Magnetic Resonance-Guided Focused Ultrasound

Policy # 00180
Original Effective Date: 09/22/2005
Current Effective Date: 05/10/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Occlusion of Uterine Arteries Using Transcatheter Embolization or Laparoscopic Occlusion is addressed separately in medical policy 00130.

Note: Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors is addressed separately in medical policy 00175.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider magnetic resonance–guided high-intensity ultrasound ablation for pain palliation in adult patients with metastatic bone cancer who failed or are not candidates for radiotherapy to be **eligible for coverage.****

Based on review of available data, the Company may consider magnetic resonance-guided high-intensity ultrasound ablation for the treatment of medicine-refractory essential tremors to be **eligible for coverage.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers magnetic resonance-guided high-intensity ultrasound ablation to be **investigational*** in all other situations including but not limited to:

- Treatment of uterine fibroids; and
- Treatment of other tumors (eg, brain cancer, prostate cancer, breast cancer, desmoid).

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Background/Overview

Uterine Fibroids

Uterine fibroids are one of the most common conditions affecting women in the reproductive years. Symptoms of uterine fibroids include menorrhagia, pelvic pressure, or pain.

Treatment

Several approaches currently available to treat symptomatic uterine fibroids include hysterectomy, abdominal myomectomy, laparoscopic and hysteroscopic myomectomy, hormone therapy, uterine artery embolization, and watchful waiting. Hysterectomy and various myomectomy procedures are considered the criterion standard treatments.

Metastatic Bone Disease

Metastatic bone disease is one of the most common causes of cancer pain.

Treatment

Existing treatments include conservative measures (eg, massage, exercise) and pharmacologic agents (eg, analgesics, bisphosphonates, corticosteroids). For patients who do not respond to these treatments, standard care is external-beam radiotherapy. However, a substantial proportion of patients have residual pain after radiotherapy, and there is a need for alternative treatments for these patients.

Essential Tremors

ET is the most common movement disorder, with an estimated prevalence of 5% worldwide. ET most often affects the hands and arms, may affect head and voice, and rarely includes the face, legs, and trunk. ET is heterogeneous among patients, varying in frequency, amplitude, causes of exacerbation, and association with other neurologic deficits.

Treatment

The neuropathology of ET is uncertain, with some evidence suggesting that ET is localized in the brainstem and cerebellum. If patients with ET experience intermittent or persistent disability due to the tremors, initial therapy is with drugs (b-blockers or anticonvulsants). For medicine-refractory patients, surgery (deep brain stimulation or thalamotomy) may be offered, though high rates of adverse events have been observed.

Magnetic Resonance-Guided Focused Ultrasound
MRgFUS is a noninvasive treatment that combines 2 technologies: focused ultrasound and magnetic resonance imaging (MRI). The ultrasound beam penetrates through the soft tissues and, using MRI for guidance and monitoring, the beam can be focused on targeted sites. Ultrasound causes a local increase in temperature in the target tissue, resulting in coagulation necrosis while sparing the surrounding normal structures. Ultrasound waves from each sonication are directed at a focal point that has a maximum focal volume of 20 nm in diameter and 15 nm in height/length. This causes a rapid rise in temperature (ie, to 65°C-85°C), which is sufficient to ablate tissue at the focal point. In addition to providing guidance, the associated MRI can provide online thermometric imaging, a temperature "map", to confirm the therapeutic effect of the ablation treatment and allow for real-time adjustment of the treatment parameters.

The U.S. Food and Drug Administration (FDA) approved the ExAblate MRgFUS system (InSightec) for 2 indications: treatment of uterine fibroids (leiomyomata) and palliation of pain associated with tumors metastatic to bone. The ultrasound equipment is specifically designed to be compatible with magnetic resonance magnets, and it is integrated into standard clinical MRI units; it also includes a patient table, which has a cradle that houses the focused ultrasound transducer in water or a light oil bath. Some models have a detachable cradle; only certain cradle types can be used for palliation of pain associated with metastatic bone cancer. For treating pain associated with bone metastases, the aim of MRgFUS is to destroy nerves in the bone surface surrounding the tumor.

MRgFUS is also being investigated for the treatment of other tumors, including breast, prostate, brain, and desmoid tumors as well as nonspinal osteoid osteoma.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
In October 2004, the ExAblate®‡ 2000 System (InSightec) was approved by the FDA through the premarket approval process for "ablation of uterine fibroid tissue in pre- or perimenopausal women with symptomatic uterine fibroids who desire a uterine sparing procedure." Treatment is indicated for women with a uterine gestational size of fewer than 24 weeks who have completed childbearing.

In October 2012, the ExAblate®‡ System, Model 2000/2100/2100 VI, was approved by the FDA through the premarket approval process for pain palliation in adults with metastatic bone cancer who

have failed or are not candidates for radiotherapy. The device was evaluated through an expedited review process. The FDA required a post approval study with 70 patients to evaluate the effectiveness of the system under actual clinical conditions.

In July 2016, the FDA approved the use of the ExAblate®‡ Neuro System for the treatment of ET in patients who have not responded to medication (b-blockers or anticonvulsant drugs) through the premarket approval process.

FDA product codes: NRZ, POH.

Rationale/Source

Description

An integrated system providing magnetic resonance-guided focused ultrasound (MRgFUS) treatment is proposed as a noninvasive therapy for uterine fibroids and pain palliation of bone metastases. MRgFUS is also being investigated as a treatment of other benign and malignant tumors as well as essential tremors.

Summary of Evidence

For individuals who have uterine fibroids who receive MRgFUS, the evidence includes 2 small randomized controlled trials (RCTs), nonrandomized comparative studies, and case series. Relevant outcomes are symptoms, quality of life, resource utilization, and treatment-related morbidity. One RCT (n=20) has reported some health outcomes but its primary purpose was to determine the feasibility of a larger trial. It did not find statistically significant differences in quality of life outcomes between active and sham treatment groups but it did find lower fibroid volumes after active treatment. This trial did not have an active comparator, the clinical significance of the primary outcome was unclear, and there were no follow-up data beyond 1 year. The second RCT (n=49) is ongoing; preliminary results at 6 weeks post treatment, comparing MRgFUS with uterine artery embolization have shown that the 2 groups are comparable in medication use and symptom improvement following treatments. Patients in the MRgFUS group reported recovering significantly faster than patients in the uterine artery embolization group, as measured by time to return to work and time to normal activities. In a separate 2013 comparative study, outcomes appeared to be better with uterine artery embolization than with MRgFUS. Long-term data on the treatment effects,

recurrence rates, and impact on future fertility and pregnancy are lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with metastatic bone cancer who have failed or are not candidates for radiotherapy who receive MRgFUS, the evidence includes a sham-controlled randomized trial and several case series. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The RCT found statistically significant improvements after MRgFUS in a composite outcome comprised of a reduction in pain and morphine use, and in pain reduction as a stand-alone outcome. A substantial proportion of patients in the treatment group experienced adverse events but most events were transient and not severe. The case series reported reductions in pain following MRgFUS treatment, consistent with the RCT. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with other tumors (eg, breast cancer, brain cancer, prostate cancer, desmoid, nonspinal osteoid osteoma) who receive MRgFUS, the evidence includes small case series. Relevant outcomes are symptoms, health status measures, and treatment-related morbidity. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with medicine-refractory essential tremors who receive MRgFUS, the evidence includes 2 systematic reviews that identified an RCT and several observational studies. Relevant outcomes include symptoms, functional outcomes, quality of life, and treatment-related morbidity. The assessment did not pool study results but concluded that, overall, MRgFUS decreased tremor severity and improved quality of life. The sham-controlled randomized trial found significant improvements in the treatment group in tremor severity, functional improvement, and quality of life after 3 months of follow-up. The improvements in hand tremor score, function, and quality of life were maintained at the 2 year follow-up. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

American Society for Radiation Oncology

In 2017, the American Society for Radiation Oncology published guidelines on palliative radiotherapy for bone metastases, which stated that external-beam radiotherapy continues to be the primary therapy for treating painful uncomplicated bone metastases. The guidelines did not mention magnetic resonance-guided focused ultrasound. If patients experience persistent or recurrent pain more than 1 month after initial treatment, the guidelines recommended retreatment with external-beam radiotherapy. As for advanced radiotherapy such as stereotactic body radiotherapy for retreatment of recurrent pain in spine bone lesions, these "may be feasible, effective, and safe, but the panel recommends that this approach should be limited to clinical trial participation or on a registry given limited data supporting routine use."

National Comprehensive Cancer Network
Guidelines from the National Comprehensive Cancer Network on bone cancer (v.1.2020), breast cancer (v.4.2020), brain cancer (v.2.2020), and prostate cancer (v.1.2020) do not mention magnetic resonance-guided ultrasound as a treatment option.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01833806[a]	A Phase IV Post Approval Clinical Study of ExAblate Treatment of Metastatic Bone Tumors for the Palliation of Pain	70	Oct 2020
NCT01473485[a]	A Study to Evaluate the Safety and Feasibility of Transcranial MRI-Guided Focused Ultrasound Surgery in the Treatment of Brain Tumors	10	Dec 2022
NCT00147056[a]	A Study to Evaluate the Safety and Feasibility of Transcranial MRI-Guided Focused Ultrasound Surgery in the Treatment of Brain Tumors	10	Dec 2022
NCT02252380[a]	A Feasibility Clinical Trial of the Magnetic Resonance Guided Focused Ultrasound (MRgFUS) for the Management of Treatment-Refractory Movement Disorders	10	Dec 2021
NCT02260752	Comparing Options for Management: Patient-Centered Results for Uterine Fibroids	3,094	Apr 2020
NCT02968784[a]	Focal ExAblate MR Guided Focused Ultrasound Treatment for Management of Organ-Confined Intermediate Risk Prostate Cancer: Evaluation of Safety and Effectiveness	68	Jun 2022
NCT01657942[a]	Focal MR Guided Focused Ultrasound Treatment of Localized Low and Intermediate Risk Prostate Lesions	101	Jan 2021
NCT03998657	A Continued Access Study to Evaluate Focal MR-Guided Focused Ultrasound Treatment of Localized Intermediate Risk Prostate Lesions	25	Dec 2022
Unpublished			

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01285960[a]	A Clinical Study to Evaluate Safety of the ExAblate Model 2100 Type 1.1 System in the Treatment of Symptomatic Uterine Fibroids	106	Apr 2016 (completed)
NCT01620359[a]	Study of ExAblate Focused Ultrasound Ablation of Breast Cancer under MR Guidance and MRI Evaluation of Ablation	14	Jul 2016 (completed)
NCT01834937[a]	A Post Approval Registry: ExAblate Treatment of Metastatic Bone Tumors for the Palliation of Pain	17	Apr 2017 (completed)
NCT00981578[a]	A Feasibility Study to Evaluate the Safety and Initial Effectiveness of ExAblate MR Guided Focused Ultrasound Surgery in the Treatment of Pain Resulting from Metastatic Bone Tumors with the ExAblate 2100 Conformal Bone System	37	Nov 2016
NCT02794558[a]	A Clinical Study to Evaluate the Safety and Effectiveness of MR Guided Focused Ultrasound Surgery in the Treatment of Early Breast Carcinomas	100	Mar 2019

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Magnetic Resonance-Guided Focused Ultrasound", 7.01.109, 8:2020.
2. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Magnetic resonance-guided focused ultrasound therapy for symptomatic uterine fibroids. TEC Assessments. 2005;Volume 20:Tab 10.

3. Barnard EP, AbdElmagied AM, Vaughan LE, et al. Periprocedural outcomes comparing fibroid embolization and focused ultrasound: a randomized controlled trial and comprehensive cohort analysis. Am J Obstet Gynecol. May 2017; 216(5): 500.e1-500.e11. PMID 28063909
4. Jacoby VL, Kohi MP, Poder L, et al. PROMISe trial: a pilot, randomized, placebo-controlled trial of magnetic resonance guided focused ultrasound for uterine fibroids. Fertil Steril. Mar 2016; 105(3): 773-780. PMID 26658133
5. Gizzo S, Saccardi C, Patrelli TS, et al. Magnetic resonance-guided focused ultrasound myomectomy: safety, efficacy, subsequent fertility and quality-of-life improvements, a systematic review. Reprod Sci. Apr 2014; 21(4): 465-76. PMID 23868442
6. Chen R, Keserci B, Bi H, et al. The safety and effectiveness of volumetric magnetic resonance-guided high-intensity focused ultrasound treatment of symptomatic uterine fibroids: early clinical experience in China. J Ther Ultrasound. 2016; 4: 27. PMID 27822376
7. Froeling V, Meckelburg K, Schreiter NF, et al. Outcome of uterine artery embolization versus MR-guided high-intensity focused ultrasound treatment for uterine fibroids: long-term results. Eur J Radiol. Dec 2013; 82(12): 2265-9. PMID 24075785
8. Rabinovici J, David M, Fukunishi H, et al. Pregnancy outcome after magnetic resonance-guided focused ultrasound surgery (MRgFUS) for conservative treatment of uterine fibroids. Fertil Steril. Jan 2010; 93(1): 199-209. PMID 19013566
9. Hurwitz MD, Ghanouni P, Kanaev SV, et al. Magnetic resonance-guided focused ultrasound for patients with painful bone metastases: phase III trial results. J Natl Cancer Inst. Apr 23 2014; 106(5). PMID 24760791
10. Liberman B, Gianfelice D, Inbar Y, et al. Pain palliation in patients with bone metastases using MR-guided focused ultrasound surgery: a multicenter study. Ann Surg Oncol. Jan 2009; 16(1): 140-6. PMID 19002530
11. Arrigoni F, Barile A, Zugaro L, et al. Intra-articular benign bone lesions treated with Magnetic Resonance-guided Focused Ultrasound (MRgFUS): imaging follow-up and clinical results. Med Oncol. Apr 2017; 34(4): 55. PMID 28244018
12. Zippel DB, Papa MZ. The use of MR imaging guided focused ultrasound in breast cancer patients; a preliminary phase one study and review. Breast Cancer. 2005; 12(1): 32-8. PMID 15657521
13. Hynynen K, Pomeroy O, Smith DN, et al. MR imaging-guided focused ultrasound surgery of fibroadenomas in the breast: a feasibility study. Radiology. Apr 2001; 219(1): 176-85. PMID 11274554

14. Gianfelice D, Khiat A, Amara M, et al. MR imaging-guided focused US ablation of breast cancer: histopathologic assessment of effectiveness-- initial experience. Radiology. Jun 2003; 227(3): 849-55. PMID 12714680
15. Gianfelice D, Khiat A, Amara M, et al. MR imaging-guided focused ultrasound surgery of breast cancer: correlation of dynamic contrast-enhanced MRI with histopathologic findings. Breast Cancer Res Treat. Nov 2003; 82(2): 93-101. PMID 14692653
16. Merckel LG, Knuttel FM, Deckers R, et al. First clinical experience with a dedicated MRI-guided high-intensity focused ultrasound system for breast cancer ablation. Eur Radiol. Nov 2016; 26(11): 4037-4046. PMID 26852219
17. McDannold N, Clement GT, Black P, et al. Transcranial magnetic resonance imaging- guided focused ultrasound surgery of brain tumors: initial findings in 3 patients. Neurosurgery. Feb 2010; 66(2): 323-32; discussion 332. PMID 20087132
18. Napoli A, Anzidei M, De Nunzio C, et al. Real-time magnetic resonance-guided high-intensity focused ultrasound focal therapy for localised prostate cancer: preliminary experience. Eur Urol. Feb 2013; 63(2): 395-8. PMID 23159454
19. Geiger D, Napoli A, Conchiglia A, et al. MR-guided focused ultrasound (MRgFUS) ablation for the treatment of nonspinal osteoid osteoma: a prospective multicenter evaluation. J Bone Joint Surg Am. May 07 2014; 96(9): 743-51. PMID 24806011
20. Avedian RS, Bitton R, Gold G, et al. Is MR-guided High-intensity Focused Ultrasound a Feasible Treatment Modality for Desmoid Tumors?. Clin Orthop Relat Res. Mar 2016; 474(3): 697-704. PMID 26040967
21. Bucknor MD, Rieke V. MRgFUS for desmoid tumors within the thigh: early clinical experiences. J Ther Ultrasound. 2017; 5: 4. PMID 28174660
22. Ghanouni P, Dobrotwir A, Bazzocchi A, et al. Magnetic resonance-guided focused ultrasound treatment of extra-abdominal desmoid tumors: a retrospective multicenter study. Eur Radiol. Feb 2017; 27(2): 732-740. PMID 27147222
23. Schaink A, Li C, Gajic-Veljanoski O, et al. Magnetic Resonance-Guided Focused Ultrasound Neurosurgery for Essential Tremor: A Health Technology Assessment. Ont Health Technol Assess Ser. 2018; 18(4): 1-141. PMID 29805721
24. Mohammed N, Patra D, Nanda A. A meta-analysis of outcomes and complications of magnetic resonance-guided focused ultrasound in the treatment of essential tremor. Neurosurg Focus. Feb 2018; 44(2): E4. PMID 29385917

25. Elias WJ, Lipsman N, Ondo WG, et al. A Randomized Trial of Focused Ultrasound Thalamotomy for Essential Tremor. N Engl J Med. Aug 25 2016; 375(8): 730-9. PMID 27557301
26. Chang JW, Park CK, Lipsman N, et al. A prospective trial of magnetic resonance-guided focused ultrasound thalamotomy for essential tremor: Results at the 2-year follow-up. Ann Neurol. Jan 2018; 83(1): 107-114. PMID 29265546
27. Lutz S, Balboni T, Jones J, et al. Palliative radiation therapy for bone metastases: Update of an ASTRO Evidence-Based Guideline. Pract Radiat Oncol. Jan 2017; 7(1): 4-12. PMID 27663933
28. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Bone Cancer. Verson 1.2020. https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf.
29. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 4.2020. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf.
30. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Central Nervous System Cancers. Version 2.2020. https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf.
31. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 1.2020. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf.

Policy History

Original Effective Date: 09/22/2005
Current Effective Date: 05/10/2021

09/07/2005	Medical Director review
09/20/2005	Medical Policy Committee review
09/22/2005	Quality Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
09/05/2007	Medical Director review
09/19/2007	Medical Policy Committee approval. Coverage eligibility unchanged.
09/03/2009	Medical Policy Committee approval
09/16/2009	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

09/09/2010	Medical Policy Committee review
09/15/2010	Medical Policy Implementation Committee approval. Added that magnetic resonance imaging (MRI)-guided ablation of other tumors, including but not limited to breast, brain, prostate cancer, and palliative treatment of bone metastases, is considered to be investigational.
09/01/2011	Medical Policy Committee review
09/14/2011	Medical Policy Implementation Committee approval. Title changed from "MRI-Guided High Intensity Ultrasound Ablation of Uterine Fibroids" to "MRI-Guided Focused Ultrasound (MRgFUS) for the Treatment of Uterine Fibroids and Other Tumors." Coverage eligibility unchanged.
10/11/2012	Medical Policy Committee review
10/31/2012	Medical Policy Implementation Committee approval
10/03/2013	Medical Policy Committee review
10/16/2013	Medical Policy Implementation Committee approval. Policy title changed from "MRI-Guided Focused Ultrasound (MRgFUS) for the Treatment of Uterine Fibroids and Other Tumors" to "MRI-Guided Focused Ultrasound (MRgFUS)". Policy changed to a single investigational statement with no change to coverage eligibility.
11/06/2014	Medical Policy Committee review
11/21/2014	Medical Policy Implementation Committee approval. No change to coverage. Title changed from MRI-Guided Focused Ultrasound (MRgFUS) to Magnetic Resonance Imaging-Guided Focused Ultrasound.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015	Medical Policy Committee review
11/16/2015	Medical Policy Implementation Committee approval. Added "Based on review of available data, the Company may consider magnetic resonance imaging (MRI)–guided high-intensity ultrasound ablation for pain palliation in adult patients with metastatic bone cancer who failed or are not candidates for radiotherapy to be eligible for coverage."
11/03/2016	Medical Policy Committee review
11/16/2016	Medical Policy Implementation Committee approval. Title change, "imaging" removed from policy statements.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
11/02/2017	Medical Policy Committee review

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11/15/2017	Medical Policy Implementation Committee approval. No change to coverage.
11/08/2018	Medical Policy Committee review
11/21/2018	Medical Policy Implementation Committee approval. A policy statement added that MRgFUS ablation may be considered eligible for coverage for the treatment of medicine-refractory essential tremors.
11/07/2019	Medical Policy Committee review
11/13/2019	Medical Policy Implementation Committee approval. No change to coverage.
04/02/2020	Medical Policy Committee review
04/08/2020	Medical Policy Implementation Committee approval. No change to coverage.
04/01/2021	Medical Policy Committee review
04/14/2021	Medical Policy Implementation Committee approval. No change to coverage

Next Scheduled Review Date: 04/2022

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0071T, 0072T, 0398T
HCPCS	C9734
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.