



CLINICAL MEDICAL POLICY	
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Disclaimer

Gateway Health™ (Gateway) medical policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Gateway HealthSM provides coverage under the medical-surgical benefits of the Company’s Medicaid products for medically necessary carpal tunnel surgical procedures to treat carpal tunnel syndrome.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person’s unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

DEFINITIONS

Carpal Tunnel – A narrow, rigid passageway of ligament and bones at the base of the hand. The carpal tunnel houses the median nerve and the tendons that bend the fingers. The median nerve provides feeling to the palm side of the thumb and to the index, middle, and part of the ring fingers. The median nerve also controls some small muscles at the base of the thumb.

Carpal Tunnel Syndrome – The clinical condition that occurs when the median nerve becomes pressed or entrapped where it passes under the transverse carpal ligament in the wrist. The median nerve becomes irritated, which leads to numbness, tingling, pain, and weakness in the hand. Typically, the syndrome affects the thumb, index, and middle fingers, and is often particularly troublesome at night. Pain may radiate proximally to the forearm or shoulder.

Open Carpal Tunnel Release – A surgical procedure performed to relieve pressure on the nerve located inside the carpal tunnel. The surgery involves severing the band of tissue in the hand and wrist to reduce pressure on the median nerve.

Endoscopic Carpal Tunnel Surgery – A less invasive surgical procedure that allows faster functional recovery and less postoperative discomfort than a traditional open release surgical procedure. The surgeon makes two half-inch incisions in the wrist and palm, inserts an endoscopic camera, observes the tissue on a screen, and cuts the carpal ligament.

Provocative Tests (Phalen’s test, Tinel’s sign, median nerve compression test, reverse Phalen’s) – Physical maneuvers which can be carried out in the clinic with little or no equipment, with the aim of temporarily increasing the carpal tunnel pressure and provoking symptoms. Some provoking symptoms include sleep, sustained hand or arm positions, and repetitive actions of the hand or wrist.

Sensory Examination – Sensory exams are the evaluation of somatic sensation. Testing focuses on pain sensation (pin prick), light touch sensation (brush), position sense, stereognosia, graphesthesia, and extinction. Some of the sensory testing include 2-point discrimination, Semmes-Weinstein monofilament, Strauch’s 10 test, etc.

Electromyogram (EMG) – A medical diagnostic test that measures the electrical activity of muscles when at rest and when in use, sometimes supplemented with needle electromyography.

Nerve Conduction Study (NCS) – A medical diagnostic test that measures the function, especially the ability of electrical conduction, of the motor and sensory nerves of the human body.

PROCEDURES

1. Carpal tunnel surgical procedures may be appropriate for patients that meet the following medical necessity criteria:
 - A. The patient has a relevant history consistent with carpal tunnel syndrome, including:
 - 1) Appropriate symptoms:
 - a) Numbness and tingling in the median nerve distribution;
 - b) Pain;
 - c) Focal swelling proximal to wrist crease;
 - d) Hand swelling;
 - e) Night paresthesia;
 - 2) Environmental factors (i.e., work-related, sports-related):
 - a) Forceful or repetitive hand movements;
 - b) Hand-arm vibration;
 - c) Traumatic event; AND
 - B. A physical examination of the patient’s affected hand(s) has been conducted, and:
 - 1) The provider performs an examination for deformity, swelling, atrophy, skin trophic changes (i.e., thenar eminence atrophy);

- 2) The provider performs clinical physical testing to confirm a CTS diagnosis, including:
 - a) A positive provocative testing (i.e., Phalen's test, Tinel's test, manual carpal compression, or hand elevation test); AND
 - b) The patient has an abnormal motor examination, consisting of:
 1. Low grade of Pinch/grip strength (*See Attachment C*); OR
 2. Weak abduction of the thumb; OR
 3. Proximal or hypothenar weakness; OR
 4. Atrophy of thenar bulk; OR
 5. Proximal atrophy; OR
 6. Abnormal reflexes; AND
 - b) The patient has an abnormal sensory examination demonstrating sensory loss in the hand, forearm OR upper arm (i.e. two-point discrimination test); AND
 - C. The provider should rule out or reveal other conditions to determine the appropriate treatment options; AND
 - D. The patient has mild CTS (*See Attachment B*) and has failed non-operative treatment measures within 3 months including:
 - 1) Local steroid injection; OR
 - 2) Splinting; OR
 - E. Conservative treatment may not be necessary in patients with severe CTS (*Please see Attachment B*); AND
 - F. Additional adjunctive testing such as an EMG or nerve conduction test may be appropriate when there is diagnosis uncertainty.
2. Gateway HealthSM may consider carpal tunnel surgery appropriate to be performed in conjunction with other major orthopedic surgical procedures.
 3. When carpal tunnel surgery services are not covered
Scientific evidence has not been established for conditions other than those listed above.

In addition, there is clinical research that identifies specific procedures that should not be performed in conjunction with carpal tunnel surgery, including:

- A. Skin nerve preservation is not a recommended procedure to be performed with a carpal tunnel release; OR
 - B. An epineurotomy is not a recommended procedure to be performed with a carpal tunnel release; OR
 - C. The following procedures carry no recommendation by the American Academy of Orthopaedic Surgeons to be performed in conjunction with carpal tunnel release surgery:
 - 1) Flexor retinaculum lengthening
 - 2) Internal neurolysis
 - 3) Tenosynovectomy
 - 4) Ulnar burse preservation
 - D. Thread Carpal Tunnel Release (TCTR)
4. Post-payment Audit Statement
The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway HealthSM at any time pursuant to the terms of your provider agreement.

Place of Service

The place of service for carpal tunnel release surgery is in the outpatient surgery setting.

SUMMARY OF LITERATURE

Carpal tunnel syndrome (CTS) is the most common entrapment neuropathy in the United States (Shi, 2011). The United States has 1-3 cases of CTS per 1,000 persons per year (AAOS, 2007). CTS is more frequent in women, with a female-to-male ratio of approximately 3:1 (Kothari, 2016). There are several possible causes of CTS, including congenital predisposition, trauma, repetitive maneuvers, gout, diabetes mellitus, hypothyroidism, obesity, and pregnancy (NIH, 2012). Repetitive motions have been an increasingly revealed cause of carpal tunnel syndrome. According to Johns Hopkins University Peripheral Nerve Surgery Center, people who engage in repetitive motions throughout their day have increasing chances to develop CTS. Some examples of people diagnosed with CTS include:

- People who use a computer keyboard and mouse for many hours throughout the day
- Carpenters
- Musicians
- Auto mechanics
- Gardeners
- Needleworkers
- Golfers
- Rowers

The high prevalence of CTS is partially due to the median nerve's extreme vulnerability to compression and injury in the wrist and palm region (Louisiana Workforce Commission, 2011). The median nerve has a high susceptibility to pressure that passes through the carpal tunnel in the concave arch space enclosed by the transverse carpal ligament (TCL) (MacDermid, 2004).

Early diagnosis of carpal tunnel syndrome is vital for a patient to receive optimal results (AAOS, 2007). In order to diagnose carpal tunnel syndrome, a qualified physician will base a determination on physical examination findings, and in specific circumstances, diagnostic testing may be used. According to the American Academy of Family Physicians (2011), "The diagnosis of carpal tunnel syndrome is primarily based on history and physical examination findings." A classic CTS clinical feature is pain or paresthesia, and bilateral CTS is the common first clinical presentation (Kothari, 2016). There are several elements of the clinical presentation that must be evaluated in order to give the correct diagnosis (MacDermid, 2004). Four elements of clinical presentation and examination include:

1. A relevant history documented from the patient regarding the symptoms, the intensity of the symptoms, the frequency of the symptoms, and environmental factors.
2. An observation of the patient to check for thenar eminence atrophy. Thenar eminence atrophy is the wasting of the thumb muscles, and occurs in advanced carpal tunnel syndrome. A patient's hand muscles will bulge from underneath the skin if the patient is positive for thenar eminence atrophy.
3. Provocative testing is necessary when diagnosing CTS. The provocative testing consists of maneuvers to stimulate CTS symptoms and should be conducted in a physical therapy clinical

examination. There are several forms of provocative testing for CTS, including Phalen’s wrist flexion test, Tinel’s test, and carpal compression testing.

4. Sensory evaluation is the final element in diagnosing carpal tunnel syndrome. Studies show that vibration and light touch threshold are affected early in nerve compression. Patients are asked to identify if touch within the median nerve distribution (on both hands) feels the same or different from a comparative site. Other sensory evaluation tests include the 10 test, the Semmes-Weinstein monofilaments (SWMF) test, West Enhanced Sensory Test filaments (WEST), Static 2-point discrimination, and Moving 2-point discrimination.

In addition to the history and physical clinical examination, the National Institute of Health has deemed X-ray studies and laboratory testing routine in order to rule out or reveal diabetes, arthritis, and fractures (NIH, 2012). The provider should find symptomatic evidence to initiate the investigation of the x-ray studies and lab work pertinent to diabetes, arthritis and fractures, including but not limited to:

Diabetes

- A1C test
- Glucose testing
- Blood sugar testing

Arthritis

- CBC/chemistry panels
- Rheumatoid Factor (RF)
- X-rays that focus on specific joints
- X-rays comparison to determine diagnosis and/or progression

Fractures

- X-rays of the bones

The American Academy of Orthopedic Surgeons (AAOS) highlights evidence-based practice (EBP) standards and the demand on physicians to use the optimal available evidence to guide the clinical decision-making process (AAOS, 2007). There is no single test that can effectively diagnose CTS, and it is unnecessary to perform all identified tests (MacDermid, 2004). Specific tests should be used in combination to diagnose in accordance with the severity of the patient’s symptoms (MacDermid, 2004). For example, the Phalen’s wrist flexion test and the carpal compression test are complimentary in terms of measuring provocation and interpretation; the two tests are also more sensitive for milder disease (MacDermid, 2004). Tinel’s test indicates severe cases of CTS and may be an additional test used to assign more aggressive treatment options, such as a carpal tunnel release (MacDermid, 2004). Nerve conduction tests and EMGs (electrodiagnostic testing) are seen as adjunctive and can be used to resolve diagnostic uncertainty (LeBlanc, 2011). Regardless of the increased diagnosing tools, there are limited studies performed combining clinical/physical testing with electrodiagnostic testing. Performance with electrodiagnostic testing and clinical presentation could not be identified in clinical studies (AAOS, 2007). There are instances where nerve conduction tests will have normal results even when the patient continues to suffer from CTS (Miedany, 2008). Several studies show there is no electrodiagnostic test that is exclusive and specific to the medical management of CTS; for example, nerve conduction tests are more specific to the diagnosis of tenosynovitis (Miedany, 2008). In some clinical cases, there has been expert opinion that nerve conduction studies and needle EMG can differentiate CTS from other peripheral nerve problems, such as polyneuropathy, brachial plexopathy, or cervical radiculopathy (AAOS, 2007). Very severe nerve injuries warrant more aggressive management and diagnostic evaluation, which add to the importance of ruling out other diagnoses. CTS treatment is based on the disease severity which is determined by the different types of diagnoses steps (LeBlanc, 2011).

Following the diagnosis parameters for carpal tunnel syndrome, the management and treatment of the condition must be executed to provide the patient with long-term relief. Most clinical literature indicates

two different paths of treatment for patients with a mild CTS condition versus patients with a moderate to severe CTS condition. Patients with mild CTS should consider six weeks to three months of conservative treatment, and the first-line therapy should be utilized (i.e., wrist splints and corticosteroids). Unfortunately, conservative management has been unsuccessful for a substantial amount of patients (Shi, 2011). Clinical studies have supported evidence that show surgical intervention has increased positive outcomes compared to conservative treatment, and surgical intervention has superior benefit in symptoms and function at six to twelve months (Shi, 2011).

Carpal tunnel release is one of the most common surgical procedures performed in the United States (NIH, 2012). There are two types of carpal tunnel release surgery:

1. Open release surgery is the traditional surgery to correct carpal tunnel syndrome
2. Endoscopic

Recurrence of carpal tunnel syndrome following surgery is rare, and the majority of patients fully recover (NIH, 2012). There is a higher rate of complications for surgical intervention, but the complications are mostly mild, and the benefits exceed the risk of the procedure (Shi, 2011). A large study shows patients with idiopathic CTS that were treated non-operatively had symptoms with an average duration between six and nine months (Brigham and Women's Hospital, 2007). According to Dr. Jonas L. Matzon (2008), 53% of participants waited two to seven weeks before changing to another non-operative treatment or surgery when the current carpal tunnel syndrome treatment failed. The National Institutes of Health (2012) recommends surgery if symptoms last for 6 months or there is evidence of a severe CTS case. Research indicates that severe CTS shows evidence of muscle damage with enhanced symptoms, such as thenar eminence atrophy (NIH, 2012).

The criteria stated in this policy is based on the recommendations of the American Academy of Orthopedic Surgeons (AAOS) as well as academic studies and reviews of CTS treatment. AAOS outlines a summary of recommendations that are compiled into an educational tool and used to guide qualified physicians through a series of treatment decisions to improve the quality and efficiency of care (AAOS, 2008).

Hayes (2016) performed a review on the Thread Carpal Tunnel Release (TCTR) procedure. The report noted that there is a very small published body of literature consisting of one case services and one cadaver study. There are no active clinical trials listed in the www.clinicaltrials.gov database. There is no National Coverage Determination (NCD) regarding this procedure on the Centers for Medicare & Medicaid Services (CMS) website. No other payer coverage policies were identified. The report concluded that there is insufficient published evidence to evaluate this technology.

Disease Classification in Carpal Tunnel Syndrome

CLASSIFICATION	DURATION	TWO-POINT DISCRIMINATION TEST	WEAKNESS	ATROPHY	ELECTROMYOGRAPHY*	NERVE CONDUCTION STUDIES*
Mild	Shorter than one year	Normal	Absent	Absent	No denervation	No to mild velocity decrease
Moderate	Shorter or longer than one year	Possible abnormality	Minimal presence	Minimal presence	No to mild denervation	No to mild velocity decrease
Severe	Longer than one year	Marked abnormality	Marked presence	Marked presence	Marked denervation	Marked velocity decrease

Source: <http://www.aafp.org/afp/2011/0415/p952.html>

Five Grades of Strength

Grade 5: Normal strength

Grade 4: Diminished strength to resistance

Grade 3: Enough strength to overcome gravity

Grade 2: Enough strength to contract but not to overcome gravity

Grade 1: Fibrillations or faintly palpable contractions

Grade 0: No contractions

CODING REQUIREMENTS

Procedure Codes

CPT/HCPCS Codes	Description
20526	Injection, therapeutic (e.g., local anesthetic, corticosteroid), carpal tunnel
29848	Endoscopy, wrist, surgical, with release of transverse carpal ligament
64721	Neuroplasty and/or transposition; median nerve at carpal tunnel

Diagnosis Codes

ICD-10 Codes	Description
G56.0	Carpal tunnel syndrome
G56.00	Carpal tunnel syndrome, unspecified upper limb
G56.01	Carpal tunnel syndrome, right upper limb
G56.02	Carpal tunnel syndrome, left upper limb
G56.03	Carpal tunnel syndrome, bilateral upper limbs

REIMBURSEMENT

Participating facilities will be reimbursed per their Gateway HealthSM contract.

POLICY SOURCE(S)

American Academy of Orthopaedic Surgeons, 2007. Clinical Practice Guideline on the Diagnosis of Carpal Tunnel Syndrome: Board of Directors. Accessed on March 28, 2017 and available at: http://www.aaos.org/Research/guidelines/CTS_guideline.pdf.

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Policy History

Date	Activity
04/15/2017	Initial policy developed
04/19/2017	QI/UM Committee approval
05/22/2017	PARP approval
07/19/2017	Provider effective date
07/25/2017	Revision: Removal of the internal Operational Guidelines.