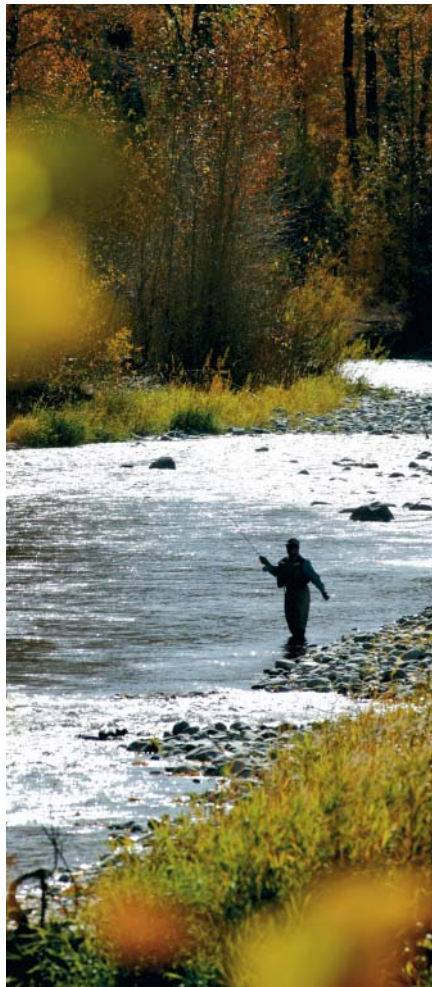


ProDisc-C Total Disc Replacement. Patient Reimbursement Information.

Patient
Assistance Line
(PAL)
800-895-7764



 **SYNTHES**[®]
Spine

Patient Reimbursement Information

Introduction

The information in this Guide is prepared by Synthes Spine as a tool to help the patient/hospital/physician during the reimbursement process. Synthes Spine does not guarantee or promise payment for ProDisc-C Total Disc Replacement (TDR) or related procedures from any insurer. All third party payors/administrators and plans differ in their policies, and it is the responsibility of the physician, hospital and patient, working together, to seek payment from the health plan. Any codes and billing information supplied here is general and for informational purposes only. Patients, physicians, and hospitals should check with the health plan to obtain specific information about the scope of benefits, payment levels, and coding requirements for the particular insurer.

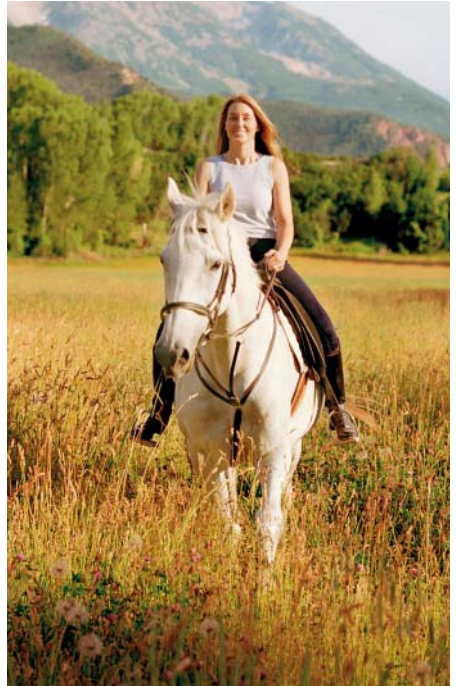


Reimbursement Assistance

You and your physician have made an important decision regarding your health care. Your physician may have told you that payment for this new therapy is not automatically covered by all insurance plans, and that you and he/she will have to work together in securing payment for this procedure.

Synthes has contracted with a hotline service to operate a patient/hospital/physician helpline known as the Patient Assistance Line (**PAL**). **PAL** is prepared to work with you and your physician to facilitate coverage and reimbursement for ProDisc-C TDR. However, these services will not guarantee coverage or payment.

PAL can assist you and your physician in documenting for your insurer the medical appropriateness of the procedure. Innovative procedures typically require complete and accurate descriptions so insurers can make benefit or coverage determinations. As you are the insured, you must take an active role in the reimbursement process.



The helpline at 800-895-7764, along with the Synthes ProDisc website (www.synthesprodisc.com), will provide the tools to help guide you.

Please utilize your **PAL** as frequently as necessary.

Patient Assistance Line (PAL)
800-895-7764

Patient Reimbursement Information

The Beginning of Coverage

When employers seek to offer medical coverage to employees, they search for a “plan” that provides the best benefits in a cost-effective manner, or they self-insure and create their own plan. A plan lists the “benefits” that are available for coverage.

A plan has to be administered, and you may be dealing with an insurance company (a third-party health insurance payor) or an administrator. The administrators, or the plan itself, act as gatekeepers to the benefits of the plan. They have a fiduciary duty to cover only those services that fall within the scope of the benefits and are medically appropriate for the patient’s particular needs.

The plan will cover a number of services and supplies, as well as many therapies, depending on the benefits. Often, a new technology or device does not receive automatic coverage, either because it was not a therapy that was common at the time the plan was written, or because it has not undergone medical review by the administrator or vendor of the plan. Disc arthroplasty (disc replacement) is a therapy that many insurers have not yet reviewed.



You are entitled to “benefits” under your plan and those benefits are seldom restricted to a specific therapy. For example, your benefits may include hospital care and physician or surgical services. These broad benefits can include certain types of surgery and perhaps spinal fusion under the plan. Similarly, benefits can encompass disc replacement (disc arthroplasty).

Seeking Authorization for Surgery

Surgery almost always requires authorization by the plan. Often this “preauthorization” is routine, yet sometimes it will not be granted. In other words, the insurer/administrator will not agree to pay for the procedure. Hospitals most often check with the plan. The process for the hospital is called “precertification” or predetermination.

While preauthorization for a procedure may not be required by all plans, physicians almost always seek “preauthorization” for major surgeries. When there is a newer and less familiar therapy/device, it is a prudent idea to seek prior approval.

Approval from a third party payor is sometimes routine. Other times, approval may be denied. Denial is seldom final and you have recourse if your surgery is denied.



Patient Reimbursement Information

Appeal of a Denial

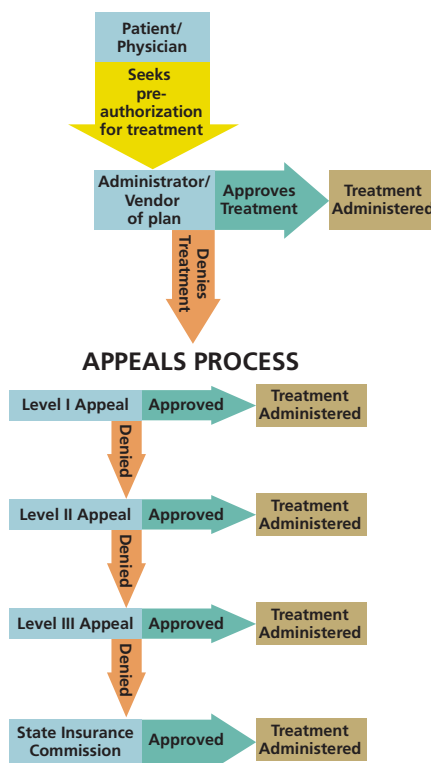
An appeal is the petitioning for payment of a benefit following a denial. In many cases, state laws, as well as the plans themselves, allow a patient to petition the plan for payment for a new therapy that is not specifically excluded by the plan. Cervical spine surgery is very seldom, if ever, an excluded benefit, and the simple fact that ProDisc-C TDR is a new therapy is not a sufficient reason for denial.

You, the patient, with the help of your physician and guidance from the **PAL**, can ask the insurer to review the initial denial and authorize payment for your surgery. This takes time and perseverance, so do not be discouraged.

The Appeals Process

There are levels of appeal. Most third-party payors have two or three levels.

The PAL at 800-895-7764 can advise you about the appeal process for your insurer.



Initial Appeal: Level I

The appeal process is not difficult. It requires both you and your physician to ask for a review of the denial. Most often the appeal is time-sensitive and must be completed by you within a certain timeframe after you have received the initial denial; **PAL** will tell you the timeframe for your third-party payor. It is very important to make clear in your appeal the exact reason for the denial of service by your insurer. An insurer may say in its denial letter the procedure was experimental, not medically necessary, not within the benefit package, or not authorized. Make sure you find out exactly the reason for the denial, so you can respond directly to that concern. Most often you, and possibly your physician, will receive written notice of denial. After initiating a first level appeal, the total time for this review process may be 30–180 days.



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Initial Appeal: Level I *continued*

Appeals usually must be in writing. Some insurers have a letter that can be downloaded from their website. If your insurer does not have such a letter, **PAL** can direct you to a website that has a sample letter for your use. Your physician may have provided you with similar information. Additionally, some insurers have an electronic appeal process which can be accessed from their website.

Review of the first level of appeal can be conducted by a staff member of the insurer who was not involved with the initial review and denial. This person will review the facts of the case. You and your physician will need to submit documentation, if this was not done during the preapproval process. That documentation includes:

- A copy of the denial
- Medical history of the patient
- Medical justification for the arthroplasty
- Clinical literature on disc arthroplasty
- FDA approval letter
- Patient Consent Form

If you are denied at Level I, you can go on to the next level. **The Patient Assistance Line at 800-895-7764** can tell you the process for your insurer.



Level II Appeal

In general, you or the physician must request this elevated level. Usually, the request must come from the physician.

PAL can tell you your insurer's requirements for this level. Make sure to read the denial of the first level appeal carefully.

Most often a physician will review a Level II appeal. Again, just as in the initial appeal, there are likely to be time requirements for you or your physician when filing the Level II appeal. This is often the most successful point in the appeals process, resulting in approval/payment. If this level is not successful there is often another option.

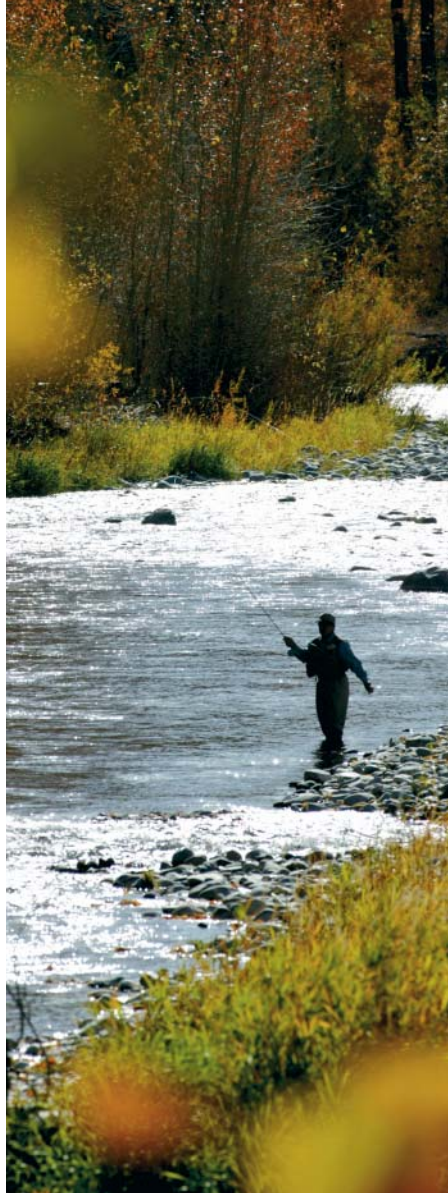
Patient Reimbursement Information

Level III or External Review

There may be a third step that you may take if a Level II review is not the final step for your insurer. Insurers and states often have rules and procedures for a review at this level. Most often it requires a physician from the same specialty area as your physician to perform the review. In many states, the law requires that the reviewing physician must also care for the same type of patient and, in some cases, must have experience in performing the same procedure as your physician. This physician will NOT be associated with the insurance company per se, other than to be on the list of doctors who act as reviewers.

The same information may be required again:

- A copy of the denial
- Medical history of the patient
- Medical justification for the arthroplasty
- Clinical literature on disc arthroplasty
- FDA approval letter
- Patient Consent Form



At this level, your physician will probably be in communication with the reviewing doctor. As disc arthroplasty becomes more familiar to all physicians and surgeons, and as insurers recognize the clinical value of the procedure, there should be less need for appeals at this level.

Last and Final Review

All states have an Insurance Commission or a contracted, independent review board (IRB/IRO) to oversee the final review. Should this level be necessary, **PAL** will be available at **(800) 895-7764** to explain this additional process in your state. As with previous appeal levels, your **PAL** will support you throughout the process to seek appropriate reimbursement for the ProDisc-C procedure selected by you and your physician.

Disclaimer

All billing and coding information contained herein is for informational purposes only. Synthes Spine makes no claims of correctness, warranty, guarantee or assertion that the information will assure payment. We strongly urge you to consult the payor to determine the requirements for reimbursement for disc arthroplasty.



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