MAGNETIC RESONANCE-GUIDED FOCUSED ULTRASOUND (MRgFUS)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Magnetic resonance-guided focused ultrasound (MRgFUS) is a non-invasive treatment that combines 2 technologies, focused ultrasound (US) and magnetic resonance imaging (MRI). MRI is used for guidance and monitoring while a focused ultrasound beam penetrates through the soft tissues and heats the targeted tissue, resulting in coagulation necrosis while sparing the surrounding normal structures. MRgFUS is indicated for the treatment of pain palliation associated with metastatic bone cancer. The aim of this treatment is to destroy nerves in the bone surface surrounding the tumor. MRI-guided focused ultrasound ablation has also been investigated as a noninvasive treatment for, uterine fibroids, and benign and malignant tumors including brain, breast and prostate.
MAGNETIC RESONANCE-GUIDED FOCUSED ULTRASOUND (MRgFUS) (cont.)

Definitions:

Adult: Age 18 years and older

Criteria:

- Magnetic resonance-guided high-intensity ultrasound ablation is considered medically necessary for pain palliation in adults with metastatic bone cancer who failed or are not candidates for radiotherapy.

- Magnetic resonance-guided high-intensity ultrasound ablation for all other indications not previously listed or if above criteria not met is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

These indications include, but are not limited to:

- Treatment of other tumors e.g., brain cancer, breast cancer and prostate cancer
- Treatment of uterine fibroids
MAGNETIC RESONANCE-GUIDED FOCUSED ULTRASOUND (MRgFUS) (cont.)

Resources:

Literature reviewed 03/01/16. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 03/05/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.


FDA Premarket Approval Database for ExAblate® 2000 System:

- FDA-approved indication: 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 less than 24 weeks who have completed childbearing.

FDA Premarket Approval Database for ExAblate 2000/2100/2100 VI System:

- FDA-approved indication: For pain palliation in adult patients with metastatic bone cancer who failed or are not candidates for radiation therapy.