WORKERS' COMPENSATION
MEDICAL ADVISORY COMMITTEE
June 2, 2017
9 a.m. – 11:30 a.m.

MAC Committee Members Present: Ronald Bowman, MD; Gary Rischitelli, MD, Jon Soffer, ANP DNP, Brad Lorber, MD; Timothy Craven MD (MCO Representative); Julio Ordonez, MD; Tom Williams, PT, Ryan Weeks (Employer Representative)

DCBS Staff Present: Cara Filsinger, Juerg Kunz, Summer Tucker

MAC Committee Members Absent: Susan Strom, DC, Lon Holston (Worker Representative) Constantine Gean, MD (Insurer Representative)

Agenda Item	Discussion
Welcome, Introductions (0:00:00)*	Dr. Bowman called the meeting to order at 9:02 a.m.
Administrative discussion (0:00:07)*	**Review and approve minutes for April 7, 2017 MAC Meeting** Dr. Lorber moved to approve the minutes, Jon Soffer seconded. All members present approved the April 7, 2017 minutes, as drafted.
Administrative discussion (0:00:18)*	**Staff Updates** Ryan Weeks has joined the committee as the employer representative.
Administrative discussion (0:01:10)*	**Review committee bylaws and elect committee chair and vice chair** The committee bylaws were substantially revised in 2014, and MAC is supposed to review them every year. MAC agreed that the bylaws are acceptable without any objections. Dr. Lorber moved that Dr. Bowman continue as chair. All members present voted in favor. Dr. Lorber nominated Dr. Rischitelli for vice-chair, Jon Soffer seconded. All members present voted in favor.
Administrative discussion (0:04:43)*	**Staff Updates** Cara provided an update on the recent *Brown v. SAIF* decision. The division is in the process of starting rulemaking to adjust the rules to what they were before *Brown v. SAIF*. ▪ A petition for reconsideration was filed with the Supreme Court, and the division is waiting to see if the court will provide further clarity. It is a normal request for reconsideration, asking the court to look at their opinion and change. However, the division will still have a normal public rulemaking process. There are temporary rules the division will need to replace since they are only effective for 180 days. ▪ Medical arbiter questions are changing to be closer to what they were in the past.

Cara believes those questions have already been changed.

- House Bill 2335 (regarding medical arbiter panels), has been passed and signed by the governor. The division will be doing rulemaking in response to the bill passing, and reaching out to MAC for input.

Dr. Rischitelli commented that the issue was interpretation of what the condition really is, and whether it is what the insurer accepted or the condition and everything that flowed from the injury. Additionally, when assessing permanent impairment, do you only assess permanent impairment for only the accepted condition, or the condition and everything else? The division is now going back to only what the insurer accepted. If there is impairment related to non accepted conditions, the worker has to get those conditions accepted.

Ryan Weeks noted that one problem he's seen is lower back injuries that are accepted as a back strain, but require many tests and treatments. Down the road, employers start asking why it has been a year and multiple surgeries for a back strain.

Dr. Bowman noted that pre-existing conditions can be a factor too. He sees a lot of middle aged workers who twist their knee, have a meniscus tear, and arthritis that has never been symptomatic. If they don't fill out a Form 827, a worker can go all the way through surgery and closure and be accepted for a knee strain. The pre-existing asymptomatic arthritis is not supposed to be considered part of the impairment.

Dr. Craven noted that Washington looks at whether the injury caused an aggravation of a pre-existing condition and asked whether Oregon uses that terminology. Dr. Bowman responded that Oregon uses the term combined condition.

Cara noted that MAC is on the list to be notified about rulemaking.

Technology review process over view (0:12:46)*

Juerg gave an overview of the medical issue review process. For the spinal cord stimulator (SCS) subcommittee, MAC is only at step two on the memo that outlines the process. MAC has received input from some stakeholders who have provided additional citations, and the next step is for the subcommittee to analyze the input from stakeholders and look at additional literature. Only after that can MAC have a discussion amongst the whole committee on whether SCS is experimental, unproven, unscientific, or outmoded. Based on that discussion, MAC needs to make a decision regarding SCS compensability and create a recommendation. Since SCS is used for multiple conditions, it is possible that MAC could differentiate between conditions and have different recommendations depending on the condition. The division would then post MAC's recommendation online and allow public input. After MAC looks at the public input, a final decision will be made and brought to the administrator of WCD. Depending on the recommendation, WCD may go through the rulemaking process to make changes to the administrative rules.

If MAC thinks that SCS should stay compensable (or compensable for certain conditions), MAC can provide guidance to providers about when it is appropriate to use. MAC did this with the artificial disc by developing relative and absolute contraindications listed in administrative rules to identify when it is appropriate to do an artificial disc.

Dr. Bowman noted that MAC is looking for specificity in exclusions and ideally level one or two evidence in a workers' compensation population. However, there is not a lot of clinical research dedicated to workers' compensation

Dr. Craven clarified that the subcommittee would report to the full committee, and then the full committee would do a vote on the recommendation. Juerg noted that MAC would create an official recommendation in writing to the WCD administrator.

Spinal Cord Stimulator – Public Testimony (0:19:00)*

Juerg summarized submitted written testimony.

- SAIF provided an updated report (this report is only concerning SAIF cases).
- Abbot is a manufacturer of SCS that submitted a letter and a list of additional references.
- Medtronic is a manufacturer of SCS that submitted a letter and list of additional references.
- Dr. Chidi Ani with OHSU Comprehensive Pain Center submitted a letter and additional references.

Testimony: Alissa Doth, Medtronic Health Economics and Research Group

- Alissa works with health ministries, payers, and health authorities to look at evidence for pain therapies (including, but not limited to Medtronic) to see how they can identify patients where pain therapy would help them.
- Alissa spoke about the way evidence is being developed for SCS in general. There is lot of level one and two evidence in broader populations, some of which include (but are not exclusive to) workers' compensation populations. Those that include both workers' compensation and non workers' compensation populations have been analyzed to see if that was a factor in determining outcomes, but that has not been a determining factor. In a lot of the studies that include workers' compensation patients, it is recognized that patients have similar outcomes with or without SCS. Alissa thinks that it opens up the opportunity to consider that if the studies that looked at both didn't see a difference, how do you consider the studies that aren't exclusive in that level one or two workers' compensation population? There are limited studies looking at that population.
- The level and types of evidence being developed are less about whether SCS works, and more around which populations it works best in and identifying the characteristics of patients that will do better. Some of the literature they provided is not specific to the workers' compensation population, but is around the care pathway and considerations that you may take around when it is the best time to provide SCS.
- There is a study from Dr. Kumar that includes workers' compensation patients, and found the earlier patients receive the therapy, the more likely they are to have relief, improved pain scores, and improved function.
- Alissa highlighted systematic literature reviews done through the Neuromodulation Appropriateness Consensus Committee. It is a group effort involving clinicians from many different societies who either treat, or refer, or have patients that have access to these therapies. The committee looks into identifying the right patients, how complications and infections can be reduced, and how clinicians can ensure every aspect of the therapy is provided appropriately to patients.
- Alissa asked that MAC look at that evidence and consider if there are recommendations from implanting physicians that also would make sense to adopt

in terms of levels of evidence or best practices for implants.
- Alissa reiterated they have moved on from whether SCS works to how to make it work better and how to find patients it will work the best in.
- Alissa noted that some of the evidence in Medtronic's letter is level one and two.

Dr. Bowman asked Alissa for Medtronic's approximate gross revenue in workers compensation for SCS in Oregon. Alissa responded that her group is separate from the commercial arm, so she did not know the figure, but could find out.

Dr. Ordonez noted that there was a big discrepancy between inpatient and outpatient procedures. Dr. Ordonez asked if that information can be provided. Alissa responded that there is a large body of economic evidence, which she would be happy to provide. A recent systematic review looked at the economic evidence and cost effectiveness. There is also a lot of evidence coming from Duke University's Neuro-Outcomes research center, which looks at administrative claims data (primarily Medicaid, Medicare, and commercial), specifically at cost data. The majority of implants in this country are done in an outpatient setting; however, the outpatient payment tends to be higher than inpatient payments for this procedure. The evidence available supports that SCS is cost effective compared to conventional medical management and reoperation (in the broader population. From a cost-effectiveness perspective, SCS is considered dominant, which means that there was a randomized control trial (RCT) that shows it is more effective and less costly if you took eligible patients and randomized whether they received SCS or reoperation. Alissa can provide a list of the cost effectiveness studies.

Dr. Craven clarified with Juerg and Dr. Bowman that though the criteria for the medical issue review process doesn't include "effective", the criterion "proven" encompasses that.

Dr. Bowman asked what specific conditions SCS is used for. Conditions include failed back syndrome, phantom limb pain, and complex regional pain syndrome (CRPS). Dr. Craven noted that the subcommittee looked at primarily failed back syndrome and CRPS. The subcommittee was focused on whether SCS is effective, not the specific conditions it should be used for.

Alissa agreed that SCS is not for mechanical pain, and in a lot of studies, there is a requirement that there isn't a mechanical problem that could be addressed with surgery. Dr. Rischitelli noted that in the literature he is familiar with, there are conflicting evidence and recommendations on SCS for ischemic pain. Alissa responded that ischemic pain is not on the label for Medtronic, and it is not current standard of practice. The National Institute for Health and Care Excellence (NICE) looked at the available evidence, and found that the comparator was not current standard of practice, so they concluded it wasn't something they could recommend because it wasn't being compared to current standard of practice.

Testimony: Dr. Chidi Ani, OHSU Comprehensive Pain Center
- Dr. Ani pointed out that SCS is being used for different conditions, and there are multiple types of SCS technologies (e.g., tonic, high frequency, or dorsal root ganglion). Additionally, different technologies are used for different pathologies. Those variations potentially give different scenarios about possibilities.
- The easy route would be to cover SCS for everything, or not cover for everything.

A lot of work needs to be done in determining where SCS works or not.

- Anecdotally, Dr. Ani has seen patients at OHSU where SCS has significantly changed their lives. He doesn't present it as evidence, but it has changed his perception of SCS.
- In the evidence Dr. Ani has looked at in the population with Chronic Regional Pain Syndrome (CRPS), it somewhat doesn't support it, especially for older, pre-high frequency technology.
- Dr. Ani pointed out that a limitation of studies can be that workers' compensation patients are traditionally excluded from most studies, especially chronic pain studies.
- Dr. Ani thinks that it is fine if you come to the conclusion that SCS doesn't work for them Oregon workers' compensation patients, but he doesn't think that is a scientific conclusion because of the confounding factor in the workers' compensation population. Dr. Ani would guess that would be the case for any treatment for the workers' compensation population.
- OHSU continues to do a lot of work in SCS research, and believe in the technology. OHSU is happy to provide support in teasing out the evidence.

Dr. Craven asked what OHSU is doing currently in SCS. Dr. Ani responded that right now, they have funding for a basic science study on the mechanisms. Currently, if you look at proposed mechanisms, there nothing concrete. OHSU has also proposed clinical studies to compare technologies.

Dr. Craven asked Dr. Ani about most studies excluding workers' compensation. Dr. Ani responded that in most studies, historically, there was a problem including workers' compensation patients in chronic pain studies because there was a background factor. In chronic pain literature, often the first thing people look for is confounders, and one of them is usually a workers' compensation claim.

Dr. Craven noted that in his review, he didn't notice workers' compensation patients being included, but he would have to check again. During the review, only the Washington state study was strictly workers' compensation. Dr. Craven assumed the studies likely included workers' compensation.

Alissa noted that in some cases, exclusion criteria are regarding litigation. If you are no longer actively litigating a workers' compensation claim, you are eligible for the study. In another case, workers' compensation patients were allowed, but SCS had to be approved by the workers' compensation carrier. In that case, workers' compensation patients weren't necessarily excluded, but it was harder for patient to have access.

Dr. Rischitelli noted that Dr. Ani states that OHSU supports SCS, and asked whether Dr. Ani is here as an individual or representative of OHSU. Dr. Ani responded that he is representing the OHSU Pain Center. He is not a paid consultant and has no industry affiliation.

Dr. Rischitelli asked Dr. Ani for his opinion on why workers would be excluded from studies. Dr. Ani noted that OHSU's questionnaire for incoming patients asks about workers' compensation because they like to have that information. Often times, they have found that there is a group of patients that tend to not get better easily (regardless of what you do). If you were to study that same kind of patient, you might have the

same problem, in that regardless of what is objectively changing, subjectively, you might not get a report of change. In this case, most of the data is collected from a report from the patient.

Dr. Rischitelli noted that by excluding workers, it makes outcomes look better. Dr. Ani responded that is why he brought up generalizability. It is fair to look at workers' compensation patients, state what the outcome was, but not generalize beyond that.

Dr. Rischitelli asked what criteria OHSU uses for screening out individuals. If certain patients aren't screened out, you are treating with no significant expectation of improvement. Dr. Ani responded that they don't change the treatment. The questionnaire information can be referred to when things don't add up, but the treatment wouldn't change. However, some patients (with potential secondary gain) have a different response to therapy sometimes.

Dr. Rischitelli asked if that information is included in patient selection. Dr. Ani responded that secondary gain or workers' compensation does not factor into decision making. It is just secondary information that might mean something when it is difficult to tease out why things aren't adding up.

Dr. Rischitelli commented that it begs the question as to why workers' compensation patients would be excluded (other than to make outcomes look better).

Dr. Ani responded that he was not speaking about studies done at OHSU, but rather studies in the chronic pain community. It is not uncommon in chronic pain literature to see workers' compensation patients excluded.

Dr. Craven asked Dr. Ani if he treats Washington state claims. Dr. Ani responded that he doesn't know. Dr. Craven noted that Washington doesn't cover SCS and asked what Dr. Ani thought about that.

Dr. Ani responded that they have always struggled with coverage, and 40 percent (possibly more) of patients are on Medicaid. They get patients that were rejected from a lot of places. OHSU does a lot of different things to give them options, and there is not lot of incentive to do a high volume of procedures. They have a strong goal set by their department and chair of the pain center to make sure they are taking care of patients as much as they can. Often, OHSU offers what they have or work out more affordable arrangements. They have had pushback from different payers, but Dr. Ani doesn't know specifically about workers compensation.

Dr. Bowman asked if there are there differences in SCS manufacturers, how many are available, and within manufacturers, what applications you can use. Dr. Ani responded that there are different technologies from different manufacturers. For instance, Nevro has high frequency, while St. Jude has burst (which is high frequency, but a different style of stimulation). There haven't been a lot of head to head studies. Nevro technology was required by the FDA to do a non-inferiority study, and it ended up as a head to head study with other types of stimulation technology. The study showed a somewhat better outcome. Still, there haven't been a lot of head to head studies, which is what is needed. When you look at different technologies and applications, you start getting combinations with potentially different outcomes.
Jon Soffer asked if Dr. Ani thinks that things will continue to evolve to a degree that

any decision MAC comes to, it would be difficult to choose a specific therapy for a problem because the technology will evolve (eventually making MAC's opinion irrelevant). Dr. Ani responded that he thinks that for both practicing physicians and in coverage matters, the intellectually lazy approach would be to do SCS for lots of things, or don't do at all. If you are willing to put in work to keep track of what is changing, he thinks it shouldn't be too hard to figure out what's useful.

Jon Soffer commented that even if MAC approves a certain therapy, if a new frequency comes out, MAC has to repeat the approval process. Dr. Ani noted he understands, and that technology is rapidly evolving. The response he's seen from patients is improved compared to older technology. It is conceivable to have a much different discussion in a couple years from now due to changes in technology and patients response. His guess is that it will become clear that SCS is very useful technology. Jon Soffer responded that it is conceivable that by that time, some technology that is currently used will become obsolete. Dr. Ani agreed. Jon Soffer noted it is unknown whether we still be paying for obsolete technology.

Dr. Ordonez commented that dorsal column technology has been used since the late 1960s, became popular in the 1970s, and then declined. It is 40 years of evolution. Dr. Ordonez doesn't think this technology will go away.

Cara said that if MAC members want to look through the literature that was submitted, please let Juerg know about the specific studies you'd like him to acquire for review. Juerg said he will contact those who testified about specifically pointing out level one and two studies and involvement of workers' compensation patients. Juerg asked the subcommittee to revisit literature. Dr. Craven asked whether the subcommittee should look at whether SCS is good for specific subgroups, and Juerg responded that it would be good to do. Cara noted that if any of the non-subcommittee members see something that the subcommittee should look at, let Dr. Craven know.

Jon Soffer clarified with Cara and Dr. Bowman that there is no administrative rule, and SCS is compensable without restriction on application. Juerg noted that SCS still has to be appropriate for the worker. Dr. Bowman commented that theoretically, MAC could find exclusionary criteria that SCS is ineffective for (proven by literature). Jon commented that it may be better to specify what SCS shouldn't be compensable for, rather than focusing on each potential compensable situation.

Dr. Craven commented that even though SCS is compensable, in an individual case, it may not be approved. The worker can appeal to the state though. Dr. Bowman noted that is what MAC did with artificial disc, since insurers were getting three level disc replacement requests.

Dr. Bowman commented that ideally, studies would include workers' compensation patients, but they are so hard to come by, MAC needs to take level one and two evidence on anything available.

Tom Williams commented that he's been keeping track of patients he's seen with SCS. One patient was a workers' compensation patient, while the other three were not. The three non workers' compensation patients reported improvement, but Tom doesn't think they would have gone back to work. The workers' compensation patient

	reported no change. Tom noted that he thinks that ability return to work is a good question to ask and something to look at in the studies. Dr. Rischitelli noted that in the SAIF data, only one person went back to work (out of 57). Dr. Rischitelli asked Alissa about the NICE study, noting it was from 2008. Alissa responded that they revisited the study in 2012 or 2013 and they decided it was still appropriate. Dr. Rischitelli asked Alissa to submit the Neuromodulation Appropriateness Consensus Committee and NICE studies to Juerg. Alissa noted that the Neuromodulation Appropriateness Consensus Committee's goal is similar to MAC to stay up to date on technologies, along with the issues and challenges patients face. Dr. Bowman asked if any of the studies looked at a pre and post physical capacity evaluation (PCE) or work capacity evaluation (WCE). Dr. Craven responded that the studies mostly looked at pain scales and questionnaires. Some looked at more functional, everyday activities. Dr. Lorber commented that opioid reduction or elimination is another thing to consider. The SAIF data looked at opioids, but didn't say what the reduction was. Ryan Weeks noted that the SAIF data showed that the average time from injury to implant was 11.9 years with minimal change to previous measurements. That person has dealt with pain management for about 12 years; they've probably recovered as much as they are going to. Jon Soffer noted that most the cases with SCS are the most difficult workers' compensation cases. Dr. Bowman commented that it is a last resort. Ryan Weeks noted that some of the previous studies showed a placebo effect equal to SCS. Dr. Craven asked how many denials for SCS were upheld or reversed, and what the grounds were for approval or denial. Juerg responded that he could find that information. Cara noted that she thinks the numbers will be small. At the next meeting, MAC will look at any new level one or two evidence. Juerg will follow up with people who submitted written testimony for more information.
Technology review: subcommittee on lumbar and cervical artificial disc (1:08:06)*	The subcommittee has been waiting on a FDA long term study that has still not been published. Dr. Lorber explained that the FDA study is comparing outcomes of artificial disc and fusion. Cara suggested revisiting this subcommittee when the FDA releases the study. Dr. Lorber noted that this topic is worth revisiting in 6 months to a year in case the FDA study or other studies come out. Cara will put this topic on the review list for a year out unless the FDA study comes out earlier.
	The meeting adjourned at 10:18 a.m. The next MAC meeting will be held on August 4, 2017.

*The audio files for the meeting minutes and public testimony (both written and audio) can be found here: http://wcd.oregon.gov/medical/mac/Pages/mac-meetings.aspx