

**Subject:** Stereotactic Radiofrequency Pallidotomy

**Policy #:** SURG.00016

**Status:** Reviewed

**Current Effective Date:** 11/17/2006

**Last Review Date:** 06/08/2006

## Description/Scope

This policy addresses the use of stereotactic radiofrequency pallidotomy for the treatment of Parkinson's disease. Stereotactic radiofrequency pallidotomy is a surgical procedure that uses stereotactic (3-D) imaging procedures to identify and localize the area of the brain needing treatment followed by surgical placement of radiofrequency emitting needles within the brain. Radiofrequency energy is used to destroy a part of the brain partly responsible for tremors related to Parkinson's disease.

## Policy Statement

### Medically Necessary:

Unilateral stereotactic radiofrequency pallidotomy with microelectrode mapping is considered **medically necessary** for patients with Parkinson's disease who meet **all** the following criteria:

1. Accurate diagnosis of idiopathic Parkinson's disease (striatonigral degeneration has been ruled out as a cause for symptoms); AND
2. Severe levodopa-induced dyskinesia or disease characterized by severe bradykinesia, dystonia, or akinesia/rigidity, or by marked 'on-off' fluctuations; AND
3. No evidence of dementia

### Not Medically Necessary:

Unilateral stereotactic radiofrequency pallidotomy with microelectrode mapping is considered **not medically necessary** when **any** of the following contraindications are present:

1. History of encephalitis or neuroleptic treatment; OR
2. Evidence of dementia or focal brain abnormality on magnetic resonance imaging (MRI); OR
3. Medical conditions that might increase risk of hemorrhage (e.g. poorly controlled hypertension); OR
4. A medical, neurological, or orthopedic disorder that might compromise assessment (cerebrovascular disease, metabolic disorders, spinal stenosis)

Unilateral stereotactic radiofrequency pallidotomy with microelectrode mapping is considered **not medically necessary** when the criteria above are not met.

### Investigational/Not Medically Necessary:

Bilateral stereotactic radiofrequency pallidotomy is considered **investigational/not medically necessary** for all indications.

The use of unilateral stereotactic radiofrequency pallidotomy is considered **investigational/not medically necessary** for all indications not addressed above.

## Rationale

Unilateral stereotactic radiofrequency pallidotomy with microelectrode mapping has been shown in the peer-reviewed medical literature to be a relatively safe and effective method of managing symptoms of Parkinson's Disease (PD) when such symptoms have become resistant to pharmacological management. Many studies have illustrated that unilateral stereotactic radiofrequency pallidotomy can vastly improve dyskinesia, bradykinesia, and

other symptoms of PD when drug intervention becomes ineffective. It must be noted that this procedure is considered inappropriate in patients with several conditions, including specific central nervous system disorders and coagulopathies, which may compromise the proper assessment of the patient or the success of the surgical procedure.

Although bilateral stereotactic radiofrequency pallidotomy has been studied in the medical literature, there is not an adequate body of research to allow conclusions on its safety. Given the current literature available, bilateral stereotactic radiofrequency pallidotomy has been seen to produce severe motor and psychiatric complications that are avoidable by using the unilateral procedure. Given the limited information available and serious complications seen with bilateral stereotactic radiofrequency pallidotomy, this procedure cannot be recommended at this time.

The use of unilateral stereotactic radiofrequency pallidotomy for conditions other than Parkinson's disease has not been adequately studied, and the safety and efficacy of such use is unknown at this time.

## **Background/Overview**

### *Description of Parkinson's Disease*

Parkinson's Disease (PD) is a progressive, incurable disease caused by the slow continuous loss of nerve cells in a part of the brain that controls muscle movement. Common symptoms of the disease include tremors or involuntary movement in the jaw and extremities, slowed movement, muscle stiffness, gradual loss of voluntary movement, gradual loss of automatic movement, postural instability and depression. It is estimated that over a half million people in the U.S. are affected, and approximately 50,000 new cases are diagnosed annually. PD is primarily an age-related disease, with average age of onset being about 60 years of age, but development of PD in people as young as 20 has been reported. Generally, the older a person becomes, the more likely he or she is to develop PD.

The exact cause of PD is not known, but there is some evidence that there may be an inheritable component to the disease. A neurologist who evaluates the symptoms and their severity usually makes the diagnosis of PD. There are no tests that can definitively identify the disease aside from a physical examination of the brain after death. The usual method of determination for patients undergoing evaluation is a trial of anti-PD medications and, on occasion, brain scans.

There is no known cure for PD. Primary management of the disease is through pharmacological therapy with one or several drugs to relieve the symptoms of the disease. No drug has been shown to effectively slow the progression of the disease. As PD progresses pharmacotherapy becomes less and less effective in managing the symptoms of the disease. When a patient's symptoms are inadequately controlled for a period of three months, despite optimal medical management, the patient's disease may be considered medically unresponsive, requiring other management methods for relief.

### *Description of Stereotactic Radiofrequency Pallidotomy*

Stereotactic Radiofrequency Pallidotomy (SRP) is a surgical technique used to treat medically unresponsive PD. SRP involves destruction of the globus pallidus, a part of the brain that has become responsible for the symptoms of PD. SRP has been shown to lead to decreased PD symptoms.

For this procedure the patient's head is placed into a metal frame, called a stereotactic frame, which is anchored to the patient's skull through the skin with four pins. This frame allows for manipulation of the patient's head without losing the ability to locate internal brain structures from the outside with radiological techniques. Once the frame is in place the exact part of the brain the surgeons wish to target is identified using a magnetic resonance imaging (MRI) and special computerized mapping techniques. These computer programs also assist in planning the surgical approach. During the surgery, a small quarter-inch hole is made in the patient's skull through which the surgeon uses a special electrode needle to precisely map the location of the globus pallidus. When mapping is complete, the electrode needle is removed and replaced with another needle, which emits high frequency sound waves and heat to damage the targeted area of the brain.

### *Proposed Benefits*

This procedure is designed to relieve the involuntary movements or muscular rigidity associated with PD by treating the side of the brain opposite the side demonstrating the most severe symptoms (contralateral side). This

procedure does not treat all the symptoms of PD, although some of the most severe symptoms should be relieved, medications are still required and the condition continues to progress.

### *Possible Risks*

Although this surgery has become relatively routine care, there are some serious potential complications that may occur, including partial blindness, disturbance in speech patterns and re-operation to control bleeding. Additionally, the operation may not alleviate the symptoms of PD and may actually make them worse in some rare cases.

## **Definitions**

**Akinesia:** difficulty beginning or maintaining a body motion

**Bradykinesia:** an abnormal slowness of movement, sluggishness of physical and mental responses

**Dementia:** a mental disorder characterized by a general loss of intellectual abilities, involving impairment of memory, judgment, and abstract thinking, as well as changes in personality

**Dyskinesia:** impairment of voluntary movement, resulting in fragmentary or incomplete movements

**Dystonia:** a neurological movement disorder characterized by involuntary muscle contractions, which force certain parts of the body into abnormal, sometimes painful, movements or postures

**Encephalitis:** inflammation of the brain that may be due to a wide variety of causes

**Levodopa:** a drug commonly used to treat the symptoms of Parkinson's Disease

**Neuroleptic treatment:** treatment of a psychotic mental illness with antipsychotic medications

**Striatonigral:** referring to the connection of a part of the brain called the striatum with another named the substantia nigra

## **Coding**

*The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.*

### **When services may be Medically Necessary when criteria are met:**

#### CPT

61720	Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; globus pallidus or thalamus (stereotactic pallidotomy)
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#### ICD-9 Procedure

92.30	Stereotactic radiosurgery, not otherwise specified
92.39	Stereotactic radiosurgery, not elsewhere classified

#### ICD-9 Diagnosis

332.0	Paralysis agitans (includes Parkinsonism or Parkinson's disease, primary and idiopathic)
332.1	Secondary Parkinsonism
781.3	Dyskinesia

### **When services are Not Medically Necessary:**

For the procedure code listed above, when criteria are not met.

### **When services are Investigational/Not Medically Necessary:**

For procedure codes listed above, for all other diagnoses not listed; or when the code describes a procedure indicated in the Policy section as investigational/not medically necessary.

## References

### Peer Reviewed Publications:

1. Alkhani A, Lozano AM. Pallidotomy for parkinson disease: a review of contemporary literature. *J Neurosurg.* 2001; 94(1):43-9.
2. Baron MS, Vitek JL, Bakay RA, et al Treatment of advanced Parkinson's disease by unilateral posterior GPi pallidotomy: 4-year results of a pilot study. *Mov Disord.* 2000; 15(2):230-7.
3. de Bie RM, de Haan RJ, Nijssen PC, et al. Unilateral pallidotomy in Parkinson's disease. A randomised, single-blind, multicentre trial. *Lancet* 1999; 354:1665-9.
4. Fazzini E, Dogali M, Sterio D, et al. Stereotactic pallidotomy for Parkinson's disease: A long term follow-up of unilateral pallidotomy. *Neurology.* 1997; 48(5):1273-1277.
5. Green J, McDonald WM, Vitek JL, et al. Neuropsychological and psychiatric sequelae of pallidotomy for PD: clinical trial findings. *Neurology.* 2002; 58(6):858-65.
6. Hallett M, Litvan I. Task Force on Surgery for Parkinson's Disease. Evaluation of surgery for Parkinson's disease. A report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology.* 1999; 53:1910-1921.
7. Harrera EJ, Viano JC, et al. Posteroventral Pallidotomy in Parkinson's Disease. *Acta Neurochir (Wein).* 2000; 142:169-175.
8. Iacono RP, Lonser RR, Mandybur G, et al. Stereotactic pallidotomy results for Parkinson's exceed those of fetal graft. *Am Surg.* 1994; (60):777-782.
9. Kopyov O, Jacques D, Duma C, et al. Microelectrode-guided posteroventral medial radiofrequency pallidotomy for Parkinson's disease. *J Neurosurg.* 1997; 87(1):52-9.
10. Lozano AM, Lang AE. Pallidotomy for Parkinson's disease. *Neurosurg Clin N Am.* 1998; 9(2):325-336.
11. Masterman D, et al. Motor, cognitive, and behavioral performance following unilateral ventroposterior pallidotomy for Parkinson disease. *Arch Neurol.* 1998; 55(9):1201-8.
12. Merello M, Starksteinb S, Nouzeilles MI, et al. Bilateral pallidotomy for treatment of Parkinson's disease induced corticobulbar syndrome and psychic akinesia avoidable by globus pallidus lesion combined with contralateral stimulation. *J Neurol Neurosurg Psychiatry.* 2001; 71:611-614.
13. Merello M, Nouzeilles MI, Kuzis G, et al. Unilateral radiofrequency lesion versus electrostimulation of posteroventral pallidum: a prospective randomized comparison. *Mov Disord.* 1999; 14(1):50-6.
14. Olanow CW, Watts RL, Koller WC. An algorithm (decision tree) for the management of Parkinson's disease (2001): Treatment guidelines. *Neurology.* 2001; 56(Suppl 5):S1-S88.
15. Ondo WG, Jankovic J, et al. Assessment of motor function after stereotactic pallidotomy. *Neurology.* 1998; 50(1): 266-270
16. Vitek JL, Bakay RA, Freeman A, et al. Randomized trial of pallidotomy versus medical therapy for Parkinson's disease. *Ann Neurol.* 2003; 53(5):558-69.

### Government Agency, Medical Society, and Other Authoritative Publications:

1. Montgomery EB Jr. Evaluation of surgery for Parkinson's disease: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology.* 2000; 55(1):154.

## Web Sites for Additional Information

1. National Library of Medicine: Medical Encyclopedia. Parkinson's disease. <http://www.nlm.nih.gov/medlineplus/ency/article/000755.htm> Accessed May 17, 2005.

## Policy History

Status	Date	Action
Reviewed	06/08/2006	Medical Policy & Technology Assessment Committee (MPTAC) review. No change to policy position.
Revised	07/14/2005	MPTAC review. Revision based on Policy Harmonization: Per-merger

Anthem and Pre-merger WellPoint.

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
Anthem, Inc.	07/27/2004	SURG.00016	Stereotactic Radiofrequency Pallidotomy
WellPoint Health Networks, Inc.	06/24/2004	4.03.04	Stereotactic Radiofrequency Pallidotomy for the Treatment of Parkinson's Disease

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Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

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