

Magnetic Resonance-Guided Focused Ultrasound

Medicare Advantage Medical Policy #MA-233

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Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Blue Advantage does not cover investigational or experimental services, including any drug, device, procedure, or service provided under the investigational arm of a clinical trial or study unless mandated by the Centers for Medicare and Medicaid Services. Coverage is limited to routine services for Category A IDE studies and to devices and related services for Category B IDE studies when not supplied by the trial sponsor. Approved IDE studies are posted on www.cms.gov/medicare/coverage/evidence.

Note: Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors is addressed separately in medical policy MA-126.

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 Health Plan may consider magnetic resonance-guided high-intensity ultrasound ablation for pain palliation in adults with metastatic bone cancer who have failed or are not candidates for radiotherapy 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 Health Plan considers magnetic resonance-guided high-intensity ultrasound ablation to be **investigational*** in all other situations including but not limited to:

- Treatment of uterine fibroids;
- Treatment of other tumors (e.g., brain cancer, prostate cancer, breast cancer, desmoid);
- Treatment of medication-refractory tremor dominant Parkinson disease.

Background/Overview

Uterine Fibroids

Uterine fibroids are 1 of the most common conditions affecting women in the reproductive years. African American women have a greater lifetime incidence of uterine fibroids compared to other racial groups. Symptoms of uterine fibroids include menorrhagia, pelvic pressure, or pain.

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Treatment

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 1 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.

Tremor-Dominant Parkinson Disease

The 3 cardinal features of Parkinson disease (PD) are tremor, bradykinesia, and rigidity. The tremor in PD is a resting tremor that occurs when the body part is not engaged in purposeful activities. Major subtypes of PD include tremor-dominant, akinetic-rigid, and postural instability and gait difficulty. The progression of PD is highly variable and patients can change subtypes as the disease progresses.

Treatment

Dopaminergic therapy (ie, levodopa or a dopamine agonist) is the first-line treatment for PD, which improves tremor. Amantadine and anticholinergics (eg, trihexyphenidyl) can also be considered as initial treatment for tremor-dominant PD or as add-on therapy in patients who have persistent tremor despite dopaminergic therapy. For medication-refractory patients, surgery (deep brain stimulation or lesioning procedures) may be offered. Lesioning procedures include conventional unilateral thalamotomy and focused ultrasound thalamotomy. Deep brain stimulation is the most frequently performed surgical procedure for the treatment of PD.

Magnetic Resonance-Guided Focused Ultrasound

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 mm in diameter and 15 mm in height/length. This causes a rapid rise in temperature (ie, to 65°C to 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

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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 4 indications: treatment of uterine fibroids (leiomyomata), palliation of pain associated with tumors metastatic to bone, medication-refractory ET, and tremor-dominant PD. 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 postapproval study with 70 patients to evaluate the effectiveness of the system under actual clinical conditions.

In November 2021, the FDA approved the use of the Exablate Prostate System for prostate tissue ablation through the premarket approval process.

In October 2023, Cordance Medical announced that the FDA granted a breakthrough device designation for its NeuroAccess device. MRgFUS for blood-brain barrier disruption (0947T) to facilitate liquid biopsy is not evaluated in this policy.

FDA product codes: NRZ, POH, PLP.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration

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approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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 magnetic resonance-guided focused ultrasound (MRgFUS), the evidence includes systematic reviews, 2 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) had preliminary results at 6 weeks post treatment, comparing MRgFUS with uterine artery embolization (UAE), and demonstrated 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. Long-term follow-up results reported a lower reintervention rate and greater improvement in symptoms after UAE compared to MRgFUS. A 2021 meta-analysis reported that, comparatively, myomectomy had the lowest re-intervention rate of the 3 regimens (myomectomy vs UAE vs MRgFUS) in all time points assessed, while the MRgFUS had the highest re-intervention rate. Long-term data on the treatment effects, recurrence rates, and impact on future fertility and pregnancy are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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, a systematic review of RCTs and observational studies, and 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. Pooled efficacy data from a systematic review reported a treatment response to MRgFUS of 79%. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

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For individuals with other tumors (eg, breast cancer, brain cancer, prostate cancer, desmoid, nonspinal osteoid osteoma) who receive MRgFUS, the evidence includes nonrandomized, uncontrolled phase II trials and several case series. Relevant outcomes are symptoms, health status measures, and treatment-related morbidity. A nonrandomized, uncontrolled phase II trial evaluating MRgFUS for prostate cancer reported a 93% success rate at 5 months and an 86% success rate at 2 years. Another nonrandomized, phase II trial in patients with prostate cancer reported that at 24 months, 88% (78 out of 89) of patients had no evidence of grade group 2 or higher prostate cancer in the treated area. Use of MRgFUS for the treatment of nonspinal osteoid osteoma consists of several larger case series, including a propensity score-matched retrospective study that reported similar reductions in pain with radiofrequency ablation and MRgFUS. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with medicine-refractory essential tremors who receive MRgFUS, the evidence includes a technology assessment, meta-analyses, and a double-blind, sham-controlled randomized trial. 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. One meta-analysis reported significant improvements in hand tremor scores from baseline up to 24 months post-treatment, with evidence of a diminishing treatment benefit over time. A second meta-analysis showed significant improvements in hand tremor scores and quality of life through 36 months post treatment. A third meta-analysis found similar improvements in tremor severity with MRgFUS to unilateral deep brain stimulation (DBS), but improvements in both were inferior to bilateral DBS. 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 an improvement in the net health outcome.

For individuals with medicine-refractory tremor-dominant Parkinson disease (PD) who receive MRgFUS, the evidence includes a systematic review and pilot RCT. Relevant outcomes include symptoms, functional outcomes, quality of life, and treatment-related morbidity. The double-blind, sham-controlled, pilot randomized trial (N=27) found significant improvements in the treatment group in tremor severity after 3 months of follow-up. The systematic review, which included the RCT plus additional small observational studies, found significant improvements in tremor severity through 12 months and quality of life through 6 months post procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US

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representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Radiology

In 2018, the American College of Radiology published appropriateness criteria for the radiological management of uterine leiomyomas (fibroids). The clinical guidance states that "MR [magnetic resonance]-guided high-intensity focused US [ultrasound] (MRgFUS) is another uterine-sparing option to treat focal leiomyomas. It is noninvasive, though each treatment may take several hours to complete. Its use currently is restricted to patients with fewer than six leiomyomas or leiomyoma volume < 900 cm³," and "although a reasonable alternative for patients unable or unwilling to tolerate sedation or anesthesia, long-term data and viability results are still lacking."

These appropriateness criteria were most recently updated in 2023, with evidence summaries provided for each reviewed clinical scenario. Table 1 summarizes the appropriateness category for specific populations with uterine fibroids.

Table 1. ACR Appropriateness Criteria: Management of Uterine Fibroids

Clinical situation	MRgFUS Appropriateness Category ^a
Reproductive age patient with uterine fibroids, symptomatic with heavy uterine bleeding or bulk symptoms (eg, pressure, pain, fullness, bladder, or bowel symptoms), and a desire to preserve fertility. Initial therapy.	Usually appropriate
Reproductive age patient with uterine fibroids, symptomatic with heavy uterine bleeding or bulk symptoms (eg, pressure, pain, fullness, bowel, or bladder symptoms), and no desire for future fertility. Initial therapy.	Usually appropriate
Reproductive age patient with uterine fibroids and concurrent adenomyosis, symptomatic with heavy uterine bleeding or bulk symptoms (eg, pressure, pain, fullness, bladder, or bowel symptoms), and no desire for future fertility. Initial therapy.	Usually not appropriate
Reproductive age patient with pedunculated submucosal uterine fibroids, symptomatic with heavy uterine bleeding. Initial therapy.	May be appropriate
Postmenopausal patient with uterine fibroids, symptomatic with heavy uterine bleeding or bulk symptoms (eg, pressure, pain, fullness, bladder, or bowel symptoms). Negative endometrial biopsy. Next step.	Usually not appropriate

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Reproductive age patient with uterine fibroids desiring pregnancy and experiencing reproductive dysfunction. Initial therapy.

May be appropriate

ACR: American College of Radiology; MRgFUS: magnetic resonance-guided focused ultrasound.

^aUsually appropriate: the imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients; May be appropriate: The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal; Usually not appropriate: The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable.

American Society for Radiation Oncology et al

In 2017, the American Society for Radiation Oncology (ASTRO) 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 MRgFUS. 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." A 2024 updated guideline, intended to replace the 2017 guideline, also does not mention MRgFUS. Recommendations for advanced radiotherapy such as stereotactic body radiotherapy (SBRT) are as follows:

- "For patients with symptomatic bone metastases treated with SBRT, 1200 to 1600 cGy in 1 fraction (nonspine) and 2400 cGy in 2 fractions (spine) are recommended."
- "For patients with symptomatic bone metastases with ECOG PS 0-2, receiving no surgical intervention, and absent neurological symptoms, SBRT is conditionally recommended over conventional palliative RT."
- "For patients with spine bone metastases that would benefit from reirradiation to the same site, treatment with SBRT is conditionally recommended."

In 2022, the American Urological Association (AUA)/ASTRO published guidance on the management of clinically localized prostate cancer. The guidance states that "there is a lack of data to date to support the use of whole gland or focal ablation for the treatment of clinically localized prostate cancer."

Congress of Neurological Surgeons

In 2025, a guideline on the role of emerging therapies for patients with metastatic brain tumors was published by the Congress of Neurological Surgeons and endorsed by the American Association of Neurological Surgeons (AANS). The guideline states that: "For interstitial modalities and magnetic resonance imaging-guided focused ultrasound, insufficient qualifying

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data were identified to create recommendations." The guideline also states that: "There is insufficient evidence to make a recommendation regarding the use of HIFU [high-intensity focused ultrasound] for parenchymal and leptomeningeal brain metastases."

National Comprehensive Cancer Network

Guidelines from the National Comprehensive Cancer Network (NCCN) on bone cancer (v.2.2025), breast cancer (v.4.2025), and central nervous system cancers (v.5.2024), do not mention magnetic resonance-guided ultrasound as a treatment option. The NCCN guideline for prostate cancer (v.2.2025) states that "Cryotherapy or other local therapies are not recommended as routine primary therapy for localized prostate cancer due to lack of long-term data comparing these treatments to radiation. At this time, the panel recommends only cryosurgery and high-intensity focused ultrasound (HIFU; category 2B) as local therapy options for RT [radiotherapy] recurrence in the absence of metastatic disease".

National Institute for Health and Care Excellence

Guidance from NICE (2018) on unilateral magnetic resonance-guided ultrasound for treatment-resistant essential tremor states "the evidence on the safety of unilateral MRI [magnetic resonance imaging]-guided focused ultrasound thalamotomy for treatment-resistant essential tremor raises no major safety concerns. However, current evidence on its efficacy is limited in quantity. Therefore, this procedure should not be used unless there are special arrangements for clinical governance, consent, and audit or research."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for the treatment of Essential Tremor is addressed by Novitas Local Coverage Determination (LCD) L38495, *Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor*. For Medicare members, coverage determinations will be made in accordance with the applicable Medicare LCD and any related billing and coding articles.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

NCT02260752- many publications, but none focusing on outcomes with MRgFUS- will leave in for now.

NCT01285960: Published in 2023 [PMID: 37553488]; focused on predictors of response- marked for removal.

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Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
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
NCT03998657 ^a	A Continued Access Study to Evaluate Focal MR-Guided Focused Ultrasound Treatment of Localized Intermediate Risk Prostate Lesions	14	Dec 2022
NCT02923011	Phase III Study to Compare the Effectiveness of Magnetic Resonance Guided Focused Ultrasound With Computed Tomography Guided Radiofrequency Ablation for Treatment of Osteoid Osteomas	56	Dec 2024
NCT03948789	Multicenter, Randomized Phase III Study of MR-Guided Focused Ultrasound Surgery for the Treatment of Uterine Fibroids (MRgFUS TUF) Compared to Myomectomy in Symptomatic Medication and Not Sufficiently Treatable Uterine Fibroids	127	Jun 2025
NCT03100474 ^a	Global Registry: ExAblate 4000 Transcranial MR Guided Focused Ultrasound (TcMRgFUS) of Neurological Disorders	500	Jan 2024
NCT02252380 ^a	A Feasibility Clinical Trial of the Magnetic Resonance Guided Focused Ultrasound (MRgFUS) for the Management of Treatment-Refractory Movement Disorders	10	Dec 2023
<i>Unpublished</i>			
NCT02260752	Comparing Options for Management: Patient-Centered Results for Uterine Fibroids	3094	Apr 2020
NCT01833806 ^a	A Phase IV Post Approval Clinical Study of ExAblate Treatment of Metastatic Bone Tumors for the Palliation of Pain	32	Jan 2022

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NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01620359 ^a	Study of ExAblate Focused Ultrasound Ablation of Breast Cancer under MR Guidance and MRI Evaluation of Ablation	14	Jul 2016 (completed)
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.

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08/18/2026 Utilization Management Committee review/approval. New policy.

Next Scheduled Review Date: 08/2027

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Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 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.

The responsibility for the content of the Health Plan Medical Policy Coverage Guidelines is with the Health Plan and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in the Health Plan Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of the Health Plan Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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, 55899, 61715
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:

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1. Consultation with 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 Health Plan’s 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 Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Blue Advantage), Blue Advantage may honor the previous health plan’s authorization

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for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Blue Advantage health plan.

Medicare Advantage Members

Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: <https://www.cms.gov/medicare-coverage-database/search.aspx>. You may wish to review the Guide to the MCD Search here: <https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx>.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®

InterQual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.