Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 9/1/24**

Title: CARPAL TUNNEL RELEASE NOVEL METHODS

Description/Background

Carpal Tunnel Syndrome (CTS) is a condition that occurs when the median nerve can become compressed at the wrist. Individuals may have symptoms of pain, weakness and/or numbness in the wrist and hand, radiating up the thumb and arm. Individuals who perform recurrent/repetitious activities are at increased risk for developing carpal tunnel syndrome. Carpal tunnel syndrome can develop with pregnancy and conditions that include rheumatoid arthritis, thyroid disease or diabetes.

Initial treatment includes resting to the affected wrist and hand, limiting activities that enhance symptoms and use of a wrist splint. Nonsteroidal anti-inflammatory drugs (NSAIDS) or oral steroids may be utilized for pain relief. Corticosteroid injections are also given to decrease swelling and pressure on the median nerve. If conservative treatment has failed, carpal tunnel release surgery via an endoscopic or open approach may be necessary.

Surgery for carpal tunnel syndrome includes cutting the transverse carpal ligament, removing pressure on the median nerve, and assists with reduction of symptoms. The conventional surgical approach is open surgery, where an incision is made at the base of the palm and the surgeon has direct view access to the ligament. Endoscopic surgery uses a small flexible tube with a camera attached and the surgeon can view the ligament for repair.

Ultrasound guided procedures has been used in the management of carpal tunnel syndrome since the 1980s. The first report of US-guided carpal tunnel release (CTR) was published in 1997, with cadaver and clinical reports confirming the safe navigation of surgical tools with US for division of the transverse carpal ligament. The MANOS CTR device was recently reported as a minimally invasive tool for CTR and may be well suited for use with US guidance[1].

MANOS
The MANOS Carpal Tunnel Release device is a blade that divides the transverse carpal ligament using wrist and palm skin punctures. The awake individual provides feedback as the surgeon navigates a 2.1-mm-diameter blunt probe across the undersurface of the ligament from a wrist incision with standard disposable nerve stimulator monitoring. The leading tip of the blunt probe is uninsulated and conducts 2 mA. The surgeon converts the blunt insulated probe into an uninsulated blade by advancing a 0.9-mm needle through the palm with a thumb-activated deployment feature. The surgeon saws the ligament through the 2 skin punctures.[1] A newer percutaneous technique, entitled “MANOS CTR”, uses passage of a blunt monitored probe under the transverse carpal ligament, using ultrasound control. The ligament is then divided after converting the blunt probe to an uninsulated blade, with ultrasound control. The MANOS technique was named after Dr. Manos from using ultrasound and a medical device called MANOS (MANOS CTR™, Thayer Intellectual Property, Inc., San Francisco, CA) for CTR, followed by three case reports.[1] 13-6 MHz transducer (Sonosite, Bothell, Washington, USA) positioned at the hook of the hamate and the tubercle of the trapezium was used to confirm safe zones of device insertion.

Thread Carpal Tunnel Release (TCTR)
(TCTR) is also a minimally invasive procedure for transecting the transverse carpal ligament by transection of the ligament with a piece of thread looped percutaneously under ultrasound guidance. The thread is routed using a spinal needle with only two puncture sites and is performed under local anesthesia and in an office setting.

Ultrasound-guided Percutaneous Carpal Tunnel Release (PCTR)
Percutaneous Carpal Tunnel Release (PCTR) combines identification and guidance of carpal tunnel anatomy using ultrasound with minimal incisions. Although the incision size varies across procedures, the reviewed studies used incision sizes ranging from ≤ 1 to 5 millimeters. The tool used to release the transverse carpal ligament also varies (e.g., hook knife, surgical thread, angled blade, needle). A percutaneous carpal tunnel release (PCTR) technique uses a hook knife introduced percutaneously at the wrist under ultrasound guidance.

Hydrodissection
The process of hydrodissection in the treatment carpal tunnel syndrome describes the delivery of injection of fluids, ex: 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. The movement may disrupt adhesions and alleviate inflammation.

Regulatory Status

Food and Drug Administration (FDA): MANOS, Thread Carpal Tunnel Release (TCTR), Percutaneous Carpal Tunnel Release (PCTR) for carpal tunnel syndrome (CTS) are types of procedures and are therefore not subject to FDA regulation. However, any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation. Orthopedic manual surgical instruments that were mentioned in the reviewed studies that have received FDA clearance are listed in Table 1.

Table 1. FDA-Cleared Products Used in Reviewed Studies for MANOS

Key: K, 510(k) premarket submission; PMA, premarket approval

Device	K Number or PMA Number	Notice Date	Indication
SX-One MicroKnife	K192873	12/20/2019	Orthopedic Manual Surgical Instrument
GE LOGIQ Book	K032477	10/22/2003	General purpose ultrasound system
Hitachi NOBLUS	K160559	10/18/2016	General purpose ultrasound system
Phillips IU22	K130499	6/18/2013	General purpose ultrasound system

Medical Policy Statement

The use of the following Carpal Tunnel Release Novel Methods including MANOS, Thread Carpal Tunnel Release (TCTR) procedures, ultrasound-guided percutaneous carpal tunnel release (PCTR) and Hydrodissection are considered **experimental and investigational** for treatment of Carpal Tunnel Syndrome (CTS).

NOTE:
Carpal tunnel release is a relatively simple and safe procedure, done easily under local anesthetic with either open or endoscopic methods. Both of these methods involve a direct visualization of the median nerve with an exceptionally low rate of incomplete release. These open and endoscopic procedures are represented by their own specific codes.

CPT code 29848 describes endoscopic release of the transverse carpal ligament of the wrist. CPT code 64721 describes a neuroplasty and/or transposition of the median nerve at the carpal tunnel and includes open release of the transverse carpal ligament.

Inclusionary and Exclusionary Guidelines

NA

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

NA

Other codes (investigational, not medically necessary, etc.):

25999[a] 64999[b]

Note: when the above codes a, b are specified as thread carpal tunnel release, MANOS, ultrasound-guided percutaneous needle release or Hydrodissection

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Petrover et al (2016)[2] evaluated the feasibility and 6 months clinical results of sectioning of the transverse carpal ligament (TCL) and median nerve decompression after ultra-minimally invasive, ultrasound-guided percutaneous carpal tunnel release (PCTR) surgery. Consecutive patients with carpal tunnel syndrome were enrolled in this descriptive, open-label study. The procedure was performed in the interventional radiology room. Magnetic resonance imaging was performed at baseline and 1 month. The Boston Carpal Tunnel Questionnaire was administered at baseline, 1, and 6 months.129 patients were enrolled into the study. Magnetic resonance imaging showed a complete section of all TCL and nerve decompression in 100% of patients. No complications were identified. In summary, Ultrasound-guided PCTR was used successfully to section the TCL, decompress the median nerve, and reduce self-reported symptoms.

Eberlin et al. (2022),[3] TUTUOR (Trial of Ultrasound guided CTR versus Traditional Open Release) is a randomized controlled trial in which 120 subjects at up to 12 sites in the United States were randomized (2:1) to receive CTR-US or mini open carpal tunnel release (mOCTR). The primary endpoint of the study is the percentage of patients who return to normal daily activities within 3 days of the procedure. Secondary endpoints of the study are median time to return to normal daily activities, percentage of patients who return to work within 3 days of the procedure, median time to return to work, Boston Carpal Tunnel Questionnaire Symptom Severity Scale (BCTQ-SSS) change score at 3 months, BCTQ Functional Status Scale (BCTQ-FSS) change score at 3 months, Numeric Pain Scale change score at 3 months, EuroQol-5 Dimension 5 -Level (EQ-5D-5L) change score at 3 months, and the incidence of device-or procedure-related adverse events at 3 months. Patient follow-up in this trial continued for 1 year. The trial aimed to determine if ultrasound guidance could improve the precision and efficacy of carpal tunnel release procedures compared to traditional open surgery methods. The results derived from the TUTOR will fill an important research gap because there is currently limited evidence directly comparing the safety and effectiveness of CTR-US and mOCTR.

Kamel et al. (2021)[4] A retrospective review was conducted of 61 ultrasound-guided carpal tunnel release procedures performed on 46 patients (15 bilateral procedures) with clinically diagnosed carpal tunnel syndrome. The procedures were performed with a single-use transection device and local anesthesia at an outpatient radiology office. Patients answered three questionnaires (Quick Disabilities of the Arm, Shoulder, and Hand [QDASH] and two parts of the Boston Carpal Tunnel Syndrome Questionnaire-the symptom severity [BCTSQ-SS] and functional status [BCTSQ-FS] scales) to assess the function of and discomfort in the

affected wrist immediately before and 2 weeks and at least 1 year after the procedure. Higher scores indicated increasing disability. Patients also answered a global satisfaction question at follow-up. The pre-procedure and post-procedure scores were compared by paired Wilcoxon signed rank tests. Ultrasound-guided carpal tunnel release quickly improves hand function and reduces hand discomfort; improvement persists beyond 1 year. CLINICAL IMPACT: Ultrasound-guided carpal tunnel release may be a safe, effective, and less invasive alternative to traditional surgery.

Guo et at. (2017)[5] concludes that thread carpal tunnel release (TCTR) is a minimally invasive procedure for transecting the transverse carpal ligament (TCL) by cutting the ligament with a piece of thread looped percutaneously under the guidance of ultrasound (US). This procedure has been proposed as an alternative technique for performing carpal tunnel release for the treatment of CTS. To date, the published evidence has been limited by interventional challenges including risk for injuring the superficial palmar arterial arch (SPA) if the needle exits too distally or a risk of incomplete transaction of distal TCL if the needle exits too proximally. Other concerns include injury of the common digital branch or the communicating branch between the ulnar nerve and median nerve, called the Berrettini branch.

Park et al. (2022)[6] is a retrospective review study of total of 22 TCTR procedures performed on 19 patients by one physiatrist during a 42-month period. The diagnosis of carpal tunnel syndrome was based on standard clinical criteria including electromyography (EMG). Patients were divided into two groups, one dissected with commercial thread and the other with Smartwire-01. The technique was standardized by keeping the entry point at the middle of the palm and the exit point at just medial to the palmaris longus tendon. The Numeric Rating Scale (NRS) and Boston Carpal Tunnel Syndrome Questionnaire (BCTQ) were used to assess monthly outcomes for 6 months following the procedure. The Wilcoxon signed rank test and the Mann-Whitney-U test were performed to analyze the above variables in the two groups. Results: There was no definite evidence that the two groups have significant differences for any of the surveyed variables. The TCTR procedure with the newly developed thread also had significant improvements for all variables, showing its effectiveness in both pain and functional ability. The NRS and BCTQ severity and functional scales showed significant decreases just after the dissection and progressive improvement during each monthly follow-up of our study until the last assessment at 6 months. Conclusion: The study suggests that, the newly developed thread is as safe and effective as the commercial thread in TCTR, we therefore recommend a randomize controlled trial with above methodology.

Wang et al. (2019)[7] the purpose of this study was to evaluate the effectiveness of ultrasound-guided percutaneous carpal tunnel release in hemodialysis patients with carpal tunnel syndrome. From February 2009 to April 2013, a prospective review of 113 consecutive cases of ultrasound-guided percutaneous carpal tunnel release was carried out in 84 hemodialysis patients. Results were analyzed by clinical subjective scale, two self-administered questionnaires, and functional evaluations at seven time points (1 week and 1, 3, 6, 12, 18, and 24 months). Results: Satisfactory symptom improvement in patients was 82%, 80%, 86%, 89%, 90%, 91%, and 90% at 1 week and 1, 3, 6, 12, 18, and 24 months postoperatively, respectively. Moderate pain was suffered in 11.5% of patients within 1 week, 8.8% within 1 month, 2.7% within 3 months, and none after 12 months postoperatively. Static two-point discrimination and Semmes-Weinstein monofilament examinations presented significant improvements after 1 week and 1 month postoperatively and with time. Postoperative grip power demonstrated recovery and a significant increase after 3 and 6 months postoperatively.

Three-jaw chuck-pinch strength showed significant increase after 1 month postoperatively. There were no operative complications. Conclusion: Ultrasound-guided percutaneous carpal tunnel release is an effective and safe procedure in hemodialysis patients with carpal tunnel syndrome. The advantages include a less invasive procedure, no tourniquet needed, only limited infiltration anesthesia, minimal soft-tissue exploration, and relatively short operation time. Our data suggest this technique can reliably relieve clinical symptoms, with early restoration of grip and pinch strength.

Neo et at. (2022)[8] Hydrodissection is an ultrasound-guided technique that has received more attention recently for its role in nerve entrapment syndromes. The purposes of this systematic review were to evaluate the safety and effectiveness of hydrodissection in carpal tunnel syndrome and to investigate the ideal parameters for injectate type, dosage, volume, and frequency; injection approach and technique; as well as operator experience and training required. The publishers searched the Embase, MEDLINE, and PubMed databases with supplemental searches in the CINAHL, Web of Science, and Google Scholar databases for relevant randomized controlled trials. Primary outcome measures were adverse outcomes and clinical effectiveness. Six randomized controlled trials involving 356 wrists were included. All studies used ultrasound guidance in their interventions. No safety-related adverse outcomes were found, although not all studies declared this. Only one study was placebo controlled and revealed symptomatic as well as functional improvements at 6 months, whereas the rest investigated hydro dissection with different injectate types. They concluded that nerve hydro dissection for carpal tunnel syndrome can be safely performed under ultrasound guidance. However, it is unclear whether the hydro dissection mechanism truly causes improvements in clinical outcomes. They were also unable to draw conclusions regarding the ideal procedure-related parameters. They recommended that future work should not only investigate safety and clinical effectiveness but also attempt to clarify the ideal procedure-related parameters.

Summary of Evidence:

The evidence reviewed individuals with carpal tunnel syndrome who had surgery through MANOS, Thread Carpal Tunnel Release (TCTR), ultrasound-guided percutaneous carpal tunnel release (PCTR) and/or hydro dissection. We reviewed one feasibility study, one randomized control trial (RCT), two case studies, and two retrospective surgery groups. Overall, these minimally invasive techniques, ultrasound-guided ones, offer promising outcomes for individuals with carpal tunnel syndrome. They tend to reduce recovery times, have lower rates of complications and allow for quicker return to normal activities compared to open surgery. However, they require specialized training and careful use to avoid potential risks of nerve or artery injury. The studies reviewed were small and larger RCTs are recommended. Further treatment comparison studies are required to determine their comparative therapeutic efficacy and effect on health outcomes.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

American Academy of Orthopedic Surgeons (AAOS): In 2016,[9] the AAOS issued an evidence-based guideline on management of CTS (AAOS, 2016). The AAOS stated that limited evidence supports that if surgery is chosen as treatment, endoscopic carpal tunnel release (ECTR) should be used because of possible short-term benefits. This guideline did not mention Ultrasound-guided Percutaneous Carpal Tunnel Release (PCTR), MANOS or Thread Carpal Tunnel Release (TCTR).

Government Regulations
National:

Local:

No LCD or NCD

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Low-Level Laser And High-Power Laser Therapy

References

1. Buncke G, McCormack B, Bodor M. Ultrasound-guided carpal tunnel release using the manos CTR system. Microsurgery. 2013 Jul;33(5):362-6. doi: 10.1002/micr.22092. Pub 2013 Feb 18. PMID: 23417956.
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9. American Academy of Orthopedic Surgeons. Management of Carpal Tunnel Syndrome Evidence-Based Clinical Practice Guideline. Endorsed by the American Society for Surgery of the Hand, American Society of Plastic Surgeons, American College of Radiology, American College of Surgeons, and the American Society of Anesthesiologists. Published February 29, 2016. Available at: Carpal Tunnel Syndrome - Clinical Practice Guideline (CPG) | American Academy of Orthopaedic Surgeons (aaos.org) Accessed 5/1/24

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 5/1/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
9/1/24	6/11/24		Joint policy established (jf) Vendor Managed: NA

Next Review Date: 2nd Qtr, 2025

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: CARPAL TUNNEL RELEASE NOVEL METHODS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Experimental/Investigational
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.