Insurance Coverage for
the TIF Procedure

PATIENT'S GUIDE TO THE APPEALS PROCESS

TIF Transoral Incisionless Fundoplication

EndoGastric Solutions®

Provided as a Service of EndoGastric Solutions, Inc.

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for GERD and Obesity

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Purpose of This Booklet

This brochure is designed to help you understand insurance coverage and the appeals process for the TIF (Transoral Incisionless Fundoplication) surgery for Gastroesophageal Reflux Disease (GERD). It will also give you the information you need to be an active participant in your own care.

This booklet is made possible through a cooperative effort between your physician and EndoGastric Solutions Inc. (EGS). It is not designed as a replacement for professional medical care or advice. Only your physician is qualified to diagnose and appropriately treat your condition and related problems.

What is the Appeals Process?

If your doctor has recommended that you have a Transoral Incisionless Fundoplication (TIF) procedure in which a device called the EsophyX® device, is used to perform a surgical fundoplasty to treat your GERD, you will want to be acquainted with the various insurance terms and coverage that you may encounter.

In the event that your healthcare plan refuses insurance coverage for the TIF procedure the first time around, don't be alarmed. It's quite common for insurers to deny coverage for a new technology. Even though the EsophyX has received FDA clearance and there have been over 2,500 TIF surgeries worldwide to date, the TIF procedure and EsophyX device may be considered "investigational" by many healthcare plans; therefore, these healthcare plans may deny coverage until they have a chance to conduct their own technology assessment.

This cautious policy is meant to be in your best interest. However, if you are denied coverage for the TIF procedure and your doctor believes that it can make a significant difference in your life, you can "appeal" the insurer's decision to deny coverage. Since the appeals process varies from plan to plan and often involves a number of steps, it may seem overwhelming at first. Don't be intimidated. This guide provides the information and tools you need to understand the process and develop an effective appeal.

Throughout the process, keep in mind that, by working closely with your doctor, EGS and your insurer, you have the best chance of developing a successful appeal and receiving the treatment you need.

If you are considering an appeal, keep in mind that, if your insurer denies coverage for a new technology that you have requested, you are entitled to have your case reviewed. Most payers are regulated by state and/or federal laws designed to ensure that patients are treated fairly. These laws require healthcare plans to act honestly and in good faith in fulfilling their obligations

Who Participates in the Appeals Process?

Three parties are frequently involved in appealing an insurer's decision to deny coverage: you, your doctor, and your employer. Occasionally, a patient advocate or advocacy group may also help champion your case before the healthcare plan. Since your doctor has the most medical knowledge and experience with your case, be sure to rely on his or her advice throughout the process.

Together, we (EGS, you, your doctor, and your employer) can be a powerful team in reversing an insurer's decision to deny coverage.

What is My Role in the Appeals Process?

Since you have the most to gain or lose from an insurer's decision, it's important that you take an active role in the appeals process. You can work to help influence the decision by:

- Learning all about the process used by your specific healthcare plan. The procedures may be explained in the patient benefits booklets distributed by your healthcare plan, or you can request a description of the process from your insurer in writing
- Personally contacting your designated healthcare plan representative by phone to discuss a decision or follow up on details of the appeals process
- Writing a thoughtful appeal letter that describes the impact of your condition on your daily activities as well as its impact on any physical therapy program that you are involved in
- Asking for advice from your employer, specifically, an individual in the Human Resources department, who can help resolve any questions you may have about your healthcare benefits and explain how the benefits apply to you
- Keeping a regular log of your contacts with the insurance company including next steps and follow-up
- Hold yourself and the insurance company to all timelines outlined in the appeal procedure

- During the appeals process, it is important that both you and your doctor keep accurate and detailed records of all interactions with the healthcare plan and monitor the timeliness of the plan's response. (See sample form for recording this information on page 18.)

What Is a Request for Prior Authorization?

Generally, before you undergo an elective surgery (surgery you choose to have performed), most doctors' offices need a prior authorization, or approval before the surgery is performed, to ensure that the surgery will be covered under the plan. For the TIF procedure, your doctor or EGS will need to request prior authorization in writing, through a letter of medical necessity.

In the letter, your doctor should discuss all of the details about your case and your medical history, summarize results of clinical studies that demonstrate why the surgery is appropriate for you, explain how you can benefit from the surgery, and why this surgery is the best treatment option for you. Typically your doctor will receive a response from your healthcare plan. You may receive a response also. If the healthcare plan approves the request for prior authorization, no further action is required. If you receive a letter indicating denial of coverage, you and your doctor should consider an appeal.

How Does the Appeals Process Work?

Each healthcare plan has its own specific appeals process, so be sure to speak to your insurer first to learn about all of the steps and timelines involved. In addition, make sure that you have a copy of the plan's guidelines for an appeal in writing. Most healthcare plans permit three levels of appeal:

The 1st level appeal:

If your physician has submitted a letter requesting prior authorization for surgery and you are denied coverage, you can appeal to have your request reconsidered. Your doctor may supply additional details about the surgery to the insurer or request that your case is considered individually – not according to the plan's usual medical policies. This is known as a request for individual consideration. Your doctor's letter should be accompanied by a letter from you explaining your condition, why you need the surgery, and why you believe that you are entitled to the surgery under the terms of your insurance plan.

The 2nd level appeal:

If your insurer reconsiders your case and still denies coverage, your doctor can write to the insurer to ask for a full and fair review of your request. In this case, an independent physician, one not involved in the original decision and not employed by the healthcare plan evaluates your case.

In the best case scenario, the physician will have the same medical specialty as your treating physician. This is known as a school to school review. In a school to school review, your doctor should request to speak with the reviewing physician. This will give your doctor the opportunity to discuss your case directly with the reviewer.

When asking for a full and fair review, you and your doctor can request that the physician selected to review your case is knowledgeable and thoroughly trained in fundoplication surgery. You should know, however, that the healthcare plan is not obliged to comply with this request.

You may also want to get your employer involved at this stage, or a patient advocate or advocacy group. Their influence can encourage your insurer to pay special attention to your case. They can also ensure that you are treated fairly and in accordance with the appeal procedure outlined by your health insurance plan.

The 3rd level appeal:

If coverage is denied after a full and fair review, you and your doctor can appeal to an outside organization, such as a local government agency, to evaluate your case. For example, the Insurance Commission within your home state may be able to take action to influence your insurer's decision. You may also want to contact your state's Department

of Insurance (DOI) to find out whether you are eligible for insurance benefits under ERISA, the Employee Retirement Income Security Act of 1974. This program may be able to provide the coverage you need. Another strategy is to contact the Division of Consumer Affairs or the local Office of the Ombudsman, if there is one in your state. The ombudsman can provide information about other avenues of appeal available to you and may even agree to act as an advocate for you. A search on your home state's internet page can provide a wealth of information on how to contact the healthcare ombudsman. Look up listings under managed care, consumer protection, or healthcare commissions to locate your Ombudsman or an equivalent representative.

Local libraries can also provide free internet services and assist in the search for an Ombudsman or patient advocacy group in your area. Government agencies for healthcare information for consumers may also be helpful, and they can be found in the Yellow Pages of your phone directory under state agencies or in the pages with a blue border that list government agencies. After you submit your third level appeal, you and your doctor have exhausted all channels in the appeals process. If your healthcare plan denies coverage and you wish to pursue the matter any further, you may want to consider legal action.

Throughout the appeals process, you and your doctor can help prompt a faster response by requesting an expedited review of your case and/or following up frequently with your designated representative of the healthcare plan. However, since TIF surgery can be considered an elective procedure, the insurer is not obligated to conduct an expedited review.

How Can I Encourage a Successful Outcome?

There are a number of steps you can take to keep your appeal moving forward and help ensure its success. The following are a few suggestions:

- Before beginning the appeals process, inquire about your insurer's requirements concerning the selection of healthcare providers and hospitals and the need for physician referrals
- Pay attention to the timelines identified in the appeals process. If you fail to meet a timeline, you may lose your right to appeal. Hold your insurer to the timelines as well.
- Note the name of the individual who signed the first letter of denial of insurance coverage. Use that person or another individual that the plan designates as the point of contact for your next level appeal.

- Stay in frequent contact with the designated representative of your insurer to make sure that your appeal is moving along
- Involve your surgeon in the appeals process.
  - Ask your doctor to write a letter supporting your appeal.
  - Also ask him or her to contact the insurer directly to speak with the person who denied coverage as well as the Medical Director or Case Manager involved
- Always make sure you understand each next step in the appeals process.
  - Don't hesitate to discuss these steps with your insurer.
  - You may also contact your local Division of Consumer Affairs or Office of the Ombudsman to assist in your appeal and help you understand each step in the appeals process.
- Involve your employer. The employer is considered the insurance plan holder, whereas the employee is the plan subscriber. If your employer is a self-funded insurer, the employer has control over the benefits and covered services.
- Keep a record of all contacts with your healthcare plan. Be sure to record:
  - The date and time of your call or letter
  - The tone of the interaction
  - The topics discussed
  - Any next steps with their due dates
  - The outcome of the call or correspondence
  - Record names, titles, departments, and phone numbers (see sample form on page 18)
- Contact your local Division of Consumer Affairs or the Office of the Ombudsman to assist in your appeal and make sure that you understand each

How Can I Write an Effective Appeal Letter?

By following the guidelines below, you can create a strong, persuasive appeal letter and ensure that you receive a timely response. You will find suggested outlines for the content of two appeal letters in the Appendix that follows. As you write your letter, keep the following points in mind.

- Tips
  - Write in a friendly, informative manner.
  - Explain:
    - Your condition and the impact it has had on your life
    - Why you need the surgery
    - Why you feel that you are entitled to the surgery under the terms of your insurance plan

- Always make your appeal in your own words. Refrain from using catch phrases or standard wording

- Try to determine whether the denial of coverage involves a medical issue (i.e., inadequate authorization of services) or an administrative issue (lack of coverage for specific services). Then address the issue in your letter, stating clearly what you want to appeal and why. Concentrate on the facts and refer back to the specific points raised by the insurer in the denial letter you have received
- Include:
  - The name of your doctor
  - The scheduled date for your surgery
  - Your insurance ID number
  - An insurance claim number, if available, and any other identifying information
  - Your contact information – phone and fax numbers, e-mail addresses, etc.

Appendix A

Outline of content for your 1st level appeal letter

This outline suggests one method of organizing you appeal. Please remember that it should tell the patient's story and present medical conclusions in the patient's own words.

[Date]
[Name of Representative from Insurance Company]
[Insurance Company Name]
[Insurance Address]
[City, State, Zip]

Re: Request for Reconsideration of a Denial of Coverage
[Your Name]
[Type of Insurance]
[Group Number/Policy Number]
[Subscriber ID Number]

Dear [Name of designated representative of insurance company]:

Paragraph 1

- State that you wish to appeal the plan's denial of coverage for the TIF procedure
- Indicate the date of the letter of denial
- State that you understand that the healthcare plan has determined that TIF is an investigational procedure
- Point out that the EsophyX device has been cleared by the FDA and has been demonstrated to be safe and effective

Paragraph 2

- Mention the condition that you have been diagnosed with and the date of the diagnosis

- Describe your condition, the various treatments you have tried and the impact of the condition on your life and on your family
- Explain that the treating physician believes that you are a good candidate for TIF, it is the best treatment for you, and that you believe, you will significantly benefit from it.
- Add that your doctor has submitted a letter of medical necessity that includes an overview of your medical history and diagnosis, a discussion of how TIF will be used to correct your condition, and his or her rationale for the surgery

Paragraph 3

- Mention that your doctor is well trained in this surgery
- Ask that the insurer reconsider the earlier decision and allow coverage for the TIF procedure for your case
- Offer to have your surgeon provide any additional information that is necessary regarding your medical history or TIF procedure/EsophyX device.
- Thank the insurer for taking the time to review your letter. Conclude by indicating that you look forward to hearing from the insurer by [date]
- Include your contact information

Sincerely,
[Your name]
[Your address, phone number, and email address]
cc: [Your doctor]
[Your employer]

Appendix B

Outline of content for your 2nd level appeal letter

This outline suggests one method of organizing your appeal letter. Please remember that you should tell your story and present your medical conclusions in your own words.

[Date]
[Name of Representative from Insurance Company]
[Insurance Company Name]
[Insurance Address]
[City, State, Zip]

Re: Request for Reconsideration of a Denial of Coverage
[Your Name]
[Type of Insurance]
[Group Number/Policy Number]
[Subscriber ID Number]

Dear [Name of designated representative of insurance company]:

Paragraph 1

- State that you wish to appeal the plan's denial of coverage for the fundoplication surgery for the treatment of GERD
- Mention that this surgery has been recommended by your doctor [specify physician's name]
- Explain that your doctor and others have treated your symptoms for some time without any real improvement
- List your symptoms and limitations

- Describe how your symptoms have affected your daily routine, loss of sleep, poor/lost productivity at work, etc.

Paragraph 2

- Mention that your doctor has discussed all of your options with you
- Indicate that you believe that the option with the greatest chance to help you is the TIF procedure
- Note that your doctor has advised you that the surgery is medically necessary
- Point out that you continue to have symptoms and side-effects, despite having been treated with medications [list which ones], therapy, or other lifestyle modifications (inclined bed, change in diet, etc.)

Paragraph 3

- State that you understand your rights to appeal the plan decision to deny surgery
- Request that your appeal be reviewed by a physician in a specialty similar to your doctor's, a surgeon who is trained in fundoplication surgery
- Note that you are aware of the insurer's timeline for reviewing the appeal [specify the number of days]

Paragraph 4

- State that you have asked your doctor to assist in the review process by providing the insurer with more medical information and data on the surgery
- Request that your doctor speak directly with the reviewer, physician to physician, to discuss your case in a consultative manner

Paragraph 5

- Conclude by stating that you look forward to a timely review and a favorable outcome
- Restate the fact that you need this surgery in order to improve your life and your ability to function
- Include your contact information

Sincerely,

[Your name]
[Your address, phone number, and email address]
cc: [Your doctor]
[Your employer]

Appendix C
(for quick reference, appeals process summary)

Request for pre-authorization

Ask your doctor to write a letter to your healthcare plan requesting insurance coverage for the non-invasive, trans-oral fundoplication surgery (TIF). If the plan approves, no further action is required.

1st level appeal

If the insurer does not approve your pre-authorization request, both you and your doctor will need to write appeal letters to the insurer. (See Appendix A for suggestions about the content of your letter).

Potential strategies:

- Ask your doctor to provide more details about the technology and clinical documentation to argue against the idea that the procedure is investigational
- Ask your doctor to submit a "request for individual consideration," based on the merits of your case and your specific needs
- Urge your doctor to contact the insurer's designated representative by phone to ask questions or clarify any issues
- If the plan approves, no further action is required

2nd level appeal

If the insurer does not approve your 1st appeal, you and your doctor will need to write another letter to the insurer.

Potential strategies:

- Request a "full and fair review" by a physician not previously involved in your case
- Ask that the review be conducted "school to school", meaning it is done by a general surgeon knowledgeable in fundoplication surgeries
- Request that the physician reviewer be knowledgeable about the TIF procedure
- Ask your doctor to discuss the case with the physician reviewer
- Try to get your employer involved in the appeal
- If the plan approves, no further action is required

3rd level appeal

If the insurer continues to deny coverage, you and your doctor will need to write another letter to the insurer.

Potential strategies:

- You and your doctor can investigate whether you qualify for benefits under ERISA

- Contact local and state agencies that can help advise you and "lobby" for your case, i.e., the Office of the Ombudsman
- Ask a representative of your employer (i.e., someone from Human Resources) to contact your insurer and act as your advocate

Post 3rd level appeal

If the 3rd level appeal proves unsuccessful, you have exhausted all steps in the appeals process. The only option remaining is to consider legal action.

Appendix D: Sample Form

(to record your contacts during the appeals process)

YOUR NAME _____

TYPE OF INSURANCE _____

MEMBER/GROUP NUMBER _____

APPEALS CASE NUMBER _____

Type of Contact	Call Date & Time	Person Contacted (Title/ Dept. Phone No.)	Issues Discussed and Outcomes/ Next Steps	Date for Follow-up
Request for Prior Authorization				
3st Level Appeal				
2nd Level Appeal				
3rd Level Appeal				
Employer				
Advocate/Advocacy Group _____ _____				
Office of the Ombudsman _____ _____				
Other				

Appendix E: Glossary of Terms

Appeals process: The process by which you seek to overcome a healthcare plan's denial of insurance coverage for a medical technology or procedure that your doctor believes is necessary.

DOI: Department of Insurance: A department within the federal or state government that oversees the functions of all healthcare plans and is the ultimate authority in the appeals process. Contact information for the Department of Insurance can be found in the yellow pages under state agencies.

ERISA: the Employee Retirement Income Security Act of 1974. A federal program that provides benefits for eligible patients and procedures that might not be covered by private healthcare plans. The Department of Insurance can assist you in determining whether you qualify for benefits under ERISA.

Full and fair review: A review of a denial of health insurance benefits that is conducted by a physician who was not involved in your insurer's original decision to deny coverage. Typically the physician reviewer has the same specialty as your physician. During the review, your case is examined on its individual merits and your specific circumstances.

Letter of medical necessity: Written by your surgeon, this letter argues that the requested surgery is necessary medically for you. Generally, the letter includes details about the surgery and a history of your case, a description of how your condition affects your life, and published literature that supports the safety and efficacy of the new technology or procedure you are requesting.

Medical policy: reimbursement guidelines and procedures that govern all members of a healthcare plan.

Office of the Ombudsman: A government office available in certain states only. The ombudsman can assist you in the appeals process by suggesting additional avenues for appeal and acting as a patient advocate. To determine if your state has an Ombudsman, contact the Division of Consumer Affairs.

Patient advocate: An individual or group that champions your case before the healthcare plan and helps bridge the gap between you and your insurer. Patient advocates can often be very effective in helping to overturn a denial of insurance coverage. A partial listing of advocacy groups is found in this Guide.

Patient benefits booklet: Distributed by the healthcare plan to its members, the booklet usually contains detailed information regarding the plan's policies, benefits, and procedures for appealing denial of insurance coverage.

Appendix F: Other Resources

Prior authorization: A request for approval of a specific medical service, typically an elective procedure. The process involves either verbal or written communication between your doctor and the insurer regarding the type of service to be performed, the reason for service, your medical history, and documentation of the success of the service. In the case of the TIF procedure performed with the EsophyX device, a letter requesting prior authorization should be submitted by your doctor to your insurer.

School-to-school review: With this type of review, an insurer hires a physician as a consultant to evaluate your appeal. The physician generally works in the same specialty as your doctor, performs identical types of procedures, and has experience in treating other patients with the same condition. Therefore, he or she is especially qualified to review your case. In the case of TIF with the EsophyX device the physician should be a surgeon who performs fundoplication.

Agencies and advocacy groups that may provide assistance during the appeals process:

- **National Association of Insurance Commissioner:**
  www.naic.org
- **Each state's Insurance Commissioner:**
  http://www.naic.org/state_contacts/sid_websites.jsp
- **Insurance Department:**
  http://www.naic.org/state_contacts/index.htm
- **National Association of Attorneys General:**
  www.naag.org
- **List of Attorneys General by state:**
  http://www.naag.org/ag/full_ag_table.php
  (Search for 'health care unit'. An appeals and grievance process should be defined. Complaint forms may be available to download.)
- **National Conference of State Legislators:**
  http://www.ncsl.org/public/leglinks.cfm
- **House of Representatives:**
  http://www.house.gov/
- **Senators:**
  http://www.senate.gov/general/contact_information/senators_cfm.cfm

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