



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Radiofrequency Ablation (RFA)
for Trigeminal Neuralgia**

Effective Date 9/15/2009
Next Review Date 9/15/2010
Coverage Policy Number 0182

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Hyperlink to Related Coverage Policies

Stereotactic Radiosurgery (SRS) and
Stereotactic Body Radiation Therapy
(SBRT)

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2009 CIGNA

Coverage Policy

CIGNA covers radiofrequency ablation as medically necessary for the treatment of trigeminal neuralgia when there is failure, contraindication or intolerance to pharmacological treatment.

CIGNA does not cover pulsed radiofrequency treatment for trigeminal neuralgia because it is considered experimental, investigational or unproven.

General Background

Trigeminal neuralgia (TGN), also called tic douloureux and Fothergill's disease, is a neurological condition affecting the sensory division of the fifth cranial (i.e., trigeminal) nerve and is characterized by recurrent episodes of severe, shock-like pain confined to the distribution of one or more of the nerve's three branches. In TGN, sudden and excruciating unilateral facial pain arises following stimulation of specific trigger zones by movement, drafts or touch.

TGN is diagnosed based upon clinical signs and symptoms. No specific diagnostic tests for TGN exist, although magnetic resonance imaging (MRI) is often used to exclude the presence of a tumor that could mimic symptoms similar to those of TGN. In younger persons with TGN, structural or other causes should be excluded (e.g., multiple sclerosis or compression due to tumors).

Pharmacotherapy is the first-line treatment for TGN and includes the use of analgesics, anticonvulsants, and/or antidepressants. If pharmacotherapy becomes ineffective, surgical treatments targeted to the root (i.e., rhizotomy), ganglion (i.e., gangliolysis) or branches of the trigeminal nerve may be utilized to eliminate pain, reduce the likelihood of recurrence, and prolong the time to recurrence. The intent of surgery is to selectively destroy pain fibers without inducing excessive sensory loss, motor dysfunction, or other complications. Invasive intracranial surgical procedures (e.g., stereotactic radiosurgery) as well as a variety of noninvasive procedures are being employed. Choice of the appropriate surgical procedure is based upon the area of nerve involvement, severity of symptoms, patient's age and comorbidities.

Radiofrequency ablation (RFA), also referred to as radiofrequency rhizotomy, thermal rhizotomy or electrocoagulation, is a commonly used noninvasive technique in which heat produced by radio waves is used to create a lesion in a sensory nerve, thereby interrupting the pain signal. During RFA, part of the sensory root of the trigeminal nerve above the ganglion or of the ganglion itself is destroyed by heat delivered through an electrode. In an effort to reduce risks, the stylet is guided by fluoroscopy, and intermittent anesthesia is employed. The correct ablation site is determined with patient feedback. If the patient is unable to localize the lesion during RFA, the surgeon may be able to complete the procedure through observation, physiological monitoring, or recording of sensory-evoked potentials induced by orthodromic (i.e., impulses conducted in the normal direction) stimulation of the three trigeminal divisions.

Pulsed radiofrequency (PRF) treatment has been proposed as an alternative therapy for TGN to avoid destruction of the nerve. PRF delivers current in intermittent bursts which allows time for heat elimination, minimizing the amount of thermal damage and thermal lesions while providing pain relief (Byrd and Mackey, 2008; Malik and Benzon, 2007). Compared to RFA, PRF is proposed to be less painful, but the duration of action is thought to be shorter and potentially, necessitating the need for repeat treatments. The evidence in the peer-reviewed literature does not support the efficacy of the use of PRF for the treatment of TGN.

U.S. Food and Drug Administration (FDA)

Ablation systems are approved by the FDA under the 510(k) process as a Class II electrosurgical cutting and coagulation accessory device. Examples of these devices include the Cool-tip™ RF Ablation System (Valleylab, Boulder, CO) and the Rita® System (Rita Medical Systems, Inc., Mountain View, CA). These devices are "intended for use in percutaneous, laparoscopic, intraoperative coagulation and ablation tissue, such as partial or complete ablation of non-resectable liver lesions and osteoma tumors" (FDA, 2006).

Literature Review - Radiofrequency Ablation: The evidence in the published peer-reviewed literature supports the safety and efficacy of RFA for the treatment of TGN. The studies include systematic reviews; prospective, uncontrolled clinical trials; comparative studies; and retrospective reviews. RFA has been compared to microvascular decompression, balloon microcompression, glycerol rhizotomy, partial trigeminal rhizotomy, neurectomy and alcohol block. Initial pain relief was reported in 83%–99% of patients treated with RFA. The treatment effect was maintained in 25–83% of patients for up to 20 years. (Lopez, et al., 2004; Cheng, et al., 2005; Sanchez-Mejia, et al., 2005; Kanpolat, et al., 2001; Mathews and Scrivani, 2000; Scrivani, et al., 1999; Zakrzewska, et al., 1999).

Literature Review - Pulsed Radiofrequency (PRF) Treatment: In 2007, Erdine et al. conducted a randomized controlled trial to compare the effects of conventional RFA (Group 1; n=20) to PRF therapy (Group 2; n=20) for the treatment of idiopathic TGN. The patients, age range 37–87 years, had been unsatisfactorily treated with medication, and other causes of the pain (e.g., tumor, multiple sclerosis) had been ruled out. Follow-up occurred monthly for six months. One day following conventional RFA, Group 1 Visual Analogue Scale (VAS) scores decreased significantly ($p<0.001$), and Patient Satisfaction Scale (PSS) results improved significantly ($p<0.05$). Following PRF, Group 2 VAS scores decreased in two of the 20 patients, with no significant differences reported in the PSS values. Because intractable pain nonresponsive to pharmacotherapy was reported three months postoperatively in all Group 2 patients, individuals were then treated with conventional RFA. Following conventional RFA, Group 2 VAS and PSS values improved significantly ($p<0.001$). At the six-month follow-up, the median VAS score was 0.5 in group 1 and 1.0 in Group 2. Group 1 did not require postoperative medication. Eighteen patients in Group 2 required pain medication up until the time they were treated with conventional RFA. Mild hypoesthesia and paresthesia were experienced following conventional RFA, and one patient was treated for anesthesia dolorosa. Limitations of the study include the small patient population and the short-term follow-up.

The initial pilot study using PRF for the treatment of idiopathic TGN (Van Zundert, et al., 2003) involved five “high-risk” patients (e.g., comorbidities, previous surgical intervention, pharmacotherapy intolerance), ages 67–81 years. Follow-up ranged from 10–26 months. Four patients were 90–100% pain-free without the use of pharmacotherapy at the last follow-up visit.

Professional Societies/Organizations

In their 2008 guidelines on the management of trigeminal neuralgia, the American Academy of Neurology and the European Federation of Neurological Societies state that patients with TGN who are refractory to medical therapy may be candidates for surgical intervention. Percutaneous procedures, including radiofrequency ablation, are a surgical option that may be considered (Cruccu, et al., 2008).

Summary

The evidence in the peer-reviewed literature supports the safety and efficacy of radiofrequency ablation (RFA) for the treatment of trigeminal neuralgia (TGN) in individuals who are refractory to pharmacotherapy. RFA has become a well established, noninvasive alternative to invasive surgical procedures (e.g., rhizotomy, microvascular decompression), avoiding the risks and complications of the invasive procedures.

Due to the limited number of clinical trials with small patient populations, short-term follow-ups and lack of sustained therapeutic benefit, the evidence in the peer-reviewed literature does not support the efficacy of pulsed radiofrequency (PRF) treatment for TGN.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT ^{®*} Codes	Description
64600	Destruction by neurolytic agent, trigeminal nerve; supraorbital, infraorbital, mental, or inferior alveolar branch
64605	Destruction by neurolytic agent, trigeminal nerve; second and third division branches at foramen ovale
64610	Destruction by neurolytic agent, trigeminal nerve; second and third division branches at foramen ovale under radiologic monitoring

ICD-9-CM Diagnosis Codes	Description
350.1	Trigeminal Neuralgia
053.12	Postherpetic trigeminal neuralgia

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
64999 [†]	Unlisted procedure, nervous system

[†]**Note:** Experimental, investigational, unproven and not covered when used to report pulsed radiofrequency treatment for trigeminal neuralgia.

*Current Procedural Terminology (CPT[®]) © 2008 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	09/15/2008	0182	Radiofrequency Ablation (RFA) for Trigeminal Neuralgia

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.