



ABPMR PIP Form

Created: 01/09/2020 • Last updated: 02/23/2020

Note: If you begin one of the Guided PIP projects and later wish to switch to another topic, your work will not automatically transfer over. In that case, we recommend copying all your work to a separate file (Word or similar) before you "Withdraw application" and start over.

Please make an initial selection below.

Which ABPMR PIP are you completing? Create my own project

Create my own PIP

1.) General Data

A) Describe, in detail, your role in the project.

Voluntary Practice Improvement Project (PIP):

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 pain reduction ,functional improvement and continuity of care of chronic pain patients.

Leon Margolin MD, PhD/Comprehensive Pain Management Institute, LLC submitted as a required for maintenance of certification of American Board of Physical Medicine and Rehabilitation

Background: Opioid epidemic crisis affects the lives of thousands of Americans on a daily basis. Since 1999 hundreds of thousands of Americans died from overdoses. On an average day in the US close to 5,800 people misuse opioids for the first time, over 1,000 Americans on an average day treated in the emergency departments for issues related to opioid misuse. The societal and healthcare cost of opioid epidemic is at least 55 billion dollars each year 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 prevention of street drug use. 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 one of the state mostly affected by 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 referred other patients to Addiction medicine evaluation is extremely important in this challenging environment of the opioid epidemic crisis. (based HHS 2017 five-point strategy).

National and state guidelines require risk stratification and close monitoring of patients on chronic opioid medication. 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) on the functional improvement and continuity of care of chronic pain patients.

B) Dates of your project:

Start date: 08/01/2019

End date: 02/23/2020

2.) Plan: Identify an area in your practice that needs improvement.

A) What is the problem you are trying to solve?

What do you want to improve? Look for inefficiencies, annoyances, or safety issues. Consider complex issues, but focus on simple solutions.

National and state guidelines require risk stratification and close monitoring of patients on chronic opioid medication. 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 s 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) 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.

Dr. Margolin maintains active certification by the ABPM&R; in PM&R; and Pain Medicine.

Our practice, Comprehensive Pain Management Institute, LLC established credible evidence based protocols based on the the “Pain Management Best Practices Inter- Agency Task Force Report”, Medicare MLN and LCD OH L36029, Medicare guidelines .

Our practice is a tertiary referral practice that gets referral 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 quality of care documentation and information for the third party payers.

Medical Necessity: Most of the Comprehensive Pain Management Institute, LLC (CPMI) patients are complex high or medium risk chronic pain patients with multiple medical or psychological co morbidities (as reflected in the NARX score sheet enclosed).

After 2011 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 population. Many of these chronic pain patients seen by the CPMI suffer from anxiety and depression, and/or drug seeking behavior and had challenges in compliance with the primary care providers program.

The state and federal guidelines required implementation of the alternative treatments to opioid medications including minimally invasive ultrasound guided procedures.

Medicare MLN defines the SBIRT screening as time spent on the structured I assessment review; the MLN does not have definitive frequency parameters for such screening. Our practice set the SBIRT protocol based on the LCD OH L36029. LCD OH L36029 sets the frequency 1-3 times in 3 months for the high-risk patients (the vast majority of the sample patients fall in this of the range high-risk patients that are the majority of our patients - 94% as above). The other 6% have other factors and elements discussed below. This frequency is also consistent with the independent billing and coding reviews that the practice has conducted.

Cost Efficiency of the Testing:

The cost of opioid epidemic is more than 55 billion dollars a year and keeps rising annually. Pain Management programs like our practice that carefully screen and test patient 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 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 the 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 (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 that 30 min of telecommunication video material, structured review of several assessments including patient's history and physical examination (at least 20-25 min according to Medicare) , PADT (at least 15-20 min as per ASAM), COMM (at least 10-15 min), Flowchart form based on SMBO Administrative Rule 4731-21-02 (at least 10-15 min), withdrawal assessment form (at least 5-10 min), point of care and conformation urine and saliva drug screen reviews (at least 10 min), OARRS reviews (at least 10 min), and several educational materials(at least 10 min). I summary, the documented time spent on SBIRT (G code) clearly significantly exceeds the 30 minute requirement of the G code billed. In addition, the initial evaluation includes 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 would not only significantly impact CPMI's 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. The quality of care we provide resulted in several clinical awards (i.e. Patient Choice Award, Most Compassionate Doctor awards for several years, 2019 "Top 10" Ohio physician award in Pain Medicine) and referrals we get from major hospitals such as OSU Medical Center, Riverside, Grant, Mt Carmel, Adina Health and University Hospitals in Cleveland and even other pain management practices.

Many of our patients are opioid-dependent, if their medications are not timely reviewed, this can cause patient morbidity incident to abruptly stopping treatment.

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 the 600 billion nationwide, we run a low cost program that saved hundreds of thousands of dollars to Medicare by identifying and referring for addiction treatments 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 puts 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 our office).

Risk Stratification for the patient in the 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 and state and national guidelines.

Please find the NARX score detailed validation and analysis attached (attachment NARX Manual, NARX clinical application). There no frequency guidelines for the G code, however 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 very high risk 34%(NARX above 200) and extremely high risk 24% (NARX above 350). Odds ratio for death from overdose is 10-12 times average (see clinical application of the NARX score attached page 67). 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 other 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 any overdose and death) <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf>, many patients obtained opioids from more than one prescriber, used multiple pharmacies and multiple classes of opioid medications, some also used sedatives or stimulants that greatly increased the risk according the CDC guidelines and NARX score database (please find original NARX score reports for each patient attached). These type of risky patients clearly require high frequency of SBIRT (G code use) based on the criteria discussed above.

Risk stratification of the sample 2 (sent by a separate e mail) demonstrated similar results.

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

Many of the CPMI patient have multiple medical co morbidities and dependant on the transportation (can schedule only a limited number of visits). Therefore on many occasions we have to schedule minimally invasive procedure and the office visit for medical management at the same date.

This study show 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 the third party insurance payers and puts emphasis on 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

(https://www.aapc.com/resources/em_utilization.aspx), 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).

You can see clearly that only 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 that need to compare my G code and office visit codes billed that would show that billed greatly below average for more expensive E/M codes for the office visits. That clearly explains the 79 times the G code was billed - it was billed for 79 follow up visits instead of more expensive office visit code.

----- Forwarded message -----

От: DAVID DEPPEN

Date: пт, 8 нояб. 2019 г. в 13:17

Subject: FW: Practice Numbers Requested - Updated

To: Leon Margin

Here are the updated numbers for you:

2014:

Office Visits - 2330

G Codes - 5104

Total Visits - 8239

2015:

Office Visits - 2056

G Codes - 5622

Total Visits - 8157

2016:

Office Visits - 1146

G Codes - 6621

Total Visits - 7885

2017:

Office Visits - 1373

G Codes - 7294

Total Visits - 8491

2018:

Office Visits - 1160

G Codes - 7907

Total Visits - 8111

2019:

Office Visits - 2317

G Codes - 8838

Total Visits - 9494

Thanks,

David Deppen

Office Manager

Practice Pro, LLC

P: 937-322-4911

This analysis proves a significant cost saving to the third-party payer of this protocol since 2014 till present.

Credible billing and coding analysis and review for the G code implementation:

----- Forwarded message -----

От: David Deppen

Date: cp, 12 мар. 2014 г. в 08:17

Subject: RE: screening G codes

To: Leon Margolin , David Guido

Here are the codes from the HCPCS book:

G0396 Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., audit, dast), and brief intervention 15 to 30 minutes

G0397 Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., audit, dast), and intervention, greater than 30 minutes

Nothing speaks to only time for MD so time spent by other associates on this service could be included. The only item that we suggest is that somewhere in the chart note it is documented that more than 30 minutes was spent covering this issue separately from other services.

Thanks,
David Deppen
Practice-Pro LLC
937-322-4911

Implementation of the LCD OH L36029:

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 sets frequency of monitoring that depends on prescribed opioid medications and other elements (see Exhibit 21) and not only on the initial psychological evaluation that used:

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

The rational for such screening LCD OH L36029 defines as:

- a. Identifies absence of prescribed medication and potential for abuse, misuse, and diversion;
- b. Identifies undisclosed substances, such as alcohol, unsanctioned prescription medication, or illicit substances;

- c. Identifies substances that contribute to adverse events or drug-drug interactions;
- d. Provides objectivity to the treatment plan; e. Reinforces therapeutic compliance with the patient;
- f. 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 clearly 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.

Example #1: DS. This patient-reported the last drink 26 years ago, however, this patient meets criteria for a high-risk patient with a chronic pain syndrome secondary failed back syndrome (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, CDC, and LCD OH L36029

We will analyze the necessity and the frequency fo 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 requires chronic pain management.

His enclosed Board of Pharmacy NARX score defines him as a high risk patient:

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).

In addition, he is currently on 60 MME daily (3 times the dangerous dose threshold per CDC guidelines), he has received more than 150 prescriptions from 5 different prescriber 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-up visits 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 as documented on the chart.

This example shows how efficient and cost-effective use of the SBIRT screening (G0397 code) use saves

enforces compliance for the high-risk patients and saves funds for third-party payers.

In addition, 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. Her enclosed Board of Pharmacy NARX score defines him as a very high-risk patient:

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). Additional risk factor more than 100MME with average 40 MME daily (please find the original NARX report enclosed). Recently patient is getting 60 MME daily. These are very dangerous doses according to the NARX and CDC guidelines attached that requires 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 patient 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. This example shows how efficient and cost-effective use of the SBIRT screening (G0397 code) use saves enforces compliance for the very high-risk patients on multiple controlled substances and saves funds for the third-party payers.

Example #3: LH

Case Review: This is a patient with spinal stenosis requires chronic pain management. In addition, the patient reported being a victim of physical domestic abuse (additional risk factor) and required chronic benzodiazepine therapy (alprazolam). Please find the urine screen report enclosed.

The patient had multiple prescriptions of alprazolam (potent benzodiazepine) combined with opioids which is a high-risk regimen for overmedication and death and requires SBIRT interventions each time the combinations are prescribed, according to the CDC guidelines (enclosed). Please find the list of the prescriptions enclosed.

In fact, completely ignored the enclosed abnormal urine drug screen (dated 11/22/2017 enclosed) which positive for non prescribed benzodiazepine (which a very high-risk factor as per enclosed CDC guidelines) and the follow up pain psychology report (January 18) that conditioned patient clearance for opioids with closed monitoring (SBIRT protocol/G codes).

26 screenings and brief interventions (SBIRT/ G codes) performed over a prolonged period of time for such a very high-risk patient are medically necessary and required by the 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 patient's prior drinking history.

This example shows how efficient and cost-effective use of the SBIRT screening (G0397 code) use saves enforces compliance 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 (please see Board of Pharmacy database list of medications enclosed). On 11/2/16 our practice performed a random urine screen that was NEGATIVE for prescribed OxyCodone (please find the urine screen enclosed). The urine screen was reviewed by Doctor of Pharmacology consultant and discussed with 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). In addition, the follow-up note dated 11/02/16 states that did not bring medications bottle for pill count and the patient states she has a lot of Percocet at home that supports this concern. Unfortunately, the patient was not compliant with the reasonable monitoring and self discharged herself.

Of note, 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.

Examples of proper use of informed consent and respect for patient autonomy.

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

Teresa is a high-risk patients (please see the enclosed Board of Pharmacy NARX score 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 please refer to the NARX score review material enclosed). The Board of Pharmacy 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 also has been coming to our practice for several years (despite multiple competing providers just a few miles away) that testifies for the quality of care she has received.

This patient “first refused the needle EMG, then left the box unchecked and then agreed to the needle EMG test”. Teresa 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.

In addition, in compliance with the OH LCD this analysis shows that in this and other cases we never SOLELY on the NCS data but on the detailed analysis we described.

Example # 6 MS ... patient testimonial difference between EMG and procedure

Mark is a high-risk patient (please see the enclosed Board of Pharmacy NARX score defines him 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). In fact, Mark recently had a urine screen positive for use of illicit marijuana (as per Pharmacology doctor attached). 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 anxieties. 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.

B) What data (objective measurements) do you have that supports this as a problem?

Review your records or begin tracking how often the issue is occurring and under what conditions.

Sample 1 and Sample 2: Rigorous categorical data based on PADT, Functional Flowchart forms, initial and follow up evaluation forms, informed consent and medical necessity forms (examples e mailed to Kendall), OARRS (Ohio PMR) etc.

Study design: Retrospective review of 155 charts (please see the list of the selected charts enclosed) that 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 (lengs of participation in months). Please see the attachment below.

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 “moderate” functional improvement. If 3 or functional parameters improved we called a very significant improvement.

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 significant impact of the testing on the patient treatment plan and compliance.

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 patient 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 3 – discharged patients:

We have reviewed the charts of patient 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.

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Statistical analysis (data in table format sent by a separate e mail):

Sample 1

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

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

Table 1

Months NARX Average/Max/Pts

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 of time (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 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
Total	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 on 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 Pts
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 changes with Months in Program:

Table 7

NARX Score vs Months in Program

Average Max Number

Patients

< 2 years 317 480 9

>2 years 292 590 31

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 the 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 of time (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 2-year group, these 3 groups are combined.

Table 8
 Months in Program vs Functional Improvement
 Significant/ Very Sig/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 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 month and continue with a significant or very significant improvement after that.

Pain Reduction analysis

Table 10
 Months in Program vs Pain Reduction
 Moderate Significant Very Sig 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):

NARX SCORES and DISCHARGE REASON

Discharge Reason Number

Patients % Total

Patients 3 months 6 Months 12 Months 2 years Av NARX

Pts

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

ADULTERATION 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 in 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. 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). Most patient positive for Fentanyl are treated in the inpatient setting, we had only one chart in the sample - the results are inconclusive for Fentanyl.

Conclusion:

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 and shows a strong impact on the :

This study has important conclusions for the 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 patient 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 by Dr. Margolin are based on the accepted guidelines and "HHS Pain management best practices inter-agency task report". The enclosed report by Michael Staples, CMBI it shows high compliance with the Ohio Pain Clinic (PMC) license requirements, Ohio Revised and Administrative Codes and exceeding minimum standard of care. The SBIRT protocol is clearly 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 payors 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 CPMI's 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 my 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 and other tests and procedures described in this study. However, this allows our patients to avoid risk of morbidity and mortality (Ohio has the highest rate 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.

Many of our patients are opioid-dependent, if their medications are not timely reviewed, this can cause patient morbidity incident to abruptly stopping treatment.

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 quality of care we provide resulted in several clinical awards (i.e. Patient Choice Award, Most Compassionate Doctor awards for several years, 2019 “Top 10” Ohio physician award in Pain Medicine) and referrals we get from major hospitals such as OSU Medical Center, Riverside, Grant, Mt Carmel, Adina Health and University Hospitals in Cleveland and even other pain management practices.

In summary, denial payments for the appropriate testing and screening procedures for drugs and alcohol (of the SBIRT protocol (G codes such as G0397) and other services in this study makes the third party payer responsible for the risk to several hundred high-risk patients and our staff.

Our practice is at the forefront of the “opioid epidemic” fight. We hope to the third-party payers as an ally in this fight acting in compliance with the HHS 5 point strategy.

C) What is your opportunity statement? State the goal you hope to achieve.

Based on record review or measurement of current performance, determine what kind of improvement you hope to make and set a timeframe to achieve it.

Our goal is to show a significant correlation the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (CPT codes 76942, 64450, 64418, 20533 and other similar codes) on the functional improvement, pain reduction and continuity of care of chronic pain patients based on rigorous retrospective chart review of 155 chronic pain patients.

D) What is the underlying cause of the performance/quality problem?

Gather and brainstorm with other physicians and staff on your unit/team. What's causing this issue? How did you determine the cause?

The SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (CPT codes 76942, 64450, 64418, 20533 and other similar codes) are crucial for a chronic pain management program.

This study shows that our protocol is indeed associated with significant functional improvement and pain reduction and effective compliance monitoring while maintaining a high level of compliance.

This is a cost-effective and cost-saving program for third party payors.

Our data shows that denial of these services or defining them as "unallowed" would interfere with patient care, compliance with the state and federal standards and put patients and staff at risk.

E) What Institute of Medicine (IOM) Quality Dimensions will be addressed by your project?

Patient Safety

Care Delivery Efficiency

Care Delivery Effectiveness

3.) Do: Describe the desired outcomes and the requirements needed to achieve them.

A) What change(s) did you implement?

You can implement one change, or you can choose to do several at a time. Be specific about the changes you made.

We implemented the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (CPT codes 76942, 64450, 64418, 20533 and other similar codes) based on the study results.

We have enhanced monitoring and patient education with additional tools, printed educational material, 30 min recorded video presentation on compliance and several educational videos on the practice YouTube channel.

4.) Study/Check: Describe the measurement used to assess the success of the plan.

A) Did you achieve your goal or target reported in your opportunity statement? What data do you have to support your conclusion?

This is a simple yes or no, and cite the evidence. After the timeframe indicated in your opportunity statement, review your performance. (It's good practice to check-in at least midway through your project, too, to see whether adjustments need to be made.) Did you meet the goal you set?

Yes, please refer to the data above.

5.) Act: Change(s) to your practice as a result of this project.

A) Will you continue with the changes you have implemented?

If you achieved your goal, describe how you will sustain your success, or how it led to new ideas. If you did not achieve your goal, how could you try again with new tactics? What will be your next process change to keep the improvement evolution going?

We will continue to implement the study results in the future using the comprehensive assessment and monitoring tools described in the study.

Our goal will be the continuation of the successful implementation of the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (CPT codes 76942, 64450, 64418, 20533 and other similar codes) based on the study results.

Our second goal would be sharing data with third-party payors.