

# IRO Express Inc.

An Independent Review Organization

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**DATE OF REVIEW:** June 16, 2008

**IRO CASE #:**

## **DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE**

The items in dispute are: removal of hardware L3/S1, extension of fusion L2/3, ICBG, pedicle screws and rods, and anterior interbody fusion L2/3 with a two day inpatient stay.

## **A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION**

Board Certified Orthopedic Surgeon

## **REVIEW OUTCOME**

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

## **INFORMATION PROVIDED TO THE IRO FOR REVIEW**

OD Guidelines

CT lumbar spine, 09/25/07 – CT Lumbar Spine w/o contrast with reconstructions:

Impression:

Office notes, Dr. 09/27/07, 10/04/07, 10/25/07, 11/01/07, 11/17/07, 01/03/08, 01/15/08, 01/17/08, 02/21/08, 03/06/08, 03/20/08

Lumbar myelogram, 11/14/07

CT post myelogram, 11/14/07

Procedure note, 02/12/08, 04/16/08

RME, Dr. 02/18/08

Note, claimant, 02/18/08

CT lumbar spine, 03/04/08

Office note, Dr. 04/03/08

Physical therapy note, 04/23/08 – PT note

Adverse Determination Letters, 05/07/08, 05/22/08

HEALTH AND WC NETWORK CERTIFICATION & QA 7/2/2008

IRO Decision/Report Template- WC

## **PATIENT CLINICAL HISTORY [SUMMARY]:**

The claimant is a female who developed low back pain while moving some heavy tubs. Her history prior to that was significant for a laminectomy in 1991 and a lumbar fusion at L4-5 and L5-S1 in 2000 with good relief. A lumbar CT obtained on 09/25/07 demonstrated extensive post surgical and degenerative changes and posterolateral fusion grafts at L4-5 and L5-S1 which were intact. The claimant presented to Dr. on 09/27/07 for low back pain bilaterally radiating towards the outer aspect of the left hip with left sided paresthesias over the front of the thigh mainly in the morning. Her symptoms were exacerbated with coughing, sneezing and straining and flexion. Dr. reviewed the CT. The examination noted flexion and extension with pain on bending forward and twisting side to side with pain on either side of the midline just over the iliac crest. There was tenderness on either side of midline with deep palpation. Sensation was normal including over the anterior thigh where she had paresthesias. Reflexes were normal and she had marked tenderness directly over the greater trochanter on the left. Low back muscular sprain, left sided trochanteric bursitis and intermittent left anterior paresthesias likely related to L3 nerve root irritation were diagnosed. Electrodiagnostic studies, therapy, medications, a trochanteric bursal injection and a firm lumbar corset were recommended. The claimant was seen for electrodiagnostic studies on 09/27/07 at which time reflexes were slightly diminished at the bilateral lower extremities, but symmetrical. Electrodiagnostic studies obtained on 09/27/07 were unremarkable for lumbar radiculopathy and/or peripheral neuropathy.

On 10/25/07 Dr. saw the claimant again for the recent worsening of her symptoms down the lower extremities greater on the left with paresthesias over the lateral calf and the dorsum of her feet. She was markedly tender directly over the posterior superior iliac spine to both sides of the low back with what appeared to be a positive Faber test on the left with direct pressure over the sacroiliac joint, had clear evidence of paresthesias over both calves laterally in the L5 dermatomes to the dorsum of both feet. Facet joint mediated pain likely from L3-4 and sacroiliac joint pain in the buttocks were diagnosed.

A lumbar myelogram and CT was obtained on 11/14/07 showing: At T11-12: 1 millimeter retrolisthesis T11 upon T12 with a 2 millimeter broad based non-focal posterior protrusion mildly indenting the sac. At L1 a 2 millimeter broad based non-focal posterior protrusion mildly indenting the sac with mild bilateral foraminal narrowing. At L2-3 a 3 millimeter broad based non-focal posterior protrusion mildly indenting the sac with mild bilateral foraminal narrowing. At L3-4 there was marked disc space narrowing and 3 millimeters of anterolisthesis of L3 upon L4. There were transpedicular screws with posterior instrumentation and laminectomy defects. There was no evidence of loosening of the hardware. The posterolateral fusion masses demonstrated some fragmentation, but there did appear to be continuous osseous bridging between the transverse processes of L3 and L4. The residual facet joints were fused. There had been no transdiscal interbody arthrodesis. At L4-5 there was marked disc space narrowing with continuous osseous bridging across the disc space and laminectomy defects. There was a 4 millimeter bony postero-central and left posterior protrusion mildly effaces the sac and the left L5 nerve root sleeve. There were transpedicular screws and instrumentation and mild bony left and mild to moderate bony right foraminal narrowing. There was no displacement of the emanating L4 nerve root sleeves. Although far laterally they were slightly effaced. The posterolateral fusion masses were continuous from L4 to L5 and the residual facet joints are fused. At L5-S1 was a prior transdiscal interbody arthrodesis with a solid fusion across the disc space. The facet

joints appear fused. The S1 nerve root sleeves were uneffaced and filled normally. There was no remarkable foraminal narrowing and the transsacral screws demonstrated no evidence of loosening.

Dr. agreed with the opinion. On 11/17/07 the claimant was given another trochanteric bursa injection. A combination of medications including Lortab, Flexeril and Ibuprofen, therapy, series of lumbar epidural steroid injections and a left sacroiliac injection were recommended. The claimant was seen by another Dr. on 01/15/08 and entered the office in a wheelchair due to painful ambulation. She stood with a most antalgic, very slow and very positive methods. She had an unsteady gait and was markedly guarded. She refused to bend forward due to pain and could not extend her back even to neutral. X-rays from 11/07 were reviewed showing a junctional level of insufficiency at what we will label L2-3 with broad based bulge emanating at this level. There was some question; there may be some fragmentation in the posterior fusion at the next level down L3-4. This was highly suspect and did appear to be enough evidence to suggest that this was a fused level. There was some lucency noted around the screw heads below this as well, which may suggest that the screws are somewhat loose. However Dr. did not feel this was the primary source of her pain. He diagnosed the claimant with an unstable junctional area above her fusion and recommended lumbar epidural steroid injections.

The claimant on 01/17/08 reported increasingly worsening symptoms including increased pain with bowel movements, coughing and sneezing with weakness of her legs, greater on the right and the need to use an electronic chair to grocery shop. On 02/12/08 she was given an L2-3 lumbar epidural steroid injection which did not provide her improvement. Dr. saw the claimant for a required medical evaluation on 02/18/08 for persistent low back pain with pain into the sacrum and coccyx and paresthesias down the legs along the anterolateral thighs then lateral calves to the top of the feet with Valsalva maneuvers. The examination noted guarded lumbar motions in all directions, more pain and triggering of paresthesias down the legs with forward flexion than extension, more tenderness over the left sacroiliac joint than the right, tenderness to palpation bilaterally over the greater trochanters. Patrick test was positive only for referred pain into the back and buttock, bilaterally, but was not specifically indicative of hip joint involvement. Pelvic rock maneuver referred to bilateral low back and the sacral area. While standing and flexed forward at the hips she reported severe pain and paresthesias down the legs, but did not do this when seated and extending her legs with the hips bent 80-90. Calf circumference was left 40 centimeters and right 42 centimeters. Reflexes were trace and then 1 plus with repeated trials, bilaterally at the knees and ankles. Pinprick sensation was intact all dermatomes and her gait was symmetrical but unusual as she walked with her knees and hips slightly flexed which she said was due to her back pain. Dr. stated that her findings were not indicative of radiculopathy other than the decreased calf circumference. He did not feel that further epidural steroid injections were needed based on her lack of response with the initial one and suggested a set of bilateral selective nerve blocks at L3 and perhaps L2, a standing MRI and McKenzie extensions. He stated if the tests identified a specific lesion it would be up to the treating physician to determine her appropriateness for surgery.

On 02/21/08 the claimant was seen again by Dr. for progressively worsened axial low back pain. There was marked tenderness to the left of the midline and on the right of midline in the low back, greater on the left. Rotation of the hip and Faber gave reproduction of buttock and back pain, mostly back pain. Straight leg raise produced

buttock pain bilaterally. Lumbar spine x-rays were repeated and showed evidence of a fracture of the most distal pedicle screw on the left side, approximately in the midshaft at the level of the posterior surface of the vertebral body. This was seen to be accentuated between flexion and extension. The oblique views also clearly show evidence of a fracture. The CT of 02/07 was reevaluated including a review with the radiologist who noted the screw appeared to be slightly bent on that study but did not appear to rise significance to merit mention on the report. He also commented that the fusion at the most proximal level appeared to be fragmented and in his eyes, was not fused within any certainty. A repeat CT was obtained on 03/04/08 showing a solid appearing L3-4 transitional L5 fusion, no loosening of the posterior instrumentation, multiple level lumbar facet arthrosis and L2-3 and L4 transitional L5 neural foraminal stenosis. Dr. spoke with Dr. radiologist who stated and amended the report to say there was no evidence of loosening of instrumentation, the left transalar screw was angled caudally but without evidence of fracture of the screw. The screw did not appear to be bent. The claimant presented on 03/20/08 for continued bilateral leg symptoms and mild axial discogenic type pain. Diskography and diagnostic facet blocks were recommended. On 04/16/08 lumbar facet block at L3-4 bilaterally were given. The requested surgery was denied by two reviews on 05/07/08 and 05/22/08 and is currently being disputed.

**ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.**

The requested removal of hardware, extension of fusion L2-L3, ICBG, pedicle screws, and anterior interbody fusion L2-l3 with two day length of stay does not appear to be medically reasonable or necessary based on review of the medical record. The records from 09/25/07 onward have been reviewed, that document her complaints, findings and treatment as well as her diagnostic studies. While there appears to be fusion of the lower lumbar segments, her treating physician indicates that her pain most likely is coming from the segment just above the fused segments due to progressive degenerative change. However, there has not been evidence of structural instability or significant disc herniation causing nerve root pressure at that next level on diagnostic studies. There have been two previous peer determinations, which entailed the reviewer talking by telephone with Dr. and it would appear that both of those reviewers felt that surgical intervention was not necessary. In light of the review today of this medical record, which would indicate no clear documentation of structural instability or significant disc herniation at the level above the fusion, then the requested surgical intervention would not appear to be medically reasonable or necessary. Therefore, this reviewer would agree with the determination of the insurance carrier based on the prior reviews and evaluation of the provided medical record.

Official Disability Guidelines Treatment in Worker's Comp 2007 Updates, (i.e. Low Back-Hardware Injection and Fusion)

Not recommended for patients who have less than six months of failed recommended conservative care unless there is objectively demonstrated severe structural instability and/or acute or progressive neurologic dysfunction, but recommended as an option for spinal fracture, dislocation, spondylolisthesis or frank neurogenic compromise, subject to the selection criteria outlined in the section below entitled, "Patient Selection Criteria for Lumbar Spinal Fusion," after 6 months of conservative care. For workers' comp populations, see also the heading, "Lumbar fusion in workers' comp patients." After screening for psychosocial variables, outcomes are improved and fusion may be recommended for degenerative disc disease with spinal segment collapse with or

without neurologic compromise after 6 months of compliance with recommended conservative therapy. [For spinal instability criteria, see AMA Guides (Andersson, 2000)] For complete references, see separate document with all studies focusing on Fusion (spinal). There is limited scientific evidence about the long-term effectiveness of fusion for degenerative disc disease compared with natural history, placebo, or conservative treatment. Studies conducted in order to compare different surgical techniques have shown success for fusion in carefully selected patients. (Gibson-Cochrane, 2000) (Savolainen, 1998) (Wetzel, 2001) (Molinari, 2001) (Bigos, 1999) (Washington, 1995) (DeBarard-Spine, 2001) (Fritzell-Spine, 2001) (Fritzell-Spine, 2002) (Deyo-NEJM, 2004) (Gibson-Cochrane/Spine, 2005) (Soegaard, 2005) (Glassman, 2006) (Atlas, 2006) According to the recently released AANS/NASS Guidelines, lumbar fusion is recommended as a treatment for carefully selected patients with disabling low back pain due to one- or two-level degenerative disc disease after failure of an appropriate period of conservative care. This recommendation was based on one study that contained numerous flaws, including a lack of standardization of conservative care in the control group. At the time of the 2-year follow up it appeared that pain had significantly increased in the surgical group from year 1 to 2. Follow-up post study is still pending publication. In addition, there remains no direction regarding how to define the “carefully selected patient.” (Resnick, 2005) (Fritzell, 2004) A recently published well respected international guideline, the “European Guidelines,” concluded that fusion surgery for nonspecific chronic LBP cannot be recommended unless 2 years of all other recommended conservative treatments – including multidisciplinary approaches with combined programs of cognitive intervention and exercises – have failed, or such combined programs are not available, and only then in carefully selected patients with maximum 2-level degenerative disc disease. (Airaksinen, 2006) For chronic LBP, exercise and cognitive intervention may be equivalent to lumbar fusion without the potentially high surgical complication rates. (Ivar Brox-Spine, 2003) (Keller-Spine, 2004) (Fairbank-BMJ, 2005) (Brox, 2006) In acute spinal cord injury (SCI), if the spine is unstable following injury, surgical fusion and bracing may be necessary. (Bagnall-Cochrane, 2004) (Siebenga, 2006) A study on improving quality through identifying inappropriate care found that use of guideline-based Utilization Review (UR) protocols resulted in a denial rate for lumbar fusion 59 times as high as denial rates using non-guideline based UR. (Wickizer, 2004) The profit motive and market medicine have had a significant impact on clinical practice and research in the field of spine surgery. (Weiner-Spine, 2004) (Shah-Spine, 2005) (Abelson, 2006) Data on geographic variations in medical procedure rates suggest that there is significant variability in spine fusion rates, which may be interpreted to suggest a poor professional consensus on the appropriate indications for performing spinal fusion. (Deyo-Spine, 2005) (Weinstein, 2006) Outcomes from complicated surgical fusion techniques (with internal fixation) may be no better than the traditional posterolateral fusion. (van Tulder, 2006) (Maghout-Juratli, 2006) Despite the new technologies, reoperation rates after lumbar fusion have become higher. (Martin, 2007) According to the recent Medicare Coverage Advisory Committee Technology Assessment, the evidence for lumbar spinal fusion does not conclusively demonstrate short-term or long-term benefits compared with nonsurgical treatment for elderly patients. (CMS, 2006) When lumbar fusion surgery is performed, either with lateral fusion alone or with interbody fusion, unlike cervical fusion, there is no absolute contraindication to patients returning even to contact sports after complete recovery from surgery. Like patients with a thoracic injury, those with a lumbar injury should be pain free, have no disabling neurological deficit, and exhibit evidence of bone fusion on x-ray films before returning. (Burnett, 2006) A recent randomized controlled trial comparing decompression with decompression and instrumented fusion in patients with foraminal

stenosis and single-level degenerative disease found that patients universally improved with surgery, and this improvement was maintained at 5 years. However, no obvious additional benefit was noted by combining decompression with an instrumented fusion. (Hallett, 2007) Discography may be supported if the decision has already been made to do a spinal fusion, and a negative discogram could rule out the need for fusion on that disc (but a positive discogram in itself would not justify fusion). Discography may help distinguish asymptomatic discs among morphologically abnormal discs in patients without psychosocial issues. Precise prospective categorization of discographic diagnoses may predict outcomes from treatment, surgical or otherwise. (Derby, 2005) (Derby2, 2005) (Derby, 1999) New research shows that healthcare expenditures for back and neck problems have increased substantially over time, but with little improvement in healthcare outcomes such as functional disability and work limitations. Rates of imaging, injections, opiate use, and spinal surgery have increased substantially over the past decade, but it is unclear what impact, if any, this has had on health outcomes. (Martin, 2008) The efficacy of surgery for nonspecific back pain is uncertain. There may be some patients for whom surgery, fusion specifically, might be helpful, but it is important for doctors to discuss the fact that surgery doesn't tend to lead to huge improvements on average, about a 10- to 20-point improvement in function on a 100-point scale, and a significant proportion of patients still need to take pain medication and don't return to full function. (Chou, 2008) Lumbar spinal fusion surgeries use bone grafts, and are sometimes combined with metal devices, to produce a rigid connection between two or more adjacent vertebrae. The therapeutic objective of spinal fusion surgery for patients with low back problems is to prevent any movement in the intervertebral spaces between the fused vertebrae, thereby reducing pain and any neurological deficits. See also Adjacent segment disease/degeneration (fusion) & Iliac crest donor-site pain treatment.

Lumbar fusion in workers' comp patients: In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that may affect overall success of the procedure, which should be considered. Until further research is conducted there remains insufficient evidence to recommend fusion for chronic low back pain in the absence of stenosis and spondylolisthesis, and this treatment for this condition remains "under study." It appears that workers' compensation populations require particular scrutiny when being considered for fusion for chronic low back pain, as there is evidence of poorer outcomes in subgroups of patients who were receiving compensation or involved in litigation. (Fritzell-Spine, 2001) (Harris-JAMA, 2005) (Maghout-Juratli, 2006) (Atlas, 2006) Despite poorer outcomes in workers' compensation patients, utilization is much higher in this population than in group health. (Texas, 2001) (NCCI, 2006) Presurgical biopsychosocial variables predict patient outcomes from lumbar fusion, which may help improve patient selection. Workers' compensation status, smoking, depression, and litigation were the most consistent presurgical predictors of poorer patient outcomes. Other predictors of poor results were number of prior low back operations, low household income, and older age. (DeBerard-Spine, 2001) (DeBerard, 2003) (Deyo, 2005) (LaCaille, 2005) (Trief-Spine, 2006) Obesity and litigation in workers' compensation cases predict high costs associated with interbody cage lumbar fusion. (LaCaille, 2007) A recent study of 725 workers' comp patients in Ohio who had lumbar fusion found only 6% were able to go back to work a year later, 27% needed another operation, and over 90% were in enough pain that they were still taking narcotics at follow-up. (Nguyen, 2007)

Lumbar fusion for spondylolisthesis: Recommended as an option for spondylolisthesis. Patients with increased instability of the spine after surgical decompression at the level of degenerative spondylolisthesis are candidates for fusion. (Eckman, 2005) This study found only a 27% success from spinal fusion in patients with low back pain and a positive single-level low-pressure provocative discogram, versus a 72% success in patients having a well-accepted single-level lumbar pathology of unstable spondylolisthesis. (Carragee, 2006) Unilateral instrumentation used for the treatment of degenerative lumbar spondylolisthesis is as effective as bilateral instrumentation. (Fernandez-Fairen, 2007) Patients with degenerative spondylolisthesis and spinal stenosis who undergo standard decompressive laminectomy (with or without fusion) showed substantially greater improvement in pain and function during a period of 2 years than patients treated nonsurgically, according to the recent results from the Spine Patient Outcomes Research Trial (SPORT). (Weinstein-spondylolisthesis, 2007) (Deyo-NEJM, 2007) For degenerative lumbar spondylolisthesis, spinal fusion may lead to a better clinical outcome than decompression alone. No conclusion about the clinical benefit of instrumenting a spinal fusion can be made, but there is moderate evidence that the use of instrumentation improves the chance of achieving solid fusion. (Martin, 2007) A recent systematic review of randomized trials comparing lumbar fusion surgery to nonsurgical treatment of chronic back pain associated with lumbar disc degeneration, concluded that surgery may be more efficacious than unstructured nonsurgical care but may not be more efficacious than structured cognitive-behavior therapy. Methodological limitations of the randomized trials prevented firm conclusions. (Mirza, 2007)

Lumbar fusion for Scheuermann's kyphosis: Recommended as an option for adult patients with severe deformities (e.g. more than 70 degrees for thoracic kyphosis), neurological symptoms exist, and pain cannot be adequately resolved non-operatively (e.g. physical therapy, back exercises). Good outcomes have been found in a relatively large series of patients undergoing either combined anterior-posterior or posterior only fusion for Scheuermann's kyphosis. (Lonner, 2007)

#### Patient Selection Criteria for Lumbar Spinal Fusion:

For chronic low back problems, fusion should not be considered within the first 6 months of symptoms, except for fracture, dislocation or progressive neurologic loss. Indications for spinal fusion may include: (1) Neural Arch Defect - Spondylolytic spondylolisthesis, congenital neural arch hypoplasia. (2) Segmental Instability (objectively demonstrable) - Excessive motion, as in degenerative spondylolisthesis, surgically induced segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after surgical discectomy. [For excessive motion criteria, see AMA Guides, 5th Edition, page 384 (relative angular motion greater than 20 degrees). (Andersson, 2000) (Luers, 2007)] (3) Primary Mechanical Back Pain (i.e., pain aggravated by physical activity)/Functional Spinal Unit Failure/Instability, including one or two level segmental failure with progressive degenerative changes, loss of height, disc loading capability. In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that may affect overall success of the procedure, which should be considered. There is a lack of support for fusion for mechanical low back pain for subjects with failure to participate effectively in active rehab pre-op, total disability over 6 months, active psych diagnosis, and narcotic dependence. [For spinal instability criteria, see AMA Guides, 5th Edition, page 379 (lumbar inter-segmental movement of more than 4.5 mm). (Andersson, 2000)] (4) Revision Surgery for failed previous operation(s) if significant functional gains are anticipated. Revision surgery for purposes of pain relief must be approached with

extreme caution due to the less than 50% success rate reported in medical literature. (5) Infection, Tumor, or Deformity of the lumbosacral spine that cause intractable pain, neurological deficit and/or functional disability. (6) After failure of two discectomies on the same disc, fusion may be an option at the time of the third discectomy, which should also meet the ODG criteria. (See ODG Indications for Surgery -- Discectomy.)

Pre-Operative Surgical Indications Recommended: Pre-operative clinical surgical indications for spinal fusion should include all of the following: (1) All pain generators are identified and treated; & (2) All physical medicine and manual therapy interventions are completed; & (3) X-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or discography (see discography criteria) & MRI demonstrating disc pathology; & (4) Spine pathology limited to two levels; & (5) Psychosocial screen with confounding issues addressed. (6) For any potential fusion surgery, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of fusion healing. (Colorado, 2001) (BlueCross BlueShield, 2002)

Milliman Care Guidelines, 12<sup>th</sup> Edition, Inpatient and Surgical Care

**A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:**

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR

- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- TEXAS TACADA GUIDELINES**
- TMF SCREENING CRITERIA MANUAL**
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**