

SAMPLE LETTER OF MEDICAL NECESSITY FOR
The Functional Anaesthetic Discography™ Procedure

Name of medical director or medical reviewer
Address

Re: Patient Name
SS#
Policy, Group or Claim # (identifying data for the carrier)
Date of birth

Dear Director of Medical Review:

I am recommending the Functional Anaesthetic Discography™ (F.A.D.™) Procedure for [insert patient name]. The claim for [insert patient name] includes the CPT code 64999 unlisted nervous system procedure. I am requesting that you review and provide authorization for this procedure and the reason for the review is the procedure is billed with an unlisted code that has not been assigned any relative value units for payment.

[Patient's name] is a [age]-year old patient who presents with a history of discogenic back pain. [Patient] experiences significant levels of pain and discomfort on a day to day basis. To date, he/she has been unresponsive to non-surgical treatment including pain medication, exercise, physical therapy and occupational therapy including back school and change in work habits. This back pain has affected my patient's physical functioning, ability to tolerate activities of daily living, and overall quality of life. He/she also complained about difficulty sleeping and interruption of sexual activity.

Based on his/her ongoing complaints and inclusive diagnostic findings, I felt it was medically necessary to perform the Functional Anaesthetic Discography Procedure to evaluate and assist in localizing the pain source for consideration of treatment options for discogenic low back pain.

The Discyphor Direct™ Catheter is a balloon anchored catheter which is inserted into one or more suspected discs to deliver anesthetic/saline. Under fluoroscopic image guidance, the DISCYPHOR DIRECT™ Outer Needle is introduced through the skin via a posterolateral approach. The DISCYPHOR DIRECT™ Inner Needle is inserted through the DISCYPHOR DIRECT™ Outer Needle into the nucleus of the target disc. The catheter is then inserted through the inner needle and into the disc. The outer and inner needles are then removed simultaneously, leaving the catheter in the disc nucleus. The balloon, located at the distal tip of the catheter, is inflated using a contrast medium to anchor the catheter within the disc nucleus during the functional testing process. The proximal end of the catheter is capped and secured to the patient with anchoring devices and/or sterile tape, and the patient is transferred to recovery.

Upon mild sedation recovery, patient tries to recreate typical low back pain by loading the spine in a functional or physiological fashion performing activities such as sitting, walking

or bending. The patient is asked to rate this pain using the Visual Analog Pain Scale (VAS) or the Numeric Pain Rating Scale (NPRS). If applicable, patient's range of motion is also noted. Patient is then injected with 0.5 - 0.7 cc of anesthetic and upon anesthetic onset, asked again to rate pain level (and applicable range of motion). A two point or greater drop in pain score would indicate that the disc level is a pain generator. Alternatively, range of motion during pain generating activity is also monitored and recorded. Significant improvement in range of motion is also indicative that the (anaesthetic) injected disc is a potential pain generator. *Comparison pain scores are measured for anaesthetic disc improvement and additional valuable information for consideration of treatment options of discogenic back pain.*

The same steps are repeated for each of the suspected discs.

Based on the specific facts as described above, I believe that this Functional Anaesthetic Discography Procedure is in accordance with accepted professional standards and is reasonable and necessary.

[Physician to include appropriate historical patient outcomes information.]

My fee for [insert procedure for comparison] is \$ xxx. Relative to the increase in time, skill, work, and additional overhead, my professional fee for the F.A.D. Procedure is \$ [insert charge]. This represents my estimation of value units of time, skill, and effort to perform the procedure. This is based on [25% or 50%] increase in the RVUs over that of [insert comparison procedure] as described above.

I appreciate your timely review and approval of this matter.

Sincerely,

The information provided in this notice is intended as general information only. It is not advice about how to code or complete or submit any particular claim for payment for the F.A.D.™ Procedure. Medtronic Spine LLC cannot guarantee coverage or reimbursement for the F.A.D.™ Procedure and makes no other representations as to selecting codes for the F.A.D.™ Procedure or compliance with any other billing protocols or prerequisites. As with all claims, physicians and hospitals are responsible for exercising their independent clinical judgment in selecting the codes that most accurately reflect the patient's condition and procedures furnished to a patient. Physicians and hospitals should refer to current, complete, and authoritative publications such as AMA CPT publications or insurer policies for selecting codes based on the care rendered to an individual patient, and may wish to contact individual carriers, fiscal intermediaries, or other third-party payers as needed.

As with most interventional procedures, the Functional Anaesthetic Discography™ (F.A.D.™) Procedure has associated risks, including serious complications. For complete information regarding indications for use, contraindications, warnings, precautions, adverse events and methods of use, please reference the devices' Instructions for Use.