

August 1, 2018

Dear Provider:

The misuse of opioids has been chronicled nationwide. The prevalence is pervasive to all demographics, young and old, rural and urban, male and female, rich and poor, and any other way one wishes to stratify members. The problems can be seen with intentional misuse and unintentional as well.

KFHC wishes to help provide tools to assist in screening and assessing appropriate use of opioids. Please see the CDC's guidelines for reference. More background information and a PDF version may be found at https://www.cdc.gov/drugoverdose/prescribing/guideline.html. The CHCF best practice guidelines checklist is also included at the end of this bulletin.

Screening Tools

Common screening tools to assess appropriateness of opioid therapy are attached. Tools to assess the initiation and/or continuation of opioid therapy include: Webster's Opioid Risk Tool (ORT), National Institutes of Drug Abuse (NIDA), Pain Assessment and Documentation Tool (PADT), and Current Opioid Misuse Measure (COMM). Others are available as well. A tool to evaluate the risk of overdose or respiratory depression is the Risk Index for Overdose or Serious Opioid-induced Respiratory Depression (RIOSORD).

Another tool in managing long term opioid use, particularly in higher risk individuals (> 50 MMED, substance use disorder, concurrent benzodiazepine, other comorbidities, ie. Sleep apnea), is the use of naloxone. This drug is on a carve-out list for KFHC. It is available to our members, the pharmacy bills the state Medi-Cal program instead of KFHC.

Sincerely,

Bruce Wearda, R.Ph. Director of Pharmacy

Centers for disease Control and Prevention (CDC) guidelines consist of 12 primary recommendations categorized into 3 practice areas:¹

Determining when to initiate or continue opioids for chronic pain

- 1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate (*recommendation category: A, quality of evidence: low*).
- 2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety (recommendation category: A, quality of evidence: very low).
- 3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy (*recommendation category: A, quality of evidence: low*).

Selection of opioid dosage, treatment duration, followup, and discontinuation

- 4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids (*recommendation category: A, quality of evidence: very low*).
- 5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day (*recommendation category: A, quality of evidence: low*).
- 6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or

¹ Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65:1–49. DOI: <u>http://dx.doi.org/10.15585/mmwr.rr6501e1</u>

less will often be sufficient; more than seven days will rarely be needed (*recommendation category: A, quality of evidence: very low*).

7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids (*recommendation category: A, quality of evidence: very low*).

Assessing risk and addressing harms of opioid use

- 8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present (*recommendation category: A, quality of evidence: very low*).
- 9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months (*recommendation category: A, quality of evidence: very low*).
- 10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs (*recommendation category: B, quality of evidence: very low*).
- 11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible (*recommendation category: A, quality of evidence: low*).
- 12. Clinicians should offer or arrange evidence-based treatment (usually medicationassisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder (*recommendation category: A, quality of evidence: moderate*).

Curbing the Opioid Epidemic:	
Checklist for Health Plans and Purchasers	1
Provider Network	
Offer or support provider education on pain management based on prescribing guidelines (CDC or medical board).	
Offer or support specific programs that help providers develop taper plans for patients on high opioid doses or combinations (opioids and benzodiazepines).	
Analyze data to identify outlier prescribers and flag for education, coaching, and/or fraud investigation.	
Ensure access to in-network pain specialists aligned with CDC guidelines for peer consultation or secondary case review.	
Create dashboards to measure comparative opioid prescribing rates and share them with providers.	
Participate in local opioid safety coalitions to support community prescribing guidelines.	
Work with inpatient and outpatient provider network to change preset opioid prescribing order sets.	
Medical Management	<u> </u>
Remove prior authorization requirement for first course of physical therapy for back pain, and ensure timely access to care.	
Add chiropractic services as a benefit.	
Add acupuncture services as a benefit.	
Add health education or mindfulness resources as a benefit.	
Train case managers on common issues in chronic pain.	
Increase access to behavioral health services for patients with chronic pain.	
Identify members losing prescribers (through retirement or loss of license, for example) and coordinate referrals to pain management or addiction treatment where needed.	
Pharmacy Benefit (All interventions should have an exception for palliative care.)	
Implement formulary dose limits (total morphine milligram equivalents, with prompt authorization review to manage exceptions).	
Implement quantity limits for new starts (with authorization requirements for ongoing treatment after first fill).	
Remove high-dose formulations from formulary (e.g., 80 mg Oxycontin, 100 mcg fentanyl).	
Remove methadone from formulary for pain.	
Remove Soma (carisoprodol) from formulary.	
Limit concurrent prescriptions for opioids and benzodiazepines.	
Remove prior authorization requirements for common non-opioid pain medications (e.g., anti-depressants, neuroleptics with indications for pain).	\checkmark
Implement pharmacy lock program for patients using multiple prescribers.	
Implement prescriber lock program for patients using multiple prescribers.	
Member Services	
Provide member education on opioid risks and non-opioid pain management strategies.	

Current Opioid Misuse Measure (COMM)™

The Current Opioid Misuse Measure (COMM)[™] is a brief patient self-assessment to monitor chronic pain patients on opioid therapy. The COMM[™] was developed with guidance from a group of pain and addiction experts and input from pain management clinicians in the field. Experts and providers identified six key issues to determine if patients already on long-term opioid treatment are exhibiting aberrant medication-related behaviors:

- Signs & Symptoms of Intoxication
- Emotional Volatility
- Evidence of Poor Response to Medications
- Addiction
- Healthcare Use Patterns
- Problematic Medication Behavior

The COMM[™] will help clinicians identify whether a patient, currently on long-term opioid therapy, may be exhibiting aberrant behaviors associated with misuse of opioid medications. In contrast, the Screener and Opioid Assessment for Patients with Pain (SOAPP®) is intended to predict which patients, being considered for long-term opioid therapy, may exhibit aberrant medications behaviors in the future. Since the COMM[™] examines concurrent misuse, it is ideal for helping clinicians monitor patients' aberrant medication-related behaviors over the course of treatment. The COMM[™] is:

- A quick and easy to administer patient-self assessment
- 17 items
- Simple to score
- Completed in less than 10 minutes
- Validated with a group of approximately 500 chronic pain patients on opioid therapy
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The COMM[™] is for clinician use only. The tool is not meant for commercial distribution.
- The COMM[™] is **NOT** a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with COMM[™] scores to decide if and when modifications to particular patient's treatment plan is needed.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

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COMM[™]

Please answer each question as honestly as possible. Keep in mind that we are only asking about the **past 30 days**. There are no right or wrong answers. If you are unsure about how to answer the question, please give the best answer you can.

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. In the past 30 days, how often have you had trouble with thinking clearly or had memory problems?	0	0	0	0	0
2. In the past 30 days, how often do people complain that you are not completing necessary tasks? (i.e., doing things that need to be done, such as going to class, work or appointments)	0	Ο	Ο	Ο	Ο
3. In the past 30 days, how often have you had to go to someone other than your prescribing physician to get sufficient pain relief from medications? (i.e., another doctor, the Emergency Room, friends, street sources)	Ο	Ο	Ο	Ο	Ο
4. In the past 30 days, how often have you taken your medications differently from how they are prescribed?	Ο	Ο	Ο	Ο	Ο
In the past 30 days, how often have you seriously thought about hurting yourself?	0	0	0	0	0
6. In the past 30 days, how much of your time was spent thinking about opioid medications (having enough, taking them, dosing schedule, etc.)?	0	0	0	0	0

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Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
7. In the past 30 days, how often have you been in an argument?	0	0	0	0	Ο
8. In the past 30 days, how often have you had trouble controlling your anger (e.g., road rage, screaming, etc.)?	0	0	0	0	0
9. In the past 30 days, how often have you needed to take pain medications belonging to someone else?	Ο	Ο	0	0	о
10. In the past 30 days, how often have you been worried about how you're handling your medications?	0	0	0	0	0
11. In the past 30 days, how often have others been worried about how you're handling your medications?	0	0	0	0	0
12. In the past 30 days, how often have you had to make an emergency phone call or show up at the clinic without an appointment?	0	Ο	Ο	Ο	0
13. In the past 30 days, how often have you gotten angry with people?	0	0	0	0	О
14. In the past 30 days, how often have you had to take more of your medication than prescribed?	0	0	0	0	0
15. In the past 30 days, how often have you borrowed pain medication from someone else?	0	0	0	0	Ο
16. In the past 30 days, how often have you used your pain medicine for symptoms other than for pain (e.g., to help you sleep, improve your mood, or relieve stress)?	0	0	0	0	0

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Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
17. In the past 30 days, how often have you had to visit the Emergency Room?	0	0	0	0	0

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Scoring Instructions for the COMM[™]

To score the COMM[™], simply add the rating of all the questions. A score of 9 or higher is considered a positive

Sum of Questions	COMM Indication
> or = 9	+
< 9	-

As for any scale, the results depend on what cutoff score is chosen. A score that is sensitive in detecting patients who are abusing or misusing their opioid medication will necessarily include a number of patients that are not really abusing or misusing their medication. The COMM[™] was intended to over-identify misuse, rather than to mislabel someone as responsible when they are not. This is why a low cut-off score was accepted. We believe that it is more important to identify patients who have only a possibility of misusing their medications than to fail to identify those who are actually abusing their medication. Thus, it is possible that the COMM[™] will result in false positives – patients identified as misusing their medication when they were not.

The table below presents several statistics that describe how effective the COMM[™] is at different cutoff values. These values suggest that the COMM[™] is a sensitive test. This confirms that the COMM[™] is better at identifying who is misusing their medication than identifying who is not misusing. Clinically, a score of 9 or higher will identify 77% of those who actually turn out to be at high risk. The Negative Predictive Values for a cutoff score of 9 is .95, which means that most people who have a negative COMM[™] are likely not misusing their medication. Finally, the Positive likelihood ratio suggests that a positive COMM[™] score (at a cutoff of 9) is nearly 3 times (3.48 times) as likely to come from someone who is actually misusing their medication (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 9 will ensure that the provider is least likely to miss someone who is really misusing their prescription opioids. However, one should remember that a low COMM[™] score suggests the patient is really at low-risk, while a high COMM[™] score will contain a larger percentage of false positives (about 34%), while at the same time retaining a large percentage of true positives. This could be improved, so that a positive score has a lower false positive rate, but only at the risk of missing more of those who actually do show aberrant behavior.

COMM™ Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ration
Score 9 or above	.77	.66	.66	.95	3.48	.08

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Opioid Risk Tool

Introduction

The Opioid Risk Tool (ORT) is a brief, self-report screening tool designed for use with adult patients in primary care settings to assess risk for opioid abuse among individuals prescribed opioids for treatment of chronic pain. Patients categorized as high-risk are at increased likelihood of future abusive drug-related behavior. The ORT can be administered and scored in less than 1 minute and has been validated in both male and female patients, but not in non-pain populations.

http://www.drugabuse.gov/nidamed-medical-health-professionals

Opioid Risk Tool

This tool should be administered to patients upon an initial visit prior to beginning opioid therapy for pain management. A score of 3 or lower indicates low risk for future opioid abuse, a score of 4 to 7 indicates moderate risk for opioid abuse, and a score of 8 or higher indicates a high risk for opioid abuse.

Mark each box that applies	Female	Male				
Family history of substance abuse						
Alcohol	1	3				
Illegal drugs	2	3				
Rx drugs	4	4				
Personal history of substance abuse						
Alcohol	3	3				
Illegal drugs	4	4				
Rx drugs	5	5				
Age between 16—45 years	1	1				
History of preadolescent sexual abuse	3	0				
Psychological disease						
ADD, OCD, bipolar, schizophrenia	2	2				
Depression	1	1				
Scoring totals						

Questionnaire developed by Lynn R. Webster, MD to asses risk of opioid addiction.

Pain Assessment and Documentation Tool

Introduction

The Pain Assessment and Documentation Tool (PADT) is a two-sided chart note designed to be easily included in a patient's medical record and to facilitate ongoing evaluation of patient pain and documentation of pain management. The PADT is intended to be administered by a clinician and includes sections to assess pain-related outcomes in four areas: analgesia, activities of daily living, adverse events (i.e., side effects), and aberrant drug-related behavior.

Progress Note Pain Assessment and Documentation Tool (PADT™)								
Patient Name: Record #:						Patient Stamp Here		
Assessment Date:								
	Current Anal	ges	ic Regimen					
Drug Name	Strength (eg, mg)		Frequency	I	Maxim	um 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 <u>physician</u> . Ask the patient the questions below, except as noted.								
Analge	sia		Activities	of Da	ailv I iv	<i>i</i> ng		
If zero indicates "no pain" and	ten indicates "pain as bad	Ple	ease indicate whether the	e pati	ient's f	unctioning	with the	
as it can be," on a scale of 0 to	10, what is your level of	cu	rrent pain reliever(s) is B	etter,	, the Sa	ame, or Wo	orse since	
pain for the following question	s?	th	e patient's last assessme	nt wi	th the	PADT.* (P	lease	
		ch	eck the box for Better, Sa	ame,	or Wo	rse for eacl	n item	
1. What was your pain level on week? (Please circle the ap	on average during the past propriate number)	be	low.)					
	7 0 0 10 Daim as had			Be	tter	Same	Worse	
No Pain U 1 2 3 4 5 6	7 8 9 10 Pain as bad							
	ds it call be	1.	Physical functioning	[
2. What was your pain level a	it its worst during the past							
week?		-	ma and a shart and the	г	_			
		2.	Family relationships	L				
No Pain 0 1 2 3 4 5 6	7 8 9 10 Pain as bad							
	as it can be			г	_			
2 M/bet nercentege of your r	ain has been relieved	3.	Social relationships	L				
3. What percentage of your p	iain nas been relieved							
between 0% and 100%.)	ite in a percentage		Mood	Г	_			
		4.	Ινιοσα	L				
4. Is the amount of pain relie	f you are now obtaining	5	Sleen nattorns	Г				
from your current pain relie	5.	Sleep patterns	L					
real difference in your life?								
		6.	Overall functioning	[
		*11	the patient is receiving I	nis or	her fir	st PADT		
5. Query to clinician: Is the patient's pain relief			sessment, the clinician sh	nould	compa	are the pat	ient's	
clinically significant?		tu	nctional status with othe	r repo	orts fro	om the last	office	
Yes No	Unsure	VIS	DIL.					
		1						

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Progress Note							
Pain Assessment and Documentation Tool (PADT™)							
<i>I</i>Is patient experien pain reliever?	Adverse E Icing any	Events side eff	ects from cu	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"			
Ask patient about pote	ential sid	e effects	s:		section below to note additional details.		
	None	Mild	Moderate	Severe	Purposeful over-sedation		
a. Nausea					Negative mood change		
					Appears intoxicated		
b. Vomiting					Increasingly unkempt or impaired		
					Involvement in car or other accident		
c. Constipation					Requests frequent early renewals		
					Increased dose without authorization		
d. Itching					Reports lost or stolen prescriptions		
		_			Attempts to obtain prescriptions from other doctors		
e. Mental cloudiness					Changes route of administration		
					Uses pain medication in response to situational stressor		
f. Sweating					Insists on certain medications by name		
					Contact with street drug culture		
g. Fatigue					Abusing alcohol or illicit drugs		
					Hoarding (ie, stockpiling) of medication		
h. Drowsiness					Arrested by police		
					Victim of abuse		
i. Other					Other:		
i. Other							
2. Patient's overall sev	erity of s	ide effe	 cts?				
		erate	Severe				
Assessment: (This sect	ion must	be com	pleted by th	e physici	an.)		
Is your overall impress	ion that	this pati	ient is benef	iting (eg,	benefits, such as pain relief, outweigh side effects) fror		
opioid therapy?	Yes		No	U	Isure		
comments:							
Specific Analgesic P	Plan:			Commer	ts:		
Continue presen	t regimeı	n					
Adjust dose of p	resent an	algesic					
Add/Adjust conc	omitant	therapy	,				
Discontinue/tape	er off opi	oid the	rapy				
Date: Physician Signature:							

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

Risk Index for Overdose or Serious Opioid-Induced Respiratory Depression (RIOSORD)

Description	Y/N	Score				
In the past 6 months, has the patient had a health care visit (outpatient, inpatient, o	r ED) invo	olving:				
Opioid dependence?		15				
Chronic hepatitis or cirrhosis?						
Bipolar disorder or schizophrenia?		7				
Chronic pulmonary disease? (e.g., emphysema, chronic bronchitis, asthma, pneumoconiosis, asbestosis)		5				
Chronic kidney disease with clinically significant renal impairment?		5				
Active traumatic injury, excluding burns? (e.g., fracture, dislocation, contusion, laceration, wound)		4				
Sleep apnea?		3				
Does the patient consume:						
An extended-release or long-acting (ER/LA) formulation of any prescription opioid or opioid with long and/or variable half-life? (e.g.,OxyContin, Oramorph-SR, methadone, fentanyl patch, levorphanol)		9				
Methadone? (Methadone is a long-acting opioid, so also write Y for "ER/LA formulation")		9				
Oxycodone? (If it has an ER/LA formulation [e.g., OxyContin], also write Y for "ER/LA formulation")		3				
A prescription antidepressant? (e.g., fluoxetine, citalopram, venlafaxine, amitriptyline)						
A prescription benzodiazepine? (e.g., diazepam, alprazolam)		4				
Is the patient's current maximum prescribed opioid dose:						
>100 mg morphine equivalents per day?		16				
50-100 mg morphine equivalents per day?						
20-50 mg morphine equivalents per day?		5				
In the past 6 months, has the patient:						
Had 1 or more ED visits?		11				
Been hospitalized for 1 or more days?						
Total Score		115				

Opioid Induced Respiratory Depression (OIRD) Probability based on Calculated Risk Index

	-,···· ,
Risk index score	OIRD probability (%)
0-24	3
25-32	14
33-37	23
38-42	37
43-46	51
47-49	55
50-54	60
55-59	79
60-66	75
≥67	86

Adapted from: Zedler B, Xie L, Wang L et al. Development of a Risk Index for Serious Prescription Opioid-Induced Respiratory Depression or Overdose in Veterans' Health Administration Patients. Pain Medicine. Jun 2015. 16;1566-1579.