** Fee-For-Service Pharmacy Provider Notice #230 – Opioid Class Criteria Changes **

August 03, 2018

Across the United States, the abuse, misuse and diversion of prescription and illicit opioids has been declared a public health emergency due to increasing rates of overdose deaths. According to the Centers for Disease Control and Prevention (CDC), in 2016 Kentucky was listed as one of the top five states that had the highest rates of death due to drug overdose. In 2017, House Bill 333 was passed, prompting the Kentucky Board of Medical Licensure (KBML) to update 201 KAR 9:260 to state that "for the purposes of treating pain as or related to an acute medical condition, a physician shall not prescribe more than a 3 day supply of a Schedule II controlled substance" subject to certain exceptions.

In continued response to the opioid crisis, the Department for Medicaid Services (DMS) and its Pharmacy and Therapeutics Committee proposed changes to the Fee-For-Service (FFS) Pharmacy Program's prior authorization requirements for opioid prescriptions. The recommendations were adopted by the Commissioner of the Department for Medicaid Services of the Cabinet for Health and Family Services by order dated May 25, 2018. The new clinical criteria are scheduled to take effect on **September 4, 2018**.

The focus of the final decisions regarding opioids is to limit the dose and duration of acute pain treatment with opioids and better manage the transition from acute to chronic use, since this is critical to reducing long-term opioid use. The update to the prior authorization requirements for opioid prescriptions aligns with recommendations of the CDC around safe and appropriate opioid prescribing as well as 201 KAR 9:260 and other state regulations. Appended to this document is the CDC checklist for prescribing opioids for chronic pain, which serves as a quick reference guide for initiating and maintaining opioid therapy for chronic, non-cancer pain.

We know this may represent a significant change for your practice and your patients; we remain available for any questions you may have before the go live date. Our collaborative goal is to ensure members receive appropriate, evidence-based pain treatment, while mitigating damage to Kentuckians from opioid medications.

Long and Short-Acting Opioid Prior Authorization Class Criteria

Note: Class criteria will be waived for members receiving hospice/palliative/end-of-life care or have a diagnosis of active cancer or sickle cell anemia. Requests for these members will be approved for 1 year.

Class Criteria for Initial Approval (exceptions apply to short-acting opioids for acute pain; additional criteria may also apply to specific formulation)

- Prescriber has evaluated the member for risk of diversion, harm or misuse:
  - Prescriber attests that KASPER report for the past 12 months has been reviewed; AND
  - Prescriber submits urine drug screen (UDS) results dated within the past 30 days; AND

- If UDS is positive for illicit or unexpected substances, prescriber attests that naloxone was or will be prescribed; AND
- Prescriber submits an assessment of baseline pain and function (e.g., PEG scale); AND
- Prescriber attestation or documentation that non-opioid therapies (e.g., exercise therapy, cognitive behavioral therapy, NSAIDs, etc.) have been tried and/or are being used and optimized as appropriate; AND
- For females of child-bearing age, prescriber attests that the member has been counseled regarding the risks of becoming pregnant while on this medication, including the risk of neonatal abstinence syndrome (NAS); AND
- Patient does NOT have respiratory depression, acute or severe bronchial asthma, or hypercarbia; AND
- Patient does NOT have known or suspected GI obstruction (e.g., paralytic ileus); AND
- Up to 1 long-acting opioid and 1 short-acting opioid may be used at a time.

Class Criteria for High Morphine Milligram Equivalent (MME) Requests – Over 90 MME per Day

- Additional criteria shall apply for NEW requests where the cumulative opioid dose across all prescriptions is > 90 morphine milligram equivalents (MME):
  - Note: Buprenorphine products (for opioid addiction treatment or pain) are not assigned an MME value and will not be included in the calculation.
  - Prescriber is, or has proof of consultation with, a Pain Management Specialist OR specialist in an appropriate discipline (e.g., orthopedist, neurologist, spine specialist, etc.) for evaluation of the source of pain and/or treatment of any underlying conditions; AND
  - Prescriber must submit clinical justification for exceeding 90 MME/day; AND
  - Prescriber attests that a naloxone prescription and associated counseling on its use was, or will be, *offered* to the member.

Class Criteria for Approval of Very High MME Requests – Over 200 MME per Day

- Additional criteria shall apply to ANY request where the cumulative opioid dose across all prescriptions is > 200 MME/day:
  - Note: Buprenorphine products (for opioid addiction treatment or pain) are not assigned an MME value and will not be included in the calculation.
  - Prescriber is, or has proof of consultation with, a Pain Management Specialist; AND
  - Prescriber submits clinical justification for exceeding 200 MME/day; AND
  - Prescriber submits documentation (e.g., progress notes) showing attempts and/or plans to taper below 200 MME/day as well as other non-opioid components (e.g., NSAIDs, physical therapy, etc.) of the treatment plan; AND
  - Prescriber attests that a naloxone prescription and associated counseling on its use, was or will be *given* to the member.

Class Criteria for Opioids and Benzodiazepines

- Additional criteria shall apply when opioids are prescribed concurrently with benzodiazepines and/or KASPER report shows a benzodiazepine prescription in the past 12 months:
  - Prescriber must submit clinical justification for the concurrent use of benzodiazepines and opioids; AND
  - Prescriber attests that the member and/or caregiver(s) have been, or will be, counseled about the increased risks of slowed or difficult breathing and/or excessive sedation, and the associated signs and symptoms; AND

- Prescriber attests that a naloxone prescription and associated counseling on its use, was or will be *given* to the member.

Class Criteria for Naloxone Prescribing

- Prescriber attests that a naloxone prescription and associated counseling on its use was, or will be, *offered* to the member when any of the following are true (e.g., found on KASPER report, medication list, or diagnosis list):
  - Opioid(s) is/are concurrently prescribed with a skeletal muscle relaxant (e.g., cyclobenzaprine); OR
  - Opioid(s) is/are concurrently prescribed with a sedative hypnotic (e.g., zolpidem); OR
  - Opioid(s) is/are concurrently prescribed with gabapentin; OR
  - Member has a history of opioid or other controlled substance overdose; OR
  - Member has a history of substance use disorder (SUD).

Class Criteria for Renewal

- Prescriber must submit proof of monitoring for evidence of diversion, harm, and misuse:
  - Attest that KASPER report has been checked within the past 3 months; AND
  - Submit most recent urine drug screen (UDS) results dated within the past 30 days; AND
  - Prescriber explanation is required if UDS is positive for illicit or unexpected substances; AND
  - If UDS is positive for illicit or unexpected substances, prescriber attests that naloxone was or will be prescribed.
- Prescriber must submit an assessment of current pain and function (e.g., PEG scale).; AND
  - Recipient must demonstrate a 30% improvement from baseline to continue current dose.
- Prescriber must report whether patient has required use of opioid rescue medication (e.g., naloxone) or has been hospitalized or otherwise treated for opioid or other controlled substance overdose in the past 6 months.

If member has opioid overdose or use of naloxone within the past 6 months, the prescriber must submit a plan for preventing future overdoses (e.g., dose reduction).

New Long-Acting Opioid Prior Authorization Criteria

Require PA for all long-acting opioids.

Length of Authorization: 6 months (1 year for active cancer, sickle cell anemia or hospice/palliative care)

Criteria for Approval:

- All opioid class criteria must be met; AND
- Patient has severe pain requiring daily, around-the-clock, long-term pain management as evidenced by:
  - Pain lasting > 3 consecutive months; AND
  - Trial and failure within the past 90 days of 1 non-opioid analgesic (i.e., NSAIDs, APAP) at maximum tolerated doses without pain relief and/or functional improvement; AND
  - Trial and failure within the past 90 days of at least 1 short-acting opioid analgesic at maximum tolerated doses without adequate relief of pain.

Renewal Criteria:

All opioid PA class criteria for renewal must be met.

New Short-Acting Opioid Prior Authorization Criteria

1. Minimum age of 18 years on codeine- and tramadol-containing products.
2. Minimum age of 18 years for any narcotic-containing cough and cold products.
3. For opioid-naïve recipients (defined as ≤ 14 days of opioid use in the past 90 days of pharmacy claims), require PA for any short-acting narcotic where:
   a. The claim is for > 7 day supply for members ≥ 18 years old; OR
   b. The claim is for > 3 day supply for members < 18 years old; OR
   c. The claim brings the cumulative supply of short-acting opioids in the past 90 days to > 14 days; OR
   d. Product is ≥ 30 MME in a single dosing unit (e.g., hydromorphone 8 mg tablet) or a concentrated liquid (e.g., morphine sulfate 20 mg/mL).

Length of Authorization: 30 days
Criteria for Approval:

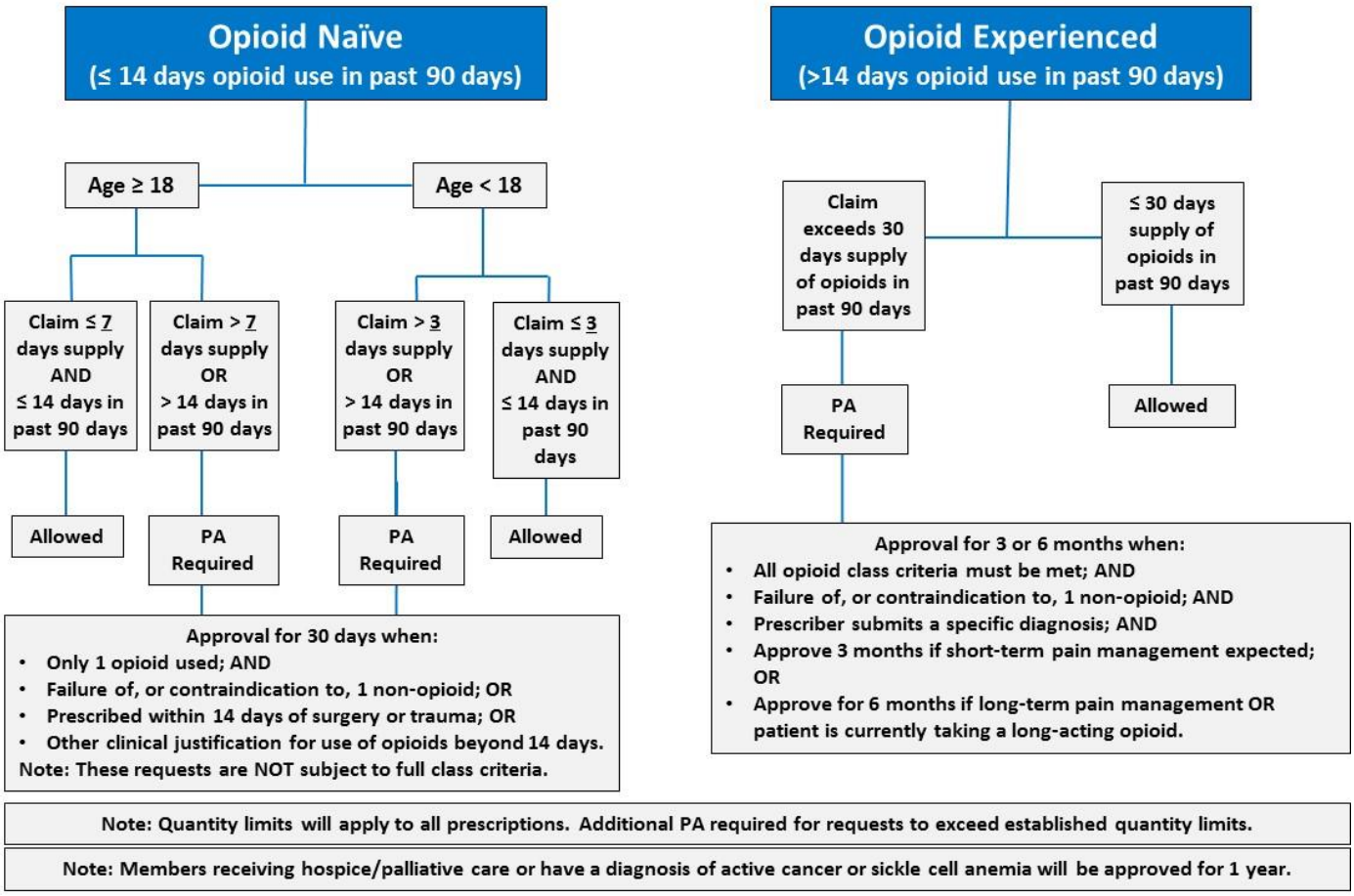
- **Note**: Approve 1 year for active cancer, sickle cell anemia, and/or hospice/palliative care.
- **Note**: Prescriber must submit PA request.
- Only 1 short-acting opioid will be used at a time; AND
- Trial and failure of, or contraindication to, at least 1 non-opioid pain medication (e.g., APAP, NSAIDs); OR
- Medication is prescribed by a treating physician within 14 days of:
  - A major surgery, any operative or invasive procedure or a delivery; OR
  - A significant trauma, being any acute blunt, blast, or penetrating bodily injury that has a risk of death, physical disability, or impairment; OR
  - Other clinical justification as to why treatment with opioids should extend beyond 14 days.
- If the request is for a high strength or concentrated dosage form, the prescriber must submit rationale why lower strength or less-concentrated products cannot be used.
- Additional clinical justification will be required for doses that exceed quantity limits.

4. For recipients with a history of opioid use (> 14 days of opioid use in the past 90 days of pharmacy claims), require PA for any claims where the incoming claim will exceed 30 days of opioid use in the past 90 days.

Length of Authorization: 3 or 6 months
Criteria for Approval:

- All opioid PA class criteria must be met; AND
- Trial and failure of, or contraindication to, at least 1 non-opioid pain medication (e.g., APAP, NSAIDs) within the past 6 months; AND
- Prescriber must submit a diagnosis more specific than pain:
  - If short-term pain management is expected/indicated; approve for 3 months; OR
  - If long-term (e.g., > 3 months) pain management is expected/indicated OR patient is currently taking a long-acting narcotic; approve for 6 months.

Criteria for Renewal:
All opioid class criteria for renewal must be met.



5. All short-acting opioid users will be subject to a quantity per day limit consistent with ≤ 90 morphine milligram equivalents (MME) per day and/or 4,000 mg per day of acetaminophen (APAP). The quantity limit cannot be overridden at point-of-sale; prescriber must submit a PA.

Proposed Quantity Limits for Oral Dosage Forms

Drug and Strength	Maximum Quantity per Day
Codeine-containing products:	
12 mg per 5 mL liquids	240 mL (160 mL if w/ APAP)
15 mg	20 tablets (12 if w/ APAP)
30 mg	20 tablets (12 if w/ APAP)
60 mg	10 tablets
Dihydrocodeine-containing tablets (16 mg)	12 tablets

Drug and Strength	Maximum Quantity per Day
Hydrocodone-containing products:	
7.5 mg per 15 mL solution	180 mL
10 mg per 15 mL solution	120 mL
2.5 mg tablets	12 tablets
5 mg tablets	12 tablets
7.5 mg tablets	12 tablets
10 mg tablets	8 tablets
Hydromorphone:	
1 mg per mL solution	20 mL
3 mg suppository	6 suppositories
2 mg tablet	10 tablets
4 mg tablet	5 tablets
8 mg tablet	PA required
Levorphanol 2mg tablets	4 tablets
Meperidine:	
50 mg per 5 mL solution	90 mL
50 mg tablet	18 tablets
100 mg tablet	9 tablets
Morphine sulfate:	
10 mg per 5 mL solution	45 mL
20 mg per 5 mL solution	22.5 mL
20 mg per mL solution	Require PA
10 mg suppositories	8 suppositories
20 mg suppositories	4 suppositories
15 mg IR tablets	6 tablets
30 mg IR tablets	Require PA
Oxycodone-containing products:	
5 mg per 5 mL solution	60 mL
2.5 mg	12 tablets
5 mg	12 tablets
7.5 mg	8 tablets
10 mg	6 tablets
15 mg	4 tablets
20 mg & 30 mg	Require PA
Oxymorphone tablets:	
5 mg	6 tablets
10 mg	3 tablets
Pentazocine-containing tablets (50 mg)	4 tablets

Drug and Strength	Maximum Quantity per Day
Tapentadol (Nucynta) tablets: 50 mg 75 mg & 100 mg	 4 tablets Require PA
Tramadol-containing products: 37.5 mg 50 mg	 8 tablets 8 tablets

For additional resources please refer to the Factsheet posted by the CDC on the Guidelines for Prescribing Opioids for Chronic Pain at https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf or the CDC website for Opioid Overdose at https://www.cdc.gov/drugoverdose/index.html.

To review the complete summary of the final PDL selections and new products to market updates and changes, please refer to the "Commissioner's Final Decisions from May 17, 2018" posted on the provider web portal at: https://kyportal.magellanhealth.com (by clicking the Resources/Documents/Committees/P&T tabs).

Thank you for helping Kentucky Medicaid members maintain access to prescription coverage by selecting drugs on the preferred drug list whenever possible. Please contact Magellan Medicaid Administration at kyproviders@magellanhealth.com for any additional information or questions you may have.

Sincerely,

Jade Range, CPhT

Jade Range, CPhT
Contracts Manager
kyproviders@magellanhealth.com

Kentucky Medicaid Fee-for-Service Pharmacy Program's Contact Information		
Clinical Support Center	1-800-477-3071 Sunday – Saturday 24 hours a day	Please contact the Clinical Support Center to request a prior authorization (PA) or to check the status of a request. **NOTE: The only drugs that are now required to be submitted via fax are Brand Medically Necessary, Buprenorphine products, Synagis®, and Zyvox®.**
Pharmacy Support Center	1-800-432-7005 Sunday – Saturday 24 hours a day	Please contact the Pharmacy Support Center when claims assistance is required. Timely filing, lock-in, and early refill (ER) overrides can be obtained through this Call Center.
Provider Services	1-877-838-5085 Monday – Friday 8:00 a.m. – 4:30 p.m.	Please contact Provider Services if you have questions about enrollment or when updating your license or bank information.
Member Services	1-800-635-2570 Monday – Friday 8:00 a.m. – 5:00 p.m.	Please contact Member Services if you are a member or if you as the provider have questions regarding the member's benefits or eligibility coverage dates.