

Policy: MP166

Section: Medical Benefit Policy

Subject: Magnetic Resonance (MR) Guided Ultrasound Ablation of Uterine Fibroids.

I. Policy: Magnetic Resonance (MR) Guided Ultrasound Ablation of Uterine Fibroids

II. Purpose/Objective:

To provide a policy of coverage regarding Magnetic Resonance (MR) Guided Ultrasound Ablation of Uterine Fibroids.

III. Responsibility:

- A. Medical Directors
- B. Medical Management Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:

Uterine fibroids (leiomyomata) are benign tumors commonly found during the reproductive years. Magnetic Resonance Focused Ultrasound therapy is a non-invasive treatment that proposes to treat symptomatic fibroids by applying a precise ultrasound beam to the tumor causing tissue destruction by thermal injury, while preserving adjacent structures. This procedure can be done as an outpatient in an MRI suite with no anesthesia or conscious sedation. One system, Exblate 2000®, has received marketing approval from the Food and Drug Administration.

EXCLUSIONS: The Plan does **NOT** provide coverage for MR Ultrasound Ablation of Uterine Fibroids because it is considered **experimental, investigational or unproven**. Although the device is FDA approved, there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven services is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment**

CODING ASSOCIATED WITH: MR Ultrasound of Uterine Fibroids

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

- 0071T Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue.
- 0072T Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue.
- 77022 Magnetic Resonance guidance for, and monitoring of, parenchymal tissue ablation
- C9734 focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Winifred S. Hayes. Hayes Inc. Online Alert- Exblate 2000® System for Ablation of Uterine Fibroids. May 2005. Accessed November 2005.

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Stewart et al. Focused Ultrasound treatment of uterine fibroid tumors: Safety and feasibility of noninvasive thermoablative technique. Am J Obstet Gynecol 2003;189(1):48-54.

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Food and Drug Administration (FDA)[website]. Center for Devices and Radiological Health (CDRH). Premarket approval P040003. October 22, 2004. Accessed on November 4, 2005 at <http://www.fda.gov/cdrh/pdf4/P040003a.pdf>.

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Stewart EA, Rabinovici J, Tempany CM, Inbar Y, Regan L, Gastout B, Hesley G, Kim HS, Hengst S, Gedroye WM. Clinical outcomes of focused ultrasound surgery for the treatment of uterine fibroids. Fertil Steril 2006;85:22-9.

National Institute for Health and Clinical Excellence (NICE). Magnetic resonance image-guided focused ultrasound for uterine fibroids. Interventional Procedures Consultation Document. London, UK: NICE; February 2007. Available at: http://www.nice.org.uk/page.aspx?o=ip_343.

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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. 2016;105(3):773-80

PA Dept. of Human Services Managed Care Operations Memorandum, General Operations OPS # 08/2018-014

ECRI ExAblate Body System (InSightec, Inc.) MRI-guided Focused Ultrasound for Treating Uterine Fibroids. Published 9/18/2017 Updated 8/3/2020

This policy will be revised as necessary and reviewed no less than annually.

Devised: 11/14/05

Revised: 11/06, 9/16 (Gender Language)

Reviewed: 11/07, 11/08, 10/09, 09/10, 9/11, 9/12, 9/13, 9/14, 9/15, 8/17, 8/18, 8/19, 8/20

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.