

Patient Pre-authorization Guide

Patient Guide to Insurance Coverage for MR guided Focused Ultrasound Surgery- Non-invasive Treatments for Uterine Fibroids

Dear Patient:

MR guided Focused Ultrasound Surgery (MRgFUS) for non-invasive treatment for uterine fibroids is a new technology which received FDA approval in October 2004. Due to its recent introduction within the medical community, many health plans have not formally completed their review of this technology or you may find that your specific health plan may not currently consider MRgFUS as a covered benefit for treatment of fibroids.

In spite of this you can always approach your carrier and request that they consider your request on a case-by-case basis. This is known as “pre-authorization” for treatment. This process for getting your health plan to approve your MRgFUS procedure may require that and your referring physician dedicate some time to navigate the pre-authorization process as defined by your health plan. You may find that your health plan initially denies your request. *Do not be discouraged.* This is their first response, not necessarily their last.

This guide provides details on how to find out if your health plan covers MRgFUS and for obtaining pre-authorization approval for treatment. It overviews the steps you can follow if you have individual health insurance or group health insurance through your employer. Your MRgFUS provider, who will actually perform the procedure, can assist you in your efforts to obtain pre-authorization and payment for this procedure.

The steps described here include:

- Step 1. Are you a candidate for MRgFUS treatment for uterine fibroids?
- Step 2. Is MRgFUS a covered benefit under your health plan?
- Step 3. Requesting pre-authorization for MRgFUS treatment
- Step 4. Obtaining the decision
- Step 5. Appealing a denial

In addition attached please find Frequently Asked Questions regarding the reimbursement process.

As more patients, such as yourselves, request coverage and undergo MRgFUS treatment, the reimbursement process will get easier and more health plans will cover this.

Step 1: Determine if you are a candidate for MRgFUS Treatment for Uterine Fibroids

Contact your referring physician or the MRgFUS treatment center to begin the pre-screening process to determine you are a candidate for MRgFUS treatment. Pre-screening diagnostic tests may require pre-authorization for the pre-treatment MRI and other diagnostic tests.

Once you have completed the required evaluation process and it is determined that you are a candidate for MRgFUS treatments, ask your physician to help you obtain pre-authorization for the MRgFUS treatment.

Step 2: Contact your Health Plan and Ask if MRgFUS is a Covered Benefit

Contact your health plan by phone or in writing to ascertain if MRgFUS is a covered benefit for the treatment of uterine fibroids under your plan. Provide them with the following MRgFUS Current Procedural Terminology (CPT) procedure codes: CPT 0071T and CPT 0072T. Plans determine this by reference to the codes used to bill for the treatment in question.

If they tell you it is an approved procedure under your covered benefits, ask them to provide you with the details and steps if you need to obtain pre-authorization of MRgFUS treatment.

If MRgFUS is not a covered benefit, ask why it is not currently considered a covered service. They may answer that it is not considered a *“medically necessary” procedure for the treatment of uterine fibroids, or it is considered an investigational or experimental procedure or it is not considered a covered benefit under your specific plan.* Ask them what information and documentation you need to submit to get them to reconsider their decision to deny this service. Record all contact information (including the person you are talking with and any person they recommend you contact) and what is discussed on the phone conversation.

Step 3: Request Pre-authorization by Health Plan for MRgFUS Treatment

The MRgFUS center should be able to help you in your efforts to secure pre-authorization from the health plan.

The pre-authorization request should include the following detailed information about your medical condition and your need to undergo MRgFUS treatment, all of which should be furnished by your physician:

1. Your medical condition with your exact diagnosis (uterine fibroids) and your symptoms associated with your fibroids.
2. The medical necessity for you to undergo MRgFUS and a description of this procedure.
3. What health problems could occur if you do not get MRgFUS treatment.
4. What other treatments or services you have already had for your fibroids, if any, and why they these other alternative treatments did not alleviate your symptoms.
5. Why MRgFUS is the most appropriate treatment for your uterine fibroids

Your physician may ask the health plan to call him or her with any questions about the letter or the MRgFUS procedure. You can get letters from both your referring physician and/or the physician from the MRgFUS center that will be performing your MRgFUS treatment.

Step 4: Followup after Submitting Request for Pre-Authorization

Contact the health plan claims office if you don't receive a reply within two weeks and ask when a decision can be expected. (Many states require insurance companies to respond within 30 days). Record the date of inquiry and the person with whom you spoke. Be patient and offer to provide any needed information.

Your health plan must provide a clinical reason for their decision, whether they approve or deny the request.

Your health plan may deny MRgFUS, because

- 1) this medical procedure is not considered "medically necessary"
- 2) they consider MRgFUS to be experimental or investigational at this time; or
- 3) they do not offer this procedure under your health plan to any plan participants and MRgFUS is not a "covered health benefit" under your plan.

Whatever the reason for the denial you have the right to appeal this, and should request details on these steps.

Step 5: Appeal Procedure

If you are denied, don't give up! Persevere. This is their first response, not necessarily the last. Request a written response, detailing the reasons for denial. You will then have something specific to answer.

The type of insurance you have determines whether state or federal law applies to the appeal process. If your plan is self-funded then ERISA (federal law) applies and the Department of Labor has jurisdiction. If it is commercial insurance, state law applies and the state Division of Insurance (DOI) has jurisdiction.

A. Reconsideration of Denial (grievance letter)

If your health plan denies your request for treatment, you should request an informal reconsideration (grievance appeal). You can do this by calling, writing or faxing the health plan.

Contact your health plan to provide you with the appropriate guidelines for your appeal. It is better to ask for your reconsideration in the form of a letter, so your request does not get lost. If you make your request by phone, record the date and who took your request. Health plans must send you a letter stating that they received your request for informal reconsideration within 5 days.

In your letter, you should tell the health plan the reasons why you disagree with their denial. If the reason for denial is that the service is not considered *medically necessary*, ask your physician to write a letter of medical necessity. Include in this letter, medical records, and documentation that supports your position for coverage in your informal reconsideration letter. You should also include published information about ExAblate and MRgFUS, including the FDA approval letter (<http://www.fda.gov/cdrh/pdf4/P040003a.pdf>), the Talk Paper issued by the FDA to inform the public about ExAblate (<http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01319.html>) and the bibliography of articles about MRgFUS (found on website: www.uterine-fibroids.org)

If the service is denied because it is “investigational” this objection can be refuted by citing experience with over 1,200 uterine fibroid treatments worldwide.

B. Written Appeal

If your health plan denies MRgFUS after an informal reconsideration, you should send a written letter to appeal their decision. You may ask your physician to write the response.

Check with your health plan for specific instructions and how long the appeal process takes. It is very important to submit your appeal as soon as you hear from your health plan that they have denied your informal reconsideration.

Your appeal letter should directly address the reason for the denial of MRgFUS. In the letter, include any additional information not included in your informal reconsideration letter. If you did not submit a letter of medical necessity with your informal reconsideration, request your referring physician write a letter of medical necessity. (See: Letters of Medical Necessity under Step 3).

Send the appeal to the claims manager (or the specified contact). Call to make sure it was received.

C. Second Appeal

If the first appeal is denied, ask again for the denial in writing. Also inquire if another appeal is possible, to a higher level person or committee. Should you be denied a second time, do not give up. Answer, or ask your physician to answer, all objections and resubmit. Be patient and persistent. Many claims have been authorized after two or more appeals

D. Higher Level of Appeal - External Independent Review

You must check with your health plan to see if you have the right to request an external independent review of their decision to deny coverage of MRgFUS. Your health plan or employer can explain to you whether your type of insurance allows for an external review and the steps to take after your appeal is denied. An external independent review requires that someone, who is not employed by the health plan, review your request for MRgFUS treatment and make a decision independent of the health plan. You must request this independent review within a certain amount of time after the health plan denies your appeal for MRgFUS treatment. Your request for this review should be mailed directly to your health plan. Your health plan will send your request for an independent review, along with all of your information, to the your State's Department of Insurance. There is no charge to you for the external independent review.

For questions of medical necessity, the independent physician who reviews your case has 21 days to contact the Department of Insurance of his or her decision. The Department of Insurance will send you the decision 5 days following receipt of the decision. For questions of coverage, the Department of Insurance will mail you a decision within 15 days of receipt of the independent physician's review. The external independent review decision is legally binding on your health plan and you. On questions of medical necessity, if you disagree with the independent review, you may have the right to go to court to further your appeal. On questions of coverage, you or the health plan can ask for

a fair hearing with the Office of Administrative Hearings. You have 30 days to request a fair hearing. Information sent with the independent review decision will explain the process for requesting a fair hearing.

Additional Information

Is the appeal process different if denial was based on decisions of medical necessity versus questions of coverage?

Yes, the appeals process will differ depending why your case was denied. The review process used will depend on whether your case is based on the question of whether MRgFUS is medically necessary or whether it is a question of coverage.

A question of medical necessity means that the health plan does not believe that MRgFUS is necessary to treat your uterine fibroids. In this case, a physician familiar with treating uterine fibroids will review all the information you have submitted during the appeals process and determine if MRgFUS is the most appropriate treatment choice for your specific case.

A question of coverage means the health plan believes that MRgFUS is not a covered benefit under the terms of your health insurance policy. An employee of your State Department of Insurance reviews questions of coverage.

For all independent reviews, it is very important that write all the reasons why the denial of MRgFUS is the wrong decision for your medical condition. Letters of medical necessity, your medical records, and MRgFUS support documents from your treating physician and the MRgFUS treatment center are critical for the independent physician to review.

Once the external independent review is in process, contact your State Department of Insurance directly to make sure they have all your information.

For ERISA Complaints: If you are employed by an employer group who is self-insured and does not buy insurance from an insurance company and is self-funded (meaning that they provide their own insurance and bear their own risk), your employer must follow a federal law, the Employee Retirement Income Security Act, known as ERISA. If your employer has self-insured health insurance, you cannot ask for an external independent review through the State Department of Insurance. Under ERISA, if your appeal was denied, you may be entitled to file a complaint with the U. S. Department of Justice. You can contact them at 1-666-444-3272 or visit their website at www.dol.gov/ebsa for information on how to file a complaint.

What if i need MRgFUS Immediately and my health plan denies my request?

If your health plan denies MRgFUS and it is determined you need these treatment immediately, you can request an Expedited Medical Review. The purpose of an Expedited Medical Review is to require that the health plan to make a quick decision based on the fact that your health is at risk. Your referring physician must certify in writing that delaying this service could cause a significant negative change in your medical condition. The health plan cannot question your physician's certification and it must make a decision 1 business day after receiving the certification and other supporting information. If the health plan still denies MRgFUS, you can appeal and ask for an external independent review. The time period allowed for the health plan to respond to this type of request is very short. Contact your State Department of Insurance and request information on Expedited Medical Review.

Suggestions for contacting your health plan:

- Always contact them in writing. Phone calls can be made, but written communication is more powerful.
- Be sure to followup all written communications with a phone call to make sure they received your letters.
- Keep a copy of all your letters for your records. Record all phone calls in a phone log.
- Keep a log of when, where, and to whom you sent your request.
- Send important documents by certified mail (return receipt), Federal Express, or by fax with a confirmation sheet.

Most importantly, be persistent.

Patient Reimbursement Frequently Asked Questions

1. Will my insurance company or health plan pay for MRgFUS?

Payment and coverage of MRgFUS will vary from health plan to health plan. MRgFUS is a recently introduced new technology for treatment of uterine fibroids and received FDA approval in October, 2004. Because this treatment option is relatively new, few insurance companies reimburse for this as part of their routine treatment options. It will be necessary for you to contact your health plan to verify whether it is a covered benefit under your plan policy. At this time, payment for MRgFUS is based on individual payer discretion and coverage is typically determined on a case-by-case basis.

2. Do I need to get pre-authorization before treatment?

Yes, you will have to contact your health plan for pre-authorization of MRgFUS treatment prior to scheduling your treatment session. You may also have to get pre-authorization for the pre-screening diagnostic tests that are required to verify you are an appropriate candidate for MRgFUS. We suggest you work with your referring physician and/or staff at the MRgFUS provider site you have been referred to for treatment. Your physician, or physician(s) at the MRgFUS site, will assist you in your efforts to get pre-approval for MRgFUS. Prior to contacting your health plan, we recommend your referring physician document the reason MRgFUS is the most appropriate treatment for your specific case. Either your referring physician, or a physician at the MRgFUS provider site, will need to provide you with documentation that supports medical necessity for treatment of your uterine fibroids and their choice of MRgFUS as the best option.

3. What should I do if my health plan denies my request for MRgFUS treatment in this pre-authorization process?

For MRgFUS to be approved by your health plan through the pre-authorization process there are 3 conditions that must be met:

- a) they must agree that treatment is necessary for your condition,
- b) they must agree MRgFUS is an appropriate treatment for your condition,
- c) they must agree to reimburse for this treatment.

If you complete the pre-authorization process and your plan does not consider MRgFUS a covered benefit (or medically necessary) and denies your initial request for treatment, you are entitled to initiate a general grievance review of their denial decision. You must contact your health plan to outline the protocol for the grievance process. You will need to follow the guidelines established by your health plan. You may also be entitled to a second more formal independent review process if your

health plan denies treatment under the grievance process. You must exhaust the grievance process before attempting to initiate the independent review process.

4. *What are the reasons why a health plan will deny MRgFUS treatment?*

A health plan will base their denial on a combination of three different rulings. The plan may rule that MRgFUS is a “non-covered service” for its eligible members; it is “not medically-necessary” for the treatment of uterine fibroids or for a patient specific case; or even though it is an approved by FDA for this condition, from an insurance company perspective they consider this an “experimental or investigational” treatment. Your right to an external independent review will be dependent on the reason cited for the denial and your health plan’s eligibility criteria for an independent review of a denial made through the grievance process.

5. *Do I need to write a letter of appeal and forward it to my health plan?*

For both the grievance and the independent review process, you are typically required to formally appeal their denial decision in writing. Prior to writing your appeals letter, go to the Web page for your health plan, or contact them directly for specific instructions on what written documentation is required to support your request for a review if their decision to deny approval. Work with your referring physician and staff to provide the appropriate documents you will need to start the appeals process. In addition to a letter of appeal, health plans require additional support documents including a letter from your referring physician recommending MRgFUS and the reasons why MRgFUS should be a covered benefit for your specific case. Additionally, other support documents that are needed include peer reviewed literature that demonstrates clinical efficacy and cost-effectiveness, medical literature and second opinions supporting medical necessity, copies of all information provided to the health plan during the appeals process, and all documentation received from the health plan during the appeals process documenting the reason for the denial.

6. *What happens if I exhaust all levels of appeal?*

Once you feel you have exhausted all avenues of appeal, you may want to consider other options for MRgFUS treatment. Under some health plans, there are legal remedies available under state, federal, Medicare, or ERISA regulations. For those who seek treatment outside of continued appeals or legal remedy, patient self-pay options may be a viable consideration. The majority of MRgFUS provider sites offer Self-Pay programs for patients desiring treatment. Please contact either your referring physician or your local MRgFUS provider to discuss financing options and alternative payment programs.

7. Do I have any other choices?

Yes. Because for some patients the need for treatment is urgent, or the patient feels this is the treatment method of choice, many decide to move forward with the treatment and pay for the procedure out of pocket. You must first contact your health plan and get a formal denial of pre-authorization of MRgFUS. Once you have this denial, you do have the right to appeal their non-coverage decision and denial of payment and request, either through your employer or health plan to be reimbursed for the expense.