Texas Medicaid

Comprehensive Opioid Management

Educational RetroDUR Mailing	☑Initial Study ☐Follow – up /Restudy

Executive Summary

Purpose:	This intervention is designed to improve the management of patients receiving treatment with opioids.		
Why Issue was Selected:	Prevention, assessment and treatment of chronic pain are challenges for healthcare providers. The prescribing of opioids should be based on careful consideration of benefits and risks associated with their use while providing patients with adequate pain management. Serious risks of opioid pain medications include opioid use disorder, overdose and death. Medical professionals are advised to exercise careful medication management to help mitigate these risks by evaluating the use of all central nervous system (CNS) agents while paying special attention to medications likely to cause sedation or respiratory depression.[1] Drug classes like benzodiazepines, when combined with opioids, have resulted in such serious side effects that the U.S. Food and Drug Administration (FDA) issued its strongest warning against their combined use.[2] Similarly, The Centers for Medicare & Medicaid Services (CMS) provided guidance on risks associated with opioids in H.R.6 section 1004, more commonly known as Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act. The recommendations are geared toward increasing patient safety by requiring states to have an automated review process in place that monitors patients concurrently prescribed opioids, benzodiazepines and/or antipsychotics.[3]		
Program Specific Information:	**Performance Indicators**	**Exceptions**	
		(<18 Years) FFS	**(<18 Years) MCO**
	1. Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics in combination with benzodiazepines	(2) 6	(8) 2,609
	2. Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics in combination with antipsychotics	(0) 3	(4) 1,689
	3. Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics in combination with benzodiazepines and antipsychotics	(0) 0	(2) 843

	4. Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics in combination with muscle relaxants	(0) 9	(0) 2,474
	5. Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics in combination with benzodiazepines and muscle relaxants	(0) 3	(0) 616
	6. Overutilization of Short-Acting Opioid Analgesics	(0) 0	(1) 1,831
	7. Underutilization of Long-Acting Opioid Analgesics	(0) 1	(5) 726
	8. Coordination of Care: Opioid analgesics from multiple prescribers	(0) 0	(4) 491
	9. Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics in combination with benzodiazepines without naloxone	(0) 5	(0) 1,896
	10. Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics and a history of substance abuse without naloxone	(0) 16	(0) 2,240
	11. Increased Risk of Adverse Drug Event (ADE): History of medication-assisted treatment (MAT) without naloxone	(0) 15	(0) 1,424
	12. Increased Risk of Adverse Drug Event (ADE): Use of tramadol in children	(4) N/A*	(144) N/A*
	13. Increased Risk of Adverse Drug Event (ADE): Use of codeine in children	(39) N/A*	(1,049) N/A*
	14. Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics without a urine drug screen	(3) 23	(34) 10,523
Setting & Population:	All patients with drug therapy for targeted medications within the past 30 to 60 days.		
Types of Intervention:	Cover letter and modified patient profiles		
Main Outcome Measures:	Re-measure performance indicators 6 months post intervention.		
Anticipated Results:	Decreased adverse drug events associated with opioid therapy, maximize the use of long-acting opioids, minimize the overutilization of short-acting opioids, as well as increase the use of naloxone to prevent opioid overdose.		

*N/A = not applicable. Candidates are under 18 years of age.

Performance Indicator #1: Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics in combination with benzodiazepines

Why has this indicator been selected?	Combining an opioid analgesic with benzodiazepines greatly increases the risk of serious side effects including extreme sleepiness, respiratory depression, coma and even death.[1-5]
Candidates (denominator):	Patients with opioid (Appendix A) analgesic therapy in the past 30 days. Excluded: medication-assisted treatment (MAT) drugs.
Exception criteria (numerator):	Candidates with 10 days or more of overlapping benzodiazepine (Appendix B) therapy in the past 30 days as well as during days 31 to 150. Excluded: patients with cancer, sickle cell or a hospice designation.

Performance Indicator #2: Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics in combination with antipsychotics

Why has this indicator been selected?	Combining an opioid analgesic with an antipsychotic greatly increases the risk of serious side effects including extreme sleepiness, respiratory depression, coma and even death.[3]
Candidates (denominator):	Patients with opioid (Appendix A) analgesic therapy in the past 30 days. Excluded: medication-assisted treatment (MAT) drugs.
Exception criteria (numerator):	Candidates with 10 days or more of overlapping antipsychotic (Appendix C) therapy in the past 30 days as well as during days 31 to 150. Excluded: patients with cancer, sickle cell or a hospice designation.

Performance Indicator #3: Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics in combination with benzodiazepines and antipsychotics

Why has this indicator been selected?	Additional medications added to a treatment regimen can increase the burden to the patient and healthcare system as well as increase the risk of adverse drug-related events. Coordination of care should be used to improve the treatment of co-morbid mental health disorders, as well as pain, while being cognizant of the high rate of opioid use disorder in this population.[3]
Candidates (denominator):	Patients with opioid (Appendix A) analgesic therapy in the past 30 days. Excluded: medication-assisted treatment (MAT) drugs.
Exception criteria (numerator):	Candidates with 10 days or more of overlapping benzodiazepine (Appendix B) and antipsychotic (Appendix C) therapy in the past 30 days as well as during days 31 to 150. Excluded: patients with cancer, sickle cell or a hospice designation.

Performance Indicator #4: Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics in combination with muscle relaxants

Why has this indicator been selected?	Combining opioid analgesics with muscle relaxants has been shown to increase the risk of overdose due to additive respiratory and central nervous system depression.[1,6]
Candidates (denominator):	Patients with opioid (Appendix A) analgesic therapy in the past 30 days. Excluded: medication-assisted treatment (MAT) drugs.
Exception criteria (numerator):	Candidates with 14 or more days of overlapping muscle relaxant therapy in the last 30 days. Excluded: patients with cancer, sickle cell or a hospice designation.

Performance Indicator #5: Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics in combination with benzodiazepines and muscle relaxants

Why has this indicator been selected?	Combining opioid analgesics with muscle relaxants and benzodiazepines has been shown to increase the risk of overdose due to additive respiratory and central nervous system depression.[1,6]
Candidates (denominator):	Patients with opioid (Appendix A) analgesic therapy in the past 30 days. Excluded: medication-assisted treatment (MAT) drugs.
Exception criteria (numerator):	Candidates with 14 or more days of overlapping muscle relaxant and benzodiazepine therapy in the last 30 days. Excluded: patients with cancer, sickle cell or a hospice designation.

Performance Indicator #6: Overutilization of Short-Acting Opioid Analgesics

Why has this indicator been selected?	Short-acting opioids require frequent administration (e.g., every 4 to 6 hours) around the clock. These agents are useful to determine the daily dose required for effective analgesia. Once this dose has been established, a long-acting opioid should be initiated and titrated to effective pain relief.[1,7,8]
Candidates (denominator):	Patients with short-acting opioid therapy and a long-acting opioid therapy in the last 30 days. Excluded: medication-assisted treatment (MAT) drugs.
Exception criteria (numerator):	Candidates who received more than 4 doses per day of short-acting opioids for the past 90 days. Excluded: patients with cancer, sickle cell or a hospice designation.

Performance Indicator #7: Underutilization of Long-Acting Opioid Analgesics

Why has this indicator been selected?	Excessive use of short-acting opioid analgesics may indicate inadequate pain relief. Although short-acting opioid analgesics are easier to titrate to pain relief, they require frequent dosing. Chronic use of short-acting opioid analgesics has been shown to increase the potential for abuse; therefore, they are best reserved for breakthrough pain. Long-acting opioids can provide sustained pain relief with less frequent dosing.[1,7,8]
Candidates (denominator):	Patients receiving a short-acting opioid without a long-acting opioid in the last 60 days. Excluded: medication-assisted treatment (MAT) drugs.
Exception criteria (numerator):	Candidates who received more than 8 fills of a short-acting opioid in the last 150 days. Excluded: patients with cancer, sickle cell or a hospice designation.

Performance Indicator #8: Coordination of Care: Opioid analgesics from multiple prescribers

Why has this indicator been selected?	Obtaining opioids from more than one prescriber may suggest inadequate pain relief. Data indicates that the use of multiple opioids is associated with a higher risk of mortality and those who receive the opioids from different prescribers or are lacking coordination of care become at highest risk for an opioid overdose. To monitor and optimize the patient's opioid usage, opioids should be prescribed by only one prescriber or one chronic pain treatment team whenever possible.[1-4]

Candidates (denominator):	Patients with opioid (Appendix A) analgesic therapy in the past 30 days. Excluded: medication-assisted treatment (MAT) drugs.
Exception criteria (numerator):	Candidates who had opioid analgesic therapy from 4 or more prescribers in the last 180 days.

Performance Indicator #9: Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics in combination with benzodiazepines without naloxone

Why has this indicator been selected?	The risk of opioid overdose increases in patients who use opioids concurrently with benzodiazepines. The CDC and FDA recommend offering naloxone to those at risk of overdose.[1,4,5]
Candidates (denominator):	Patients 18 years and older with opioid (Appendix A) analgesic therapy in the past 30 days. Excluded: medication-assisted treatment (MAT) drugs.
Exception criteria (numerator):	Candidates with greater than 7 days of overlapping benzodiazepine (Appendix B) therapy in the past 30 days and no history of naloxone therapy in the past 730 days.

Performance Indicator #10: Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics and a history of substance abuse without naloxone

Why has this indicator been selected?	The risk of opioid overdose increases in patients with a history of substance abuse. The CDC and FDA recommend offering naloxone to those at risk of overdose. [1,4,5]
Candidates (denominator):	Patients 18 years and older with opioid (Appendix A) analgesic therapy in the past 30 days. Excluded: medication-assisted treatment (MAT) drugs.
Exception criteria (numerator):	Candidates with a diagnosis of substance abuse and no history of naloxone therapy in the past 730 days.

Performance Indicator #11: Increased Risk of Adverse Drug Event (ADE): History of medication-assisted treatment (MAT) without naloxone

Why has this indicator been selected?	The FDA recommends that providers prescribe naloxone to their patients utilizing medication-assisted treatment (MAT) to reduce the risk of adverse events.[5]
Candidates (denominator):	Patients 18 years and older with medication-assisted treatment (MAT) therapy in the past 180 days.
Exception criteria (numerator):	Candidates with no history of naloxone therapy in the past 730 days.

Performance Indicator #12: Increased Risk of Adverse Drug Event (ADE): Use of tramadol in children

Why has this indicator been selected?	The use of tramadol and tramadol ER (extended-release) has not been studied in patients less than 16 years of age and 18 years of age, respectively. Therefore, the use of tramadol is not recommended in these populations.

	Tramadol is converted in the liver to the active form of the opioid, called O-desmethyltramadol. Patients who are ultra-rapid CYP2D6 metabolizers may develop toxic blood levels.[9]
Candidates (denominator):	Patients with tramadol therapy in the past 60 days.
Exception criteria (numerator):	• Candidates less than 16 years of age receiving tramadol IR/ODT (immediate-release or orally disintegrating tablets) • Candidates less than 18 years of age receiving tramadol ER (extended-release)

Performance Indicator #13: Increased Risk of Adverse Drug Event (ADE): Use of codeine in children

Why has this indicator been selected?	Codeine's activity depends on a certain enzyme pathway in the liver that partially converts the drug into morphine, its strongest analgesic metabolite. Children who are ultra-rapid metabolizers can produce potentially dangerously high concentrations of morphine in their bodies too quickly, which can lead to serious adverse events including death. [9]
Candidates (denominator):	Patients with codeine therapy in the past 30 days.
Exception criteria (numerator):	Candidates less than 18 years of age receiving a product containing codeine.

Performance Indicator #14: Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics without a urine drug screen

Why has this indicator been selected?	Urine drug screens are a helpful tool for clinicians to assess medication use as well as improve patient safety, when results are unexpected, which is why the CDC recommends their use at least annually.[1]
Candidates (denominator):	Patients with opioid (Appendix A) analgesic therapy for at least 90 of the past 120 days. Excluded: medication-assisted treatment (MAT) drugs.
Exception criteria (numerator):	Candidates without evidence of a urine drug screen in the last year. Excluded: patients with cancer, sickle cell or a hospice designation.

Appendices:

Appendix A	
Specific Therapeutic Category (STC)	**STC Description**
H30	OPIOID ANALGESIC, SALICYLATE, AND XANTHINE COMB.
H3A	OPIOID ANALGESICS
H3M	OPIOID,NON-SALICYL.ANALGESIC,BARBITURATE,XANTHINE
H3N	OPIOID ANALGESIC AND NSAID COMBINATION
H3R	OPIOID AND SALICYLATE ANALGESICS,BARBIT,XANTHINE
H3U	OPIOID ANALGESIC AND NON-SALICYLATE ANALGESICS
H3X	OPIOID ANALGESIC AND SALICYLATE ANALGESIC COMB
H3Z	OPIOID ANALGESIC,NON-SALICYLATE,XANTHINE COMB
S7G	SKELETAL MUSCLE RELAXANT,SALICYLAT,OPIOID ANALGESC

Appendix B	
STC	**STC Description**
H20	ANTI-ANXIETY - BENZODIAZEPINES
H21	SEDATIVE-HYPNOTICS – BENZODIAZEPINES
H2X	TRICYCLIC ANTIDEPRESSANT-BENZODIAZEPINE COMBINATIONS
H4A	ANTICONVULSANT - BENZODIAZEPINE TYPE

Appendix C	
STC	**STC Description**
H2G	ANTIPSYCHOTICS,PHENOTHIAZINES
H7O	ANTIPSYCHOTICS,DOPAMINE ANTAGONISTS,BUTYROPHENONES
H7P	ANTIPSYCHOTICS,DOPAMINE ANTAGONISTS, THIOXANTHENES
H7S	ANTIPSYCHOTICS,DOPAMINE ANTAGONST,DIHYDROINDOLONES
H7T	ANTIPSYCHOTIC,ATYPICAL,DOPAMINE,SEROTONIN ANTAGNST
H7U	ANTIPSYCHOTICS, DOPAMINE AND SEROTONIN ANTAGONISTS
H7X	ANTIPSYCHOTICS, ATYP, D2 PARTIAL AGONIST/5HT MIXED

H7Z	SSRI-ANTIPSYCH, ATYPICAL,DOPAMINE,SEROTONIN ANTAG
H8W	ANTIPSYCHOTIC-ATYPICAL,D3/D2 PARTIAL AG-5HT MIXED

References

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2. FDA Drug Safety Communication: FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning. September 2017. Available at: https://www.fda.gov/Drugs/DrugSafety/ucm518473.htm. Accessed 8/2020.
3. Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018, H. R. 6, 115th Cong. (2018)
4. Department of Health and Human Services, Center for Medicare and Medicaid Services, CMCS Informational Bulletin. Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction, February 28, 2016. Available at: https://www.medicaid.gov/federal-policy-guidance/downloads/cib-02-02-16.pdf. Accessed 8/2020.
5. FDA News Release: FDA Requiring Labeling Changes for Opioid Pain Medicines, Opioid Use Disorder Medicines Regarding Naloxone. Issued July 23, 2020. Available at: https://www.fda.gov/news-events/press-announcements/fda-requiring-labeling-changes-opioid-pain-medicines-opioid-use-disorder-medicines-regarding. Accessed 8/2020.
6. Reeves RR, Burke RS. Carisoprodol: abuse potential and withdrawal syndrome. Curr Drug Abuse Rev. 2010; 3:33-8.
7. Fine PG, Mahajan G, McPherson ML. Long-Acting Opioids and Short-acting Opioids: Appropriate Use in Chronic Pain Management. Pain Medicine 2009; 10: S79-S88.
8. Tennant F. Critical Transition from Short-to-Long-Acting Opioid Therapy. Practical Pain Management 2007; 7:9. Available at: https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/critical-transition-short-long-acting-opioid-therapy Accessed 8/2020
9. FDA Drug Safety Communication: FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women. Issued January 11, 2018. https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm Accessed 8/2020.

Messid	Internal	External
114181	Codeine Use in Youth	INCREASED RISK OF ADE - CODEINE USE IN YOUTH: Based on pharmacy claims, your patient that is less than 18 years of age has recently received a codeine product. The FDA has added a boxed warning to the official prescribing information for codeine warning of potentialadverse effects, including reported deaths. Codeine is contraindicated for all children 12 years and younger as well as in those 12-18 years post-tonsillectomy and/or adenoidectomy. Please consider an alternative analgesic for use in your young patients or, if you feel codeine is most appropriate, please monitor them closely for potential adverse effects.
3561	Underutilization of Long-Acting Opioid	POTENTIAL UNDERUTILIZATION OF LONG-ACTING OPIOID ANALGESICS: According to pharmacy claims data, it appears that your patient has utilized short-acting opioid analgesics chronically. This pattern of use may reflect an opportunity for the use of a long-acting opioid. Long-acting opioids may provide sustained pain relief with a reduced dosing frequency and reduced risk for potential toxicities associated with opioids. Please consider whether your patient may benefit from a long-acting opioid analgesic.
3597	Multiple Prescribers: Coordination of Care	MULTIPLE PRESCRIBERS- COORDINATION OF CARE: Potential Coordination of Care Issues: According to claims data, it appears that your patient has received multiple opioid analgesics from multiple prescribers during the past 6 months. We recognize that your patient may have a clinical indication for the chronic use of opioids, but there is a concern that this pattern of use may indicate suboptimal pain relief or potential problems with coordination of care. Chronic pain management guidelines recommend that opioid analgesics be prescribed by one physician to encourage continuity of care with regular assessments to review opioid tolerability, adequacy of pain relief and to
8243	Overuse Short-Acting Opioid - Titrate Long-Acting Opioid	POTENTIAL OVERUSE OF SHORT-ACTING OPIOID, TITRATE LONG-ACTING OPIOID: According to pharmacy claims data, it appears your patient is receiving a long- acting opioid and continues to receive excessive quantities of short-acting opioid analgesics. This pattern of use may reflect inadequate painrelief. If appropriate, please titrate this patient's long-acting opioid analgesic to provide sustained analgesia and minimize the use of short-acting opioids.
9109	Pediatric: Tramadol ER Use Not Recommended	INCREASED RISK OF ADVERSE EVENT-TRAMADOL ER NOT INDICATED IN CHILDREN: According to pharmacy claims data, your patient has received tramadol extended-release (ER) and is younger than 18 years of age. Because the safety and efficacy of tramadol ER has not been established in children younger than 18 years of age, its use in this population is not recommended. Please consider the use of alternative analgesic therapy.
83	Pediatric: Use Not Recommended: Tramadol IR	INCREASED RISK OF ADVERSE EVENT-TRAMADOL NOT INDICATED IN CHILDREN: According to pharmacy claims data, your patient has received tramadol immediate-release (IR) or orally disintegrating tablets (ODT) and is younger than 16 yearsof age. Because the safety and efficacy of tramadol has not been established in children younger than 16 years of age, its use in this population is not recommended. Please consider the use of alternative analgesic therapy.
10083	Opioid and Muscle Relaxant	CONCURRENT USE OF AN OPIOID AND A SKELETAL MUSCLE RELAXANT: Based on pharmacy claims data, it appears your patient is receiving an opioid and a skeletal muscle relaxant concurrently. Both of these classes of medications are CNS depressants and their effects are additive. Use of these agents in combination increases the risks of adverse effects and the lethality of overdose, including the risks of unintentionally taking too much medication. Please review the need for continuing this combination of medications.

10084	Triple Threat: Opioid, Benzodiazepine and Muscle Relaxant	CONCURRENT USE OF AN OPIOID, BENZODIAZEPINE, AND SKELETAL MUSCLE RELAXANT: Based on pharmacy claims data, it appears your patient is receiving an opioid, a benzodiazepine and a skeletal muscle relaxant product concurrently. All three classes of medications are CNS depressants and their effects are additive. Use of these agents in combination increases the risks of adverse effects and the lethality of overdose, including the risks of unintentionally taking too much medication. Please review the need for continuing this combination of medications.
113709	Double Threat: Opioid and Antipsychotic	DOUBLE THREAT: OPIOID AND ANTIPSYCHOTIC- According to submitted pharmacy claims data, it appears your patient is receiving concurrent therapy with an opioid and an antipsychotic. Title I of H.R.6 - SUPPORT for Patients and Communities Act addresses Medicaid regulations to combat the opioid crisis. States are required to monitor when patients receive opioids concurrently with antipsychotics due to the risk for adverse drug events related to the additive central nervous system depression. Please review your patient's medication profile and consider if a change in therapy is warranted to improve the safety of this drug regimen.
113708	Double Threat: Opioid and Benzodiazepine	DOUBLE THREAT: OPIOID AND BENZODIAZEPINE- According to submitted pharmacy claims data, it appears your patient is receiving concurrent therapy with an opioid and a benzodiazepine. The U.S. Food and Drug Administration and the Centers for Disease Control and Prevention have both issued a warning for this combination of central nervous system depressants due to the risk of extreme sleepiness, respiratory depression, coma and death. Please review your patient's medication profile and consider if a change in therapy is warranted to improve the safety of this drug regimen.
113707	Triple Threat: Opioid/Benzodiazepine/Antipsychotic	TRIPLE THREAT: OPIOID/BENZODIAZEPINE/ANTIPSYCHOTIC- According to submitted pharmacy claims data, it appears your patient is receiving concurrent therapy with an opioid, benzodiazepine, and an antipsychotic. This combination of medications is not recommended due to risk of adverse events secondary to CNS depression. Title I of H.R. 6 - SUPPORT for Patients and Communities Act addresses Medicaid regulations to combat the opioid crisis. States are required to monitor when patients receive opioids concurrently with antipsychotics and/or benzodiazepines. Please review your patient's medication profile and consider if a change in therapy is warranted to
16508	IADE: Use of Opioids and Benzodiazepines Without Naloxone	IADE: USE OF OPIOIDS AND BENZODIAZEPINES WITHOUT NALOXONE- According to recent pharmacy claims, your patient has received an opioid and a benzodiazepine in the last 30 days with 7 or more days of overlapping therapy. Patients on opioids and benzodiazepines concomitantly are at an increased risk of adverse events including overdose. The Centers for Disease Control and Prevention along with the U.S. Food and Drug Administration recommend that patients be co-prescribed a naloxone product indicated to revers an opioid overdose. Patient education along with naloxone therapy can reduce the risk of overdose. Please evaluate the treatment plan for this patient to determine the best course of action.

16510	IADE: Use Opioids with a Hx Substance Abuse and No Naloxone	IADE: USE OF OPIOIDS WITH A HISTORY OF SUBSTANCE ABUSE AND NO NALOXONE- According to submitted pharmacy and medical claims, your patient has had therapy with an opioid and also has a diagnosis of substance abuse and has not been prescribed a naloxone product indicated to reverse an opioid overdose. Patients on opioids with a history of substance abuse are at an increased risk of adverse events including overdose. The Centers for Disease Control and Prevention as well as the U.S. Food and Drug Administration recommend that naloxone be co-prescribed for these patients. Patient education along with naloxone therapy can reduce the risk of opioid overdose. Please evaluate the treatment plan for this patient to determine the best course of action.
115194	Use of Medication Assisted Treatment (MAT) without Naloxone	USE OF MEDICATION ASSISTED TREATMENT WITHOUT NALOXONE: According to recent pharmacy and medical claims, your patient has received medication-assisted treatment (MAT) in the last 45 days and has not been prescribed a naloxone product indicated to reverse an opioid overdose. The U.S. Food and Drug Administration (FDA) recommends that naloxone be prescribed to patients utilizing MAT in an effort to help reduce opioid overdose and death. Please review the treatment plan for this patient to determine the best course of action.

TEXAS
Health and Human Services

Cecile Erwin Young
Executive Commissioner

<<Date>>

«dea»
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«add3»

RE: Safe and Effective Management of Patients Receiving Opioids

Dear Dr. <<Name>>:

Thank you for providing quality care for Texas Fee-For-Service (FFS) Medicaid patients. The content of this letter has been approved by the Texas Drug Utilization Review (DUR) Board, whose function is to promote safe and cost-effective drug therapy and provide opportunities for continuous improvement of care.

This retrospective claims review was designed to assist you in identifying patients who may be at risk of opioid-related adverse drug events. In 2016, the Centers for Disease Control and Prevention (CDC) issued recommendations for safer and more effective use of opioid therapy. The guidelines focused on prudent use of long- and short-acting opioids, coordination of care among prescribers and the dangers of combining opioids and other central nervous system depressants.[1] In 2018, the Food and Drug Administration (FDA) implemented new restrictions on the use of codeine for cough and pain, as well as tramadol for pain in children. Single-ingredient codeine and all tramadol-containing products are not FDA-approved in children.[2] Also in 2018, the United States Congress passed "The Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act'' or the ''SUPPORT for Patients and Communities Act'' to promote opioid use disorder prevention, recovery and treatment.[3] Some provisions included in the SUPPORT Act include safety edits for opioids, maximum daily morphine equivalents as well as prescription drug monitoring programs. The SUPPORT Act also requires states to have an automated review process in place to monitor patients concurrently prescribed opioids and benzodiazepines and/or antipsychotics to increase patient safety.[3] This year, the FDA followed up on their previous restrictions with requiring label changes for opioids and opioid use disorder (OUD) medications regarding naloxone.[4] The intense focus on safe use of opioids by so many well-respected organizations, as well as the desire of the Board and Medicaid leadership to provide quality care to Texas patients, was the foundation for this review.

The 2016 CDC Chronic Pain Guidelines are available at:
https://www.cdc.gov/drugoverdose/prescribing/guideline.html.

The FDA news release is available at: https://www.fda.gov/news-events/press-announcements/fda-requiring-labeling-changes-opioid-pain-medicines-opioid-use-disorder-medicines-regarding.

The Texas Prescription Monitoring Program is available at: https://www.pharmacy.texas.gov/pmp/.

The total Texas Medicaid Fee-For-Service performance indicators for all patients (including those <18 years) with opportunities for improving the safe and effective management of opioids are shown in the table below.

Total Texas Medicaid FFS Specific Data

Comprehensive Opioid Management	Number of Patients with Opportunities*	
	<18 Years	**</=18 Years**
1. Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics in combination with benzodiazepines	2	6
2. Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics in combination with antipsychotics	0	3
3. Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics in combination with benzodiazepines and antipsychotics	0	0
4. Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics in combination with muscle relaxants	0	9
5. Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics in combination with a benzodiazepine and a muscle relaxant	0	3
6. Overutilization of Short-Acting Opioid Analgesics	0	0
7. Underutilization of Long-Acting Opioid Analgesics	0	1
8. Coordination of Care: Opioid analgesics from multiple prescribers	0	0
9. Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics in combination with benzodiazepines without naloxone	0	5
10. Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics and a history of substance abuse without naloxone	0	16
11. Increased Risk of Adverse Drug Event (ADE): History of medication-assisted treatment (MAT) without naloxone	0	15
12. Increased Risk of Adverse Drug Event (ADE): Use of tramadol in children	2	N/A
13. Increased Risk of Adverse Drug Event (ADE): Use of codeine in children	39	N/A
14. Increased Risk of Adverse Drug Event (ADE): Use of opioid analgesics without a urine drug screen	3	23

*Based on data through September 2020.

The enclosed patient profiles reflect one or more of the above issues and are provided as a medical record reminder for when your patients return for their next appointments.

We acknowledge that there may be clinical variables influencing an individual patient's management that are not apparent in claims data. However, we believe the issues identified may assist you in caring for your patient(s). It is possible that your license number may have been inadvertently assigned to the claim as an error at the pharmacy during the billing process. **Also, some prescribed medications as well as some recommended laboratory monitoring or physical examinations may not appear on the patient's profile because they may have been privately purchased or were not billable to Medicaid Services.** We thank you for reviewing this information and caring for Texas Medicaid patients, and we welcome the opportunity to discuss any comments or concerns you may have about our quality management program. Please feel free to call our office at 1-866-923-7208 with questions or concerns. If your mailing address is incorrect, it must be updated through the Texas Medical Board online at **http://www.tmb.state.tx.us/page/change-address.**

Sincerely,

Medicaid Drug Use Review Board
Vendor Drug Program H-630

Intervention Indicator Summary
Monitor and modify treatment for patients using central nervous system (CNS) depressants concurrently[1,3-5,7,9] • Many organizations (including the CDC, FDA and CMS), as well as federal legislation in the SUPPORT Act, have provided guidance on the concurrent use of CNS depressants in an effort to combat the opioid crisis. Using CNS depressants concurrently may result in excessive sleepiness, respiratory depression, coma and possibly death. This retrospective claims review specifically targets concurrent use of opioids, benzodiazepines, antipsychotics and muscle relaxants. • When a patient is prescribed multiple CNS depressants, the risk of adverse drug events increases. To reduce that risk, guidance recommends: not using the drug combination when possible, monitoring for adverse drug events including respiratory depression and sedation and patient education regarding the risks. If there are no alternative treatment options, the drug therapy should be used at the lowest dose and for the shortest duration. • Opioids should not be abruptly discontinued in a patient who is physically dependent. No standard opioid tapering schedule exists that is suitable for all patients. Create a patient-specific plan to gradually taper the dose of the opioid and ensure ongoing monitoring and support, as needed, to avoid serious withdrawal symptoms, worsening of the patient's pain or psychological distress. • Clinicians should regularly check their prescription drug monitoring program (PDMP) for CNS depressants prescribed by other providers. • Additional recommendations for reducing adverse drug events from using multiple CNS depressants are found in the information below.
Avoid the use of opioids concurrently with benzodiazepines[1,3,4-6,10] • The combination of these drug classes can result in excessive sleepiness, respiratory depression, coma and death. This drug combination should be reserved for patients with inadequate alternative treatment options. If the combination is required, the dose and duration should be the lowest/shortest to treat the condition and the patient should be monitored closely for respiratory depression and sedation. • Benzodiazepine anxiolytics are recommended as short-term, adjunctive therapy in the management of anxiety by most experts and treatment guidelines. Other FDA-approved medications that are not controlled substances, such as second-generation antidepressants or buspirone (second-line) are recommended as treatments of choice for long-term management of anxiety. In addition, consideration should be given to the use of psychosocial and behavioral therapies as more definitive interventions in chronically anxious patients (see Table 1).
Monitor and modify the treatment of opioids used concurrently with antipsychotics[1,3-5] • The combination of these drug classes can result in excessive sleepiness, respiratory depression, coma and death. When this drug combination is used, the dose and duration should be the lowest/shortest to treat the condition and the patient should be monitored closely for respiratory depression and sedation. • Coordination of care is essential to improve the treatment of comorbid mental health disorders as well as pain while being cognizant of the high rate of opioid use disorder in this population.
Identify overutilization of opioids[1] • 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 increasing dosage to ≥50 morphine milligram equivalents (MME)/day and should avoid or carefully justify a decision to titrate dosage to ≥90 MME.

- Patients in whom the benefits of opioid therapy outweigh the harms can be continued on the short-acting opioid (immediate release/IR or short-acting/SA formulation) used during the initial trial of opioid therapy. The decision to convert from an IR/SA opioid to a long-acting opioid (extended-release/ER or long-acting/LA formulation) should be individualized to each patient.
- ER/LA opioids should be reserved for management of pain severe enough to require daily, around-the-clock, long-term opioid therapy when alternative treatment options such as nonopioid analgesics or IR/SA opioids are ineffective, not tolerated or inadequate to provide sufficient pain management. ER/LA opioids should not be used as "as needed" pain relievers.

Identify underutilization of ER/LA opioids[1]

- Excessive use of IR/SA opioids for breakthrough pain with concurrent ER/LA opioids may indicate inadequate pain relief and can increase the risk of abuse and/or overdose. ER/LA opioids can provide sustained pain relief with less frequent dosing. Experts indicated that there was not enough evidence to determine the safety of using IR/SA opioids for breakthrough pain when ER/ LA opioids are used for chronic pain outside of active cancer pain, palliative care or end-of-life care, and that this practice might be associated with dose escalation.

Identify coordination of care issues for patients receiving opioids from multiple prescribers[1]

- Obtaining opioid analgesics from more than one provider may suggest inadequate coordination of care. To monitor and optimize a patient's opioid usage, opioids should be prescribed by only one physician or one pain management team whenever possible. Treatment from one physician encourages continuity of care and can improve pain management.

Promote the use of naloxone in patients using opioids with benzodiazepines, patients with a history of substance abuse or medication-assisted treatment[1,4-5]

- The combination of opioids and benzodiazepines results in an increased risk for overdose due to excessive sleepiness, respiratory depression, coma and even death.
- Patients with a prior history of substance abuse or an overdose and those using medication-assisted treatment are also at an increased for overdose.
- The FDA, CDC and CMS recommend prescribing a naloxone product indicated to reverse an opioid overdose in patients who are at an increased risk of overdose. Naloxone reverses the potential life-threating effects of opioids including respiratory depression, sedation and hypotension by allowing the opioid overdose victim to resume normal breathing.

Limit use of codeine and tramadol for pain in children younger than 18 years[2,8]

- Codeine is contraindicated to treat pain or cough in children younger than 12 years.
- Tramadol is contraindicated to treat pain in children younger than 12 years.
- Codeine and tramadol are contraindicated in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids.
- Codeine and tramadol should be avoided in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
- According to the World Health Organization (WHO) pharmacologic pain treatment guidelines, acetaminophen or ibuprofen are the first step treatments of choice for children with mild pain. If pain severity associated with a medical illness is assessed as moderate or severe, the administration of a strong opioid may be necessary. Morphine is the medicine of choice for the second step, although other strong opioids should be considered and made available to ensure an alternative to morphine in case of intolerable side effects.

Monitor patients using opioids by utilizing urine drug screens[1]

- Concurrent use of opioid pain medications with other CNS depressants, including illicit drugs, can increase the risk for an overdose. Urine drug screens can provide a clinician with information about drug use that is not reported by the patient and is recommended by the CDC to be utilized at least annually.

Table 1: Preferred Alternatives to Benzodiazepines for Chronic Anxiety Disorders[10]

Pharmacologic Interventions	Non-Pharmacologic Interventions
Selective Serotonin Reuptake Inhibitors (SSRIs)	Cognitive-Behavioral Therapy
Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)	Cognitive Restructuring
Buspirone	Applied Relaxation

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