjusting for potential confounding factors, persons receiving ES did significantly better in regard to improvement in their swallowing function than persons receiving TDT (p = 0.003). The authors concluded that the findings of this non-concurrent cohort study suggested that dysphagia therapy with transcutaneous ES is superior to traditional dysphagia therapy alone in individuals in a long-term acute care facility. They also stated that confirmation of these findings with a prospective, placebo-controlled, randomized clinical trial is needed before a definitive determination regarding the effectiveness of ES dysphagia therapy can be made.

Kiger et al (2006) compared the outcomes using transcutaneous neuromuscular ES (VitalStim therapy) to outcomes using traditional swallowing therapy for deglutition disorders. A total of 22 patients had an initial and a follow-up video-fluoroscopic swallowing study or fiberoptic endoscopic evaluation of swallowing and were divided into an experimental group that received VitalStim treatments and a control group that received traditional swallowing therapy. Outcomes were analyzed for changes in oral and pharyngeal phase dysphagia severity, dietary consistency restrictions, and progression from non-oral to oral intake. Results of chi-square analysis showed no statistically significant difference in outcomes between the experimental and control groups.

Shaw and colleagues (2007) carried out a retrospective analysis of 18 patients with dysphagia who received VitalStim therapy. All subjects underwent pre-therapy evaluation by speech-language pathologists, including modified barium swallow and/or functional endoscopic evaluation of swallowing and clinical evaluation of swallowing that included assessment of laryngeal elevation, diet tolerance, and swallowing delay, and were then assigned an overall dysphagia severity score. After therapy, all
patients underwent the same assessments. Twelve of the 18 subjects also underwent a functional swallowing telephone survey months (range of 1 to 21 months) after their therapy to evaluate if the improvement was worthwhile and sustained. Eleven of the 18 patients (61%) demonstrated some improvement in their swallowing; 6 of the 18 patients (33%) were improved enough to no longer require a feeding tube. However, of the 5 patients categorized as having "severe dysphagia" before therapy, only 2 showed any improvement, and these patients still required a feeding tube for adequate nutrition. Telephone surveys did confirm that those who improved with their therapy seemed to maintain their progress and that most patients were satisfied with their therapy. The authors concluded that VitalStim therapy seems to help those with mild-to-moderate dysphagia. However, the patients with the most severe dysphagia did not gain independence from their feeding tubes.

In a meta-analysis, Carnaby-Mann and Crary (2007) evaluated the effect of transcutaneous neuromuscular electrical stimulation (NMES) on swallowing rehabilitation. The authors concluded that this preliminary meta-analysis revealed a small but significant summary effect size for transcutaneous NMES for swallowing. Because of the small number of studies and low methodological grading for these studies, caution should be taken in interpreting this finding. These results support the need for more rigorous research in this area. This is in agreement with the observation of Steel et al (2007) who noted that although ES approaches to the restoration and rehabilitation of swallowing is an exciting area of research which holds promise for future clinically relevant technology and/or therapy, implementation of ES in clinical swallowing rehabilitation settings still remains pre-mature.

Miller et al (2014) performed a systematic literature search in the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, the DAHTA database, the Health Technology Assessment Database and MEDLINE or PubMed considered studies on the use of neuromuscular electrostimulation (NMES) in otorhinolaryngology that have been published in German or English. The search identified 180
studies. These were evaluated and relevant studies were included in the further evaluation. The authors concluded that in the fields of otorhinolaryngology and phoniatry/pediatric audiology, clinical studies investigating the effects of NMES on facial and laryngeal paresis, as well as dysphonia and dysphagia have been carried out. The evidence collected to date is encouraging; particularly for the treatment of certain forms of dysphagia and laryngeal paresis.

Per-Oral Endoscopic Myotomy (POEM):

The American college of Gastroenterology (ACG)'s clinical guideline on “Diagnosis and management of achalasia” (Vaezi et al, 2013) identified POEM as experimental. It stated that “Randomized prospective comparison trials with standard laparoscopic myotomy and/or PD [pneumatic dilation] are needed and POEM should only be performed in the context of clinical trials with the understanding that other effective well-studied alternatives are available”.

Von Renteln et al (2013) stated that pilot studies have indicated that per-oral endoscopic myotomy (POEM) might be a safe and effective treatment for achalasia. These investigators performed a prospective, international, multi-center study to determine the outcomes of 70 patients who underwent POEM at 5 centers in Europe and North America. Three months after POEM, 97 % of patients were in symptom remission (95 % CI: 89 % to 99 %); symptom scores were reduced from 7 to 1 (p < 0.001) and lower esophageal sphincter (LES) pressures were reduced from 28 to 9 mm Hg (p < 0.001). The percentage of patients in symptom remission at 6 and 12 months was 89 % and 82 %, respectively. The authors concluded that POEM was found to be an effective treatment for achalasia after a mean follow-up period of 10 months. The main drawbacks of this study were the lack of a control group and the short-term follow-up.

In a prospective trial, Verlaan et al (2013) evaluated the effect of POEM on esophagogastric function. Patients were greater than 17 years of age with achalasia and an Eckardt score of greater than or equal to 3. Before and 3 months after POEM, 10
consecutive patients underwent esophageal manometry, timed barium esophagograms, and EndoFLIP as well as an esophago-gastro-duodenoscopy (EGD). Main outcome measures were Eckardt symptom score, LES resting pressure, centimeters of barium stasis, esophagogastric junction (EGJ) distensibility, and reflux esophagitis. Compared with scores before POEM, patient symptom scores were significantly reduced (1, interquartile range [IQR 0 to 1] versus 8 [IQR 4 to 8]; p = 0.005). Lower esophageal sphincter pressure decreased significantly (6.0 mm Hg [IQR 2.6 to 7.4] versus 19.0 mm Hg [IQR 13.0 to 28.0]; p = 0.008). Esophageal emptying increased significantly, and a 5-min barium column measured 2.3 cm (IQR 0 to 3.2 cm) versus 10.1 cm (IQR 5.7 to 10.8 cm; p = 0.005). Esophagogastric junction distensibility increased significantly (6.7 mm²/mm Hg [IQR 3.8 to 16.6] versus 1.0 mm²/mm Hg [IQR 0.4 to 2.3]; p = 0.02) at 50 ml. In 6 of 10 patients, reflux esophagitis was seen. Of these patients, 3 reported reflux symptoms. The authors concluded that POEM improves esophagogastric function and suggested favorable long-term results based on Eckardt score, esophageal manometry, esophageal emptying, and EGJ distensibility. Moreover, they stated that long-term follow-up of larger series will determine whether the high rate of reflux esophagitis affects the clinical application of POEM. The main drawbacks of this study were small number of patients, and short-term follow-up.

Onimaru et al (2013) evaluated the safety and effectiveness of POEM for surgical myotomy failure as a rescue second-line treatment, and discussed the treatment options adapted in achalasia recurrence. A total of 315 consecutive achalasia patients received POEM from September 2008 to December 2012 in the authors’ hospital. A total of 11 (3.5 %) patients, who had persistent or recurrent achalasia and had received surgical myotomy as a first-line treatment from other hospitals, were included in this study. Patient background, barium swallow studies, EGD, manometry, and symptom scores were prospectively evaluated. In principle, all patients in whom surgical myotomy failed received pneumatic balloon dilatation (PBD) as the first line "rescue" treatment, and only if PBD failed were patients considered for rescue POEM. The PBD alone was effective in 1 patient, and in the remaining 10 patients, rescue
POEM was performed successfully without complications. Three months after rescue POEM, significant reduction in LES resting pressures (22.1 ± 6.6 mm Hg versus 10.9 ± 4.5 mm Hg, p < 0.01) and Eckardt symptom scores (6.5 ± 1.3 versus 1.1 ± 1.3, p < 0.001) were observed. The authors concluded that short-term results of POEM for failed surgical myotomy were excellent; long-term results are awaited.

Yang and Wagh (2013) stated that achalasia is a motility disorder of the esophagus, characterized by a peristalsis of the esophageal body and incomplete relaxation of the LES. Treatment of achalasia is currently aimed at decreasing the resting pressure in the LES. Per-oral endoscopic myotomy is an emerging novel endoscopic procedure for the treatment of achalasia with initial data suggesting an acceptable safety profile, excellent short-term symptom resolution, low incidence of post-procedural gastro-esophageal reflux (GER), and improvement in manometric outcomes. The authors concluded that further prospective randomized trials are needed to evaluate the long-term effectiveness of this promising technique compared to other treatment modalities for achalasia.

Friedel et al (2013) stated that the volume of POEMs performed worldwide has grown exponentially. In fact, surgeons who have performed Heller myotomy have embraced POEM as the preferred intervention for achalasia. However, the authors stated that the niche of POEM remains to be defined and long-term results are awaited.

Pescarus et al (2014) stated that POEM is a new minimally invasive endoscopic treatment for achalasia. Since the first modern human cases were published in 2008, around 2,000 cases have been performed worldwide. This technique requires advanced endoscopic skills and a learning curve of at least 20 cases. Per-oral endoscopic myotomy is highly successful with over 90% improvement in dysphagia while offering patients the advantage of a low impact endoscopic access. The main long-term complication is GER with an estimated incidence of 35%, similar to the incidence of GER post-laparoscopic Heller with fundoplication. The authors concluded that although POEM
represents a paradigm shift in the treatment of achalasia, more long-term data are needed to further define its role in the treatment algorithm of this rare disease.

Bredenoord et al (2014) noted that treatment of achalasia is complicated by symptom recurrence and a significant risk for severe complications. Endoscopic myotomy was developed in the search for a highly effective treatment with lower risks. Since its introduction in 2010, several centers have adopted the technique and published excellent short-term results of open label series. These researchers stated that randomized trials with long-term end-point comparing POEM with the established treatments such as balloon dilation and surgical myotomy are now warranted, before POEM can be regarded as the routine clinical care for achalasia patients.

Furthermore, an UpToDate review on “Overview of the treatment of achalasia” (Spechler, 2014) states that “Long-term data from randomized trials are necessary to compare POEM with laparoscopic surgical myotomy and pneumatic dilation before POEM can be recommended”.

**Pharyngeal Motor Cortex Stimulation:**

Michou et al (2012) examined the behavioral and neurophysiological effects of a new neurostimulation technique (paired associative stimulation [PAS]), applied to the pharyngeal motor cortex, on swallowing function in healthy individuals and patients with dysphagia from stroke. These researchers examined the optimal parameters of PAS to promote plasticity by combining peripheral pharyngeal (electrical) with cortical stimulation. A virtual lesion was used as an experimental model of stroke, created with 1-Hz repetitive transcranial magnetic stimulation over the pharyngeal cortex in 12 healthy individuals. They tested whether hemispheric targeting of PAS altered swallowing performance before applying the technique to 6 patients with severe, chronic dysphagia from stroke (mean of 38.8 +/- 24.4 weeks post-stroke). Ten minutes of PAS to the unlesioned pharyngeal cortex reversed (bilaterally) the cortical suppression induced by virtual lesion (lesioned: F(1,9) = 21.347, p = 0.001;
contralesional: $F(1,9) = 9.648, p = 0.013$; repeated-measures analysis of variance) compared with sham PAS. It promoted changes in behavior responses measured with a swallowing reaction time task ($F(1,7) = 21.02, p = 0.003$; repeated-measures analysis of variance). In patients with chronic dysphagia, real PAS induced short-term bilateral changes in the brain; the unaffected pharyngeal cortex had increased excitability ($p = 0.001; 95\%\ CI: 0.21$ to $0.05$; post-hoc paired t test) with reduced penetration-aspiration scores and changes in swallowing biomechanics determined by videofluoroscopy. The authors concluded that the beneficial neurophysiological and behavioral properties of PAS, when applied to unlesioned brain, provide the foundation for further investigation into the use of neurostimulation as a rehabilitative approach for patients with dysphagia from stroke.

**Repetitive Peripheral/Transcranial Magnetic Stimulation:**

Khedr and Abo-Elfetoh (2010) examined the effect of repetitive transcranial magnetic stimulation (rTMS) applied to the motor area of both hemispheres in patients with acute lateral medullary infarction (LMI) or other brainstem infarctions. The study included 22 patients with acute ischemic stroke who had severe bulbar manifestation -- 11 patients had LMI, and 11 had another brainstem infarction. They were randomly allocated to receive active ($n = 11$) or sham ($n = 11$) rTMS of the esophageal motor cortex. Each patient received 300 rTMS pulses at 3 Hz and an intensity of $130\%$ resting motor threshold to each hemisphere for 5 consecutive days. Clinical ratings of dysphagia and motor disability were assessed before and immediately after the last session, and then again after 1 and 2 months. There were no significant differences in baseline clinical assessment of swallowing between active and sham groups. Active rTMS improved dysphagia compared with sham rTMS in both groups of patients, ($p = 0.001$ for both); the LMI group also improved the scores in the Barthel Index. All improvements were maintained over 2 months of follow-up ($p = 0.001$). The authors concluded that these findings suggested that rTMS could be a useful adjuvant strategy in neurorehabilitation of dysphagia due to LMI or other brainstem infarction, although further assessment is needed in multi-center clinical trials.
Momosaki et al (2014) examined the safety and feasibility of a 6-day protocol of bilateral (rTMS combined with intensive swallowing rehabilitation for chronic post-stroke dysphagia. In-hospital treatment was provided to 4 post-stroke patients (age at treatment ranged from 56 to 80 years; interval between onset of stroke and treatment: 24 to 37 months) with dysphagia. Over 6 consecutive days, each patient received 10 sessions of rTMS at 3 Hz applied to the pharyngeal motor cortex bilaterally, followed by 20 mins of intensive swallowing rehabilitation exercise. The swallowing function was evaluated by the Penetration Aspiration Scale (PAS), Modified Mann Assessment of Swallowing Ability (MMASA), Functional Oral Intake Scale (FOIS), laryngeal elevation delay time (LEDT) and Repetitive Saliva-Swallowing Test (RSST) on admission and at discharge. All patients completed the 6-day treatment protocol and none showed any adverse reactions throughout the treatment. The authors concluded that the combination treatment improved laryngeal elevation delay time in all patients. They stated that the proposed protocol of rTMS plus swallowing rehabilitation exercise seemed to be safe and feasible for chronic post-stroke dysphagia, although its effectiveness needs to be confirmed in a large number of patients.

In a pilot study, Momosaki et al (2015) examined the safety and feasibility of a 6-day protocol of in-hospital repetitive peripheral magnetic stimulation combined with intensive swallowing rehabilitation (rPMS-ISR) for post-stroke dysphagia. Subjects were 8 patients with dysphagia caused by bilateral cerebral infarction (age of 62 to 70 years; time from onset of stroke: 27 to 39 months). Repetitive PMS was applied to the suprahyoid muscles, at strength set at 90% of the minimal intensity that elicited pain with a parabolic coil. One train of stimuli comprised 20 Hz for 3 sec followed by 27-sec rest. A single session included delivery of repetitive 20 trains of stimuli over 10 mins, followed by 20 mins of swallowing rehabilitation. Each patient received this combination treatment twice-daily, morning and afternoon, over 6 consecutive days. Swallowing function was evaluated before and after intervention. Repetitive PMS-ISR induced significant improvement in swallowing ability, laryngeal elevation delay time, penetration aspiration scale, and swallowing quality.
of life \((p < 0.01)\), but had no significant effect on the functional oral intake scale. The authors concluded that the 6-day in-hospital RPMS-ISR protocol appeared safe and feasible for post-stroke patients with dysphagia. The combination protocol improved swallowing function. They stated that further larger studies are needed to confirm its effectiveness.

Pisegna and colleagues (2016) evaluated the effects of non-invasive brain stimulation on post-stroke dysphagia. A total of 13 databases were systematically searched through July 2014. Studies had to meet pre-specified inclusion and exclusion criteria. Each study's methodological quality was examined. Effect sizes were calculated from extracted data and combined for an overall summary statistic. A total of 8 RCTs were included. These trials revealed a significant, moderate pooled effect size \((0.55; 95\% \text{ CI: } 0.17 \text{ to } 0.93; p = 0.004)\). Studies stimulating the affected hemisphere had a combined effect size of \(0.46\) \((95\% \text{ CI: } \text{-0.18} \text{ to } 1.11; p = 0.16)\); studies stimulating the unaffected hemisphere had a combined effect size of \(0.65\) \((95\% \text{ CI: } 0.14 \text{ to } 1.16; p = 0.01)\). At long-term follow-up, 3 studies demonstrated a large but non-significant pooled effect size \(0.81, p = 0.11\). The authors concluded that this review found evidence for the effectiveness of non-invasive brain stimulation on post-stroke dysphagia. A significant effect size resulted when stimulating the unaffected rather than the affected hemisphere. This finding is in agreement with previous studies implicating the plasticity of cortical neurons in the unaffected hemisphere. The authors stated that non-invasive brain stimulation appeared to assist cortical reorganization in post-stroke dysphagia; however emerging factors high-lighted the need for more data.

**ERBE Electrocautery:**

Siersema (2008) stated that esophageal strictures are a problem commonly encountered in gastro-enterological practice and can be caused by malignant or benign lesions. Dysphagia is the symptom experienced by all patients, regardless of whether their strictures are caused by malignant or benign lesions. The methods most frequently used for palliation of malignant esophageal strictures are stent placement (particularly in patients
with an expected survival of 3 months or less) and brachytherapy (in patients with a life expectancy of more than 3 months). Brachytherapy has been shown to be beneficial in patients with an expected survival of longer than 3 months with regard to (prolonged) dysphagia improvement, complications and quality of life. The mainstay of benign esophageal stricture treatment is dilation. Although dilation usually results in symptomatic relief, recurrent strictures do occur. In order to predict which types of strictures are most likely to recur, it is important to differentiate between esophageal strictures that are simple (i.e., focal, straight strictures with a diameter that allows endoscope passage) and those that are more complex (i.e., long (greater than 2 cm), tortuous strictures with a narrow diameter). These complex strictures are considered refractory when they cannot be dilated to an adequate diameter. Novel treatment modalities for refractory strictures include temporary stent placement and incisional therapy.

Hordijk and colleagues (2009) stated that benign gastro-esophageal anastomotic strictures are common and often refractory to treatment. Various endoscopic dilation techniques have been reported, but none of these methods has been proven to be superior. In a randomized, prospective, multi-center study, these researchers compared the safety and effectiveness of dilation of previously untreated anastomotic strictures by using electrocautery incision (EI) and Savary bougienage (SB). A total of 62 patients with an anastomotic stricture after esophago-gastrostomy and dysphagia Atkinson grades II to IV were included. Patients were treated with EI or SB. Objective and subjective results were compared with baseline and 1, 3, and 6 months after the first treatment. Complications of both treatments were noted. Primary end-points after 6 months were the mean number of dilation sessions and success rate (percentage of patients with less than or equal to 5 dilations in 6 months). Study participation ended after 6 months or if dysphagia grades II to IV recurred despite 5 treatment sessions. No complications occurred with both treatments. There was no significant difference between the EI and SB groups in the mean number of dilations (2.9; 95 % CI: 2.7 to 4.1 versus 3.3; 95 % CI: 2.3 to 3.6; p = 0.46) or the success rate (80.6 % versus 67.7 %, p =
0.26 and 96.2 % versus 80.8 %, p = 0.19). The authors concluded that this prospective trial demonstrated that EI of gastro-esophageal anastomotic strictures is a safe therapy and equivalent to SB as a primary therapy. EI can be used as an alternative or additional therapy to SB. Limitations of this trial: In a small study with negative primary end-points, secondary end-points and subgroup analyses are hypothesis generating only.

Alonso-Larraga et al (2011) stated that dysphagia is a common problem after surgical stenosis (5 % to 55 %) and can be refractory to conventional endoscopic treatment in 22 % of cases. It has been proposed that electro-incision is an alternative and effective treatment. These researchers evaluated the effectiveness of electro-incision with the insulation-tipped diathermic Knife-2 (IT-Knife-2) in the treatment of dysphagia produced by surgical anastomotic strictures. Longitudinal and case-series studies from August 2009 to June 2010 were selected for analysis. A total of 8 consecutive patients with anastomotic stricture-associated dysphagia and naive to endoscopic treatment were included. These investigators performed 3 or more radiated cuts in the stricture until passage of the gastroscope was achieved with IT-Knife-2 and electrocautery (ERBE IC 200) with a 70-100 W energy cut-off and 25 W coagulation. These researchers carried out measurements at baseline and 15 days after the intervention, evaluating the dysphagia by the Atkinson grading scale and endoscopic changes. The majority of patients were at clinical stage IV with an Eastern Cooperative Oncology Group score of 1 to 3 and Karnofsky between 40 and 90. At the time of endoscopic diagnosis, patients had dysphagia grade II and III. Strictures in all of the cases were short in length and had a diameter of minor than 5 mm. At 15 days of the intervention, no patient demonstrated dysphagia (p = 0.0013) and the anastomotic diameters was more than 9.5 mm and without evidence of stenosis (p = 0.0001). None of the patients presented post-incisional complications. The authors concluded that electro-incision with IT-Knife-2 is effective as primary treatment for the relief of benign dysphagia associated with post-surgical anastomotic stenosis. This was a small study (n = 8) with short-term follow-up (15 days). These preliminary findings need to be validated by well-designed studies.
Also, an UpToDate review on “Oropharyngeal dysphagia: Clinical features, diagnosis, and management” (Lembo, 2015) does not mention electrocautery as a therapeutic option.

**Palliative Radiotherapy (Including Intra-Cavitary Radiotherapy and Intra-Luminal Brachytherapy):**

Adamson et al (2014) noted that the single most distressing symptom for patients with advanced esophageal cancer is dysphagia. Among the more effective treatments for relief of dysphagia is insertion of a self-expanding metal stent (SEMS). It is possible that the addition of a palliative dose of external beam radiotherapy may prolong the relief of dysphagia and provide additional survival benefit. The ROCS (Radiotherapy after Oesophageal Cancer Stenting) trial will assess the effect of adding palliative radiotherapy after esophageal stent insertion. The study is a randomized multi-center phase III trial, with an internal pilot phase, comparing stent alone versus stent plus palliative radiotherapy in patients with incurable esophageal cancer. Eligible participants are those with advanced esophageal cancer who are in need of stent insertion for primary management of dysphagia. Radiotherapy will be administered as 20 Gray (Gy) in 5 fractions over 1 week or 30 Gy in 10 fractions over 2 weeks, within 4 weeks of stent insertion. The internal pilot will assess rates and methods of recruitment; pre-defined criteria will determine progression to the main trial. In total, 496 patients will be randomized in a 1:1 ratio with follow up until death. The primary outcome is time to progression of patient-reported dysphagia. Secondary outcomes include survival, toxicity, health resource utilization, and quality of life. An embedded qualitative study will explore the feasibility of patient recruitment by examining patients' motivations for involvement and their experiences of consent and recruitment, including reasons for not consenting. It will also explore patients' experiences of each trial arm. These investigators stated that the ROCS study will be a challenging trial studying palliation in patients with a poor prognosis. The internal pilot design will optimize methods for recruitment and data collection to ensure that the main trial is completed on time. As a pragmatic trial, study strengths include collection of all follow-up data in the usual place of care, and a
focus on patient-reported, rather than disease-orientated, outcomes. Exploration of patient experience and health economic analyses will be integral to the assessment of benefit for patients and the National Health Service (NHS). The trial was registered with Current Controlled Trials (registration number: ISRCTN12376468) on July 10, 2012.

In a Cochrane review, Dai and associates (2014) analyzed the effectiveness of different interventions used in the palliation of dysphagia in primary esophageal and gastro-esophageal carcinoma. In this updated review (January 2014), these investigators searched, according to the Cochrane Upper Gastrointestinal and Pancreatic Diseases model, the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library), MEDLINE, EMBASE and CINAHL; and major conference proceedings (up to January 2014). Only RCTs were included in which patients with inoperable or unresectable primary esophageal cancer underwent palliative treatment. Different interventions like rigid plastic intubation, SEMS insertion, brachytherapy, external beam radiotherapy, chemotherapy, esophageal bypass surgery, chemical and thermal ablation therapy, either head-to-head or in combination, were included. The primary outcome was dysphagia improvement. Secondary outcomes included recurrent dysphagia, technical success, procedure related mortality, 30-day mortality, adverse effects and quality of life. Data collection and analysis were performed in accordance with the methods of the Cochrane Upper Gastrointestinal and Pancreatic Diseases Review Group. These researchers included 3,684 patients from 53 studies. Self-expanding metallic stent insertion was safer and more effective than plastic tube insertion. Thermal and chemical ablative therapy provided comparable dysphagia palliation but had an increased requirement for re-interventions and for adverse effects. Anti-reflux stents provided comparable dysphagia palliation to conventional metal stents. Some anti-reflux stents might have reduced gastro-esophageal reflux and complications. Newly-designed double-layered nitinol (Niti-S) stents were preferable due to longer survival time and fewer complications compared to simple Niti-S stents. Brachytherapy might be a suitable alternative to SEMS in providing a survival advantage and
possibly a better quality of life, and might provide better results when combined with argon plasma coagulation or external beam radiation therapy. The authors concluded that SEMS insertion is safe, effective and quicker in palliating dysphagia compared to other modalities. However, high-dose intra-luminal brachytherapy is a suitable alternative and might provide additional survival benefit with a better quality of life. Some anti-reflux stents and newly-designed stents lead to longer survival and fewer complications compared to conventional stents.

Combinations of brachytherapy with SEMS insertion or radiotherapy are preferable due to the reduced requirement for re-interventions. Rigid plastic tube insertion, dilatation alone or in combination with other modalities, and chemotherapy alone are not recommended for palliation of dysphagia due to a high incidence of delayed complications and recurrent dysphagia.

Yamashita and colleagues (2015) stated that intra-cavitary radiotherapy (ICRT) for the palliative treatment of advanced esophageal cancer with dysphagia is currently performed at the University of Tokyo Hospital (Tokyo, Japan). In the present study, 24 patients exhibiting advanced esophageal cancer with dysphagia received palliative ICRT, which was delivered 5 mm below the esophageal mucous membrane, with the exception of 1 case, was administered at a dose of 6 Gy/fraction. Specific patients additionally underwent definitive or palliative external beam radiation therapy for esophageal cancer a minimum of 3 months prior to ICRT. The effect of treatment on symptom alleviation was examined by comparing the dysphagia score prior to and following ICRT, with the patients' medical records and a questionnaire used to calculate a dysphagia score ranging from 0 (no dysphagia) to 4 (total dysphagia). In consideration of the individual efficacy of the treatment, the maximum number of repeated ICRT fractions was 4 (median of 1.7 times). A trend in the improvement of the symptom of dysphagia was observed in response to esophageal ICRT, with the average dysphagia score markedly decreasing from 2.54 to 1.65, however, the difference was not significant (p = 0.083). Furthermore, pain was the most frequent side-effect of the esophageal ICRT and no patients exhibited severe complications. The authors concluded that esophageal ICRT at a dose of 6 Gy/fraction may present an
effective strategy for relieving the symptom of dysphagia in cases of advanced esophageal cancer. These preliminary findings need to be validated by well-designed studies.

*The Intensive Dysphagia Rehabilitation Approach (e.g., the Swallow STRONG Multi-Disciplinary Oropharyngeal Strengthening Program:)

Rogus-Pulia et al (2016) noted that dysphagia is associated with malnutrition, aspiration pneumonia, and mortality in older adults. Strengthening interventions have shown promising results, but the effectiveness of treating dysphagia in older adults remains to be established. The Swallow STREngthening OropharyNGeal (Swallow STRONG) Program is a multi-disciplinary program that employs a specific approach to oropharyngeal strengthening, device-facilitated (D-F) isometric progressive resistance oropharyngeal (I-PRO) therapy, with the goal of reducing health-related sequelae in veterans with dysphagia. Participants completed 8 weeks of D-F I-PRO therapy while receiving nutritional counseling and respiratory status monitoring.

Assessments were completed at baseline, 4, and 8 weeks. At each visit, videofluoroscopic swallowing studies were carried out. Dietary and swallowing-related quality of life questionnaires were administered. Long-term monitoring for 6 to 17 months after enrollment allowed for comparison of pneumonia incidence and hospitalizations to the 6 to 17 months before the program. Veterans with dysphagia confirmed with videofluoroscopy (n = 56; 55 males, 1 female; mean age of 70 years) were enrolled. Lingual pressures increased at anterior (effect estimate = 92.5, p < 0.001) and posterior locations (effect estimate = 85.4, p < 0.001) over 8 weeks. Statistically significant improvements occurred on 8 of 11 subscales of the Quality of Life in Swallowing Disorders (SWAL-QOL) Questionnaire (effect estimates = 6.5 to 19.5, p < 0.04) and in self-reported sense of effort (effect estimate = -18.1, p = 0.001). Higher Functional Oral Intake Scale scores (effect estimate = 0.4, p = 0.02) indicated that participants were able to eat less-restrictive diets. There was a 67% reduction in pneumonia diagnoses, although the difference was not statistically significant. The number of hospital admissions decreased significantly (effect estimate = 0.96; p = 0.009) from
before to after enrollment. The authors concluded that the findings of this study suggested that the Swallow STRONG multi-disciplinary oropharyngeal strengthening program may be an effective treatment for older adults with dysphagia. These preliminary findings need to be validated by well-designed studies.

In an intervention study (before-after trial) with 4-week follow-up through an online survey, Malandraki and colleagues (2016) examined the effects of the Intensive Dysphagia Rehabilitation approach on physiological and functional swallowing outcomes in adults with neurogenic dysphagia. A consecutive sample of subjects (n = 10) recruited from outpatient university clinics were included in this analysis. All subjects were diagnosed with adult-onset neurologic injury or disease. Dysphagia diagnosis was confirmed through clinical and endoscopic swallowing evaluations. No subjects withdrew from the study. Participants completed the 4-week Intensive Dysphagia Rehabilitation protocol, including 2 oropharyngeal exercise regimens, a targeted swallowing routine using salient stimuli, and caregiver participation. Treatment included hourly sessions twice-weekly and home practice for approximately 45 minutes/day. Outcome measures evaluating pre- and post-treatment included airway safety using an 8-point Penetration Aspiration Scale, lingual isometric pressures, self-reported swallowing-related QOL, and level of oral intake. Also, patients were monitored for adverse dysphagia-related effects; QOL and adverse effects were also assessed at the 4-week follow-up (online survey). The Intensive Dysphagia Rehabilitation approach was effective in improving maximum and mean Penetration Aspiration Scale scores (p < 0.05, $\eta^2(2) = 0.8146$ and $p < 0.05, \eta^2(2) = 0.799708$, respectively) and level of oral intake ($p < 0.005$, Cohen d = -1.387). Of the 5 patients who were feeding tube-dependent initially, 2 progressed to total oral nutrition, and 2 progressed to partial oral nutrition; 1 patient remained tube-dependent; QOL was significantly improved at the 4-week follow-up (95% CI: 6.38 to 14.5; $p < 0.00$), but not at the post-treatment. No adverse effects were observed/reported. The authors concluded that the Intensive Dysphagia Rehabilitation approach was safe and improved physiological and some functional swallowing outcomes in this
Progressive Muscle Diseases:

In a Cochrane review, Jones and colleagues (2016) examined the effects of interventions for dysphagia in people with long-term, progressive muscle disease. On January 11, 2016, these investigators searched the Cochrane Neuromuscular Specialized Register, the Cochrane Central Register of Controlled Trials (CENTRAL), Medline, Embase, AMED, LILACS, and CINAHL. They checked references in the identified trials for additional RCTs and quasi-RCTs. They also searched ClinicalTrials.gov and the World Health Organization International Clinical Trials Registry Platform on January 12, 2016 for ongoing or completed but unpublished clinical trials. These researchers included RCTs and quasi-RCTs that evaluated the effect of interventions for managing dysphagia in adults and children with long-term, progressive muscle disease, compared to other interventions, placebo, no intervention, or standard care. In this review update, the authors decided to include trials of people with sporadic inclusion body myositis (IBM) on the basis that it presents as a long-term, progressive muscle disease with uncertain degenerative and inflammatory etiology and is typically refractory to treatment. They applied standard Cochrane methodological procedures. There were no RCTs that reported results in terms of the review’s primary outcome of interest, weight gain or maintenance. However, these researchers identified 1 RCT that assessed the effect of intravenous immunoglobulin (IVIG) on swallowing function in people with IBM. The trial authors did not specify the number of subjects who had dysphagia. There was also incomplete reporting of findings from video-fluoroscopic investigations, which was one of the review’s secondary outcome measures. The study did report reductions in the time taken to swallow, as measured using ultrasound. No serious adverse events (AEs) occurred during the study, although data for the follow-up period were lacking. It was also unclear whether the non-serious AEs reported occurred in the treatment group or the placebo group. These investigators assessed this study as having a high risk of bias and uncertain CIs for the review outcomes, which limited the sample; however, further investigation is needed before it can be widely applied.
overall quality of the evidence. Using GRADE criteria, the authors
down-graded the quality of the evidence from this RCT to “low”
for efficacy in treating dysphagia, due to limitations in study
design and implementation, and indirectness in terms of the
population and outcome measures. Similarly, they assessed the
quality of the evidence for AEs as “low”. From their search for
RCTs, these researchers identified 2 other non-randomized
studies, which reported the effects of long-term IVIG therapy in
adults with IBM and lip-strengthening exercises in children with
myotonic dystrophy type 1. Headaches affected 2 participants
treated with long-term IVIG therapy, who received a tailored dose
reduction; there were no AEs associated with lip-strengthening
exercises. Both non-randomized studies identified improved
outcomes for some participants following the intervention, but
neither study specified the number of participants with dysphagia
or demonstrated any group-level treatment effect for swallowing
function using the outcomes pre-specified in this review. The
authors concluded that there is insufficient and low-quality RCT
evidence to determine the effect of interventions for dysphagia in
long-term, progressive muscle disease. Clinically relevant effects
of IVIG for dysphagia in patients with IBM can neither be
confirmed or excluded using the evidence presented in this
review. They stated that standardized, validated, and reliable
outcome measures are needed to assess dysphagia and any
possible treatment effect. Clinically meaningful outcomes for
dysphagia may require a shift in focus from measures of
impairment to disability associated with oral feeding difficulties.

CPT Codes / ICD-10 Codes / HCPCS Codes

Information in the [brackets] below has been added for clarification
purposes. Codes requiring a 7th character are represented by "+":

Therapy for the management of dysphagia other than esophageal
dilation or stent placement:

CPT codes covered if selection criteria are met:
92507  Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual

92508  Treatment of speech, language, voice, communication, and/or auditory processing disorder; group, 2 or more individuals

92526  Treatment of swallowing dysfunction and/or oral function for feeding

92610  Evaluation of oral and pharyngeal swallowing function

92611  Motion fluoroscopic evaluation of swallowing function by cine or video recording

92612  Flexible fiberoptic endoscopic evaluation of swallowing by cine or video recording

92613  physician interpretation and report only

CPT codes not covered for indications listed in the CPB:

Repetitive peripheral magnetic stimulation, Swallow STRONG
multi-disciplinary oropharyngeal strengthening program - no specific code:

43229  Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed) [not covered for ERBE electrocautery]

64550  Application of surface (transcutaneous) neurostimulator

64612  Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)

64616  neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)

90867  Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management

90868  subsequent delivery and management, per session

90869  subsequent motor threshold re-determination with delivery and management
95873  Electrical stimulation for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)

95874  Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)

97014  Application of a modality to one or more areas; electrical stimulation (unattended)

97032  Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes

97810 - 97814  Acupuncture

**HCPCS codes covered if selection criteria are met:**

G0153  Services performed by a qualified speech-language pathologist in the home health or hospice setting, each 15 minutes

S9128  Speech therapy, in the home, per diem

**HCPCS codes not covered for indications listed in the CPB:**

E0720  Transcutaneous electrical nerve stimulation (TENS) device, two lead, localized stimulation

E0730  Transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation

E0745  Neuromuscular stimulator, electronic shock unit

G0283  Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care

J0585  Botulinum toxin type A, per unit

J0587  Botulinum toxin type B, per 100 units

**ICD-10 codes covered if selection criteria are met:**
Cerebrovascular disease, dysphagia, sequelae

Dysphagia

Esophageal dilation:

CPT codes covered if selection criteria are met:

43196  Esophagoscopy, rigid, transoral; with insertion of guide wire followed by dilation over guide wire

43213  Esophagoscopy, flexible, transoral; with dilation of esophagus, by balloon or dilator, retrograde (includes fluoroscopic guidance, when performed)

43214  with dilation of esophagus with balloon (30 mm diameter or larger) (includes fluoroscopic guidance, when performed)

43220  Esophagoscopy, rigid or flexible; with balloon dilation (less than 30 mm diameter)

43226  with insertion of guide wire followed by dilation over guide wire

43229  Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)

43233  Esophagogastroduodenoscopy, flexible, transoral; with dilation of esophagus with balloon (30 mm diameter or larger) (includes fluoroscopic guidance, when performed)

43249  Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with balloon dilation of esophagus (less than 30 mm diameter)
43253  Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided transmural injection of diagnostic or therapeutic substance(s) (eg, anesthetic, neurolytic agent) or fiducial marker(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)

43270  Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)

43450  Dilation of esophagus, by unguided sound or bougie, single or multiple passes

43453  Dilation of esophagus, over guide wire

**ICD-10 codes covered if selection criteria are met:**

K22.2  Esophageal obstruction

Q39.0 - Q39.4  Congenital malformations of esophagus

**ICD-10 codes not covered for indications listed in the CPB:**

I69.091  Cerebrovascular disease, dysphagia, sequelae
I69.191
I69.291
I69.391
I69.891
I69.991

R13.10 - R13.19  Dysphagia

**Stent Placement:**

**CPT codes covered if selection criteria are met:**

43212  Esophagoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)
43256 Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with transendoscopic stent placement (includes predilation)

43266 Esophagogastroduodenoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)

Other HCPCS codes related to the CPB:

C1876 Stent, noncoated/noncovered, with delivery system
C1877 Stent, noncoated/noncovered, without delivery system

ICD-10 codes covered if selection criteria are met:

C15.3 - Malignant neoplasm of esophagus
C15.9

The above policy is based on the following references:


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AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0625 Dysphagia Therapy

There are no amendments for Medicaid.