



CLINICAL MEDICAL POLICY	
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Products:	Pennsylvania Medicare Assured
Application:	All participating and nonparticipating hospitals and providers
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Policy History

Date	Activity
11/01/2024	Provider Effective date
09/18/2024	QI/UM Committee review
09/18/2024	Annual Review: No change to clinical criteria. Updated 'Summary of Literature', 'Informational', and 'Reference Sources' sections.
04/01/2024	Provider Effective date
07/19/2023	QI/UM Committee review
07/19/2023	Annual Review: No changes to clinical criteria. Reformatted 'Procedures' section to match Medicaid guidance. Updated 'Summary of Literature' and 'Reference Sources' sections.
10/01/2022	Provider Effective date
07/20/2022	QI/UM Committee review
07/20/2022	Annual Review: No changes to clinical criteria. Reformatted 'Procedure' section numbering. Updated 'Summary of Literature' and 'Reference Sources' sections.
09/20/2021	Provider Effective Date
07/21/2021	QI/UM Committee Review
07/21/2021	Annual Review: Updated medical necessity language, 'any/and' statements, and

	formatting. Reformatted criteria in Procedure section 1.D. Updated Summary of Literature, and Reference sections.
07/06/2017	Initial policy developed

Disclaimer

Highmark WholecareSM medical policy is intended to serve only as a general reference resource regarding 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

Highmark WholecareSM may provide coverage under the medical-surgical benefits of the Company's Medicare 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.

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.

Carpal Tunnel Syndrome (CTS) – 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.

Hydrodissection – The process of Hydrodissection in the treatment of CTS for delivering an injection of fluids, usually normal saline, through a peripheral nerve block needle to help dissect entrapped nerves or move tendons or fascia surrounding a nerve to treat neurologic and musculoskeletal conditions. Purportedly, the movement may disrupt adhesions and alleviate inflammation.

Thread Carpal Tunnel Release (TCTR) – TCTR is an alternative to traditional CTS surgery. This technique uses a percutaneous approach via ultrasound to guide the transection of the transverse carpal ligament with a piece of thread looped around the ligament. This is purportedly designed to cut only the ligament while not damaging adjacent tissue.

Ultrasound-Guided Percutaneous Carpal Tunnel Release (PCTR) – PCTR combines identification and guidance of carpal tunnel anatomy using an ultrasound with minimal incisions as an alternative approach to carpal tunnel release surgery.

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 (endoscopic or open approach) may be considered medically necessary for patients who meet ALL of the following criteria:
 - A. An individual has a relevant history of consistent carpal tunnel syndrome, including ANY ONE of these appropriate symptoms:
 - 1) Persistent pain, sensory loss, or paresthesia in the median nerve distribution; OR
 - 2) Focal swelling proximal to wrist crease; OR
 - 3) Hand swelling; OR
 - 4) Night paresthesia; OR
 - 5) Environmental factors (i.e., work-related, sports-related):
 - a) Forceful or repetitive hand movements; OR
 - b) Hand-arm vibration; OR
 - c) Traumatic event; AND
 - B. A physical examination of the individuals affected hand(s) has been conducted, with ANY ONE the following:
 - 1) The provider has performed an examination for deformity, swelling, atrophy, skin trophic changes (i.e., thenar eminence atrophy); OR
 - 2) The provider has performed two (2) or more clinical physical examination maneuvers to confirm a CTS diagnosis, which include ANY of the following:
 - a) A positive provocative testing (i.e., Phalen’s test, Tinel’s test, manual carpal compression, or hand elevation test); OR

- b) The individual has an abnormal motor examination, consisting of:
 - I. Low grade of Pinch/grip strength; OR
 - II. Weak abduction of the thumb; OR
 - III. Proximal or hypothenar weakness; OR
 - IV. Atrophy of thenar bulk; OR
 - V. Proximal atrophy; OR
 - VI. Abnormal reflexes; OR
- c) The individual 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 has established that conditions have been treated as clinically appropriate and temporary precipitating factors are not present; AND
- D. The individual currently has moderate to severe CTS with significant evidence of nerve injury on electrodiagnostic study, OR has failed non-operative treatment measures within three (3) months including:
 - 1) Oral medications (e.g. NSAIDs, steroids); OR
 - 2) Glucocorticoid injection; OR
 - 3) Splinting.

Note: Highmark WholecareSM may consider a repeat carpal tunnel release surgery (endoscopic or open approach) medically necessary following a previously failed carpal tunnel release surgery. Individual approval consideration will be reviewed by a Medical Director on a case-by-case basis.

Note: Highmark WholecareSM may consider carpal tunnel surgery appropriate to be performed in conjunction with other major orthopedic surgical procedures.

- 2. Carpal tunnel surgery procedures are considered not medically necessary for any conditions not listed in this policy because the scientific evidence has not been established.

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

- Skin nerve preservation
- Epineurotomy
- Flexor retinaculum lengthening
- Internal neurolysis
- Tenosynovectomy
- Ulnar burse preservation
- Thread carpal tunnel release (TCTR)
- Ultrasound-guided percutaneous needle release (PCTR)
- Hydrodissection

- 3. Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark WholecareSM at any time pursuant to the terms of your provider agreement.

- 4. Place of Service

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

Operational Guidelines ***Do not include on external version***

- This medical policy will be applied to both professional providers and facility providers on a preservice, prepayment basis.
- The tables included below are for informational use only.
- Claims not meeting the medical necessity guidelines and coding requirements should deny as not medically necessary. Any requests for services that do not meet criteria set in the policy may be evaluated by a Medical Director as a program exception on a case-by-case basis.
- CPT code 64999 listed in the Coding Requirements section is not covered when applied to the diagnosis codes listed in the Coding Requirements section.

Coverage Determination

Highmark WholecareSM follows the coverage determinations made by CMS as outlined in either the National Coverage Determinations (NCD), or the state-specific Local Coverage Determination (LCD)/Local Coverage Article (LCA).

There are currently no published NCDs, LCD, or LCAs available during the development of this medical policy.

Summary of Literature

Carpal tunnel syndrome (CTS) is the most common entrapment neuropathy in the United States (Shi, 2011). CTS is the most common compressive neuropathy affecting the upper extremity and is an important cause of lost workplace productivity. The prevalence of CTS is estimated to be 0.7/10,000 workers. (AAOS, 2016).

According to the National Institutes of Health (NIH), CTS is often the result of a combination of factors that increase pressure on the median nerve and tendons in the carpal tunnel, rather than a problem with the nerve itself. These factors may include trauma or injury to the wrist that cause swelling, such as sprain or fracture; an overactive pituitary gland; an underactive thyroid gland; and rheumatoid arthritis. Other factors that may contribute to the compression include mechanical problems in the wrist joint, repeated use of vibrating hand tools, fluid retention during pregnancy or menopause, or the development of a cyst or tumor in the canal. Often, no single cause can be identified (NIH, 2020).

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). Carpal tunnel release is one of the most common surgical procedures performed in the United States (NIH, 2020).

Early diagnosis of CTS is vital for a patient to receive optimal results. In order to diagnose CTS, 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). One physical examination maneuver is not enough to definitely diagnose carpal tunnel syndrome (AAOS, 2016). There are several elements of the clinical presentation that must be evaluated in order to give the correct diagnosis (MacDermid, 2004).

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, 2020). 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 testing
 - Glucose testing
 - Blood sugar testing
- Arthritis
 - CBC/Chemistry Panels
 - Rheumatoid Factor (RF)
 - X-rays focusing on specific joints
 - X-ray comparisons to determine diagnosis and/or progression
- Fractures
 - X-rays of the bones

The American Academy of Orthopedic Surgeons (AAOS) guidelines on the management of carpal tunnel syndrome do not recommend the use of MRI imaging and/or Upper Limb Neurodynamic Testing based on "moderate evidence" (AAOS, 2024). The 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. There is no single test that can effectively diagnose CTS, and it is unnecessary to perform all identified tests. Specific tests should be used in combination to diagnose in accordance with the severity of the patient's symptoms. 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. 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, 2024). There are instances where nerve conduction tests will have normal results even when the patient continues to suffer from CTS. 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, 2024). 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. Clinical studies have supported evidence that shows 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. Imaging, MRI, and sonography are not recommended unless a space occupying lesion is suspected. (Shi, 2011).

There are two types of carpal tunnel release surgery:

- Open release surgery (OCTR) is the traditional surgery to correct carpal tunnel syndrome, which can be performed through a standard incision or a limited incision.
- Endoscopic carpal tunnel release (ECTR), which can be performed through a single or double portal.

Recurrence of carpal tunnel syndrome following treatment is rare. Less than half of individuals report their hand(s) feeling completely normal following surgery. Some residual numbness or weakness is common (NIH, 2020). 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. Treatments for carpal tunnel syndrome should begin as early as possible, under a doctor's direction. Underlying causes such as diabetes or arthritis should be treated first (NIH, 2020).

Although some PCTR devices have received PMA premarket approval, there are still unanswered questions to the contraindications of the percutaneous procedure, the release extent at the deepest layer portions, best approach, best location, and best advancing direction of the instrument (Nakamichi 2010, de la Fuente 2012, McShane 2012, Rojo-Manuante 2013).

Hydrodissection is another novel procedure that is commonly used in the treatment of carpal tunnel syndrome (CTS) for delivering injectate around the nerve. Hydrodissection also uses platelet-rich plasma (PRP) for CTS, which functions as growth factors that support the regeneration and repair of damaged nerves. The benefits of nerve hydrodissection, include significant and long-lasting pain relief, improvement in function and range of motion, and a decrease in the use of analgesics (Inovo Medical). The literature on hydrodissection has mixed conclusions. Some insurers indicate a low-level of evidence and lack of randomization/blinding, which does not demonstrate effectiveness, leading to inevitable selection bias (Cass, 2016).

UpToDate (2019) recommends surgical decompression for most patients with CTS who have severe median nerve injury, characterized by significant axonal degeneration on nerve conduction studies or denervation on needle EMG, unless there is a clear temporary precipitating factor such as pregnancy. Patients who lack evidence of significant axonal loss or denervation can be treated initially with nonsurgical measures. Surgical decompression can be beneficial to patients with CTS who lack evidence of axonal loss or denervation if symptoms do not respond to an adequate trial of nonsurgical measures.

Rationale

In 2018, the results of a prospective clinical study investigating of hydroneurolysis and hydrodissection in the treatment of CTS was reported. A total of 31 CTS sufferers who refused an open operation were treated with a simple ultrasound-guided injection at the proximal carpal tunnel. Follow up with Q-DASH score and visual analogue scale was collected in 2, 4 and 8 weeks. At the end of 8 weeks only 2 of 14 patients (control group) treated with infiltration only experienced clinical improvement. The remaining 16 patients experienced worsening of CTS and all were waiting for surgical repair. The authors concluded that treatment of nerve entrapment syndromes with normal saline hydrodissolution is non-effective as a conservative treatment (Malahais, et al., 2018).

A systematic review found that evidence of low quality suggests that ECTR is associated with less time spent out of work or daily activities and that patients treated with ECTR return to work on average 10 days earlier than those treated with OCTR. The quality of evidence is low to very low regarding complications, reoperations and recurrence of symptoms and does not favor either of the interventions; future studies are unlikely to alter this conclusion primarily due to the rare nature of the outcomes. Low quality evidence suggests an uncertain advantage of ECTR with respect to minor complications. The effect of a learning curve might be responsible for reduced recurrences and reoperations with ECTR in studies that are more recent (Vasiliadis, Nikolakopoulou, Shrier, et al., 2015).

A randomized controlled trial was conducted to investigate manual therapy versus surgery in the treatment of carpal tunnel syndrome. This trial was conducted in a tertiary public hospital and included 120 women with CTS who were randomly allocated to manual therapy or surgery. The participants received 3 sessions of physical therapy, including desensitization maneuvers of the central nervous system or carpal tunnel release combined with a tendon/nerve gliding exercise program at home. The trial showed that, in the long term, manual therapy, including desensitization maneuvers of the central nervous system, resulted in similar outcomes and similar surgery rates compared with surgery in women with CTS. Both interventions were combined with a tendon/nerve gliding exercise program at home. Women with CTS may receive similar benefit from a more conservative treatment—manual therapy—as they would from surgery (Fernández-de-las-Peñas, 2020).

Coding Requirements

Procedure Codes

CPT Code	Description
29848	Endoscopy, wrist, surgical, with release of transverse carpal ligament
64721	Neuroplasty and/or transposition; median nerve at carpal tunnel

Non-covered Procedure Codes

CPT Code	Description
64999	Unlisted procedures, nervous system

Diagnosis Codes

ICD-10 Code	Description
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 Highmark WholecareSM contract.

Informational

Disease Classification in Carpal Tunnel Syndrome

<i>Classification</i>	<i>Duration</i>	<i>Two-point discrimination test</i>	<i>Weakness</i>	<i>Atrophy</i>	<i>Electromyography*</i>	<i>Nerve conduction studies*</i>
Mild	Shorter than 1 year	Normal	Absent	Absent	No denervation	No to mild velocity decrease
Moderate	Shorter or longer than 1 year	Possible abnormality	Minimal presence	Minimal presence	No to mild denervation	No to mild velocity decrease
Severe	Longer than 1 year	Marked abnormality	Marked presence	Marked presence	Marked denervation	Marked velocity decrease

* - If performed

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

The Medical Research Council of Great Britain (MRC) system is the best known and most commonly used muscle strength grading system for manual muscle testing (MMT) worldwide (James, 2007).

Grade	Muscle State
0	No contraction
1	Flicker or trace of contraction
2	Active movement with gravity eliminated
3	Active movement against gravity
4	Active movement against gravity and resistance
5	Normal power

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