



# Long-Acting Opioids Policy Criteria

Ryan Pistoresi, PharmD, MS  
Assistant Chief Pharmacy Officer  
Clinical Quality and Care Transformation  
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# Background and Goals

- Washington and the United States are facing an opioid epidemic
  - From 2011–2015, there were approximately 700 deaths annually (approximately 2 per day) across Washington state due to opioids<sup>6</sup>
- On October 7, 2016, Governor Jay Inslee signed Executive Order 16-09, for state agencies to address the opioid crisis
  - Goal 1 of Executive Order 16-09 directs state agencies to prevent inappropriate opioid prescribing and to reduce opioid misuse and abuse
- The primary goal of this opioid criteria is to align HCA opioid policies to be consistent with the 2015 AMDG and 2016 CDC opioid guidelines and to reduce the amount of unnecessary opioids in the community
  - This policy is designed to allow access to appropriate opioids that provide clinically-meaningful improvements in pain and function and without unnecessary administrative burden for providers and health systems



# 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](http://www.agencymeddirectors.wa.gov)



**AMDG** agency medical directors' group

A collaboration of state agencies, working together to improve health care quality for Washington State citizens

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 —

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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  
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College of Physicians and Surgeons of Newfoundland and Labrador  
Government of Nunavut  
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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,<sup>1</sup> Gilbert J. Fanciullo,<sup>2</sup> Perry G. Fine,<sup>3</sup> Pamela Davies,<sup>6</sup> Marilee I. Donovan,<sup>7</sup> David A. Fishbain,<sup>8</sup> Aaron M. Gilson,<sup>11</sup> Alexander Kelter,<sup>12</sup> Alexander M. Kirsch,<sup>13</sup> Steven D. Passik,<sup>15</sup> Gavril W. Pasternak,<sup>16</sup> Russell K. Porten,<sup>17</sup> Richard G. Roberts,<sup>19</sup> Knox H. Todd,<sup>20</sup> and Christine M. Tait  
SOCIETY—AMERICAN ACADEMY OF PAIN MEDICINE OPIOIDS GUIDELINE



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# Presentation Overview

- Guideline Recommendations on Initiating Long-Acting Opioids
- Expedited Authorization Criteria for Long-Acting Opioid Prescriptions for **Chronic** Pain Conditions
- Long-Acting Opioid Prior Authorization Criteria

# Guideline Recommendations on Initiating Long-Acting Opioids

# Clinical Guideline Recommendations

- CDC Recommendation 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)
  - Fair-quality evidence found that initiating with ER/LA opioids leads to a **higher risk of overdose** than when initiating with IR opioids<sup>1</sup>.
  - Experts indicated that there is **not enough evidence to determine the safety of using IR 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<sup>1</sup>. **Avoiding the use of IR opioids in combination with ER/LA opioids is preferable<sup>1</sup>.**



# Clinical Guideline Recommendations

- AMDG Guidelines:
  - Duration of opioid action (long-acting vs. short-acting) has been linked to unintentional overdose. Patients receiving long-acting opioids had a 2.5-fold increase risk of overdose compared to those receiving short-acting opioids after adjusting for age, sex, opioid dose and other characteristics<sup>2</sup>.
  - Long-acting formulations should only be prescribed for opioid-tolerant patients who have been taking  $\geq 60$  MED daily for a week or longer<sup>2</sup>.
- Canadian Recommendation R08: During an opioid trial, select the most appropriate opioid for trial therapy using a stepped approach, and consider safety. (Grade C).
  - Controlled-release opioids are available in high-dose formulations which increase the risk of abuse and overdose<sup>3</sup>.
  - When conducting a trial of opioid therapy, start with a low dosage, increase dosage gradually and monitor opioid effectiveness until optimal dose is attained<sup>3</sup>.



# Clinical Guideline Recommendations

- FDA News Release (Sept 10, 2013): FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics
  - The updated indication states that ER/LA opioids are indicated for the management of pain severe enough to **require daily, around-the-clock, long-term opioid treatment** and for which **alternative treatment options are inadequate**<sup>7</sup>.
  - The updated indication further clarifies that, because of the risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death, these drugs should be reserved for use in patients for whom **alternative treatment options** (e.g., non-opioid analgesics or immediate-release opioids) **are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain**; ER/LA opioid analgesics are not indicated for as-needed pain relief<sup>7</sup>.





# Expedited Authorization Criteria for Opioid Prescriptions for Chronic Pain Conditions

# Expedited Authorization Criteria

- Expedited authorizations will allow patients with specific **chronic** medical conditions that require “daily, around-the-clock, long-term opioid treatment” to receive prescriptions for long-acting opioids without prior authorization.
- Chronic medical conditions that qualify for unrestricted EA:
  - Active cancer treatment
  - Hospice/palliative care/end-of-life care



# Prior Authorization Criteria

# Prior Authorization

- Prior authorization will be required if **≤ 7 day supply** of immediate-release opioids have been prescribed in the previous 28 day look-back period.
  - This assumes that the patients are opiate naïve and should start on an immediate-release opioid prior to a long-acting opioid per clinical guidelines<sup>1,2</sup>
- If requested alongside a prior authorization for an immediate-release opioid, the authorizations may use the same information.
- If a prior authorization has been approved for continuing immediate-release opioid prescriptions, then the long-acting opioid will undergo “specific” authorization criteria relevant to ensuring appropriate use.
- Prior authorization is used to ensure opioids are medically necessary and that clinically-meaningful improvements in pain and function are achieved.



# Prior Authorization

- Trial and failure of **non-opioid medications** and/or **non-pharmacologic therapy**
  - Non-pharmacologic and non-opioid therapies are preferred over opioid therapies<sup>1</sup>
  - Pain is multidimensional and requires a multimodal approach<sup>2</sup>
  - Populations at higher MEDs have poorer health outcomes<sup>3</sup>
  - 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 therapies<sup>1</sup>
  - 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 overdose<sup>2</sup>
  - 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 concurrent use of **benzodiazepines** and for reporting the **previous and new MEDs**
  - Concurrent use of opioids and benzodiazepines increases the risk for overdose<sup>1</sup>
  - 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 or other drug-drug interactions) and contraindications;
  - 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<sup>2,3,4</sup>
- 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 overdose<sup>4</sup>
  - 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 OUD<sup>1</sup>
  - 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 goals<sup>4</sup>
  - AMDG Chronic 4; Canadian Recommendation R05; APS 2.2



# Prior Authorization

- Justification for **extended-release opioid**
  - Initiating treatment with ER opioids increases the risk of overdose compared to IR opioids<sup>1</sup>
  - 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 OUD<sup>1</sup>
  - CDC Recommendation 6



<b>Recommendation:</b>	<b>Rationale</b>	<b>Citation</b>
<p>trial and failure of non-opioid medications and/or non-pharmacologic therapy</p> <p>trial and failure of physical therapy should include demonstration from the patient on proper technique and compliance with therapy plan</p>	<p>Non-pharmacologic and non-opioid therapies are preferred<sup>1</sup>;</p> <p>Pain is multidimensional and requires a multimodal approach<sup>2</sup>;</p> <p>Populations at higher MEDs have poorer health outcomes<sup>3</sup></p>	<p>CDC Recommendation 1; 5; AMDG Non-opioid Recommendations; Canadian R9; R10</p>
<p>in combination with appropriate non-opioid medications and/or non-pharmacologic therapy; (opioids are not first-line therapy)</p>	<p>Non-pharmacologic and non-opioid therapies are preferred<sup>1</sup>;</p>	<p>CDC Recommendation 1; AMDG Acute 1 APS 9.1</p>
<p>baseline assessments of measurable, objective pain scores and function scores for which to demonstrate clinical benefit of opioid therapy</p>	<p>Opioids are not considered medically necessary without a clinically meaningful improvement in pain and function</p>	<p>AMDG Acute 6; Canadian R1 APS 5.1</p>
<p>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</p>	<p>Patients with mental health conditions are more likely to experience misuse, abuse, and overdose<sup>2</sup></p>	<p>CDC Recommendation 10; 12; AMDG Subacute 5; 6; 7; 8 Canadian R2 APS 6.1</p>
<p>after checking the PDMP for avoiding concurrent use with benzodiazepines and for reporting the previous and new MEDs/day</p>	<p>Concurrent use of opioids and benzodiazepines increases the risk for overdose<sup>1</sup></p>	<p>CDC Recommendations 9; 11; AMDG Acute 5; Subacute 4 Canadian R6</p>
<p>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.)</p>	<p>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<sup>2,3,4</sup></p>	<p>CDC Recommendation 3; AMDG Subacute 7 Canadian R1; R2 APS 1.1; 1.2; 1.3</p>
<p>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</p>	<p>Patient understanding may lead to fewer treatment failures, intolerable adverse events or misuse, abuse, and overdose<sup>4</sup></p>	<p>CDC Recommendation 2; AMDG Acute 3; 4 Canadian R5 APS 2.1</p>
<p>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</p>	<p>Increased length of therapy associated with increased risk of OUD<sup>1</sup></p>	<p>CDC Recommendation 7; AMDG Subacute 3; Canadian R12; R13; R15</p>
<p>signed pain contract that encompasses these requirements for the patient</p>	<p>Written pain contracts may be the most effective way of ensuring understanding of opioid therapy<sup>4</sup></p>	<p>AMDG Chronic 4; Canadian R5 APS 2.2</p>
<p>opioid is an immediate release (IR) formulation or documentation for rationale of an extended-release (ER) opioid</p>	<p>Initiating treatment with ER opioids increases the risk of overdose vs. IR<sup>1</sup></p>	<p>CDC Recommendation 4; Canadian R8</p>
<p>the anticipated length of treatment (# of days beyond 7 or 3 day supply or # of tablets above the product-specific QLL)</p>	<p>Increased length of therapy associated with increased risk of OUD<sup>1</sup></p>	<p>CDC Recommendation 6;</p>

# Authorization Criteria Specific to Long-Acting Opioids



# Specific Authorization for LAOs

- Authorization for the approval of long-acting opioids following the approval of immediate-release opioids will require:
  - Documented inadequate response to IR opioid therapy
  - The expected duration of treatment for both IR and/or ER opioids
  - Information on how the strength/dose/frequency of the immediate-release opioid will change, including a new MED





# Specific Authorization for LAOs

- Approval for the use of long-acting opioids will also require the following criteria:
  - Trial and failure of all preferred products prior to approval of a non-preferred product
  - Maximum of 1 unit per day for 24-hour oral formulations, maximum of 2 units per day for all other oral formulations.



# 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.
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5. Maughan BC, Hersh EV, Shofer FS, Wanner KJ, Archer E, Carrasco LR, Rhodes KV. Unused opioid analgesics and drug disposal following outpatient dental surgery: A randomized controlled trial. Drug Alcohol Depend. 2016 Sep 16.
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7. FDA. FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics. Sep 10, 2013. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367726.htm>



# Questions?

Ryan Pistoiresi, PharmD, MS

Assistant Chief Pharmacy Officer

Clinical Quality and Care Transformation

[ryan.pistoiresi@hca.wa.gov](mailto:ryan.pistoiresi@hca.wa.gov)

Tel: 360-725-0473