

AccuReview

An Independent Review Organization

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Notice of Independent Review Decision

[Date notice sent to all parties]: November 12, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Methadone 10 mg 2 PO q 12 hrs Qty 120

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

This physician is Board Certified in Anesthesiology with over 12 years of experience.

REVIEW OUTCOME:

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

Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male whom was injured while on the job on xx/xx/xx. He slipped on the wet floor and fell violently hitting his head, neck, and back. He is currently diagnosed with chronic pain. The claimant's original injury led to fusions of his lower back and chronic pain in his neck and upper extremities that have persisted since that time. His pain is a mixed nature including both axial symptoms and neuropathic symptoms in both the arms and both the legs. He also has neck pain and headaches as well. Under the care, the claimant's pain was controlled with a combination of therapies including spinal cord stimulator and narcotic treatments. He was also on adjunctive drugs which controlled his symptoms as well to some extent.

02-22-10: Lumbar Spine. Impression: 1. Postsurgical changes at L4/5 with solid fusion. 2. Right-sided neural foraminal stenosis secondary to facet arthrosis at L5/S1.

02-22-10: Cervical Spine CT. Impression: Dorsolateral spondylotic changes at C3/4. No evidence of central canal or neural foraminal compromise. Otherwise unremarkable exam.

11-15-12: Initial Visit. Claimant presented for continued request to control his chronic pain. He was on Suboxone which did not manage his pain control. He is currently on Cymbalta which apparently has stabilized his mood a great deal at 60mg twice a day. Previous doctor's notes indicated that the claimant was compliant with the Suboxone regimen. Reason for visit is that he is not interested in prescribing anything other than Suboxone to the claimant with respect to opiates for control of his pain. That is the core issue. The claimant also has a spinal cord stimulator implanted in his lower back. He stated that it is a unit and that it affords him a modest amount of pain relief in his back and legs and appears to be functioning fairly well. He analogizes the stimulator to be similar to scratching a spot that itches. When the stimulator is on it relieves the symptoms to some extent, but once he stops scratching the symptoms return. Unfortunately, that is exactly what the stimulator does. It does not fix the underlying problem, which unfortunately there likely is no long term cure for him. He did have a narcotic intrathecal trial as well under care. His trial did not afford him adequate relief of symptoms, which probably tells us that his symptoms have a more neuropathic nature to them if nothing else; there are no records from that trial. The claimant trialed Lyrica and Neurontin with significant side effects. Probably the most successful narcotic he has been on for controlling his overall symptoms was Methadone at approximately 30 mg two or three times a day. The claimant has chronic neuropathic pain from both neck and lower back injuries that is now seeking narcotic analgesic therapy to control a mixed picture of somatic and neuropathic complaints in his back, legs, upper and lower extremities. He is not an abuser of medication as far as we can tell. The claimant has approximately been on disability for the last six years and was actually able to work for a number of years after his injury through the benefit of narcotic analgesics, primarily the Methadone, as he recalls. The claimant's ADLs are greatly handicapped by his pain. His goals of therapy are to be able to return to more normal activities around the house like cooking, cleaning, and activities in the yard. He has no prospect for returning to work at this point and has no intention to do so. He is looking for quality of life and control of his symptoms that facilitate his ability to function in normal ADLs. PE: Musculoskeletal: head and neck: cervical ROM is relatively full by observation, paracervical spasm is present. Spine, ribs, and pelvis: he has well-incisional scars consistent with previous multilevel lower lumbar fusion and also with percutaneous electrode placement in the lumbar area. The generator is in the right iliac fossa and is well healed as well. Assessment: Status of Existing Problems: Assessed: S/P SCS implant; dysthymia, situational, pain, chronic, postoperative NEC; syndrome, Postlaminectomy, lumbar; WC1 back pain; WC1 neck pain; Drug dependence. New Problems: drug dependence 304.90; S/P SCS Implant; dysthymia, situational; pain, chronic due to trauma; pain, chronic postoperative NEC; syndrome, Postlaminectomy lumbar. Comments: In order to return the claimant to a more functional and active lifestyle, we will reinstate Methadone starting at 10

mg twice a day; Suboxone will be discontinued and continue Cymbalta. Refer claimant to behavioral therapist to see if he needs help with coping strategies. Follow-up in two weeks.

06-25-13: Operative Report. Preoperative Diagnosis: 1. Status post spinal cord stimulator implantation. 2. Lumbar Postlaminectomy syndrome. 3. Spinal cord stimulator battery end of life. Postoperative Diagnosis: 1. Status post spinal cord stimulator implantation. 2. Lumbar Postlaminectomy syndrome. 3. Spinal cord stimulator battery end of life.

10-31-13: XSPTORCOM – Thoracic Spine Complete. Findings: There are postoperative changes with two dorsal column stimulator wires in the posterior aspect of the lower thoracic spinal canal. The entry point for the wires is not visible on the lateral projection but on the frontal view may be at the T12-L1 level. The electrodes from both wires extend from the superior aspect of T8 to the mid aspect of T9. There is otherwise mild thoracic spondylosis. There is minimal anterior wedging of mid and lower thoracic vertebrae but no fracture demonstrated.

01-02-14: Office Visit. CC: neck and back pain 8/10, unchanged. Claimant is here for medication follow-up, reported a relatively stable symptom control month with his chronic pain. His stimulator continued to perform in the desired fashion for control of the symptoms. His Methadone helps with the remaining symptoms. ROS: Musculoskeletal: complained of joint pain, muscle aches, back pain, loss of strength, stiffness, muscle cramps, joint swelling, and muscle weakness. Neurologic: complained of numbness, tingling. Assessment: Status of Existing Problems: Assessed: S/P SCS generator revision; pain chronic due to trauma; pain, chronic postoperative NEC; syndrome, Postlaminectomy lumbar. Plan: Cymbalta 60mg CPEP 1 po BID, Methadone HCL 10mg 2 po Q12hrs for pain, #120.

02-13-14: Office Visit. Claimant presented with request to be taken off all narcotics. The spinal stimulator is a powerful tool to help him control those neuropathic symptoms and back pain symptoms. With his recent testosterone related polycythemia and the fact that the narcotics could be suppressing his testosterone level, he request to see how he does drug free. Will assist him in this transition through the next couple of months. Assessment: Status of Existing Problems: Assessed: S/P SCS generator revision; pain chronic due to trauma; pain, chronic postoperative NEC; syndrome, Postlaminectomy lumbar. Plan: Claimant will be switched from Methadone to hydrocodone 4-6 per day to wean off Methadone and next month will wean off hydrocodone. New prescriptions: Cymbalta 60mg CPEP 1 po BID, Norco 10/325 1 PO Q4hr prn pain.

03-12-14: Office Visit. CC: neck and back pain 8/10, moderately worse since last visit. The transition from Methadone to Hydrocodone has left his pain at an increased overall level. Claimant remained committed to trying to get off pain medications completely and wanted to continue in the same direction; stimulator continued to aide in progress for controlling symptoms. He did experience some

mild irritability type symptoms consistent with perhaps mild withdrawal from the Methadone, but not too significant. Assessment: Status of Existing Problems: Assessed: S/P SCS generator revision; pain chronic due to trauma; pain, chronic postoperative NEC; syndrome, Postlaminectomy lumbar. Plan: Claimant will reduce to 3-4 tablets per day maximum. Prescriptions: Cymbalta 60mg CPEP 1 po BID, Norco 10/325 1 po Q4hr prn pain, NTE 4/day.

04-09-14: Office Visit. CC: neck and low back; bilateral leg pain; pain 8/10, much worse since last visit. Claimant has been successful to reducing down to three pain pills a day, relying more and more heavily on his stimulator. Claimant stated that his pain is getting incrementally worse as we come down each notch on the medicine, but he remained committed to being weaned from narcotics. Assessment: Status of Existing Problems: Assessed: S/P SCS generator revision; pain chronic due to trauma; pain, chronic postoperative NEC; syndrome, Postlaminectomy lumbar. Plan: Claimant will be reduced to two pain pills over the next 30 days and then transition to milder strength for final step down. Continue Cymbalta unchanged and stimulator.

05-07-14: Office Visit. CC: LBP, neck pain, bilateral leg pain, 8/10 and slightly worse. Claimant reported good pain control with his stimulator and his medication but his legs are getting weaker and weaker, feeling that he can barely walk any distance at all before his legs feel like they are going to go limp. PE: Musculoskeletal: RLE and LLE: SLR positive in the L5 distribution. Assessment: Status of Existing Problems: Assessed: S/P SCS generator revision; pain chronic due to trauma; pain, chronic postoperative NEC; syndrome, Postlaminectomy lumbar. Plan: Recommend x-ray to re-evaluate back. The adjacent segment issue could be evolving here. HE is clearly having spinal claudicatory symptoms, though, and his exam is positive for radicular features. Continue his present medications unchanged. Will transition him to a Tylenol-free form of hydrocodone or over to oxycodone and reduce Cymbalta to 1 tab per day.

05-29-14: XR Spine Lumbosacral. Impression: postoperative changes and mild scoliosis. Findings appear stable compared to 12/9/2006 exam.

07-02-14: Office Visit. CC: LBP, neck pain, bilateral leg pain, 9/10 moderately worse. Claimant is having trouble getting his compounded hydrocodone pain for by the insurance company and has been rationing medication due to the high cost. Claimant has plateaued from medication weaning. He is requesting to be placed back on Methadone, believed to be largely precipitated by difficulties getting the compound hydrocodone. Assessment: Status of Existing Problems: Assessed: S/P SCS generator revision; pain, chronic postoperative NEC; syndrome, Postlaminectomy lumbar. New problems: opioid type dependency continuous. Plan: Methadone will be reinstated and referred to surgeon at claimant's request; prescriptions: Methadone HCL 10mg 2 po Q12hr for pain, Cymbalta 60mg SPEP 1 po QD; UDS next visit.

07-22-14: Office Visit. CC: LBP, neck pain, bilateral leg pain, 7/10 and unchanged. Claimant had a UDS positive for THC; he does admit or deny use.

He stated that the THC was to help with withdrawals due to inability to afford hydrocodone compound. Explained that we will not be able to prescribe medications if he continues to use illicit drugs as it is illegal. Will repeat UDS today. Assessment: Status of Existing problems: Assessed: opioid type dependence continuous; OTH pain disorder related psychological factors; drug dependence, dysthymia situational; pain, chronic due to trauma; pain, postoperative NEC; syndrome, Postlaminectomy lumbar; WC1 neck pain; WC1 back pain. Plan: oral and urine specimen collected, return in one week, continue Methadone HCL 10mg, take 2 po Q12hr for pain, Cymbalta 60mg SPEP 1 po QD.

07-24-14: Millennium UDT RADAR Report. Consistent Results: methadone hydrochloride-positive. Inconsistent results-none.

07-30-14: Office Visit. CC: LBP, neck pain, bilateral leg pain, 7/10 and unchanged. Claimant had a UDS positive for benzodiazepines, he admitted to taking Lunesta for sleep effort but has not done so in quite some time. He is not aware of taking any benzodiazepine medications at all. Will repeat UDS today to rule out a false positive. Assessment: Status of Existing problems: Assessed: opioid type dependence continuous; S/P SCS generator revision; pain, chronic due to trauma; pain, postoperative NEC. Plan: urine and oral specimen collected and a DPS search will be ordered if test is again positive for benzos, return in one week, continue Methadone HCL 10mg, take 2 po Q12hr for pain, Cymbalta 60mg SPEP 1 po QD.

07-30-14: Millennium ODT RADAR Report at Millennium Laboratories. Positive finding for Methadone.

07-31-14: Pre-Authorization. Claimant suffers from chronic and severe neck pain, back pain, and post laminectomy syndrome, lumbar. He has trouble getting the compounded hydrocodone paid by the insurance company due to the fact that the insurance carrier will not authorize his compounded hydrocodone without paper billing and will not allow digital transmission of that from the pharmacy; therefore he has been switched back to methadone to assist with his pain. Methadone was initiated on 11/15/12 and the claimant's response is re-evaluated in monthly follow-up visits. Claimant reported relief in his back and leg complaints when taking Methadone as prescribed, therefore this medication is medically necessary.

07-31-14: Letter of Medical Necessity. Methadone is a very cost effective narcotic analgesic that has excellent pain relieving properties, not only for his axial musculoskeletal symptoms, but also for his neuropathic pain complaints. The claimant has been on this medication for a long time and understands the risks.

08-06-14: UR. Reason for denial: The claimant is currently diagnosed with chronic pain. A request was made for 120 tablets of methadone 10mg (two tablets Q12 hours). The history is significant for several surgeries including two carpal tunnel surgeries, left shoulder arthroscopy, lumbar fusion, and spinal cord stimulator implantation. On 7/30/14, he presented for a follow-up evaluation with

complaints of neck, low back, and bilateral leg pain. His current medications include Cymbalta, methadone, amlodipine, and HCTZ. A urine drug screen was stated to have been done and showed the presence of benzodiazepines which were not prescribed. This was recommended to be repeated. A letter of medical necessity dated 7/31/14 was also submitted and stated that methadone has "excellent pain relieving properties, not only for the claimant's musculoskeletal symptoms, but also for his neuropathic pain complaints." However, his current MED is at 360, which far exceeds the recommended 100 MED for chronic non-malignant pain. It is unclear why he has not returned to work considering the large amount of opioid he is taking. As per ODG, continuation of opioids is recommended if the claimant has returned to work and has not improved functioning and pain. A more recent urine drug screen that showed consistent findings was also not provided. Medical necessity is not established. Without the opportunity to speak, there is not information necessary to certify this request. While the request medication does not meet medical necessity based on information presented it is expected that the ordering provider will follow recommended medication guidelines for safe discontinuation. Based on the clinical information submitted for this review and using evidence-based, peer-reviewed guidelines referenced above, this request is non-certified. Addendum: Call received on 8/6/14 from NP. It was discussed that there has been long term use of high levels of methadone for an extended period without documentation of maintenance of function or return to work. She stated that the drug screen that showed positive for benzodiazepine was repeated and was negative. She consulted who was unwilling to discuss a mutual certification. Therefore there is no change in determination and it was discussed that the claimant cannot be abruptly taken off this medication.

08-27-14: Office Visit. CC: LBP, neck pain, bilateral leg pain, 6/10 and unchanged. Claimant has received information that his workers' comp carrier will no longer cover Methadone. Even though Methadone is a very inexpensive medication out of pocket, the claimant does not have means to pay for it. We will not discontinue his Methadone, as he is a perfect candidate for the Methadone that he takes for neuropathic symptoms. HE functions at a fairly high level with the medicine. Assessment: Status of Existing problems: Assessed: opioid type dependence continuous; S/P SCS generator revision. Continue current medications and follow up in one month.

09-17-14: UR. Reason for denial: There was a previous non-certification for methadone and the claimant was unable to pay for this out of pocket. A letter from the claimant requested the medication for medical necessity for chronic neuropathic pain. A lumbar spinal fusion had been performed at L4-5 in 1997 with a spinal cord stimulator placement in June 2013. Medications included Cymbalta, methadone, amlodipine, and HCTZ. An evaluation in July 2014 documented a normal gait a normal gait and station as well as musculoskeletal examination. There was a normal mental status with no deficits documented. A prior urine toxicology screen documented inconsistent findings with the presence of benzodiazepines which were not listed as maintenance medications. This is a non-certification of an appeal of Methadone 10 mg 2 by mouth every 12 hours

#120. The previous non-certification on August 6, 2014, was due to lack of physical examination findings supporting the necessity for high levels of methadone and positive inconsistent urine toxicology screenings. The previous non-certification is supported. Additional records included a progress note from August 2014 and an appeal request from the claimant. The guidelines would not support continued, high dose opioid medications for chronic pain. Failure of prior conservative treatment modalities for neuropathic pain was not been noted. Documentation of inconsistent urine toxicology screens was documented and there was no discussion of how this was being dealt with. Methadone and benzodiazepines together significantly raise the risk of adverse events. The claimant has not however, exceeded the recommended morphine equivalent dosing for chronic malignant pain. The current morphine equivalent dose is 120. The physical examination findings have not documented substantial deficits in range of motion or musculoskeletal deficits to support persistent subjective reports of pain and high opioid requirements. The claimant has been off this medication as of the most recent progress note provided. The request for an appeal of Methadone 10 mg 2 by mouth every 12 hours #120 is not certified.

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

Previous adverse determinations are upheld and agreed upon. Claimant underwent a lumbar spinal fusion at L4-5 in 1997 with a spinal cord stimulator placement in June 2013. Medications included Cymbalta, methadone, amlodipine, and HCTZ. An evaluation in July 2014 documented a normal gait a normal gait and station as well as musculoskeletal examination. There was a normal mental status with no deficits documented. A prior urine toxicology screen documented inconsistent findings with the presence of benzodiazepines that were not listed in the prescribed medications. Additional records provided do not, per guidelines, support continued, high-dose opioid medications for chronic pain. There is not adequate documentation of failed conservative therapies. Additionally, the claimant has not exceeded the recommended morphine equivalent dosing of 120 for chronic malignant pain. Therefore, this request is non-certified.

Per ODG:

Methadone	<p>Recommended as a second-line drug for moderate to severe pain, only if the potential benefit outweighs the risk, unless methadone is prescribed by pain specialists with experience in its use and by addiction specialists, where first-line use may be appropriate. Due to the complexity of dosing and potential for adverse effects including respiratory depression and adverse cardiac events, this drug should be reserved for use by experienced practitioners (i.e. pain medicine or addiction specialists). (ICSI, 2009)</p> <p>Methadone is considered useful for treatment when there is evidence of tolerance to other opiate agonists or when there is evidence of intractable side effects due to opiates. Limited evidence suggests there may be a role for this drug for neuropathic pain, in part secondary to the N-methyl-D-aspartate (NMDA) receptor effect. While methadone is considered safe and effective when used as prescribed it has been suggested by government</p>
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	<p>agencies such as the National Drug Intelligence Center that patients prescribed methadone should be monitored by a physician well trained in the pharmacodynamic and pharmacokinetic properties of the drug, particularly if the patient is opioid naïve. In addition, the patient should be made aware of potential adverse effects including drug-drug interactions. If methadone is used, see Opioids, criteria for use for general recommendations.</p> <p><i>FDA Activity:</i> Increased reports by the FDA of severe morbidity and mortality have prompted the following. In November 2006 the FDA issued a black-box warning for methadone that stated, in part, that methadone treatment should only be initiated if potential benefits outweigh risks of treatment. Their particular concerns included respiratory and cardiac related complications, including death. In the same month they issued a monograph, “Information for Healthcare Professionals, Methadone Hydrochloride, FDA ALERT [11/2006]: Death, Narcotic Overdose, and Serious Cardiac Arrhythmias.” In July 2007 the FDA issued “Public Health Advisory, Methadone Use for Pain Control May Result in Death and Life-Threatening Changes in Breathing and Heart Beat.” (National Drug Intelligence Center, 2007)</p> <p><i>Pharmacokinetics and pharmacodynamics:</i> Increased morbidity and mortality appears, in part, secondary to the long and variable half-life of the drug (8-59 hours; up to 110 hours in patients with cancer). Pain relief on the other hand only lasts from 4-8 hours. It may take several days to weeks to obtain adequate pain control. Genetic differences appear to influence how an individual will respond to this medication. Following oral administration, significantly different blood concentrations may be obtained. Vigilance is suggested in treatment initiation, conversion from another opioid to methadone, and when titrating the methadone dose. Frequent or large dose changes are generally not necessary after initial titration. If analgesia is lost this may reflect the addition of a medication that affects metabolism. (Weschules 2008) (Fredheim 2008)</p>
<p>Medications for subacute & chronic pain</p>	<p>Recommended as indicated below. Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient’s preference. Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others. (Chou, 2006) There are multiple medication choices listed separately (not</p>

all recommended). See [Anticonvulsants for chronic pain](#); [Antidepressants for chronic pain](#); [Antidepressants for neuropathic pain](#); [Antidepressants for non-neuropathic pain](#); [Antiemetics](#) (for opioid nausea); [Anxiety medications in chronic pain](#); [Anti-epilepsy drugs](#) (AEDs); [Anti-Inflammatories](#); [Benzodiazepines](#); [Boswellia Serrata Resin](#) (Frankincense); [Buprenorphine](#); [Cannabinoids](#); [Capsaicin](#); [Cod liver oil](#); [Compound drugs](#); [Curcumin](#) (Turmeric); [Cyclobenzaprine](#) (Flexeril®); [Duloxetine](#) (Cymbalta®); [Gabapentin](#) (Neurontin®); [Glucosamine](#) (and Chondroitin Sulfate); [Green tea](#); [Herbal medicines](#); [Implantable drug-delivery systems](#) (IDDSs); [Injection with anaesthetics and/or steroids](#); [Insomnia treatment](#); [Intrathecal drug delivery systems, medications](#); [Intravenous regional sympathetic blocks](#) (for RSD, nerve blocks); [Ketamine](#); [Medical food](#); [Methadone](#); [Milnacipran](#) (Ixel®); [Muscle relaxants](#); [Nonprescription medications](#); [NSAIDs](#) (non-steroidal anti-inflammatory drugs); [NSAIDs, GI symptoms & cardiovascular risk](#); [Opioids](#) (with links to multiple topics on opioids); [Opioid-induced constipation treatment](#); [Proton pump inhibitors](#) (PPIs); [Pycnogenol](#) (maritime pine bark); [Salicylate topicals](#); [Tapentadol](#); [Topical analgesics](#); [Uncaria Tomentosa](#) (Cat's Claw); [Venlafaxine](#) (Effexor®); [White willow bark](#); & [Ziconotide](#) (Prialt®).

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)**