

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™ Catheter is a balloon anchored catheter which is inserted into one or more suspected discs. To aid in catheter placement, an 18-g Discyphor™ Introducer Needle is placed on the annulus of the suspected disc(s). Then a 25-g Discyphor™ Spinal Needle is placed into the center of the disc. A Discyphor™ Guidewire is inserted through the Discyphor Spinal Needle. This Discyphor Guidewire assists in inserting the Discyphor™ Catheter into the center of the disc, where the Discyphor Spinal Needle was

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As with most interventional procedures, the Functional Anaesthetic Discography procedure has associated risks, including serious complications. For complete information regarding indications for use, warnings, precautions, adverse events, and methods of use, please reference the device's Instructions for Use. *KYPHON* is a registered trademark, and *Ahead of the Curve*, *Discyphor*, and *Functional Anaesthetic Discography* are trademarks, of Kyphon Inc. ©2008 Kyphon Inc. All Rights Reserved. 16000945-01

inserted. Once the Discyphor Guidewire is inserted into the disc and confirmed by radiographic imaging, the Discyphor Spinal Needle is removed. The Discyphor Catheter is inserted over the wire into the disc through the 18-g Discyphor Introducer Needle until the balloon anchor is inside the disc nucleus. The Discyphor Guidewire and Introducer Needle are removed after the Discyphor Catheter has been inserted to the desired location. The small balloon at the distal end of the Discyphor Catheter is inflated under radiographic imaging. The proximal end of the Discyphor Catheter is then capped and secured to the side of the patient with sterile tape. The patient is moved to recovery.

Upon mild sedation recovery, patient tries to recreate typical low back pain by loading the spine in a functional or physiological fashion during such activities such as sitting, walking or bending. The patient is asked to rate this pain using the Visual Analog Pain Scale (VAS). Patient is then injected with 0.5 - 0.7 cc of anesthetic and asked again to measure pain level. After allowing appropriate time for the onset of the anesthetic, the patient is asked to perform/assume the same pain eliciting activities/postures and then asked to rate their pain level on the VAS. 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,

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