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Review Article

Impact of Screening and Brief Intervention (SBIRT), Urinary Drug Testing, Minimally Invasive Procedures, and Electromyography on Pain Reduction, Functional Improvement, and Continuity of Care in Chronic Pain Patients

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Abstract

With the alarming explosion of overdose risk in the opioid epidemic since 1999, Opiate Use Disorder (OUD) has cost in excess of $600 billion, harming the economy and killing tens of thousands nationally. According to research conducted in 2017 on opioid mortality, data showed Ohio to be the second-highest opioid mortality state in the US, representing more than 2.6 times the death rate per 100,000 population compared to the US average (39.2 in OH vs. 14.6 in US, see Figure 1 below).

Although socioeconomic factors play a role, authors suggest that lack of availability or the consistent denial of these services by insurance carriers play a role in this situation. A recent Ohio Department of Health report showed that the population of patients susceptible to the opioid epidemic was in fact at least twice the non-minority risk level for COVID 19 pandemic (Figure 2). The recent AMA brief [26] alarms about great concern over increased opioid mortality during COVID 19 pandemic.

This retrospective chart review study provides a systematic analysis of the Screening and Brief Intervention (SBIRT), urinary drug testing, minimally invasive procedures and electromyography on the pain reduction and functional improvement of moderate to high risk chronic pain patients, with risk level determined by NARX scores.

Key Points

SBIRT protocol is mandatory for the compliant operation of a pain management clinic providing medical management to the population with a significant percent of high-risk patients in the high-risk area like Ohio.

Nerve Conduction Studies (NCS)/ Nerve Conduction Velocity (NCV) with or without needle EMG tests as part of the effort to document organic pathology (both initial tests and follow up tests) are medically necessary tests and cost-effective tests that have a strong statistically significant contribution to the proper choice of medications and procedure for chronic pain patients and strongly associated with functional improvement and pain reduction [18].

Using Pain Assessment and Documentation Tool (Figure 3 – PADT) and other validated assessment tools, we demonstrated a statistically significant impact of these services on pain reduction and functional improvement of moderate to high risk (as defined by NARX score and other factors) chronic pain patients over a 2 year period. Using these services and testing since 2011, our practice has been able to identify patients in need and refers to Addiction medicine evaluation and treatment for more than 2000 high-risk patients (who would otherwise be at significant risk of opioid mortality, morbidity, diversion, and incarceration).

Denial coverage for these services by third-party payers or defining them as "Unallowable costs" puts the practice in noncompliance with the guidelines described above, making the ethical operation of the practice impossible and putting patients and staff at considerable risk.

Objective data (Figure 1) shows that a new approach described in this review by the medico-legal system and third

party payors required to address the opioid crisis and protect the population at the high risk for COVID 19 epidemic (Figure 2).

Background

Opioid epidemic crisis affects the lives of thousands of Americans on a daily basis. Since 1999 hundreds of thousands of Americans have died from overdoses. On an average day in the US close to 5,800 people misuse opioids for the first time, and over 1,000 Americans on an average day are treated in the emergency departments for issues related to opioid misuse. The societal and healthcare cost of the opioid epidemic is at least 600 billion dollars and it continues to rise. Proper screening of pain management program patients (including SBIRT protocol G codes, POC UDS, and NCV/EMG) for narcotic medications is extremely important in the prevention of street drug use. The 2018 National Drug Threat Assessment conducted by the Drug Enforcement Administration, showed that prescription drugs such as "Opioids were responsible for the most overdose deaths of any illicit drugs since 2001" and "heroin-related deaths nearly doubled from 2013 to 2016". Ohio is one of the states most affected by the opioid crisis. Ohio has one of the highest death rates related to the Opioid crisis. Efficient and Ethical pain management program that uses appropriate testing to document organic pathology and screen appropriate candidates for pain medications and refer other patients to Addiction medicine evaluation is extremely important in this challenging environment of the opioid epidemic crisis.

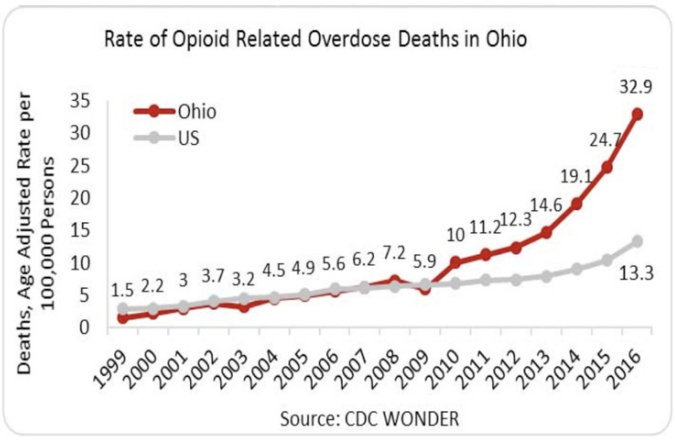


Figure 1: Based on 2017 government Opioid mortality data, Ohio is rated number two in the US with more than 2.6 times death rate per 100,000 population compared to US average rate (39.2 in OH vs. 14.6 average).

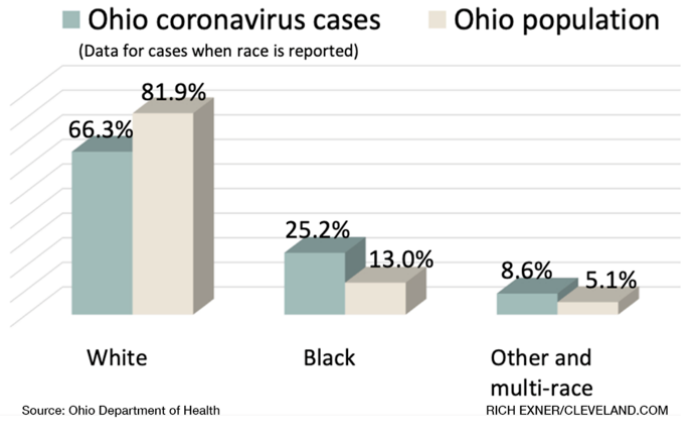


Figure 2: Based on the age, medical comorbidities, socio-economic challenges and possible immunosuppressive effect of Opioids, our patient is at increased risk for the COVID-19 pandemic.

The national and state guidelines require risk stratification and close monitoring of patients on chronic Opioid medication [1]. This study tests the impact of the frequency of the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) functional improvement and continuity of care of chronic pain patients. This is frequency of the SBIRT protocol (G codes such as G0397), POC UDS (80307, 80304) and minimally invasive procedures (76942, 64450, 64418, 20533 and other similar codes are based on the "Pain Management Best Practices Inter-Agency Task Force Report", Medicare MLN and LCD OH L36029, Medicare guidelines for the presumptive and definitive testing [1,10,15].

Our practice is a tertiary referral practice that gets referrals for high-risk patients. This is the reason for conducting this study that tests the impact of the frequency of the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) functional improvement and continuity of care of chronic pain patients for the quality of care documentation and information for the third-party payers.

Consequences of denial labeling as unallowed service for SBIRT and other services.

Unfortunately, on many occasions' providers face denial of the SBIRT and other services by the private and the government insurance plans. When the insurance carriers challenge the

necessity of SBIRT protocol (G codes), it denies coverage for procedures that are required by the Ohio state law (please review Michael Staples attached) and creates a "catch 22 scenario" that puts the patients and the staff at risk. These procedures include face to face time spent by physician and the nurse practitioners, more than 30 min of telecommunication video material, structured review of several assessments including patient's history and physical examination, PADT [2], COMM [3], Flowchart form based on SMBO Administrative Rule 4731-21-02 [4], withdrawal assessment form, point of care and conformation urine and saliva drug screen reviews, OARRS reviews, and several educational materials. The initial evaluations include additional assessments such as SOAPP-R and ORT and additional educational materials.

Denial payments for the appropriate testing and screening procedures for drugs and alcohol required by the state and national guidelines not only significantly impact pain program ability to function as a business, but also puts an extremely vulnerable patient population at risk. Our patient population is unique as compared to many of our peers. Our patients are extremely complex; we take pride in creating individualized treatment plans which do require a significant amount of testing and time for screening for substance and alcohol use. However, this allows our patients to achieve an extraordinary level of function relative to managing their pain and prevent morbidity and mortality.

At the time of the COVID-19 pandemic additional requirements for SBIRT, withdrawal screening and mental screening suggested by the American Academy of Pain Medicine [17]. Denial of these services exposes staff and patients for additional risks during the pandemic and depletes necessary practice funds required for the personal protection equipment suggested by the American Academy of Pain Medicine [17] during the COVID-19 pandemic.

National and state guidelines require documentation of the organic pathology as part of a comprehensive evaluation in a pain management clinic. NCV, EMG, and Autonomic testing is part of such evaluation.

For example, Mayo Clinic Proceedings [5] that were adopted by the state of Ohio and referenced on each printed copy of the OARRS report, reported that in the area of pain management "The predominant reason for inappropriate care was a failure of the prescribing physician to adequately verify patient's prior medical history". Appropriate testing including NCV and EMG is a step in such verification.

Most of the patients referred to Comprehensive Pain Management Institute, LLC (CPMI) for the evaluation of chronic pain in two or more extremities, or have the diagnosis of peripheral neuropathy, lumbar, or cervical radiculopathy suggested by the referring provider.

The numbers of NCV/EMG tests are based on the OH local coverage determination [6]. All patients had a comprehensive evaluation including initial, follow up evaluation forms, PADT forms enclosed, and extensive review of OARRS reports offered a written consent based on the AANEM guidelines [7] with a detailed explanation of the risk and benefits of the tests. NCV is reviewed and incorporated into the treatment plan.

The most commonly tested nerves in the upper extremities were sensory ulnar, median and radial studies, motor median, ulnar, radial, and in selected cased Axillary studies with Median and Ulnar F waves. For the low extremities the studies included sensory Sural, Superior Peroneal, Motor studies included Common Peroneal, Tibial nerves, and Common Peroneal, and Tibial nerve; F waves and H reflex studies selected based on the comprehensive assessment results. The needle examination typically included (UE) Cervical Paraspinals, Deltoid, Biceps, Extensor Carpi Radialis, Triceps, Flexor Carpi Radialis, APB muscle, (LE) Lumbar Paraspinals, Vastus medialis, Extensor Hallucis Longus, Biceps Femoris, Peroneus Longus, Medial Gastrocnemius, the studies selected based on the comprehensive assessment result.

Between 2011-2015 as a result of regulatory changes in the state of Ohio (including HB 93 law), CPMI received a high number of referral/evaluation requests for high risk challenging patient populations.

Many of these chronic pain patients seen by the CPMI suffer from anxiety and depression, and/or substance use disorders, drug-seeking behavior and had a poor tolerance of the NCV/EMG testing and poor cooperation with the test, especially with the needle part of the test (EMG), (this part performed with inserting EMG needle in 6-12 sites) and frequently refused by the challenging patient population. All the patients signed a written consent based on the AANEM guidelines [6,7].

Cost Efficiency

The cost of the opioid epidemic is more than 600 billion dollars and keeps rising annually. Pain Management programs like our practice that carefully screen and test patients to properly document organic pathology and utilize alternative treatments, careful monitoring, and SBIRT approach not only prevent significant morbidity and mortality but save very significant costs to the healthcare system.

Insufficient testing, monitoring, SBIRT screening and lack of alternatives to opioid medications can potentially result in either prescribing opioid medications to not appropriate candidates that can potentially overdose or divert medications to other people, or not prescribing 5/9 appropriate pain medications to patients who may look for alternatives "On the street" with significant risks or morbidity and mortality.

The host of hospitalization including ER, inpatient care, ICU, detoxification, and maintenance programs is astronomic and can be reduced by patient screening treatment in outpatient programs like our practice (Comprehensive Pain Management Institute). This approach is also supported by the 2017 five-point strategy by the HHS.

When the insurance carriers challenge the necessity of SBIRT protocol (G codes), it denies coverage for procedures that are required by the Ohio state law and creates a "catch 22 scenario" that puts the patients and the staff at risk. These procedures include face to face time spent by physician and the nurse practitioners, more than 30 min of telecommunication video material, structured review of several assessments including patient's history and physical examination, PADT, COMM, Flowchart form based on SMBO Administrative Rule 4731-21-02, withdrawal assessment form, point of care and conformation urine and saliva drug screen reviews, OARRS reviews, and several educational materials. The initial evaluations include additional assessments such as SOAPP-R and ORT and additional educational materials.

Insufficient testing, monitoring, SBIRT screening, can potentially result in either prescribing opioid medications to not appropriate candidates that can potentially overdose or divert medications to other people, or not prescribing appropriate pain medications to patients who may look for alternatives "on the street" with significant risks or morbidity and mortality. The host of hospitalization including ER, inpatient care, ICU, detoxification, and maintenance programs are astronomic and can be reduced by patient screening and testing including NCV/EMG testing and other testing.

Our practice performs the NCV/EMG testing and another testing for a fraction of the cost charged by main hospitals in the area including the Ohio State University clinic.

It is difficult for many patients to find alternative providers. If left untreated, patients may turn to illicit means of obtaining substitute medications which drastically increases the risk of overdose and death (overdose death rate in Ohio is the highest in the nation and is up more than 800% since 2013). The cost of the opioid epidemic is estimated as more than 600 billion nationwide, we run a low-cost program that saves hundreds of thousands of dollars to Medicare by identifying and referring for addiction treatments for hundreds of patients using our SBIRT protocol. We billed much lower rates than comparable hospital-based programs and chose lower-cost codes (i.e. G codes vs. office visit and time codes).

In summary, denial payments for the appropriate testing and screening procedures for drugs and alcohol put in danger about several hundred high-risk patients (just in December of 2019 we had a case of assault by a discharged drug-seeking patient and an attempted assault by another patient at our office).

Denial payments for the appropriate testing and screening procedures for drugs and alcohol required by the state and national guidelines would not only significantly impact pain program (such as CPMI) ability to function as a business, but would also put an extremely vulnerable patient population at risk. Our patient population is unique as compared to many of our peers. Our patients are extremely complex; we take pride in creating individualized treatment plans which do require a significant amount of testing and time for screening for substance and alcohol use. However, this allows our patients to achieve an extraordinary level of function relative to managing their pain and prevent morbidity and mortality.

Methodology

Risk Stratification for the patient in sample 1 (please see NARX table below):

NARX Score analysis of the patients in the sample.

Our treatment protocol, including the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) is based on patient risk stratification, NARX risk stratification (validated by the CMS) LCD OH L36029 [27] and state and national guidelines.

NARX score is a nationally validated risk score accepted in the state of Ohio and many other states [9]. There are no frequency guidelines for the G code, however, the NARX score (that shows the risk of overdose and death) seems to be the golden standard accepted by the CMS and Medicare. The clinical recommendations by the CMS and SMBO attached (attachment NARX Manual, NARX clinical application).

Only 6% of the sample 1 patients (3/50 pts) are low risk (NARX below 100)

Only 16% are high risk (NARX 100-189) Odd ratio for overdose increased 10 times (chapter 12 Overdose Risk Score page 63 attached).

The rest are at a very high risk of 34% (NARX above 200) and an extremely high risk of 24% (NARX above 350). The odds ratio for death from overdose is 10-12 times average (see the clinical application of the NARX score attached page 67). The odd ratio for overdose increased 10-12 times or more (chapter 12 Overdose Risk Score page 63 attached).

Undoubtedly the patient with this type of risk would require frequent G code screening and another testing such as EMG.

The vast majority of the "sample 1" patients were on increased risk dose of the opioids (more than 20 MME- increased risk of death as per CDC 2016 guidelines increased adjusted Hazard Ratio (HR) for an overdose and death) [10], many patients obtained opioids

from more than one prescriber, used multiple pharmacies and multiple classes of opioid medications, some also used sedatives or stimulates that greatly increased the risk according to the CDC guidelines and NARX score database (please find original NRAX score reports for each patient attached).

These types of risky patients require a high frequency of SBIRT (G code use) based on the criteria discussed above.

Risk stratification of sample 2 (sent by a separate email) demonstrated similar results.

Use of SBIRT G code vs. use of the E/M office visit codes.

Many of the CPMI patients have multiple medical comorbidities and dependent on transportation (can schedule only a limited number of visits). Therefore on many occasions, we have to schedule the minimally invasive procedure and the office visit for medical management on the same date.

This study shows the advantages of using SBIRT/G codes rather instead of E/M level 3 or 4 codes in these encounters. This approach provides cost-saving to third party insurance payers and emphasizes the screening and brief intervention approach which is crucial in managing high-risk patients on opioid medications.

Cost-saving secondary to use of G code use vs more expensive office visit (E/M) codes:

According to the national standards for Pain Medicine [11] office visit codes, 99213 and 99214 combined constitute almost 100% of the total visit billings (48.8% for 99213 + 44.9% 99214). These codes are more expensive than G codes and can also be combined with time codes.

Our billing data analysis below shows that in our practice these more expensive office visit codes (99213 and 99214) constitute only 16-30 percent of the total annual visits.

Our practice started the appropriate use of G codes since its inception in 2014 (which explains the 91% percent increase in comparison to 2013).

The use of these codes was based on the certified biller and coder review below and saved Medicare tens of thousands of dollars (as proven by the billing and coding data below).

Between 16-30 % of our follow up visits were billed as the more expensive E/M codes 99213, 99214, the rest were billed as G codes instead of more expensive office visit codes.

In other words, analysis of G code and office visit codes E/M codes billed shows significant cost savings in using G codes vs. the use of more expensive E/M codes for the office visits. That is clearly demonstrated in the patient example 1: the 79 times the G code was billed - it was billed for 79 follow up visits instead of more expensive office visit code.

Coding and billing statistics for our office

	Office Visits	G Codes	Total Visits
2014	2330	5104	8239
2015	2056	5622	8157
2016	1146	6621	7885
2017	1373	7294	8491
2018	1160	7907	8111
2019	2317	8838	9494

Implementation of the LCD OH L36029 [27]

Our study also provides a clear proof that frequency of the SBIRT/G code monitoring should depend on the compliance with the prescribed opioid medications and NARX score risk stratification, rather than reliance on the self-reported risk factors like alcohol or drug use in the initial evaluation by the staff or by a pain psychologist.

LCD OH L36029 [27] sets the frequency of monitoring that depends on prescribed opioid medications and other elements and not only on the initial psychological evaluation that used. These are the factors that set the frequency of testing and screening (including the SBIRT/ G codes use).

- Patient history, physical examination, and previous laboratory findings
- Current treatment plan
- Prescribed medication(s)
- Risk assessment plan

The rationale for such screening LCD OH L36029 defines as:

- Identifies the absence of prescribed medication and potential for abuse, misuse, and diversion;
- Identifies undisclosed substances, such as alcohol, unsanctioned prescription medication, or illicit substances;
- Identifies substances that contribute to adverse events or drug-drug interactions;
- Provides objectivity to the treatment plan; e. Reinforces therapeutic compliance with the patient;
- Provides additional documentation demonstrating compliance with patient evaluation and monitoring; g. Provide diagnostic information to help assess individual patient response to medications (e.g., metabolism, side effects, drug-drug interaction, etc.) over time for ongoing management of prescribed medications.

All these elements and factors are documented in our records and evaluated in our study. We would like to illustrate the importance of this approach using the examples below:

Patient examples that show an efficient SBIRT implementation that enables successful patient participation in the program and timely detection of aberrant drug-seeking behavior.

(Patient examples reviewed by the ABPMR without protective health care information disclosure and provide examples of the common cases mistakenly denied overlooked by providers and denied by third party payers).

Example #1: DS. This patient-reported the last drink 26 years ago, however, this patients meet criteria for a high-risk patient with a chronic pain syndrome failed back syndrome after (s/p)4 back surgeries). This is an example of SBIRT screening directed towards compliance with the prescribed opioid substances and confirmation of the lack of the non prescribed narcotic substances as per SMBO, Ohio Board of Pharmacy and NARX (25), CDC, and LCD OH L36029 We will analyze the necessity and the frequency of the SBIRT and G code screening (SBIRT /G code) code at least 79 SBIRT (G code) performed since 2015) and the impact on patient compliance and participation in the program.

Case Review: This is a patient s/p 4 back surgeries that require chronic pain management.

NARX score analysis/ example 1

Narcotic Score 470 Sedative Score 170 Overdose Risk Score 190 (Odds ratio for overdose and death is about 10 times higher than average please refer to the NARX score review material enclosed (25 In addition, he is currently on 60 MME daily (Three times the dangerous dose threshold per CDC guidelines), he has received more than 150 prescriptions from 5 different prescribers using 2 different pharmacies including high-risk substances like Oxycodone, Morphine Sulphate and Fentanyl (that is responsible for a large number of overdoses and death).

Since this is a high-risk patient on chronic opioid medications, he requires frequent follow-ups and compliance monitoring. Our practice monitored the patient compliance with at least 79 screenings and brief interventions performed over the span of the last 3-4 years. This number is conservative for this type of patient and required by the SMBO, Ohio Board of Pharmacy and NARX, CDC, and LCD OH L36029.

The screenings are related to continuous exposure to different narcotic substances and not to his prior drinking history as described above. Of note, this chart was reviewed by the Board of Pharmacy in 2015 and found fully compliant.

Use of different codes for this patients would have resulted in increased cost for the third party payers.

This example shows how efficient and cost-effective use of the SBIRT screening (G0397 code) use saves significant costs funds for the third party payers and enforces compliance for the high-risk patients.

Also, this patient has been coming to our practice for close to 5 years (despite multiple competing providers just a few miles away) and even volunteered a video testimonial (together with close to 70 other patients).

Example #2: LH, on the initial interview with the pain psychologist – the patient did not report any history of alcohol or drug abuse. The Board of Pharmacy NARX score defines this patient as a very high-risk patient:.

NARX score analysis/example 2

Narcotic Score 451 Sedative Score 290 Overdose Risk Score 370 Stimulant Score 20 (Odds ratio for overdose and death is about at least 12 times higher than average or more please refer to the NARX score review material enclosed [25] Additional risk factor more than 100MME with an average 40 MME daily (please find the original NARX report enclosed). Recently patients are getting 60 MME daily. These are very dangerous doses according to the NARX and CDC guidelines attached that require frequent SBIRT (G code screenings).

The patient received more than 82 prescriptions for several types of medications including Percocet, Oxycodone, Morphine, Hydrocodone, Phentermine, Lyrica, and Gabapentin from 7 prescribers and 5 pharmacies.

44 screenings and brief interventions (SABIRT/G code) performed over the span of the last 3-4 years for such risk patients is a reasonable required number as per SMBO, Ohio Board of Pharmacy, and NARX, CDC, and LCD OH L36029. The screenings are related to continuous exposure to different narcotic substances.

Use of different codes for this patients would have resulted in increased cost for the third party payers.

This example shows how efficient and cost-effective use of the SBIRT screening (G0397 code) saves enforcement for the very high-risk patients on multiple controlled substances and saves funds for third-party payers.

Example #3: LH

Case Review: This is a chronic pain patient with a symptomatic spinal stenosis who requires chronic pain management. Besides, the patient reported being a victim of physical domestic abuse (additional risk factor) and required chronic benzodiazepine therapy (alprazolam).

The patient had multiple prescriptions of alprazolam (potent benzodiazepine) combined with opioids (12) which is an additional high-risk factor for overmedication and death that requires SBIRT interventions each time the combination is prescribed according to the CDC guidelines. Please find the list of the prescriptions enclosed.

The patient had an abnormal urine drug screen which positive for non prescribed benzodiazepine (which a very high-risk factor combination of medications as per accepted guidelines) and the follow up pain psychology report that conditioned patient clearance for opioids with closed monitoring (SBIRT protocol/G codes). 26 screenings and brief interventions (SBIRT/ G codes) performed over for such a very high-risk patient is a reasonably required r as per SMBO, Ohio Board of Pharmacy and NARX, CDC, and LCD OH L36029.

The screenings are related to continuous exposure to a combination of benzodiazepines narcotic substances and not to the patient's prior drinking history. Use of different codes for this patients would have resulted in increased cost for the third party payers. This example shows how efficient and cost-effective use of the SBIRT screening (G0397 code) saves enforcement for the high-risk patients on opioids and benzodiazepines and saves funds for the third-party payers.

Cases 1-3 show that despite the initial denial of prior risk factors (i.e drinking history) on the initial psychological interview, NARX score and structured assessment analysis can help to implement proper SBIRT/ G code screening for safety and compliance.

Example #4: JM

Patient chart review shows that the patient was prescribed on October 20, 2016, 30 tablets of OxyCodone 5 /APAP 325 for 15 days as per state prescription monitoring system (OARRS). On 11/2/16 our practice performed a random urine screen that was NEGATIVE for prescribed OxyCodone. The urine screen was reviewed by a Doctor of Pharmacology consultant and discussed with a pain psychologist, both of them requested tight monitoring because of concern for medication diversion (which is considered a felony by the state of Ohio and federal law).

Also, the follow-up note dated 11/02/16 states that the patient did not bring medication bottles for a pill count. The patient claimed she "has a lot of Percocet at home" raising additional concerns about hoarding and medication misuse. Unfortunately, the patient was not compliant with the reasonable monitoring and self-discharged herself.

NARX score analysis/example 4

This patient has a high NARX score (Narcotic score 371, Sedative score 150, Overdose risk score 170), she received opioid medications from 7 prescribers, using 4 pharmacies based on the Board of Pharmacy database.

In summary, our management of the case was appropriate and mandated by the federal and state law, SMBO, Ohio Board of Pharmacy, DEA, and CDC regulations. Patient examples of proper use of informed consent and respect for patient autonomy based on the AANEM policies and guidelines [6,7].

In the previous part of the study dedicated to the EMG/ NCV protocol, we introduced the use of informed consent in our practice. The following examples analyze the use of the informed consent by the patients.

Example # 5

ST This is a high-risk patient (NARX score analysis defines her as a high-risk patient: Narcotic Score 441 Sedative Score 200 Overdose Risk Score 340 (Odds ratio for overdose and death is about 10 times higher than average as per Ohio PMDS (OARRS) manual [25]. The Board of pharmacy summary also mentioned more than 5 opioids or sedative providers from 4 pharmacies. Proper testing such as NCV/EMG testing is necessary for such a patient for documentation of organic pathology.

This patient "First refused the needle EMG, then left the box unchecked and then agreed to the needle EMG test". The patient refused the needle EMG in 2014, later when the patient required prolonged care in 2016, and in 2017 she agreed to the needle testing. In 2016 she gave verbal consent (not marking the checkbox is irrelevant based on the AANEM ethical guidelines enclosed) and 2017 she gave both verbal and written consent which is also consistent with the guidelines. Patient informed consent for and against the testing was respected each time as per AANEM and Medicare consent policy. The 2014 and 2016 tests were both carpal tunnel evaluation exempt by the AANEM policy and provided credible information even without the needle testing.

Example # 6 MS

MS is a high-risk patient. (NARX score analysis defines her as a high-risk patient: Narcotic Score 381 Sedative Score 160 Overdose Risk Score 210 (Odds ratio for overdose and death is about 10 times higher than average please refer to the NARX score review material enclosed [25]. Mark recently had a urine screen positive for use of illicit marijuana (as per consultation with the Doctor of Pharmacology consultant). The Board of pharmacy also mentioned more than 4 opioids or sedative providers from 2 pharmacies (total more than 50 prescriptions). Proper monitoring testing such as NCV/EMG testing and alternative procedures are necessary for this patient.

This patient also has been seen at our practice for several years (despite multiple competing providers just a few miles away) that testifies for the quality of care she has received. Close follow up that included an interview by pain psychologist and psychological assessments helped to address patient anxiety. This patient initially refused the needle EMG testing. Even though the test is called "Needle" EMG, the test is performed using a recording probe (and not a needle) in a conventional sense (nothing is injected through the EMG "needle"). Therefore it's quite natural for a patient to refuse the needle EMG testing that does not directly relieve the pain (and also involves 6-12 probe sticks).

At the same time, the patient agreed to the nerve block injection that involved one small needle stick that provides immediate pain relief through medications injected through the needle. Patient informed consent for and against the testing was respected each time as per AANEM and Medicare consent policy. The 2014 and 2016 tests were both carpal tunnel evaluation exempt by the AANEM policy and provided credible information even without the needle testing.

POC UDS testing

Use of the POC UDS testing performed in compliance with the state and federal guidelines as part of the patient monitoring program using the risk stratification scale discussed above. Data shows a significant impact of the testing on the patient treatment plan and compliance [13-15].

Ultrasound-guided procedures

Ultrasound-guided procedures (peripheral nerve blocks, trigger point injections, and others). The minimally invasive procedures are cost-effective alternatives to the opioid medications required by the guidelines. All the patients received the informed consent and the medical necessity forms. Statistical analysis shows a strong impact of these procedures on the patient treatment plan and compliance.

Analysis of sample 2 – discharged patients

We have reviewed the charts of patients positively screened for non-compliance with the patient contract (illicit substance abuse, failed pill counts, doctor shopping, urine screens negative for prescribed medications, and other issues) using the SBIRT protocol (G codes) that we discussed.

Methods

- A retrospective review of charts of regular and incomplete studies to assess the impact of the test on the treatment decision making (such as choosing non-opioid adjuvant medications and opioid medications, pain reduction and functional improvement as documented by PADT forms and performance of proper clinical assessment that justify study repletion in the selected group of patients.
- The retrospective review studies the impact of the frequency of the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) on the treatment decision making (such as choosing non-opioid adjuvant medications and opioid medications), pain reduction and functional improvement as documented by PADT forms and performance of proper clinical assessment as all the compliance and participation in the program (lengths of participation in months).

When pain reduction was 30%-50% we defined it as a "Moderate", above 50% a "Significant" and more than 70% a very significant pain reduction. When functional improvement as documented by PADT included 2 parameters or more, we called it significant, if only one parameter we called it a "moderate" functional improvement. If three or more functional parameters improved we called a very significant improvement. The effect is illustrated with several patient example analyses.

Results

SBIRT and UDS and procedure impact analysis

Sample 1

NARX Score (risk stratification) and SBIRT protocol screening effectiveness analysis.

The table below how the average NARX scores change with Months in Program:

Table 1:

Months	Average	Max	Number Patients
Short (1 month)	308	450	6
Medium (>1 month, < 2 years)	271	390	13
Long (2 years)	309	770	23

NARX Score (risk stratification) and SBIRT protocol screening effectiveness analysis results

Enforcing and monitoring patient compliance is a major challenge for pain management programs. The average and the maximum NARX scores reflect the high risk and the very high-risk profile of our patient population. Our SBIRT protocol and other tests and treatment described in the study is effective in monitoring and enforcing the high-risk patient compliance for prolonged periods (more than 23 months).

Functional Improvement Analysis

The table below compares Months in Program vs Functional Improvement (based on the PADT and other tools). Given the low number of patients in the 'less than a 2-year group, these 3 groups are combined.

Table 2:

	Moderate	Significant	Very	Total
Less than 2 years	16	7	6	29
2 years	5	1	20	26
	21	8	26	55

Table 3:

% of Row Totals for the table above.

	Moderate	Significant	Very
Less than 2 years	55.2%	24.1%	20.7%
2 years	19.2%	3.8%	76.9%

For example, of the 26 patients with 2 years of treatments (for whom we also had data on Functional Improvement), 20 of them or 76.9% showed Very Significant Improvement.

Performing a chi-square test in Table 3 (combining the first 2 columns to enhance the test) shows there is a significant difference in 'months of Treatment ($p<.01$).

Functional Improvement Analysis Results

There is a significant relation (at .05 level) between Months in Program and Functional Improvement. The SBIRT protocol and other treatments in our program showed a strong statistically significant impact on the patient functional improvement – which is the main outcome measure of the pain management program.

Pain Reduction analysis

Table 5:

	Moderate	Significant	Very	Total
Less than 2 years	22	4	2	28
2 years	17	5	4	26
Total	39	9	6	54

Table 6:

% of Row Totals for Table above

	Moderate	Significant	Very
Less than 2 years	78.6%	14.3%	7.1%
2 years	65.4%	19.2%	15.4%

Most patients had only moderate pain reduction (72.2%). Of the patients in the program for 2 years, 15% (4 out of 26) had Very Significant pain reduction while 65% of the 2-year patients had Moderate Pain Reduction.

Performing a chi-square test on Table 5 (combining the last 2 columns to enhance the test) shows there is a significant difference in 'months of Treatment ($p=.02$).

Pain Reduction analysis results

We demonstrated a very significant pain ($p=.02$) reduction over time in our program. As time participation in the program increases (more than 2 years), the pain reduction becomes more significant.

Statistical analysis

Sample 2

NARX Score (risk stratification) and SBIRT protocol screening effectiveness analysis

The table below how the average NARX scores change with Months in Program

Table 7:

NARX Score vs Months in Program

	Average	Max	Number Patients
< 2 years	317	480	9

NARX Score (risk stratification) and SBIRT protocol screening effectiveness analysis results (sample 2):

Enforcing and monitoring patient compliance is a major challenge for pain management programs. As we have observed in sample 1, in sample 2 the average and the maximum NARX scores reflect the high risk and the very high-risk profile of our patient population. Our SBIRT protocol and other tests and treatment described in the study is effective in monitoring and enforcing the high-risk patient compliance for prolonged periods (more than 23 months).

Functional Improvement Analysis

The table below compares Months in Program vs Functional Improvement (based on the PADT and other tools). Given the low number of patients in the 'less than a 2-year group, these 3 groups are combined.

Table 8:

Months in Program vs Functional Improvement

	Significant	Very	Total
< 2 years	5	6	11
2 years	8	25	33

Table 9:

% of Row Totals for the table above

	Significant	Very
< 2 years	45.5%	54.5%
2 years	24.2%	75.8%

The table below compares Months in Program vs Functional Improvement (based on the PADT and other tools). Given the low number of patients in the 'less than a 2-year group, these 3 groups are combined.

Functional Improvement Analysis Results

All the patients in the sample stayed in the program for 6 months or longer, most of the patients for 2 years or longer. All the patients achieved functional improvement at 6 months and continue with significant or very significant improvement after that.

Pain Reduction analysis

Table 10:

Months in Program vs Pain Reduction

	Moderate	Significant	Very	Total
< 2 years	4	5	0	9
2 years	0	21	11	32

The difference between the "< 2 years" group and the "2 years" group is statistically significant (binomial test, P<.01)

Table 11:

% of Row Totals for Above Table

	Moderate	Significant	Very
<2 years	44.4%	55.6%	0.0%
2 years	0.0%	65.6%	34.4%

Pain Reduction analysis results

We demonstrated a very significant pain (p=.01) reduction over time in our program. As time participation in the program increases (more than 2 years), the pain reduction becomes more significant.

Sample 3 (discharged patients)

Discharge Reason	Number Patients	% Total Patients	3 months	6 Months	12 Months	2 years	Average NARX Score	Number with NARX Score
COC	14	35.9%	7	2	4	1	367	14
THC	2	5.1%	2	0	0	0	160	1
METH	2	5.1%	2	0	0	0	80	1
ETOH	12	30.8%	2	2	5	3	442	11
FENT	1	2.6%	1	0	0	0	50	1
ADLTERATION OF URINE	3	7.7%	3	0	0	0	236	3
BUP	5	12.8%	4	0	0	1	486	5

Two-thirds of all Discharge reasons were for COC or FPC.

Dividing the patients into 3 groups, COC, FPC, ALL Others, there is no significant difference in Average NARX Score amongst the 3 groups (t-test at .05 level).

Discharged patient analysis results

Data shows the high complexity and the high-risk status of our patients. The most discharged patient tested positive for cocaine (COC) and ETOH (35.9 and 30.8 percent), the highest NARX score was associated with buprenorphine (486).

NCV/EMG study analysis results

All initial and repeated tests were performed after a comprehensive evaluation and proper documentation of medical necessity as required by the AANEM guidelines and Ohio LCD.

All NCV tests with or without EMG testing had a documented impact on the narcotic and non-narcotic medication prescriptions, pain reduction, and functional improvement.

There was a significant association between pain reduction and functional improvement.

	Pain Reduction	Functional Improvement
Moderate	58.3%	20.8%
Significant	16.7%	25.0%
Very Significant	25.0%	54.2%

Applying a chi-square statistic to patient outcomes of functional improvement, we observe: that NCV and NCV+EMG are statistically significant at the .05 level.

Association between the repetition of the test and functional improvement (number of studies and percent of patients):

	Moderate	Significant
No Repeat	5	5
Repeat	0	14

	Moderate	Significant
No Repeat	20.8%	20.8%
Repeat	0.0%	58.3%

Conclusion

SBIRT analysis

The use of the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) show a significant documented positive effect on increasing overall patient safety, encouragement of safe controlled substance prescribing for practitioners, maintaining compliance with State and Federal laws and regulations, reduction of patient overdose deaths, early detection and intervention of substance use disorder, and improving overall standards of care.

The vast majority of patients in the sample fit the high-risk profile which requires frequent SBIRT monitoring. CPMI SBIRT protocol is associated with effective long-term monitoring of compliance of the chronic pain patients on opioid medications and effective diagnostics of aberrant drug-seeking behavior and referral to Addiction Medicine evaluation. Our protocol is based on the "Pain Management Best Practices Inter-Agency Task Force Report", Medicare MLN and LCD OH L36029, Medicare guidelines for the presumptive and definitive testing, Medicare CPT code definitions.

This study has important conclusions for third-party payers and clinicians. SBIRT protocol (G codes such as G0397) is mandatory for a compliant pain management practice. Without proper implementation of the SBIRT protocol (G codes such as G0397), a safe and compliant pain management program is hardly possible, and patients and staff are exposed to significant risks.

Alcohol/substance abuse structured assessments and brief interventions of 30 minutes or longer, under code G0397 (SBIRT protocol) performed at Comprehensive Pain Management Institute, LLC are based on the accepted guidelines and "HHS Pain management best practices inter-agency task report" and required for the state and federal guidelines compliance. The SBIRT protocol is documented on all the charts in the study and compliant with the Medicare MLN # and LCD OH L36029.

This study shows a significant positive impact of the SBIRT protocol on pain reduction and function improvement is well documented in this study. SBIRT protocol is mandatory for the compliant operation of a pain management clinic providing medical management to the population with a significant percent of high-risk patients in the high-risk area like Ohio. Denial coverage for these services by third-party payers or defining them as "unallowable costs" puts the practice in noncompliance with the guidelines described above making the ethical operation of the practice impossible and putting patients and staff at considerable risk.

Denial payments for the appropriate testing and screening procedures for drugs and alcohol (such as of the SBIRT protocol (G codes such as G0397) required by the state and national guidelines) would not only significantly impact of a pain program ability to function as a business, but would also put an extremely vulnerable patient population at risk. The chronic pain patient population is unique as compared to many other specialties. Our patients are extremely complex; we take pride in creating individualized treatment plans which do require a significant amount of testing and time for screening for substance and alcohol use and other tests and procedures described in this study. However, this allows our patients to avoid the risk of morbidity and mortality (Ohio has one of the highest rates of opioid mortality per 1000 population in the country) and achieve significant pain relief and improvement in the level of function relative to managing their pain.

NCV/EMG analysis

Using a chi-square test, we can and conclude (with $P<.01$) that repeating the test has a positive association with functional improvement.

The association can be explained by the fact that an additional comprehensive evaluation was performed prior to the test and additional NCV and EMG test results were incorporated in the treatment plan that helped to achieve additional functional improvement.

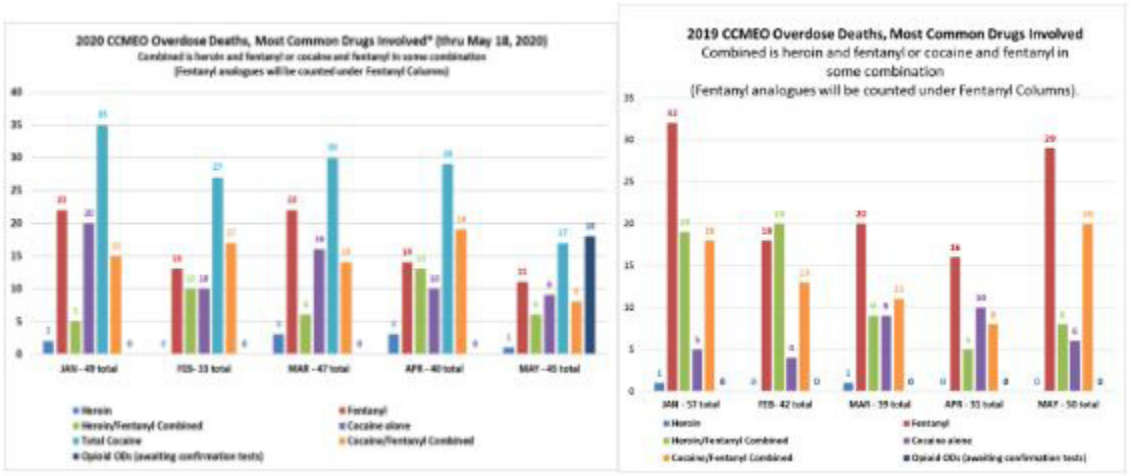
A functional improvement which is the main goal of pain management program (which is more important that pain reduction) has most strong statistically significant improvement with the use

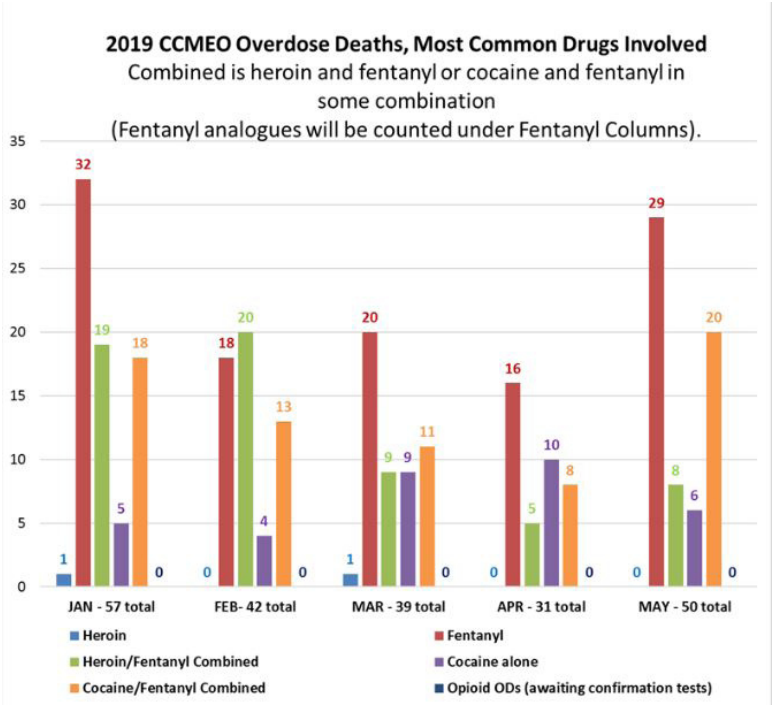
of the NCV and EMG testing (with or without the needle testing). These findings underscore the medical necessity and cost-effectiveness of the NCV and EMG tests based on the sample examined.

NCV with or without needle EMG tests as part of the effort to document organic pathology (both initial tests and follow up tests) are medically necessary tests and cost-effective tests that have a strong statistically significant contribution to the proper choice of medications and procedure for chronic pain patients and strongly associated with functional improvement and pain reduction.

Despite a possible improvement in 2018-2019 data, objective data (figure 1) shows that a new approach described in this review by the medico-legal system and third party payers required to address the opioid crisis and protect the population at the high risk for COVID 19 epidemic (figure 2). These trends are confirmed by the Cuyahoga County Medical Examiner's Office (figure 4 and 5) for 2019 and the beginning of the 2020. Of note, Cuyahoga County is one the most affected counties by COVID-19 as well.

Figure 4,5 and 6 (Cuyahoga County Medical Examiner's Office)





As a small independent office, without a special research budget me have done our best to provide SBIRT care with is compliant with the best standards in the specialty based on the American Board of Physical medicine and Rehabilitation and HHS guidelines discussed above.

We advocate for large prospective studies and provider and third party payor education on these subjects.

Additional risks of SBIRT denials during the COVID-19 pandemic American Academy of Pain Medicine (AAPM)

American Academy of Pain Medicine (AAPM) recently made recommendations for COVID-19 pandemic 20) additional requirements for SBIRT including additional withdrawal screening and mental screening suggested. Denial of the SBIRT and other services exposes staff and patients for additional risks during the pandemic. In addition the AAPM guidelines required using expensive personal protective equipment (such as N-95 masks). Denials of the SBIRT and other services deplete necessary practice funds required for the personal protection equipment and creates additional risks for staff and patients. The recent AMA brief [26] alarms about great concern over increased opioid mortality during COVID 19 pandemic.

Concerns for singling out minority patient populations and practices

There are multiple concerns raised about racial disparity, social injustice in context of the opioid crisis. Specifically concerns related to the fact that minority populations and practices targeted with unjust denials of the SBIRT and other essential services. On many occasions, these denials are done without a proper review process specified in the Medicare integrity manual, without adequate expert review and with no expert review at al. That is one the reasons for the increased gap between opioid mortality in Ohio and average nation levels (2,6 time higher in Ohio, see Figure 1).

Huge Medicare Medic Aid HMOs silence criticism of these policies and denials by ignoring business integrity and patients safety retaliatory recoupment and forcing providers to resign from the plan. Several concerns were raised about Caresource the billion dollar HMO that controls more then 50% of the Ohio market by more than ten senators (Figure 7, 4) in 2018. In April 2020 Case Western Reserve University, Board of Health of Cuyahoga County organized a conference on the Racial Disparity, Social Justice and the Opioid Crisis Conference at Case Western Reserve University [21] (the conference had to be postponed because of the pandemic). In June 2020, both Columbus and Cleveland proclaimed racism a public health emergency [22,23]. It is important to see these declaration and concerns translated into practical changes to avoid additional risk to the medical personnel and patients.

Concerns of the overregulated environment

As discussed during the Case Western Reserve University meeting [16], regulations, audits and supervision are necessary in middle of the opioid crisis. At the same time excessive regulations that interfere with efficient function of the pain clinics (the first responders in the opioid crisis), manipulation of the regulatory agencies by the retaliatory complaints from patients discharged for non compliance result in a significant worsening of the opioid crisis. (Figure 1).

SBIRT and other services denials and security risks to the staff and patients

The recent survey by the American Academy of Pain Medicine found high rate of finds high rate of violent threats toward pain practitioners [24]. Our practice has suffered from property damage, threats to the staff and recently from an unprovoked assault of the physician and two female medical assistants by a violent patient with aberrant drug seeking behavior.

The Columbus city prosecutor (Case 2020 CR B 001416) mentioned that "Because of the lack of funding secondary to insurance denials of essential services (such as screening and brief intervention for drug and alcohol) (pain practices like ours) do not have appropriate funding for additional security measures".

This is a real public safe and health crisis that requires urgent attention.

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Expert panel of the American Board of Physical Medicine and Rehabilitation (ABPMR)

Roneet Lev MD, Chief Medical Office, White House Office of National Drug Control Policy Executive Office of The President.

Sabaitu I. Mansarai a Senior Executive Service (SES) with the Office of National Drug Control Policy where she is the Assistant Director for Public Health, Education and Treatment Task Force in support of combating the opioid crisis.

Ohio Opioid Task Force, Cuyahoga County Board of Health

Case Western Reserve University continuous education program expert panel

This data was reviewed and approved by the American Board of Physical Medicine and Rehabilitation [19].

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Progress Note
Pain Assessment and Documentation Tool (PADT™)

Patient Name: _____ **Record #:**_____

Assessment Date: _____

Patient Stamp Here

Current Analgesic Regimen

Drug Name	Strength (eg, mg)	Frequency	Maximum Total Daily Dose

The PADT is a clinician-directed interview; that is, the clinician asks the questions, and the clinician records the responses. The Analgesia, Activities of Daily Living, and Adverse Events sections may be completed by the physician, nurse practitioner, physician assistant, or nurse. The Potential Aberrant Drug-Related Behavior and Assessment sections must be completed by the physician. Ask the patient the questions below, except as noted.

Analgesia

If zero indicates "no pain" and ten indicates "pain as bad as it can be," on a scale of 0 to 10, what is your level of pain for the following questions?

1. What was your pain level on average during the past week? (Please circle the appropriate number)

No Pain 0 1 2 3 4 5 6 7 8 9 10 Pain as bad as it can be

2. What was your pain level at its worst during the past week?

No Pain 0 1 2 3 4 5 6 7 8 9 10 Pain as bad as it can be

3. What percentage of your pain has been relieved during the past week? (Write in a percentage between 0% and 100%.)

_____

4. Is the amount of pain relief you are now obtaining from your current pain reliever(s) enough to make a real difference in your life?

☐ **Yes** ☐ **No**

5. Query to clinician: Is the patient's pain relief clinically significant?

☐ **Yes** ☐ **No** ☐ **Unsure**

Activities of Daily Living

Please indicate whether the patient's functioning with the current pain reliever(s) is Better, the Same, or Worse since the patient's last assessment with the PADT.* (Please check the box for Better, Same, or Worse for each item below.)

	Better	Same	Worse
1. Physical functioning	☐	☐	☐
2. Family relationships	☐	☐	☐
3. Social relationships	☐	☐	☐
4. Mood	☐	☐	☐
5. Sleep patterns	☐	☐	☐
6. Overall functioning	☐	☐	☐

***If the patient is receiving his or her first PADT assessment, the clinician should compare the patient's functional status with other reports from the last office visit.**

(Continued on reverse side)

Progress Note

Pain Assessment and Documentation Tool (PADT™)

Adverse Events

1. Is patient experiencing any side effects from current pain reliever? ☐ Yes ☐ No

Ask patient about potential side effects:

	None	Mild	Moderate	Severe
a. Nausea	☐	☐	☐	☐
b. Vomiting	☐	☐	☐	☐
c. Constipation	☐	☐	☐	☐
d. Itching	☐	☐	☐	☐
e. Mental cloudiness	☐	☐	☐	☐
f. Sweating	☐	☐	☐	☐
g. Fatigue	☐	☐	☐	☐
h. Drowsiness	☐	☐	☐	☐
i. Other_____		☐	☐	☐
j. Other_____		☐	☐	☐

Potential Aberrant Drug-Related Behavior

This section must be completed by the physician

Please check any of the following items that you discovered during your interactions with the patient. Please note that some of these are directly observable (eg, appears intoxicated), while others may require more active listening and/or probing. Use the "Assessment" section below to note additional details.

- ☐ Purposeful over-sedation
- ☐ Negative mood change
- ☐ Appears intoxicated
- ☐ Increasingly unkempt or impaired
- ☐ Involvement in car or other accident
- ☐ Requests frequent early renewals
- ☐ Increased dose without authorization
- ☐ Reports lost or stolen prescriptions
- ☐ Attempts to obtain prescriptions from other doctors
- ☐ Changes route of administration
- ☐ Uses pain medication in response to situational stressor
- ☐ Insists on certain medications by name
- ☐ Contact with street drug culture
- ☐ Abusing alcohol or illicit drugs
- ☐ Hoarding (ie, stockpiling) of medication
- ☐ Arrested by police
- ☐ Victim of abuse
- ☐ Other: _____

_____

_____

2. Patients overall severity of side effects?

☐ None ☐ Mild ☐ Moderate ☐ Severe

Assessment: (This section must be completed by the physician.)

Is your overall impression that this patient is benefiting (eg, benefits, such as pain relief, outweigh side effects) from opioid therapy? ☐ Yes ☐ No ☐ Unsure

Comments: _____

_____

Specific Analgesic Plan:

Comments:_____

- ☐ Continue present regimen
- ☐ Adjust dose of present analgesic
- ☐ Switch analgesics
- ☐ Add/Adjust concomitant therapy
- ☐ Discontinue/taper off opioid therapy

Date:_____ **Physicians Signature:** _____

Provided as a service to the medical community by Janssen Pharmaceutica Products, L.P.

MEDICAL EXAMINER'S OFFICE

For Immediate Release
May 19, 2020
Contact: Christopher Harris, (216) 443-7157; cbharris@cuyahogacounty.us

Medical Examiner: 9 Overdose Deaths in 48 Hours

CLEVELAND – Cuyahoga County Medical Examiner Dr. Thomas Gilson, today issued a public health alert, stating that Cuyahoga County has suffered 9 suspected overdose deaths in 48 hours. Toxicology testing has not yet confirmed which drug(s) have caused this recent increase. The Cuyahoga County Medical Examiner's Office is continuing to monitor fatality trends during the COVID-19 shutdown.

"The Medical Examiner's Office has seen 9 fatalities in last 48 hours which is measurably higher than what we have been seeing for the first four months of 2020. The interruption of drug use due to COVID-19 may mean users tolerance has dropped and therefore they are at higher risk of overdose and fatality," said Dr. Gilson. **"Additionally, any disruption of the illicit drug supply due to COVID-19 may mean that users are subject to a wide variety of other dangerous substances being substituted without their knowledge."**

FREE fentanyl test strips are available at the following locations:

- Circle Health Services (12201 Euclid Ave, Cleveland, OH 44106 | 216.721.4010)
- Care Alliance Clinic (2916 Central Avenue Cleveland, OH 44115 | 216.535.9100)
- Care Alliance Clinic (1530 St. Clair Avenue, Cleveland OH 44114 | 216.781.6724)

If you or anyone that you know is actively using or recovering from opioid addiction, contact Project DAWN for information at 216-778-5677. Eligible program participants, are given FREE Naloxone kits – the opioid reversing antidote.

Additionally, the Alcohol, Drug Addiction and Mental Health Services (ADAMHS) Board of Cuyahoga County provides a 24-hour crisis hotline at 216-623-6888.

United States Senate

WASHINGTON, DC 20510

March 1, 2018

Pamela B. Morris
President & Chief Executive Officer
CareSource
230 North Main Street
Dayton, Ohio 45402

Dear Ms. Morris:

We write to share our concern over the reported utilization of several industry practices that, when used in the context of pain management and substance use disorder treatment and recovery, may be counterproductive to efforts to address our nation's opioid epidemic. We urge you to reexamine CareSource's current policies and procedures to identify and, more importantly, rectify, any practices that could be contributing to or exacerbating our country's drug addiction crisis.

Our country continues to fight back against the worst drug overdose epidemic in its history. According to the Centers for Disease Control and Prevention (CDC), drug overdoses accounted for more than 63,600 deaths in 2016 – an average of 174 drug overdose deaths per day. These tragedies are not limited to one group of individuals; rather, deaths resulting from drug overdose continue to increase across all populations – men and women, young and old, urban and rural, and across all races. And the cost of this epidemic extends beyond the loss of human lives – according to a recent economic analysis conducted by the Council of Economic Advisors, the economic impact of this addiction crisis represents a loss of nearly $504 billion annually, a number roughly equivalent to three percent of the entire country's gross domestic product (GDP). Without additional investments and changes to the status quo, these numbers will only continue to increase at an exponential rate.

Despite these devastating statistics, the pain that drives many individuals to these addictive drugs in the first place remains a problem. A 2015 analysis by the National Institutes of Health (NIH) estimated that more than 25 million adults experience chronic pain and nearly 40 million adults experience severe levels of pain. These numbers will only continue to increase as our nation grows older. In order to make progress in our nation's fight against the addiction epidemic, we must do more to ensure all Americans – whether they are suffering from chronic or acute pain – have access to non-addictive pain management options.

Unfortunately, it is often much harder for an individual to seek non-addictive pain medications or non-pharmacologic treatment options at the outset of treatment than it is to get a prescription opioid. We understand that there are many reasons for this, including restrictions on benefit design, the high cost of alternative pain treatments, the limited availability and effectiveness of clinically proven alternatives, a lack of clinician awareness regarding alternatives, and ingrained prescribing practices. However, it is important to note that opioid prescribing decisions are not governed solely by clinicians. Health insurance coverage policies play a significant role when it comes to accessing non-addictive pain treatment options, which is why we are urging CareSource to look into its benefit design and internal practices and take a more active role as it relates to preventing and treating addiction. If a clinician chooses to prescribe a non-addictive therapy to treat chronic pain, which is simply overridden by an insurance algorithm that defaults to the cheapest opioid alternative, an opportunity to turn the tide against addiction may be missed.

Recent news reports have raised serious concerns over a lack of insurer accountability when it comes to this epidemic. Take Ms. Lauren Kafka, for example. Ms. Kafka recently wrote about her experience recovering from surgery to correct a torn rotator cuff.[1] Her surgeon and two separate physical therapists recommended renting a cool-therapy device to help manage her pain throughout her recovery. Coverage for this device was denied by her insurance plan, leaving Ms. Kafka with two options: (1) pay out-of-pocket for the device rental; or (2) resort to the opioid painkillers covered by her insurance. Ms. Kafka made the decision to try to take the minimum number of pills necessary to aid in her recovery, and while she was able to pay out-of-pocket for the device rental fees to help decrease her dependence on opioids throughout her recovery, others in her situation may opt to elect only the covered drugs and find themselves at a higher risk for dependence.

Ms. Alisa Erkes, a patient with chronic abdominal pain, was forced to switch from using Butrans, a pre-dosed buprenorphine painkiller patch, to morphine when her insurance provider stopped covering the patch.[2] Though both buprenorphine and morphine are opioids, morphine is categorized as having a higher risk of abuse, dependence, and overdose. Similarly, Ms. Amanda Jantzi, a patient with a painful bladder condition, weaned herself off opioids using the non-opioid painkiller drug Lyrica, only to find that it was not covered by her new insurance policy when she switched employers.[3] While we recognize that Lyrica remains an expensive option with its own set of risks, this example highlights how substituting a traditional opioid may not always be appropriate in circumstances where another option may exist – whether it be pharmacologic or non-pharmacologic. In each of these examples, despite the efforts by both patients and providers to seek out non-addictive pain management options, it was the default policies of the insurers that dictated the available therapy – pushing each individual toward the cheapest and easiest fix: a potentially addictive opioid. Whenever possible, non-addictive options and drugs with a lower risk of addiction and/or abuse should be utilized.

An insurance policy's benefit design may also hinder access to non-pharmacological, or nondrug, pain management alternatives, which can provide valuable support and relief for patients in lieu of narcotics. Mr. Douglas Scott is one such patient who experienced opioid dependence following back and spine injuries from two car accidents.[4] Luckily, Mr. Scott's insurance covered treatment at a local clinic specializing in alternative pain management techniques, and he was able to be successfully weaned off of opioids. Evidence has shown that patients participating in such comprehensive pain rehabilitation programs can experience significant and sustained improvement in pain severity and functioning.[5] Unlike Mr. Scott, however, not all patients have coverage for such programs, which can cost upwards of $20,000; and we encourage CareSource to explore such options and offer them to beneficiaries where clinically appropriate.

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[1] https://www.npr.org/sections/health-shots/2017/11/25/566032620/the-insurance-company-paid-for-opioids-but-not-cold-therapy

[2] https://www.nytimes.com/2017/09/17/health/opioid-painkillers-insurance-companies.html?_r=0

[3] https://www.nytimes.com/2017/09/17/health/opioid-painkillers-insurance-companies.html?_r=0

[4] https://www.nytimes.com/2016/06/23/business/new-ways-to-treat-pain-without-opioids-meet-resistance.html

[5] https://insights.ovid.com/pubmed?pmid=18804915

Lastly, we note reports that some insurance coverage plans appear to act as a barrier to accessing medication-assisted treatment (MAT) for individuals who are working to overcome addiction. Medical necessity requirements, high deductibles and copayments, prior authorization rules, and low reimbursement rates can delay and deter treatment, despite the wealth of evidence demonstrating the effectiveness of MAT. Furthermore, insurers that do cover MAT seldom cover all three Food and Drug Administration (FDA)-approved medications - methadone, buprenorphine and naltrexone – which are not interchangeable in their indications and uses. Similar hurdles exist for access to residential rehabilitation centers and detox facilities, for which insurers will often require "medical necessity" before covering care.

For example, Mr. Sean Mattos, a patient struggling with addiction, unsuccessfully went through two outpatient addiction programs before entering a residential facility, only to find that his insurer would not cover the full duration of treatment he required.[6] Despite agreement by his overseeing clinicians that he was not ready to leave the facility, Mr. Mattos was forced to call his insurer while in treatment to request coverage to remain under the facility's care, before ultimately paying $8000 of the $23,000 bill out of pocket. In response to such unfortunate situations and a desire to remedy them, we appreciate that multiple major insurers have recently lifted their prior authorization requirements for MAT – a step forward in reducing barriers to care. However, such efforts must be replicated and expanded across the industry in order for them to make a meaningful difference.

While we appreciate the work CareSource is already doing to help address this epidemic, and we are encouraged by recent industry led efforts to reevaluate some policies in light of the addiction epidemic, we remain concerned by the rules and authorization requirements that may be employed by insurance companies that could potentially limit beneficiary access to non-addictive and alternative pain management options as well as addiction treatment options. In order to effectively address this ongoing epidemic, we believe insurance companies must take additional steps to ensure they are playing a more active role in addiction prevention and treatment and providing beneficiaries full access to the range of clinically appropriate services available. Eliminating cost-sharing requirements for overdose reversal drugs is not enough. Insurer policies such as prior authorization, drug tiering, abrupt formulary changes, preferred pricing lists, restrictions or additional cost-sharing requirements for non-pharmaceutical interventions, lengthy and burdensome appeals process, and other clinician incentives can be insurance tools that, when used improperly, may harm efforts to combat addiction and should be reviewed to avoid furthering the current epidemic.

It is time for insurance industry leaders like CareSource to reexamine these policies in light of the substance/opioid use disorder and update your coverage policies in a way that maximizes the accessibility and affordability of a wide range of safe alternatives to narcotics. The insurance industry is on the front line of this epidemic, and we need your help identifying what policies are working and what barriers to less-addictive pain treatment options and substance use disorder treatments exist.

[6] http://www.modernhealthcare.com/special/opioid-addiction

Recognizing there is a difference in the way insurers are able to design their benefits across commercial, Medicare, and Medicaid books of business, we respectfully request that you respond to the following questions by March 30, 2018:

1. What internal policies and procedures does CareSource have in place that may create a barrier to accessing affordable non-addictive or less addictive pain treatments, including those that are non-pharmacological?

2. What flexibilities does CareSource offer to ensure that individuals struggling with acute or chronic pain receive the least addictive pain treatment option, in a timely manner?

3. What internal policies and procedures does CareSource have in place that may create a barrier to accessing affordable options for medication-assisted treatment and other behavioral therapy options for addicted individuals?

4. What flexibilities does CareSource offer to ensure that individuals struggling with substance use disorder receive the proper treatment, in a timely manner?

5. What non-pharmacological alternative pain therapies, such as acupuncture, does CareSource offer to beneficiaries? Do alternative pain therapy options vary by benefit design? If so, are there any barriers or restrictions preventing the use of alternative or innovative pain therapy options in federal programs, such as Medicare or Medicaid?

6. How often does CareSource review and update its list of approved pain management options and services, both pharmacological and non-pharmacological? As less addictive treatment options become available, how quickly are you able to cover them?

7. How often does CareSource review and update its list of approved addiction treatment options and services, both pharmacological and non-pharmacological? As additional substance use disorder treatments become available, how quickly are you able to cover them?

8. Does CareSource have a fail-first, stepped, or medical necessity standard for non-addictive, including non-pharmacological, or abuse-deterrent options for pain management?

9. Does CareSource have a fail-first or medical necessity standard for medication-assisted treatment or other behavioral therapy options for individuals who have a substance use disorder?

10. When reviewing coverage appeals from beneficiaries, members, or providers, at what level of appeal does CareSource implement a clinician review? How quickly are appeals escalated for individuals struggling with severe pain needs? How quickly are appeals escalated for individuals struggling with access to addiction services?

11. When it comes to opioids and other controlled substances, does CareSource implement a unique set of internal policies or controls?

12. What is the typical difference, if any, in cost-sharing for members/beneficiaries using non-addictive, including non-pharmacological pain management approaches vs. potentially addictive therapies?

13. What are the typical cost-sharing amounts for members/beneficiaries using medication-assisted treatment options or other behavioral therapy options offered by CareSource? Are any addiction treatment options offered to beneficiaries without cost-sharing requirements?

14. Does CareSource cover all three medication-assisted treatment drug options (methadone, buprenorphine and naltrexone) and if not, what is the rationale for exclusion?

15. How does CareSource identify individual members/beneficiaries who may already be struggling with substance use disorder? Are any policies or procedures waived for these individuals when it comes to accessing alternative options for pain management?

16. Is it your belief that all of CareSource's internal policies and procedures live up to both the letter and the spirit of the *Mental Health Parity Act*, as intended by Congress?

17. Recognizing there are always ways to improve these processes, are there other plan designs or benefit flexibilities you could implement to improve access to less addictive pain management options or the full range of treatment options?

18. Are there any additional factors that Congress should be aware of as it considers the nation's substance abuse/opioid crisis?

It is critical that we ensure access to clinically appropriate, non-addictive pain management options for all Americans across all payers as well as comprehensive coverage for the full range of addiction treatment services, from medication-assisted treatment options to inpatient and outpatient therapy.

Thank you for your attention to this matter. We look forward to working with you on policies that will make it as easy for an individual to access addiction treatment and non-addictive remedies for pain as it is for them to access opioids in the first place.

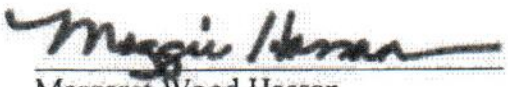
Sincerely,

Sherrod Brown
United States Senator

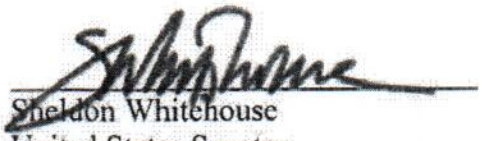
Edward J. Markey
United States Senator

Jeanne Shaheen
United States Senator

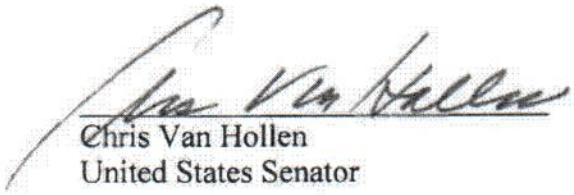
Tammy Baldwin
United States Senator



Margaret Wood Hassan
United States Senator

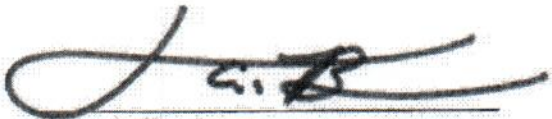


Sheldon Whitehouse
United States Senator

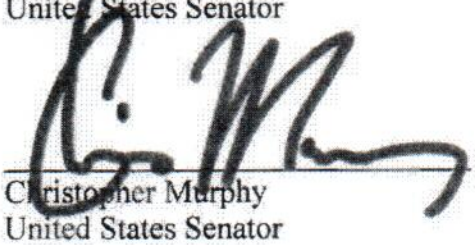


Chris Van Hollen
United States Senator

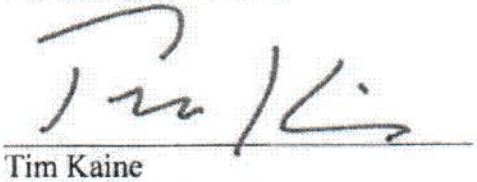
Richard Blumenthal
United States Senator



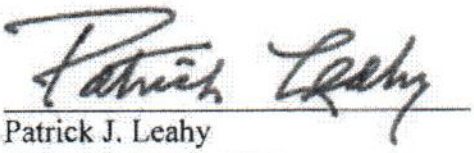
Cory A. Booker
United States Senator



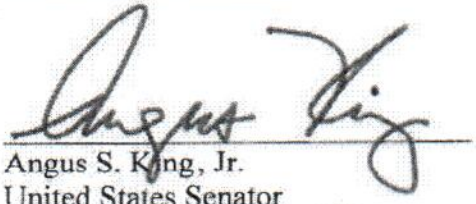
Christopher Murphy
United States Senator



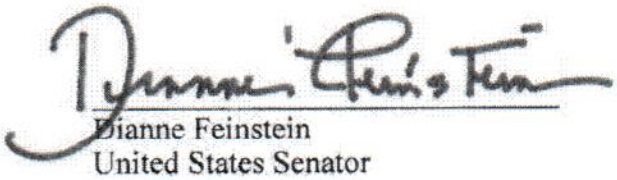
Tim Kaine
United States Senator



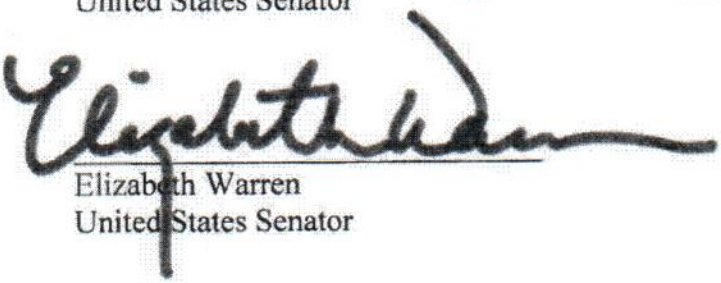
Patrick J. Leahy
United States Senator



Angus S. King, Jr.
United States Senator



Dianne Feinstein
United States Senator



Elizabeth Warren
United States Senator