Opioid Policy Criteria for Children and Adolescents

Ryan Pistoresi, PharmD, MS
Assistant Chief Pharmacy Officer
Clinical Quality and Care Transformation
January 26, 2016
Background and Goals

• Washington state and the United States are facing an opioid epidemic
  – Between 2011–2015, there were approximately 700 deaths annually due to opioids (approximately 2 per day) across Washington state

• 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 for the general population, “especially adolescents”

• On December 16, 2016, the CDC published in its weekly MMWR data and commentary on “the need for continued prevention efforts around prescription opioids”.2
  – The MMWR also includes a note that a recent study found no evidence between efforts to reduce opioid prescribing and heroin overdoses but that they may reduce exposure.
Background and Goals

• In 2012, Blue Cross Blue Shield of Massachusetts, an insurer of 2.8 million, implemented a policy limiting quantities of opioids for acute pain and avoiding opioids as first-line therapies for chronic pain in\(^3\).
  • The program resulted in a 15% decrease in the average monthly prescribing rate (34 prescriptions per 1000 members per month to 29 prescriptions per 1000 members per month) and a 15% decrease in the average percentage of members with prescriptions per month (2.58% to 2.24%)\(^3\).

• Other states and health plans around the US are developing policies for opioids addressing the opioid epidemic.
  • In May, 2016, Maine passed a state law (SP0671 – LD 1646) that limits prescriptions to a 7 day supply for acute pain, no more than a 30 days supply for chronic pain, and no more than 110 MMEs per day\(^4\).
  • In June, 2016, Rhode Island passed a state law (H 8224 SUBSTITUTE A) limiting opiate prescriptions to 30 MMEs total daily with a maximum total of 20 doses\(^5\).
  • Other states (MA, NY) and payers are implementing updated opioid policies
Background and Goals

• 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

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

Interagency Guideline on Prescribing Opioids for Pain

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

American Pain Society
Presentation Overview

• Initial Opioid Prescriptions for **Opiate Naïve** Children and Adolescents
  – Recommended Criteria

• Expedited Authorization Criteria for **Acute** Pain Conditions in Children and Adolescents

• Expedited Authorization Criteria for **Chronic** Pain Conditions in Children and Adolescents

• Prior Authorization Criteria
Initial Opioid Prescriptions for Opiate Naïve Children and Adolescents

Recommended Criteria
Recommended Criteria

• ≤ 18 tablets per prescription for patients age 20 and younger

• ≤ 3 day supply

• ≤ 6 tablets per day**
  **Liquids will be limited to 6 dosages per day. High potency opioids will be limited to 90 MEDs

• immediate-release (IR) dosage form
Rationale for Recommended Criteria

• ≤ 18 tablets per prescription for patients age 20 and younger

• ≤ 3 day supply
  – CDC Recommendation 6 states increased length of therapy for treatment of acute pain is associated with increased risk of OUD\(^1\).

  – “3 days or less will often be sufficient; more than 7 days will rarely be needed.” \(^6\)

  – These limits will reduce the amount of unnecessary opioids dispensed to youth.
Rationale for Recommended Criteria

- ≤ 18 tablets per prescription for patients age 20 and younger
  - Washington Health Alliance and Bree Collaborative released a call to action for health insurance plans to consider a limit of 3 days or 10 pills for youth.\textsuperscript{12}
  
  - Data from the DOH show acute opioid prescribing to youth in WA is for a median #20 and 3 day supply. Approximately 58.2\% of prescriptions with known specialists are prescribed by dentists.\textsuperscript{13}
    
  - 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 criteria\textsuperscript{8}.
    
  - Another study on upper extremity surgery patients (n=250) found that patients were prescribed a mean 29 pills but consumed only a mean of 10 opioid pills. This means a mean 19 pills per subject were reported unused, resulting in 4,639 leftover tablets. Over half of the subjects reported taking the opioid medication for 2 days or less\textsuperscript{11}. 
Rationale for Recommended Criteria

• ≤ 6 tablets per day
  – CDC Recommendation 5 states that clinicians should prescribe the lowest effective dose and to use caution > 50 MEDs.
  – Canadian Recommendations R09 supports this recommendations as populations at higher MEDs have poorer health outcomes.

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)
Rationale for Recommended Criteria

• **≤ 6 tablets per day**

  – The 6 tablet threshold is designed to limit the number of units (pills) 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 for a 7-day supply. A 50 MED limit for hydrocodone 2.5mg would be 140 tablets for a 7-day supply!

  – A 90 MED limit is being considered for high-potency opioids, which aligns with the CDC guidelines.
Rationale for Recommended Criteria

• Immediate-release (IR) dosage form

  – CDC Recommendation 4 recommends that an opioid trial begin with an immediate-release opioid⁶.

  – Canadian Recommendation R08 supports this recommendation by recommending immediate-release opioids with the least potential for abuse or OUD⁷.
# Rationale for Recommended Criteria

## Best-Practices to Encourage:

<table>
<thead>
<tr>
<th>Best-Practices to Encourage:</th>
<th>Citations</th>
</tr>
</thead>
<tbody>
<tr>
<td>if possible, a <strong>trial and failure of non-opioid medications and/or non-pharmacologic therapy</strong> prior to prescribing opioids</td>
<td><strong>CDC Recommendation 1; 5; AMDG Non-opioid; Canadian R9; R10</strong></td>
</tr>
<tr>
<td>in <strong>combination with appropriate non-opioid medications and/or non-pharmacologic therapy</strong>: (opioids are not first-line therapy)</td>
<td><strong>CDC Recommendation 1; AMDG Acute 1 APS 9.1</strong></td>
</tr>
<tr>
<td><strong>baseline assessments of measurable, objective pain scores and function scores</strong> for which to demonstrate clinical benefit of opioid therapy</td>
<td><strong>AMDG Acute 6; Canadian R1 APS 5.1</strong></td>
</tr>
<tr>
<td>a completed <strong>screening for mental health, substance use disorder, and naloxone use</strong></td>
<td><strong>CDC Recommendation 10; 12; AMDG Subacute 5; 6; 7; 8 Canadian R2 APS 6.1</strong></td>
</tr>
<tr>
<td>after <strong>checking the PDMP for concurrent use of benzodiazepines</strong></td>
<td><strong>CDC Recommendations 9; 11; AMDG Acute 5; Subacute 4 Canadian R6</strong></td>
</tr>
<tr>
<td>after a <strong>comprehensive documentation of the pain condition and patient’s medical history</strong>, evaluating the patient for the history of, diagnosis of, and patient risk of addiction, abuse, and overdose of opioids, for <strong>adverse events</strong> (such as respiratory or cardiac distress, use of other sedatives or stimulants), <strong>contraindications</strong>, and <strong>special populations</strong> (CKD, COPD, elderly, sleep apnea, etc.)</td>
<td><strong>CDC Recommendation 3; AMDG Subacute 7 Canadian R1; R2 APS 1.1; 1.2; 1.3</strong></td>
</tr>
</tbody>
</table>
Expedited Authorization Criteria for Acute Pain Conditions for Children and Adolescents
Expedited Authorization Criteria

- Expedited authorizations will allow patients with specific **acute** medical conditions to receive prescriptions above the recommended criteria without prior authorization
  - **Up to 14 days** and **up to 84 tablets**

- Examples of acute medical conditions for unrestricted EA:
  - Sick cell anemia crises
  - Severe burns and major trauma
  - Intra-articular bleeding
  - Acute fractures or obstructions (biliary tree, kidney/ureter)
  - Select surgeries
Expedited Authorization Criteria for Chronic Pain Conditions for Children and Adolescents
Expedited Authorization Criteria

• Expedited authorizations will allow patients with specific **chronic** medical conditions to receive prescriptions above the recommended criteria without prior authorization
  
  – **No limits** (prescriptions may be > 6 tablets)

• Chronic medical conditions that qualify for unrestricted EA:
  
  – Active cancer treatment
  
  – Hospice/palliative care/end-of-life care
Prior Authorization Criteria
Prior Authorization

• For an initial prescription that does not meet the recommended criteria and that are not dispensed within the recommended criteria are subject to prior authorization.

• Prior authorization will be required for continuing opioid prescriptions following 6-weeks of therapy or if prescribed above 90 MEDs. Prior authorization will not be required for continuing opioid prescriptions so long as they are prescribed within the recommended criteria from slide 8.

• 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**
- **In combination** with appropriate **non-opioid medications** and/or **non-pharmacologic therapy**
- **Baseline assessment** of measurable, objective pain scores and function scores for which to demonstrate clinical benefit of opioid therapy
- 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
- After **checking the PDMP** for concurrent use of benzodiazepines and for reporting the previous and new MEDs
- After a **comprehensive documentation** of the pain condition and the patient’s medical history
- 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”
- 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
- Anticipated **length of treatment** (# of days or the # of tablets above the quantity level limit)
- After a **signed pain contract** that encompasses these requirements for the provider and patient
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\(^6\)
  
  – Pain is multidimensional and requires a multimodal approach\(^9\)
  
  – Populations at higher MEDs have poorer health outcomes\(^7\)

  – 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
  
  – 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\(^9\)
  – 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\(^6\)
  – 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\textsuperscript{7,9,10}

– 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\(^\text{10}\)
  - **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$^6$
  - CDC Recommendation 7; AMDG Subacute 3; Canadian Recommendation R12, R13, R15
Prior Authorization

• Anticipated **length of treatment** (# of days or the # of tablets above the quantity level limit)
  – Increased length of therapy is associated with increased risk of OUD\textsuperscript{6}
  – **CDC** Recommendation 6

• 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\textsuperscript{10}
  – **AMDG** Chronic 4; **Canadian** Recommendation R05; **APS** 2.2


Questions?

Ryan Pistoresi, PharmD, MS
Assistant Chief Pharmacy Officer
Clinical Quality and Care Transformation
ryan.pistoresi@hca.wa.gov
Tel: 360-725-0473