

LASER INTERSTITIAL THERMAL THERAPY

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[Instructions for Use](#) ⓘ

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Related Commercial Policy

- [Intrauterine Fetal Surgery](#)

Community Plan Policy

- [Laser Interstitial Thermal Therapy](#)

COVERAGE RATIONALE

Laser interstitial thermal therapy is unproven and not medically necessary for treating ANY condition or diagnosis due to insufficient evidence of efficacy.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

CPT Code	Description
19499	Unlisted procedure, breast
32999	Unlisted procedure, lungs and pleura
53899	Unlisted procedure, urinary system
55899	Unlisted procedure, male genital system
64999	Unlisted procedure, nervous system

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DESCRIPTION OF SERVICES

Laser interstitial thermal therapy/thermotherapy (LITT) is an emerging treatment modality. The LITT treatment produces focal thermal ablation leading to lesion cyto-reduction through tissue coagulation, necrosis, and cellular apoptosis. Historically, laser ablation techniques have been limited by an inability to assess ablation progress and parenchymal temperature during the course of treatment. Advances in MRI capabilities have overcome these limitations, leading to the use of this technology for select conditions.

CLINICAL EVIDENCE

Epilepsy

A systematic review and analysis by Lagman et al. examined 2 commercially available magnetic resonance-guided laser interstitial thermal therapy (MRgLITT) systems used in neurosurgery: the Visualase® thermal therapy and NeuroBlate® Systems. Data extraction was performed in a blinded fashion. Twenty-two articles reflecting 223 patients were included in the analysis. The majority of patients received treatment with Visualase (n=154, 69%) with epilepsy being the most common indication (n=8 studies, 47%). Brain mass was the most common indication for NeuroBlate (n=3 studies, 60%). There were no significant differences, except in age, wherein the NeuroBlate group was nearly

twice as old as the Visualase group ($p < 0.001$). Frame, total complications, and length-of-stay were non-significant when adjusted for age and number of patients. Several limitations were cited in this analysis, including but not limited to inherent bias in selection and reporting and recognized issues of retrospective studies. The authors concluded that MRgLITT procedures have demonstrated effectiveness in the treatment of a variety of epilepsy etiologies and tumor pathologies. While laser neurosurgery has evolved over recent decades and clinical indications are currently being defined, long-term outcomes have yet to be fully elucidated (2017).

In a retrospective review, Waseem et al. evaluated a number of outcome measures, including seizure freedom, neuropsychological performance, complications, and other considerations on 38 patients presenting exclusively with mesial temporal lobe epilepsy (MTLE) and no other lesions (including neoplasia) who underwent MRgLITT. Eighteen (53%) had an Engel class I outcome, 10 patients had repeat procedures/operations, and 12 post-procedural complications occurred. Follow-up time ranged from 6 to 38.5 months. There was a decreased length of procedure time, hospitalization time, and analgesic requirement when compared to open surgery. In cases of well-localized MTLE, MRgLITT may offer similar (albeit slightly lower) rates of seizure freedom versus traditional surgery. The authors concluded that MRgLITT may be an alternative treatment option for high risk surgical patients and, more importantly, could increase referrals for surgery in patients with medically refractory MTLE. However, data is limited and long-term outcomes have not been evaluated. Further investigation is required to understand the potential of this minimally invasive technique for MTLE (2016).

Kang et al. (2016) prospectively tracked seizure outcome from a single center study which included 20 patients with drug-resistant MTLE who underwent MRgLITT from December 2011 to December 2014. Surgical outcome was assessed at 6 months, 1 year, 2 years, and at the most recent visit. Volume-based analysis of ablated mesial temporal structures was conducted in 17 patients with mesial temporal sclerosis (MTS) and results were compared between the seizure-free and not seizure-free groups. Following LITT, proportions of patients who were free of seizures impairing consciousness (including those with auras only) are as follows: 8 of 15 patients after 6 months (53%), 4 of 11 patients after 1 year (36.4%), and 3 of 5 patients at 2-year follow up (60%). Median follow-up was 13.4 months post-LITT. Seizure outcome after LITT suggests an "all or none" response. Four patients had anterior temporal lobectomy (ATL) after LITT; 3 are seizure-free. There were no differences in total ablated volume of the amygdalohippocampus complex or individual volumes of hippocampus, amygdala, entorhinal cortex, parahippocampal gyrus, and fusiform gyrus between seizure-free and non-seizure-free patients. Contextual verbal memory performance was preserved after LITT, although decline in noncontextual memory task scores were noted. The authors concluded that stereotactic MRgLITT is a safe alternative to ATL in patients with medically intractable MTLE. Individualized assessment is warranted to determine whether the reduced odds of seizure freedom are worth the reduction in risk, discomfort, and recovery time. Larger prospective studies are needed to confirm preliminary findings, and to define optimal ablation volume and ideal structures for ablation. Limitations to this review include a prospective review in a single center, as well as small sample size.

Tao et al. (2018) assessed outcomes of a combination therapy using both invasive electroencephalography-guided and stereotactic MRgLITT in the treatment of 19 individuals with drug-resistant MTLE. In all, 52% achieved freedom from disabling seizures at mean follow-up of 24 months. Further differentiating those with and without MTS, 73% and 30% of patients, respectively, were seizure-free at 2 years. The authors concluded that this technology can be a safe and effective alternative to traditional surgical approaches, particularly in patients with MTS, but larger-scale studies are likely needed.

A 2016 systematic review of LITT analyzed 2 studies on epilepsy and 4 on intracranial lesions (2 of which assessed the same patient population). Three studies were case series, and 2 were non-randomized controlled studies. There was substantial heterogeneity among the included studies, in terms of LITT device used, type of LITT, comparator, patient population, and outcomes measured. Among the 2 studies on epilepsy, 1 found that the LITT group experienced significantly less decline in famous face recognition and common names compared to stereotactic laser ablation hippocampotomy (SLAH). The other study found no statistically significant difference between seizure rates for those who had MRgLITT compared to anterior mesial temporal resection. Findings showed that length of stay (LOS) was significantly shorter as was surgical time for those in the MRgLITT group, and the need for pain control was significantly less. Despite not finding a statistically significant improvement in seizure rates for those in the LITT group, this result suggests that LITT is equally effective at reducing seizures, while resulting in less pain, and shorter LOS. The authors did note that LITT is not included in any clinical practice guidelines or incorporated into clinical care pathways for brain tumors or epilepsy (Leggett et al.).

Shukla et al. (2017) performed a review and summary of the evidence to date on the utilization of MRgLITT for MTLE and other seizure disorders. In a review, the authors concluded that MRgLITT is a safe and effective therapeutic option for epilepsy in both the adult and pediatric populations. With improved outcomes and better side effect profile than other minimally invasive procedures, it enables surgical management of patients who are not good candidates for, or are otherwise opposed to, open resection. Study limitations included small sample sizes, the lack of availability of long-term outcomes data, and a scarcity of RCTs. Future studies may seek to address these gaps.

To report the feasibility, safety, and clinical outcomes of an exploratory study of MRgLITT as a minimally invasive surgical procedure for the ablation of epileptogenic foci in children with drug-resistant, lesional epilepsy, Lewis et al. (2015) performed a retrospective chart review of all MRgLITT procedures at a single tertiary care center. All procedures were performed using a U.S. Food and Drug Administration (FDA)-cleared surgical laser ablation system (Visualase Thermal Therapy System). Predefined clinical and surgical variables were extracted from archived medical records. From May 2011 to January 2014, 17 patients underwent 19 MRgLITT procedures. Mean age at seizure onset was 7.1 years, and mean age at surgery was 15.3 years. Surgical substrates were mixed but mainly composed of focal cortical dysplasia (n = 11). Complications occurred in 4 patients. Average postoperative hospital LOS was 1.56 days. Mean follow-up was 16.1 months (n = 16; range 3.5-35.9 months). Engel class I outcome was achieved in 7 patients (7/17; 41%), Engel class II in 1 patient (1/17; 6%), Engel class III in 3 patients (3/17; 18%), and Engel class IV in 6 patients (6/17; 35%). Three patients (3/8; 38%) with class I and II outcomes and 5 patients (5/9; 56%) with class III and IV outcomes had at least 1 prior resection. Fisher's test was not statistically significant for the association between Engel class outcome and previous resection. The authors concluded that the study provided descriptive results regarding the use of MRgLITT in a mixed population of pediatric, lesional, drug-resistant epilepsy cases. Further multicenter, prospective studies are required to delineate optimal candidates for MRgLITT, and larger cohorts are needed to more accurately define outcome and complication rates.

Professional Societies

American Association of Neurological Surgeons (AANS)

The AANS has not taken a position on LITT for treating patients with refractory epilepsy.

American Academy of Neurology (AAN)

The AAN policies and guidelines do not address LITT for treating patients with epilepsy.

Brain Tumors

An extensive literature search was performed by Ashraf et al. on LITT and laser therapy in the context of glial tumors, metastatic lesions, pediatric brain tumors, and radiation necrosis. Reported complications in each series also were reviewed. Multiple studies have demonstrated the use, outcomes, and complications associated with LITT in neurosurgery over the past decade. While these same studies have consistently reported an overall benefit of LITT in cases in which traditional approaches are less advantageous, there have been complications reported from local effects of thermal damage, technical error, and edema development. Increased experience with the technology has reduced complications and brought more promising results, but standard protocols are lacking. The authors concluded that while LITT has shown efficacy in the treatment of gliomas, intracranial metastases, radiation necrosis, and pediatric brain tumors, larger studies and clinical trials must be done to develop standardized protocols and indications for use (2018).

Eichberg et al. (2018) performed a pilot study on 4 individuals with recurrent cerebellar metastases who were treated with MR-LITT. The extrapolated average time for the lesion to shrink to below the initial size was 294.5 days. There was a trend toward a decrease in average edema volume from the preoperative MRI of 17.8 cm to final postoperative follow-up MRI of 3.4 cm. No postoperative hydrocephalus or complications occurred. The authors concluded that MR-LITT appears to be a safe and promising treatment for recurrent posterior fossa metastatic lesions up to 7.2 cm. Further RCTs are needed to further study the long-term efficacy of this therapy.

Tovar-Spinoza and Choi published the preliminary results of the first series of pediatric brain tumors treated with MRgLITT at a single pediatric center. Outcomes were evaluated retrospectively for 11 patients with 12 tumors of 6 different types, all treated with the Visualase thermal laser system (Medtronic) between February 2012 and August 2014. Medical records, radiological findings, surgical data, complications, and results of tumor volumetric analyses were reviewed. A single laser and multiple overlapping ablations were used for all procedures. The mean hospital LOS was 3.25 days, and the mean follow-up time was 24.5 months. Tumor volume in all patients decreased in the first 3 months after surgery and continued to decrease by the 4- to 6-month followup. Two patients experienced transient post-ablation complications. The authors concluded that MRgLITT is an effective first- or second-line treatment for select pediatric brain tumors. Larger multiinstitutional clinical trials are necessary to evaluate its use for different types of lesions to further standardize practices (2016).

Ivan et al. (2016) conducted a meta-analysis on the use of MR-LITT in the treatment of newly diagnosed high-grade gliomas (HGG). Eighty-five articles were identified plus 1 that is pending publication. Four articles were accounted for in this review in which 25 adults underwent LITT treatments. On average, 83% of the pretreatment lesion volume was ablated. The average tumor volume treated was 16.5 cm., and the mean follow-up time was 7.6 months. Median overall survival was 14.2 months (range 0.1-23 months). The median progression-free survival was 5.1 months (range 2.4-23 months); however, these data are limited by the relatively short follow-up of the patients reviewed and small sample size. Only one participant suffered a major perioperative complication (CNS infection). The researchers concluded that MR-LITT is a safe and promising technology for the treatment of small, yet difficult-to-treat newly diagnosed HGG, and that future randomized studies are needed to evaluate the role of this technology.

Hayes conducted a review of published literature on LITT for treatment of glioblastoma. Eighteen abstracts were retrieved, including 6 prospective studies (collective number of study participants = 64); 5 retrospective studies (n=127, collectively); 1 cost-benefit analysis ; 3 systematic reviews; and 3 review articles. A few abstracts for pediatric studies of LITT for glioblastoma were noted but were not retrieved as this report was focused on adult glioblastoma. Researchers concluded that there is sufficient published evidence to evaluate LITT for treatment of glioblastoma, however the study abstracts present conflicting findings regarding this technology. Full text review is required to confirm abstract content and, therefore, conclusions about the safety and efficacy of this technology cannot be made until a full assessment has been completed (2017).

Lee et al. (2016) conducted a review of the peer reviewed literature evaluating the role of LITT in the treatment of recurrent HGGs for which current treatments have limited efficacy, and to discuss the possible role of LITT in the disruption of the blood-brain barrier to increase delivery of chemotherapy locoregionally. Six of 17 articles were thought to be most appropriate for this review. Sixty-four lesions in 63 patients with recurrent HGGs were treated with LITT. Frontal (n = 34), temporal (n = 14), and parietal (n = 16) were the most common locations. Permanent neurological deficits, vascular injuries, and wound infection were seen in 7, 2, and 1 patients, respectively. Ablation coverage of the lesions ranged from 78% to 100%. The authors concluded that although experience using LITT for recurrent HGGs is growing, current evidence is insufficient to offer a recommendation about its role in the treatment paradigm for recurrent HGGs.

Barnett et al. conducted a systematic review and meta-analysis of the peer-reviewed literature to identify studies which examined extent of resection (EOR) or extent of ablation (EOA) and major complications (defined as neurocognitive or functional complications which last >3 months post-surgery) associated with either brain LITT or open craniotomy in HGGs in or near areas of eloquence. Eight studies on brain LITT (n = 79) and 12 craniotomy studies (n = 1,036) were identified which examined either/both EOR/EOA and complications. Meta-analysis demonstrated an EOA/EOR of 85.4 ± 10.6% with brain LITT versus 77.0 ± 40% with craniotomy (mean difference 8%) and major complications of 5.7% and 13.8% for LITT and craniotomy, respectively. The authors concluded that in patients presenting with HGGs in or near areas of eloquence, early results demonstrate that brain LITT may be a viable surgical alternative (2016).

Evidence-based clinical practice guidelines endorsed by the Agency for Healthcare Research and Quality (AHRQ) do not address LITT in the management of patients with diffuse low grade glioma (Ryken, et al. 2015) or progressive glioblastoma (Olson et al., 2014).

Professional Societies

American Society for Radiation Oncology (ASTRO)

ASTRO does not address LITT in an executive summary of its evidence-based clinical practice guidelines on treatment for glioblastoma (Cabrera, 2016).

American Association of Neurological Surgeons (AANS)

AANS does not address LITT in its evidence-based clinical practice guideline for management of progressive glioblastoma (2014).

Breast Tumors

Kerbage et al. (2017) performed a systematic review to evaluate the scientific publications investigating the LITT approach in malignant and benign breast disease. Three preclinical studies and 8 clinical studies (2 including fibroadenomas and 6 including breast tumors) were reviewed. Although the feasibility and safety of LITT have been confirmed in a phase I trial, heterogeneous inclusion criteria and methods seem to be the main reason for LITT not being yet an extensively used treatment option. The authors concluded that further development is necessary before this technique can be used in daily practice.

Haraldsdóttir et al. (2015) reviewed the effect of immunological changes induced by interstitial laser thermotherapy (ILT) on long-term outcome of patients with breast tumors. Twenty-four patients with invasive breast tumors were treated with ILT followed by standard surgical excision. Immunohistological reactions on immunocompetent cells were performed on specimens obtained before and after ILT. Follow-up time ranged from 91-136 months. The authors concluded that ILT did not have any long-term adverse effects. The clinical impact should be examined in a larger patient population.

Hayes conducted a review of published literature describing outcomes of LITT for treatment of breast tumors. Evidence consisted of 10 abstracts which included 1 prospective comparative study (n = 17), 6 prospective uncontrolled studies (collective number of study participants = 664), and 3 review articles. Only 4 of the 7 study abstracts described LITT for breast tumors specifically. Those studies were very small, with overlap of investigators and possible overlap of patient groups. The remaining 3 studies described outcomes of LITT for breast tumor-related

liver metastases rather than breast tumors per se and were included for informational purposes. Researchers concluded that there is insufficient published evidence to assess the safety and/or impact of LITT on health outcomes or patient management when treating of breast tumors (2018).

Prostate Tumors

A systematic review & meta-analysis by Valerio et al. (2017) summarized the evidence regarding sources of energy employed in focal therapy for treatment of prostate tumors. Thirty-seven articles reporting on 3230 patients undergoing focal therapy were selected, with one of the focal therapies being LITT. Four prospective Stage 1 to 2a studies evaluating LITT in 50 patients have been reported in literature. One study included only men with low-risk disease, whereas the other studies included also Gleason $\leq 4+3$, although risk stratification was not clearly reported. The median age was 63.5 yrs; median PSA was 5.4 ng/ml; median follow-up was 4.5 months with all series including mandatory sampling after treatment. In the Stage 1 study, all men underwent radical prostatectomy, whereas in the other 3 studies men underwent TRUS standard and/or targeted biopsy. Overall, the presence of significant and insignificant tumors was 4.8% and 22.2%, respectively. The probability of transition to secondary local treatment was 0%; overall and disease-specific survival, pad-free continence and potency preservation were 100% and 100%, respectively. No adverse events were reported in any study. The authors concluded that focal therapy seems safe and appears to offer good preservation of genito-urinary function. Tumor control in studies with intention to treat is encouraging, although this needs to be verified against standard of care in high quality comparative effectiveness trials.

Hayes conducted a review of published literature on MRI-guided focal laser ablation for the treatment of prostate tumors. Eight abstracts were retrieved which included prospective studies, a longitudinal outcomes study, a case series, 2 case reports, and a consensus paper. The 7 clinical studies retrieved evaluated very small numbers of patients (total N=64) using poor-quality study designs, without standardization of prostate-specific antigen (PSA), clinical stage, Gleason score, or life expectancy. Oncological follow-up was either not performed or was short-term (3-12 months). Researchers concluded that there was insufficient published evidence to assess the safety and/or impact on health outcomes or patient management with MRI-guided focused laser ablation for the treatment of prostate tumors (2016).

Bone Tumors

Spinal LITT (sLITT) appears to be a promising modality for treatment of epidural metastatic spine disease in patients who are poor candidates for larger-scale procedures, and it works well with spinal stereotactic radiosurgery to maximize local control and palliate pain. Utilizing intraoperative MRI guidance, sLITT was performed on 19 individuals with a variety of tumor types where metastatic vertebral disease was identified. The degree of epidural infiltration ranged from the tumor extending to the epidural space without displacement of the dura to epidural compression displacing the spinal cord with complete obliteration of the cerebrospinal fluid space. Median number of vertebral segments treated was 1 (range 1–3), with 80% of the involvement being the thoracic spine. Median hospital LOS was 2 days (range 1–14). One participant experienced post procedure transient L1 monoparesis, which resolved after 8 weeks. A second sLITT procedure was required at 16 and 33 weeks post procedure for 2 patients. One patient required salvage surgical intervention because of delayed progressive neurologic deterioration, and 1 patient developed a pathologic compression fracture 2 months post treatment requiring percutaneous stabilization. Mean preoperative Visual Analog Scale scores of 4.72 improved to 2.56 at 1 month and remained improved at 3 months postoperatively. Thirteen participants decreased their use of pain medication, whereas 3 increased medication usage (although only 1 of the 3 was a result of back pain). Preoperative mean quality of life index of 0.67, was unchanged at 1 month postoperatively, and improved to 0.83 at 3 months. MRI at 2 months post procedure showed a mean reduction in epidural tumor thickness of 22%, and the numeric scale of graded epidural compression showed an improvement from a preoperative mean of 3.8 to 2.9. The authors stated that the role of sLITT in the management of spinal metastasis needs to be compared with conventional surgery in a prospective RCT, and that this initial evidence on the potential applicability of the technique will lay the foundation to pursue such a study (Thomas et al., 2017).

A Hayes report was performed on the use of LITT for the treatment of osteoid osteoma. A small body of literature was identified that spanned over 20 years which included a total of 14 abstracts (1 prospective uncontrolled study, 2 retrospective comparative studies, 6 retrospective uncontrolled studies, 1 retrospective cost comparison, 3 case reports, and 1 systematic review). with a total N = . Most of the studies were small and uncontrolled (total N = 354). Overlap of investigators was noted for several of the studies, which means there may have been overlap of patient groups as well. Researchers concluded that while there is sufficient published evidence to evaluate this technology, the study abstracts present conflicting findings regarding LITT for the treatment of osteoid osteoma. Full-text review is required to confirm abstract content and, therefore, conclusions about the safety and efficacy of this technology cannot be made until a full assessment has been completed (2018).

Professional Societies

American Academy of Orthopaedic Surgeons (AAOS)

The AAOS does not endorse LITT for treatment of osteoid osteoma (2014).

Radiation Necrosis

Medvid et al. discussed radiation necrosis (RN) in an overview of applications of MRgLITT when treating brain pathology. Studies during the past 20 years report the use of LITT to treat a variety of brain lesions. The most studied lesions include glioma and metastases. Epilepsy and RN represent a much smaller subset of treated lesions reported in the literature, but RN is one of the 4 most common indications for the procedure. LITT induces resolution of RN, but long-term data are limited due to low numbers and lack of sufficient long-term follow-up. The authors concluded that LITT may provide a safe curative option in cases of RN. While studies offer a plethora of evidence on the safety profile of the procedure, evidence is limited because to date, all studies consist of noncontrolled, nonrandomized retrospective reports, case series, or case reports, thus predisposing to selection bias. Also, many of the studies mix multiple disease entities to increase the number of enrolled subjects; this mixture makes the evaluation of survival benefits for a given disease difficult (2015).

The National Comprehensive Cancer Network (NCCN) Practice Guidelines do not address laser thermal therapy or laser ablation as treatment in tumors of the prostate, central nervous system, bone, or lung, or as treatment for radiation necrosis (2018).

There are multiple clinical trials studying LITT for various conditions which are in varying stages of activity. Additional information is available at: www.clinicaltrials.gov.

Professional Societies

American Society of Clinical Oncology (ASCO)

ASCO clinical guidelines do not address laser thermal therapy as treatment in tumors of the genitourinary system, head and neck, breast, bone, or in neurooncology (2018).

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

LITT is a procedure and, therefore, not subject to FDA regulation.

The NeuroBlate® System (Monteris Medical, MN) enables MRI-guided neurosurgical ablation, monitoring 3-D and providing real time imaging to support a surgeon's clinical decision matrix. The device was FDA approved on October 26, 2016. Additional information is available at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K162762>. (Accessed April 30, 2018)

The Visualase® Thermal Therapy System (Medtronic, MN) provides advanced MRI-guided laser ablation technology for thermal ablation markets, including neurosurgery. Delivery of laser energy results in rising temperatures in the target area, destroying the unwanted tissue. The device was FDA approved on September 10, 2008. Additional information is available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K081656>.

(Accessed April 30, 2018)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for laser interstitial thermal therapy. Local Coverage Determinations (LCDs) do not exist at time.

(Accessed April 17, 2018)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
12/01/2018	<ul style="list-style-type: none">Simplified coverage rationale (no change to guidelines)Archived previous policy version 2018T0584C

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.