JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS105
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		Approval Date	07/08/2024
	Subject **PPMCO Short-Acting & Long-Acting Opioids**	*Supersedes Date*	N/A
		Page	1 of 6

This document applies to the following Participating Organizations:

Priority Partners

Keywords: opioids

Table of Contents		Page Number
I.	**POLICY**	**1**
II.	**POLICY CRITERIA**	**1**
	A. Non-Formulary Opioids Requests	**1**
	B. Formulary Long-acting Opioids Prior Authorization Requests	**3**
	C. Opioid Quantity Exception Requests	**3**
	D. 7-Day Opioid Supply Exception Requests	**4**
	E. Morphine Milligram Equivalent (MME) Exception Requests	**4**
III.	**OPIOID QUANTITY LIMITS**	**4**
IV.	**AUTHORIZATION PERIOD/LIMITATIONS**	**5**
V.	**EXCLUSIONS**	**5**
VI.	**REFERENCES**	**5**
VII.	**APPROVALS**	**5**

I. POLICY

1. Short-acting & Long-Acting narcotic analgesics (opioids) may be subject to prior authorization and/or quantity limits to ensure safe dosing and appropriate use consistent with FDA and CDC recommendations. These products require prior authorization for doses greater than the established quantity limit. The process for initiating a prior authorization request can be found in policy PHARM 20.
2. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.

II. POLICY CRITERIA

A. **Non-Formulary Opioids Requests**:

1. **Non-formulary short-acting opioids** may be approved when ALL the following criteria are met:
   a. Documentation has been submitted showing the following:
      I. Diagnosis of breakthrough pain while the patient is opioid tolerant, and receiving opioid therapy for underlying persistent cancer pain
      II. Patient is utilizing an adequate dosing of a long-acting (maintenance, around-the-clock) opioid
      III. Patient is able to comply with child-safe storage and disposal requirements
      IV. Patient has evidence of medical necessity supported by ONE of the following:
         i. Therapeutic failure of two or more adequately dosed short-acting formulary opioids within the previous 180 days per pharmacy claims
         ii. Allergy to one formulary drug
         iii. Successful drug maintenance on the requested medication when changing to an alternative drug may produce a potential health risk
      V. Prescriber has attested to ALL the following:

i. Prescriber has reviewed controlled substance prescriptions in the Prescription Drug Monitoring Program through CRISP (Chesapeake Regional Information System) for prescriptions from other providers
ii. Naloxone prescription has been provided or offered to patient/patient's household.
iii. Patient will have random urine drug screen
A. *Caveat: Urine drug screening is not applicable for patients being discharged from inpatient facility and transitioning to outpatient care
iv. A Patient-Prescriber Pain Management/Opioid Treatment Agreement/Contract has been signed, and placed in the patient's medical record
A. *Caveats: Patient-Prescriber is not applicable for patients being discharged from inpatient facility and transitioning to outpatient care. However, provider must attest to ALL of the following:
1. The risks and benefits associated with opioid use have been discussed with the patient/ patient's household
2. One of the following:
a. The prescribed treatment will be for 30 days or less
b. The need for further opioid use will be re-evaluated by an outpatient provider within 30 days

2. **Non-formulary long-acting opioids** may be approved when ALL the following criteria are met:
a. Documentation has been submitted showing the following:
I. Patient has evidence of medical necessity supported by ONE of the following:
i. Therapeutic failure of two or more adequately dosed long-acting formulary opioids within the previous 180 days per pharmacy claims
ii. Allergy to one formulary drug
iii. Successful drug maintenance on the requested medication when changing to an alternative drug may produce a potential health risk
II. Prescriber has attested to ALL the following:
i. Prescriber has reviewed controlled substance prescriptions in the Prescription Drug Monitoring Program through CRISP (Chesapeake Regional Information System) for prescriptions from other providers
ii. Naloxone prescription has been provided or offered to patient/patient's household.
iii. Patient will have random urine drug screens
A. *Caveat: Urine drug screening is not applicable for patients being discharged from inpatient facility and transitioning to outpatient care
iv. A Patient-Prescriber Pain Management/Opioid Treatment Agreement/Contract has been signed, and placed in the patient's medical record
A. *Caveats: Patient-Prescriber is not applicable for patients being discharged from inpatient facility and transitioning to outpatient care. However, provider must attest to ALL of the following:
1. The risks and benefits associated with opioid use have been discussed with the patient/ patient's household
2. One of the following:
a. The prescribed treatment will be for 30 days or less

b. The need for further opioid use will be re-evaluated by an outpatient provider within 30 days

B. **Formulary Long-acting Opioids Prior Authorization Requests** (Formulary medications can be found here: https://www.ppmco.org/wp-content/uploads/2023/03/ppmco_formulary.pdf):
1. Formulary long-acting opioid products may be approved when the following criteria are met:
   a. Documentation of ONE of the following:
      I. Patient has a diagnosis of cancer, sickle cell anemia, is in hospice care, in long-term care, or palliative care (diagnosis code Z51.5)
      II. Prescriber has attested to ALL the following:
         i. Prescriber has reviewed controlled substance prescriptions in the Prescription Drug Monitoring Program through CRISP (Chesapeake Regional Information System) for prescriptions from other providers
         ii. Naloxone prescription has been provided or offered to patient/patient's household.
         iii. Patient will have random urine drug screens
            A. *Caveat: Urine drug screening is not applicable for patients being discharged from inpatient facility and transitioning to outpatient care
         iv. A Patient-Prescriber Pain Management/Opioid Treatment Agreement/Contract has been signed, and placed in the patient's medical record
            A. *Caveats: Patient-Prescriber is not applicable for patients being discharged from inpatient facility and transitioning to outpatient care. However, provider must attest to ALL of the following:
               1. The risks and benefits associated with opioid use have been discussed with the patient/patient's household
               2. One of the following:
                  a. The prescribed treatment will be for 30 days or less
                  b. The need for further opioid use will be re-evaluated by an outpatient provider within 30 days

C. **Opioid Quantity Exception Requests** for quantities greater than Plan's Quantity Limits (QL) (*Quantity Limit of formulary medications can be found here: https://www.ppmco.org/wp-content/uploads/2023/03/ppmco_formulary.pdf):
1. Quantities of short-acting opioids greater than the Plan's QLs may be approved when ALL the following criteria are met:
   a. Documentation has been submitted showing the following:
      I. Documented diagnosis of severe chronic pain that requires a continuous, around-the-clock opioid analgesic for an extended period of time
      II. The patient has received a recent, documented pain management assessment by a physician
      III. The patient has tried and failed the recommended dosage interval of the requested medication
      IV. The requested dose does not exceed FDA recommendations or accepted clinical dosing guidelines
      V. The patient must be using an adequate dose of a long-acting (maintenance, around-the-clock) opioid
      VI. Other pain management regimens have been inadequate
      VII. Prescriber has attested to ALL the following:
         i. Prescriber has reviewed controlled substance prescriptions in the Prescription Drug Monitoring Program through CRISP (Chesapeake Regional Information System) for prescriptions from other providers
         ii. Naloxone prescription has been provided or offered to patient/patient's household

iii. Patient will have random urine drug screens
iv. A Patient-Prescriber Pain Management/Opioid Treatment Agreement/Contract has been signed, and placed in the patient's medical record

D. **7-Day Opioid Supply Exception Requests** for opioid-naïve patients (Opioid naive" is defined as patients who have not filled an opioid prescription within the previous 90 days):
1. Requests for quantities of short-acting opioids greater than 7-day supply may be approved when the following criteria are met:
   a. Documentation has been submitted showing that greater than a 7-day supply of the requested medication is medically necessary
   b. The prescriber has reviewed controlled substance prescriptions in the Prescriptions Drug Monitoring Program through CRISP (Chesapeake Regional Information System) for prescriptions from other providers

E. **Morphine Milligram Equivalent (MME) Exception Requests** for opioid quantities that exceed a comprehensive 90 daily MME (This 90 MME limit considers all recent opioid prescriptions (formulary and non-formulary) dispensed within the previous 90 days; Formulary medications can be found here: https://www.ppmco.org/wp-content/uploads/2023/03/ppmco_formulary.pdf):
1. *Opioids that are subject to non-formulary status, PA requirements, or quantity limits are required to fulfill the exception criteria for these utilization parameters as applicable, in addition to meeting the below criteria for an MME exception*
2. 90 MME opioid exception requests may be approved when the following criteria are met:
   a. Documentation of ONE of the following:
      I. Patient has a diagnosis of cancer, sickle cell anemia, is in hospice care, in long-term care, or palliative care (diagnosis code Z51.5)
      II. Prescriber has attested to ALL the following:
         i. Prescriber has reviewed controlled substance prescriptions in the Prescription Drug Monitoring Program through CRISP (Chesapeake Regional Information System) for prescriptions from other providers
         ii. Naloxone prescription has been provided or offered to patient/patient's household.
         iii. Patient will have random urine drug screens
            A. *Caveat: Urine drug screening is not applicable for patients being discharged from inpatient facility and transitioning to outpatient care
         iv. A Patient-Prescriber Pain Management/Opioid Treatment Agreement/Contract has been signed, and placed in the patient's medical record
            A. *Caveats: Patient-Prescriber is not applicable for patients being discharged from inpatient facility and transitioning to outpatient care. However, provider must attest to ALL of the following:
               1. The risks and benefits associated with opioid use have been discussed with the patient/patient's household
               2. One of the following:
                  a. The prescribed treatment will be for 30 days or less
                  b. The need for further opioid use will be re-evaluated by an outpatient provider within 30 days

III. OPIOID QUANTITY LIMITS

A. QL is set at 90 MME per day for all opioids when total quantity is below 180 tablets/capsules/suppositories.

B. QL is set at 180 tablets/capsules/suppositories for all other opioids
C. QL for butorphanol 10mg/ml nasal spray is 10 ml
D. QL for buprenorphine patches 5 per 30 days
E. QL fentanyl patches 10 per 30 days
F. QL for liquids is set at:
   1. 1000 ml for all codeine containing oral solutions
   2. 2750 ml for all hydrocodone/acetaminophen oral solutions
   3. 675 ml for hydromorphone oral solution 1mg/ml
   4. 1800 ml for oxycodone oral solution 5mg/mL
   5. 90mL for oxycodone concentrate solution 20mg/mL
   6. 1800 ml oxycodone acetaminophen oral solution 5-325mg/5ml
   7. 2700 ml meperidine oral solution 50mg/5ml

IV. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval for short-acting and long-acting opioids may be for up to 6 months.
B. Approval for continuation of therapy may be extended in 12-month intervals with documentation showing beneficial patient response, as well as continued affirmation on the applicable attestations.

V. EXCLUSIONS

A. Requests will not be approved for:
   1. Patients who do not meet above requirements
   2. Patient is currently taking or has a recent history of treatment for opiate dependence, including treatment with Suboxone, buprenorphine (Subutex), or methadone maintenance programs
B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

VI. REFERENCES

1. Johns Hopkins HealthCare Policy PHARM16: Requests for Non-formulary Medications.
2. Johns Hopkins HealthCare Policy PHARM20: Step Therapy, Prior Authorization and Quantity Limits
3. World Health Organization. Cancer pain relief. Geneva: World Health Organization, 1990.
4. Chou R et al. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *J Pain* 2009: 10: 113-30
5. CDC guidance: https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm
6. CMS guidance: https://www.medicaid.gov/federal-policy-guidance/downloads/cib-02-02-16.pdf
7. DHMH website: https://mmcp.dhmh.maryland.gov/healthchoice/opioid-dur-workgroup/Pages/medicaid-opioid-response.aspx

VII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE

07/19/2017	MEDS 21and MEDS 28 conversion to new policy MEDS 105 per DHMH regulations
07/27/2017	Updated Exclusions section regarding physician samples
04/16/2020	Criteria Layout Update (no criteria changes)
09/01/2020	Clarification of non-formulary opioid criteria
05/13/2021	Updated authorization guidance
07/28/2022	Criteria Layout Revision; Added criteria for 7-day supply exception
07/08/2024	Criteria Layout Update (no criteria changes)

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