



Opioid Policy Criteria

Ryan Pistoresi, PharmD, MS
Assistant Chief Pharmacy Officer
Clinical Quality and Care Transformation
October 19, 2016

Background

Sources

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016



Continuing Education Examination available at <http://www.cdc.gov/mmwr/cme/conted.html>.



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Interagency Guideline on Prescribing Opioids for Pain

Developed by the Washington State Agency Medical Directors' Group (AMDG) in collaboration with an Expert Advisory Panel, Actively Practicing Providers, Public Stakeholders, and Senior State Officials.

www.agencymeddirectors.wa.gov

AMDG agency medical directors' group
A collaboration of state agencies, working together to improve health care quality for Washington State residents.

*Written for Clinicians who Care for People with Pain
3rd Edition, June 2015*

Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain

Part A: Executive Summary and Background
Part B: Recommendations for Practice

PART B

— Recommendations for Practice —

Published by the
National Opioid Use Guideline Group (NOUGG)
a collaboration of:

Federation of Medical Regulatory Authorities of Canada
College of Physicians & Surgeons of British Columbia
College of Physicians & Surgeons of Alberta
College of Physicians and Surgeons of Saskatchewan
College of Physicians & Surgeons of Manitoba
College of Physicians and Surgeons of Ontario
Collège des médecins du Québec
College of Physicians and Surgeons of New Brunswick
College of Physicians and Surgeons of Nova Scotia
College of Physicians and Surgeons of Prince Edward Island
College of Physicians and Surgeons of Newfoundland and Labrador
Government of Nunavut
Yukon Medical Council

April 30 2010 Version 5.6

<http://nationalpaincentre.mcmaster.ca/opioid/>

Opioid Treatment Guidelines

Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain

Roger Chou,¹ Gilbert J. Fanciullo,² Perry G. Fine,³ Pamela Davies,⁶ Marilee I. Donovan,⁷ David A. Fishbain,⁸ Aaron M. Gilson,¹¹ Alexander Kelter,¹² Alexander M. Lipton,¹³ Steven D. Passik,¹⁵ Gavril W. Pasternak,¹⁶ Russell K. Porten,¹⁷ Richard G. Roberts,¹⁹ Knox H. Todd,²⁰ and Christine M. Tait
SOCIETY—AMERICAN ACADEMY OF PAIN MEDICINE OPIOIDS GUIDELINE



RESEARCH
EDUCATION
TREATMENT
ADVOCACY



Presentation Overview

- Initial Opioid Prescriptions
 - Guideline-Recommended Criteria
 - Expedited Authorization Criteria
 - Options for Prescriptions over Limits
 - Prior Authorization Criteria
- Sub-Acute Opioid Prescription Criteria
- Chronic Opioid Prescription Criteria



Initial Opioid Prescriptions

Guideline-Recommended Criteria



Guideline-Recommended Criteria

- ≤ 7 day supply for patients age 18 and older **OR**
 ≤ 3 day supply for patients age 17 and younger
- ≤ 50 MEDs (morphine milligram equivalents per day)
- \leq product-specific quantity level limit (QLL)
- immediate-release (IR) dosage form

Guideline-Recommended Criteria

- **≤ 7 day supply for patients age 18 and older OR**
≤ 3 day supply for patients age 17 and younger
 - CDC Recommendation 6 states increased length of therapy for treatment of acute pain is associated with increased risk of OUD¹
 - “Some experts thought that a range including 7 days was too long given the expected course of severe acute pain for most acute care pain syndromes seen in primary care.”¹

Prescribe no more than needed

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.
- 3 days or less will often be sufficient; more than 7 days will rarely be needed.

(Recommendation category: A; Evidence type: 4)



Guideline-Recommended Criteria

- **≤ 50 MEDs (morphine milligram equivalents per day)**
 - CDC Recommendation 5 and Canadian Recommendations R09 state that clinicians should prescribe **the lowest effective dose**.

R09	Recommendation Statement	
R09	When conducting a trial of opioid therapy, start with a low dosage, increase dosage gradually and monitor opioid effectiveness until optimal dose is attained. (Grade C).	Optimal dose

- Populations at higher MEDs have poorer health outcomes³
- Doses >50 MEDs will require documentation that benefits outweigh risks for the specific patient (see Expedited Authorization and Prior Authorization sections)

5 Use caution at any dose and avoid increasing to high dosages

- 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 increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

(Recommendation category A: Evidence type: 3)

Guideline-Recommended Criteria

- **≤ product-specific quantity level limit (QLL)**
 - The quantity level limit threshold is designed to limit the number of units (tablets) available in the community.
 - If the prescription limit is based only on MEDs, then it may allow for more unused units. An MED limit alone does not adequately address the excess opioids in the community.
 - A 50 MED limit for hydrocodone 5 mg prescriptions would be capped at 70 tablets per adult prescription. A 50 MED limit for hydrocodone 2.5mg would be 140 tablets!
 - A recent study (n=79) found that 54% of opioids remained 21 days following dental surgery, suggesting a need to cap prescriptions based on the number of units, along with other guideline criteria.
 - A table is being developed to document the maximum amount of tablets that meet the product-specific QLL, the 50 MEDs limit, and the 3-day, 7-day, or acute EA days supply limit for each strength of each medication.



Guideline-Recommended Criteria

Ingredient	Dosage Form	Dosage Type	Drug Name	Strength	Limit per 3 Day Supply	Limit per 7 Day Supply
Hydrocodone	Tablets	immediate release oral tablet	hydrocodone/ acetaminophen	2.5 mg	18	42
			[generic; Lorecet; Lortab; Maxidone; Norco; Verdrocet; Vicodin; Xodol; Zydone]	5 mg	18	42
				7.5 mg	18	42
				10 mg	15	35
				hydrocodone/ ibuprofen	2.5 mg	18
			[generic; Ibudone; Reprexain; Vicoprofen; Xylon]	5 mg	18	42
				7.5 mg	18	42
				10 mg	15	35
			hydrocodone/ homatropine	5 mg	18	42
			[generic; Tussion]			



Guideline-Recommended Criteria

- **Immediate-release (IR) dosage form**

- CDC Recommendation 4 and Canadian Recommendation R08 recommend that an opioid trial begin with an immediate-release opioid.

R08	Recommendation Statement	
R08	During an opioid trial, select the most appropriate opioid for trial therapy using a stepped approach, and consider safety. (Grade C).	Stepped opioid selection

- The Canadian Guidelines state that controlled-release (CR) opioids may increase the risk of overdose and abuse and that codeine and tramadol may have lower abuse risk than others³.

Use immediate-release opioids when starting

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: Evidence type: 4)

Additional cautions for

- Methadone
- Transdermal fentanyl
- Immediate-release opioids combined with ER/LA opioids

Guideline-Recommended Criteria

Additional Recommendations:	Citations
if possible, a trial and failure of non-opioid medications and/or non-pharmacologic therapy prior to prescribing opioids	CDC Recommendation 1; 5; AMDG Non-opioid; Canadian R9; R10
in combination with appropriate non-opioid medications and/or non-pharmacologic therapy ; (opioids are not first-line therapy)	CDC Recommendation 1; AMDG Acute 1 APS 9.1
baseline assessments of measurable, objective pain scores and function scores for which to demonstrate clinical benefit of opioid therapy	AMDG Acute 6; Canadian R1 APS 5.1
a completed screening for mental health, substance use disorder, and naloxone use	CDC Recommendation 10; 12; AMDG Subacute 5; 6; 7; 8 Canadian R2 APS 6.1
after checking the PDMP for avoiding concurrent use with benzodiazepines	CDC Recommendations 9; 11; AMDG Acute 5; Subacute 4 Canadian R6
after a comprehensive documentation of the pain condition and patient's medical history , evaluating the patient for the history of, diagnosis of, and patient risk of addiction, abuse, and overdose of opioids, for adverse events (such as respiratory or cardiac distress, use of other sedatives or stimulants), contraindications , and special populations (CKD, COPD, elderly, sleep apnea, etc.)	CDC Recommendation 3; AMDG Subacute 7 Canadian R1; R2 APS 1.1; 1.2; 1.3
do not prescribe opioids for conditions that have not been studied in placebo-controlled trials: headache, irritable bowel syndrome, pelvic pain, temporomandibular joint dysfunction, atypical face pain, non-cardiac chest pain, Lyme disease, whiplash, and repetitive strain injury	Canadian R4



Initial Opioid Prescriptions

Expedited Authorization Criteria



Expedited Authorization Criteria

- Expedited authorizations will allow patients with specific **chronic** medical conditions to received prescriptions above the guideline-recommended criteria without prior authorization
 - **> 7 day supply** and **>50 MEDs**
- Chronic medical conditions that qualify for unrestricted EA:
 - Active cancer treatment
 - Hospice/palliative care/end-of-life care

Expedited Authorization Criteria

- Expedited authorizations will allow patients with specific **acute** medical conditions to received prescriptions above the guideline-recommended criteria without prior authorization
 - **Up to 14 days, up to 120 MEDs (AMDG), no product-specific QLL**
- Acute medical conditions that qualify for unrestricted EA:
 - Sick cell anemia crises
 - Severe burns and major trauma
 - Intra-articular bleeding
 - Acute fractures or obstructions (biliary tree, kidney/ureter)



Initial Opioid Prescriptions

Options for Prescriptions over Limits



Over Days Supply or QLL

- Prescriptions written above the days supply limit or the product-specific quantity level limit can be allowed up to the appropriate days supply limit or quantity level limit:
 - Oxycodone 5mg i PO Q6H PRN pain #56
(14 day supply, max 4 tablets per day) for an adult
 - Written for **14 day supply** (30 MEDs)
 - **Dispense #28 for 7 day supply.**
 - Hydrocodone/APAP 2.5mg/325mg i-ii PO Q4-6H PRN pain #84
(7 day supply, max 12 tablets per day) for an adult
 - Written for 7 day supply (30 MEDs), but **above product-specific QLL** (#42)
 - **Dispense #42 for 7 day supply.**



Over Days Supply or QLL

- Morphine oral solution 10mg/5mL 2.5-5mL PO Q6H PRN pain #100 (5 day supply, max 20mL per day) for a **child**
 - Written for **5 day supply** (40 MEDs)
 - **Dispense #60 for 3 day supply.**

- Hydrocodone/APAP 5mg/325mg i PO Q4-6H PRN pain #18 (3 day supply, max 6 tablets per day) for a **child**
 - Written for **3 day supply** (30 MEDs)
 - **Dispense #18 for 3 day supply.**



Over MEDs Limit

- Prescriptions written above the MEDs will require clinical review given that the medication, strength, or directions will need to be change to meet the CDC recommended limit:
 - Hydrocodone/APAP 10mg/325mg i PO Q4-6H PRN pain #30 (5 day supply, max 6 tablets per day) for an adult
 - Written for **60 MEDs**. Will need to review instructions or strength
 - An alternative could be #25 for 5 days supply (50 MEDs)
 - Hydromorphone 4mg i PO Q3H PRN pain #24 (3 day supply, max 8 tablets per day) for an adult
 - Written for **128 MEDs** and **above QLL**. Will need to review instructions or strength and quantity
 - An alternative could be #12 for 3 days (48 MEDs)



Extended-release Opioids

- Criteria for extended-release opioids will be presented at the **December DUR Board Meeting.**

Initial Opioid Prescriptions

Prior Authorization Criteria



Prior Authorization

- For an initial prescription (no opioid prescription in the last 30 days) that does not meet the guideline-recommended criteria and that are not dispensed within the guideline-recommended criteria are subject to prior authorization.
- Prior authorization will also be required for continuing opioid prescriptions beyond the initial opioid prescription (following an initial prescription within a 30-day period).
- Prior authorization is used to ensure opioids are medically necessary and that clinically-meaningful improvements in pain and function are achieved.



Prior Authorization

- Justification for **extended-release opioid**
 - Initiating treatment with ER opioids increases the risk of overdose compared to IR opioids¹
 - CDC Recommendation 4; Canadian Recommendation R08

- Anticipated **length of treatment** (# of days beyond 7 or 3 days supply or the # of tablets above the product-specific QLL)
 - Increased length of therapy is associated with increased risk of OUD¹
 - CDC Recommendation 6



Prior Authorization

- Trial and failure of **non-opioid medications** and/or **non-pharmacologic therapy** and/or **lower MED doses**
 - Non-pharmacologic and non-opioid therapies are preferred over opioid therapies¹
 - Pain is multidimensional and requires a multimodal approach²
 - Populations at higher MEDs have poorer health outcomes³
 - CDC Recommendations 1 and 5; AMDG Non-Opioid Recommendations; Canadian Recommendations R09 and R10

Prior Authorization

- **In combination** with appropriate **non-opioid medications** and/or **non-pharmacologic therapy**
 - Non-pharmacologic and non-opioid therapies are preferred over opioid therapies¹
 - CDC Recommendation 1; AMDG Acute 1; APS 9.1
- **Baseline assessment of measurable, objective pain scores** and **function scores** for which to demonstrate clinical benefit of opioid therapy
 - Opioids are not considered medically necessary without clinically meaningful improvements in pain and function
 - AMDG Acute 6; Canadian Recommendation R01; APS 6.1



Prior Authorization

- A **complete screening for mental health, substance use disorder, naloxone use**, and informing the patient of urine drug screens to test for presence of opioids and for the absence of other drugs
 - Patients with mental health conditions are more likely to experience misuse, abuse, and overdose²
 - CDC Recommendation 10 and 12; AMDG Subacute 5, 6, 7, and 8; Canadian Recommendation R02; APS 6.1



Prior Authorization

- After **checking the PDMP** for avoiding concurrent use with **benzodiazepines** and for reporting the **previous and new MEDs**
 - Concurrent use of opioids and benzodiazepines increases the risk for overdose¹
 - CDC Recommendation 9 and 11; AMDG Acute 5, Subacute 4; Canadian Recommendation R06

Prior Authorization

- After a **comprehensive documentation** of the **pain condition** and the **patient's medical history**, evaluating the patient for history of, diagnosis of, and patient risk of:
 - addiction, abuse, and overdose of opioids;
 - for adverse events (such as respiratory or cardiac distress, use of sedatives or stimulants);
 - contraindications; and
 - special populations (CKD, COPD, elderly, sleep apnea, etc.)
- Patients with poorly defined pain conditions, at risk for OUD, at risk for adverse events or are members of special populations are at higher risk for poorer outcomes with opioid therapy^{2,3,4}
- CDC Recommendation 3; AMDG Subacute 7; Canadian Recommendation R01 and R02; APS 1.1, 1.2, 1.3



Prior Authorization

- After discussing with the patient **realistic goals of pain management therapy**, such as reasonable and attainable goals for pain, function, adverse events and general “ups and downs”
 - Patient understanding may lead to fewer treatment failures, intolerable adverse events and/or misuse, abuse and overdose⁴
 - CDC Recommendation 2; AMDG Acute 3, 4; Canadian Recommendation R05; APS 2.1



Prior Authorization

- After **discussing discontinuation** as an option, either if the medication is not producing positive health outcomes or if the patient can transition to non-opioid therapies or if the patient is showing signs of substance use disorder
 - Increased length of therapy is associated with increased risk of OUD¹
 - CDC Recommendation 7; AMDG Subacute 3; Canadian Recommendation R12, R13, R15

Prior Authorization

- After a **signed pain contract** that encompasses these requirements for the provider and patient
 - Written pain contracts may be the most effective way of ensuring understanding of opioid therapy and pain and function goals⁴
 - AMDG Chronic 4; Canadian Recommendation R05; APS 2.2



Recommendation:	Rationale	Citation
opioid is an immediate release (IR) formulation or documentation for rationale of an extended-release (ER) opioid	Initiating treatment with ER opioids increases the risk of overdose vs. IR ¹	CDC Recommendation 4; Canadian R8
the anticipated length of treatment (# of days beyond 7 or 3 day supply or # of tablets above the product-specific QLL)	Increased length of therapy associated with increased risk of OUD ¹	CDC Recommendation 6;
trial and failure of non-opioid medications and/or non-pharmacologic therapy and/or lower MED doses trial and failure of physical therapy should include demonstration from the patient on proper technique and compliance with therapy plan	Non-pharmacologic and non-opioid therapies are preferred ¹ ; Pain is multidimensional and requires a multimodal approach ² ; Populations at higher MEDs have poorer health outcomes ³	CDC Recommendation 1; 5; AMDG Non-opioid Recommendations; Canadian R9; R10
in combination with appropriate non-opioid medications and/or non-pharmacologic therapy; (opioids are not first-line therapy)	Non-pharmacologic and non-opioid therapies are preferred ¹ ;	CDC Recommendation 1; AMDG Acute 1 APS 9.1
baseline assessments of measurable, objective pain scores and function scores for which to demonstrate clinical benefit of opioid therapy	Opioids are not considered medically necessary without a clinically meaningful improvement in pain and function	AMDG Acute 6; Canadian R1 APS 5.1
a completed screening for mental health, substance use disorder, naloxone use, and inform patient of urine drug screens to test for presence of opioids and for absence of other drugs	Patients with mental health conditions are more likely to experience misuse, abuse, and overdose ²	CDC Recommendation 10; 12; AMDG Subacute 5; 6; 7; 8 Canadian R2 APS 6.1
after checking the PDMP for avoiding concurrent use with benzodiazepines and for reporting the previous and new MEDs/day	Concurrent use of opioids and benzodiazepines increases the risk for overdose ¹	CDC Recommendations 9; 11; AMDG Acute 5; Subacute 4 Canadian R6
after a comprehensive documentation of the pain condition and patient's medical history, evaluating the patient for the history of, diagnosis of, and patient risk of addiction, abuse, and overdose of opioids, for adverse events (such as respiratory or cardiac distress, use of other sedatives or stimulants), contraindications, and special populations (CKD, COPD, elderly, sleep apnea, etc.)	Patients with poorly defined pain conditions, at risk for OUD, at risk for adverse events or are members of special populations are at higher risk for poorer outcomes with opioid therapy ^{2,3,4}	CDC Recommendation 3; AMDG Subacute 7 Canadian R1; R2 APS 1.1; 1.2; 1.3
after discussing with the patient realistic goals of pain management therapy, such as reasonable and attainable goals for pain, function, side effects, and ups and downs	Patient understanding may lead to fewer treatment failures, intolerable adverse events or misuse, abuse, and overdose ⁴	CDC Recommendation 2; AMDG Acute 3; 4 Canadian R5 APS 2.1
discuss discontinuation as an option, either if medication is not producing positive health outcomes or if patient can transition to non-opioid therapy or if patient is showing signs of substance use disorder	Increased length of therapy associated with increased risk of OUD ¹	CDC Recommendation 7; AMDG Subacute 3; Canadian R12; R13; R15
signed pain contract that encompasses these requirements for the patient	Written pain contracts may be the most effective way of ensuring understanding of opioid therapy ⁴	AMDG Chronic 4; Canadian R5 APS 2.2

Sub-Acute Opioid Prescription Criteria



Sub-acute Opioid Phase

- For approved prescriptions between 4-6 weeks of therapy, prior authorization will include additional criteria to confirm a clinically meaningful benefit of opioid therapy
- Appropriate criteria from the previous prior authorization criteria will still apply:
 - expected length of treatment
 - checking the PDMP and reporting new MEDs
 - continued documentation of patients benefits and risks
 - etc.



Sub-acute Opioid Phase

- Documentation to confirm a **clinically meaningful benefit of opioid therapy**, demonstrated by **objective measures in pain and function** and no increase in risk for negative consequences, such as OUD or adverse events
 - Improvements of at least 30% in pain and function scoring
 - Questions and scales to be provided at **December DUR Board Meeting**
 - Paying for opioids without clinically meaningful improvement in pain and function is not considered medically necessary
 - AMDG Chronic 1, 4, 8

Sub-acute Opioid Phase

- Consolation with a **pain specialist**
 - Pain specialists may be necessary for the proper treatment of complex pain patients
 - Consultation with a pain specialist will be required for any prescription >120 MEDs
 - AMDG Chronic 2; Canadian Recommendation R16



Sub-acute Opioid Phase

- Following the administration of a **urine drug screening**
 - A urine drug screening can help measure compliance with opioid therapy and screen for substance use disorder
 - AMDG Chronic 8; Canadian Recommendation R03; APS 5.2, 5.3
- After a **review of the signed pain contract** and a review of patient compliance and achievement of patient goals
 - Written pain contracts may be the most effective way of ensuring understanding of opioid therapy and pain and function goals
 - AMDG Chronic 4; Canadian Recommendation R05; APS 2.2



Chronic Opioid Prescription Criteria



Chronic Opioid Phase

- Criteria for the Chronic Opioid Phase will be presented at the **December DUR Board Meeting**

Citations

1. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. *MMWR Recomm Rep* 2016;65(No. RR-1):1–49.
2. Agency Medical Director’s Group. Interagency Guideline on Prescribing Opioids for Pain 3rd Edition. AMDG. Olympia, WA. Jun 2015.
3. National Opioid Use Guideline Group (NOUGG). Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain Part B Recommendations for Practice Version 5.6. National Pain Centre. McMaster University. Hamilton, ON. Apr 2010.
4. Chou R, Fanciullo GJ, Fine PG, et al. Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. *The journal of pain : official journal of the American Pain Society*. 2009;10(2):113-130.



Questions?

Ryan Pistoresi, PharmD, MS

Assistant Chief Pharmacy Officer

Clinical Quality and Care Transformation

ryan.pistoresi@hca.wa.gov

Tel: 360-725-0473

