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

<table>
<thead>
<tr>
<th>Plan: Aetna Better Health</th>
<th>Submission Date: 05/01/2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy Number: 0288</td>
<td>Effective Date:</td>
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<tr>
<td></td>
<td>Revision Date:</td>
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<tr>
<td>Policy Name: Stereotactic Cingulotomy</td>
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</tr>
</tbody>
</table>

Type of Submission – Check all that apply:
- [x] New Policy*
- [ ] Revised Policy
- [ ] Annual Review – No Revisions

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

**CPB 0288 Stereotactic Cingulotomy**

Policy is new to Aetna Better Health of Pennsylvania.

Name of Authorized Individual (Please type or print):

Dr. Bernard Lewin, M.D.

Signature of Authorized Individual:

[Signature]
Clinical Policy Bulletin: Stereotactic Cingulotomy

**Number:** 0288

**Policy**

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

Aetna considers stereotactic cingulotomy medically necessary when it is used as a last resort to provide pain relief for members with terminal cancer pain.

Aetna considers stereotactic cingulotomy experimental and investigational for the following indications (not an all inclusive list) because its effectiveness (including long-term outcomes) for these indications has not been established.

- Treatment of chronic, intractable non-malignant pain (e.g., post-stroke pain)
- Treatment of drug addiction
- Treatment of psychiatric disease (e.g., affective disorders, aggressive behavior, anxiety, depression, obsessive-compulsive disorders, personality disorders, schizophrenia, and Tourette’s disorder).

**Background**

Since its inception, functional neurosurgery (or psychosurgery) has been over-shadowed by ethical questions and doubts resulting from inadequate reporting of outcomes. In the 1940s and early 1950s prior to the introduction of major psychotropic agents, psychosurgery became popular in the United States. Pre-frontal lobotomies were indiscriminately performed for intractable mental illness, in particular, depression, anxiety, and obsessive-compulsive disorders (OCDs). However, its side effects, especially the “frontal lobe syndrome”, led to the need for more refined surgical approaches; the most important of these was the use of stereotaxis. Cingulotomy, subcaudate tractotomy, limbic leucotomy, and anterior capsulotomy are generally the stereotactic treatments of choice today.

MRI-guided stereotactic cingulotomy consists of lesioning the white matter deep to the cingulate gyrus. Reports suggest that pain secondary to cancer is relieved in 30 % to 90 % of patients following cingulotomy or cingulotomy combined with midbrain tractotomy. This procedure seems to be of most benefit when there is a major element of suffering. The results have been less encouraging in non-malignant chronic pain, but it has been suggested that cingulotomy may be useful in cases in which depressive symptoms dominate the clinical picture.

The literature on the use of neuroablation procedures performed on the brain is non-existent in regards to chronic non-malignant pain, and limited in regards to psychiatric illnesses. Most available studies are limited by the use of retrospective designs, variations in diagnostic systems, the lack of independent clinical raters, use of a variety of psychosurgical techniques, and the lack of true control...
Stereotactic Cingulotomy

groups. Such irreversible, modern psychosurgical techniques performed on the brain in an effort to affect the psyche require prospective long-term follow-up studies to further define the role of surgery in treating various intractable psychiatric disease.

Jung et al (2006) examined the long-term effectiveness and adverse cognitive effects of stereotactic bilateral anterior cingulotomy as a treatment for patients with refractory OCD. A total of 17 patients suffering from refractory OCD underwent stereotactic bilateral anterior cingulotomies and were followed for 24 months. The Yale-Brown Obsessive-Compulsive Scale (Y-BOCS), the Clinical Global Impression and other neuropsychological tests were used to evaluate the effectiveness and cognitive changes of cingulotomy. The tests were taken before and 12 and 24 months after surgery. The mean improvement rate of the Y-BOCS score achieved from the baseline was 48%. Eight patients (47%) met the responder criteria. During the 24-month follow-up, there were no significant adverse effects observed after surgery. The authors concluded that bilateral anterior cingulotomy was effective for the treatment of refractory OCD, and no other significant adverse cognitive effects on long-term follow-up were found. The success rate in this study was fair and its findings need to be validated by well-designed studies.

Brotis et al (2009) stated that stereotactic cingulotomy constitutes a psycho-surgical procedure nowadays advocated in the treatment of medically intractable OCD, chronic pain and drug addiction. From its theoretical conception to the first cingulectomies performed and modern stereotactic-guided cingulotomies, various target localization methods, different surgical techniques, and numerous lesioning devices have been utilized. These investigators performed a literature review related to cingular lesion placement in an effort to identify misconceptions of the past, recapitulate existing knowledge and recognize targets for further research. The initial animal and human electrophysiologic experimental data regarding the role of the cingulate cortex in various behavioral and cognitive functions were meticulously reviewed. The clinical indications, surgical technique and the clinical results and complications of open cingulectomies were examined. The anatomic target localization methodologies, surgical technique, and the outcome of the initial stereotactic cingulotomy procedures were reviewed, and the evolution of the imaging techniques, stereotactic devices, and lesioning strategies were followed. The modern advanced surgical techniques, clinical outcome and the procedure-associated complications were analyzed with particular emphasis on the emotional, behavioral, and cognitive procedure-induced changes. The authors concluded that large-scale prospective studies with strict inclusion and well-defined, objective outcome criteria are needed for defining the role of stereotactic cingulotomy in the current psycho-surgical armamentarium.

Jimenez et al (2012) performed a preliminary study on the safety and effectiveness of bilateral cingulotomy and anterior capsulotomy in patients with aggressive behavior. Twenty-three psychiatric patients showing aggressive behavior refractory to conventional treatment were initially evaluated. The subjects were clinically selected using the Overt Aggression Scale (OAS) and the Global Assessment of Functioning Scale (GAF). Each case was carefully reviewed by the Ethics Committee of Mexico's General Hospital. Once selection criteria were met, stereotactic lesions were made using radiofrequency on the anterior limb of the internal capsule and supragenual cingulum. Statistical differences were evaluated with a Wilcoxon test at 6 months and at 4 years. A total of 10 patients underwent surgery. Their OAS and GAF scores decreased after the procedure at the 6-month (p < 0.05) and at the 4-year (p = 0.068) follow-up; 4 patients showed mild and transitory post-surgical complications (hyperphagia and somnolence). The authors concluded that bilateral anterior capsulotomy in combination with cingulotomy may reduce aggressive behavior and improve clinical evaluations. Very strict clinical and ethical evaluations were applied prior to considering patients for this treatment. These preliminary findings were confounded by the combinational use of cingulotomy and capsulotomy. Well-designed studies are needed to confirm the effectiveness of cingulotomy in the treatment of individuals with aggressive behavior.

Leveque and colleagues (2013) stated that radiosurgery for psychiatric disorders had been performed for more than 50 years. The use of deep brain stimulation has recently been expanded to the investigational treatment of specific psychiatric disorders. A literature review of past studies
incorporating radiosurgical stereotactic lesions for psychiatric disorders was performed to provide historic context and possible guidance for current and future attempts at treating psychiatric disorders, especially by gamma capsulotomy. The anatomic target localization, dose selection, and the outcome of the radiosurgical procedures were reviewed, and the evolution of lesioning strategies were analyzed with particular emphasis on the dose selection. The authors concluded that large-scale prospective studies with strict inclusion and well-defined, objective outcome criteria are needed for defining the role of radiosurgery for the treatment of psychiatric disorders. Cingulotomy and gamma capsulotomy were among the keywords used in this review.

Nuttin and associates (2014) noted that for patients with psychiatric illnesses remaining refractory to “standard” therapies, neurosurgical procedures may be considered. Guidelines for safe and ethical conduct of such procedures have previously and independently been proposed by various local and regional expert groups. To expand on these earlier documents, representative members of continental and international psychiatric and neurosurgical societies, joined efforts to further elaborate and adopt a pragmatic worldwide set of guidelines. These were intended to address a broad range of neuropsychiatric disorders, brain targets and neurosurgical techniques, taking into account cultural and social heterogeneities of healthcare environments. The proposed consensus document highlighted that, while stereotactic ablative procedures such as cingulotomy and capsulotomy for depression and OCD are considered “established” in some countries, they still lack level I evidence. Further, it is noted that deep brain stimulation in any brain target hitherto tried, and for any psychiatric or behavioral disorder, still remains at an investigational stage. Researchers are encouraged to design randomized controlled trials, based on scientific and data-driven rationales for disease and brain target selection. The authors concluded that experienced multi-disciplinary teams are a mandatory requirement for the safe and ethical conduct of any psychiatric neurosurgery, ensuring documented refractoriness of patients, proper consent procedures that respect patient's capacity and autonomy, multi-faceted pre-operative as well as post-operative long-term follow-up evaluation, and reporting of effects and side effects for all patients.

### CPT Codes / HCPCS Codes / ICD-10 Codes

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

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>61720</td>
<td>Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; globus pallidus or thalamus</td>
</tr>
<tr>
<td>61735</td>
<td>Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; subcortical structure(s) other than globus pallidus or thalamus</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G89.3</td>
<td>Neoplasm related pain (acute) (chronic) [used as a last resort to provide pain relief for members with terminal cancer pain]</td>
</tr>
<tr>
<td>Z51.5</td>
<td>Encounter for palliative care [terminal care]</td>
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</tbody>
</table>

**ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>F11.20 - F11.21</td>
<td>Drug dependence</td>
</tr>
<tr>
<td>F12.20 - F12.21</td>
<td></td>
</tr>
<tr>
<td>F13.20 - F13.21</td>
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</tbody>
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The above policy is based on the following references:

223.


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0288 Stereotactic Cingulotomy

There are no amendments for Medicaid.

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