Chronic Opioid Therapy

I. Policy

University Health Alliance (UHA) will reimburse for chronic opioid therapy (COT) for chronic non-cancer pain when it is determined to be medically necessary and when it meets the medical criteria guidelines (subject to limitations and exclusions) indicated below.

Definitions of key terms in this policy, taken from the 2016 US Center for Disease Control Guidelines for Prescribing Opioids for Chronic Pain, are as follows:

Chronic pain is considered within this policy as pain that typically lasts >3 months or past the time of normal tissue healing. Chronic pain can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause. The limitations within this policy do not apply to active cancer, palliative, or end of life opioid therapy. Note: “Active cancer” does not include most non-invasive chronic cutaneous or similar malignancies.

Long-term opioid therapy is defined as use of opioids on most days for >3 months.

II. Criteria/Guidelines

Chronic Opioid Therapy (COT) is covered (subject to Limitations) when the following guidelines have been considered:

A. Before initiating COT, the following guidelines apply:

1. Providers should only consider adding opioid therapy if expected benefits for both pain and function are anticipated to outweigh risks to the patient.
   a. Given uncertain benefits and substantial risks, experts agreed that opioids should not be considered first line or routine therapy for chronic pain (i.e., pain continuing or expected to continue longer than 3 months or past the time of normal tissue healing) outside of active cancer, palliative, and end-of-life care.
      i. Nonpharmacologic therapy such as exercise therapy and Cognitive Behavioral Therapy (CBT) should be used to reduce pain and improve function in patients with chronic pain.
      ii. Nonopioid pharmacologic therapy should be used when benefits outweigh risks and should be combined with nonpharmacologic therapy to reduce pain and improve function.
   b. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate, to provide greater benefits to patients in improving pain and function.

2. Clinicians should conduct a history, physical examination, and appropriate testing, including an assessment of risk of substance abuse, misuse, or addiction.
   a. Risk Stratification may be assisted by a standardized tool such as the ORT, CAGE-AID, PHQ-9, SOAPP-R, or PADT.
   b. Providers should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, or higher opioid dosages (≥50 MME), are present.
c. Providers should use additional caution and increased monitoring to minimize risks of opioids prescribed for patients with renal or hepatic insufficiency, patients over 65 years old, patients who are or may become pregnant, patients with moderate or severe sleep apnea, patients with mental health conditions, patients with history of substance abuse, or patients with a history of a non-fatal overdose; as these patients represent higher risk of adverse effects to include death from opioids.

3. Providers should avoid prescribing opioid pain medication for patients receiving benzodiazepines whenever possible. Concurrent use is likely to put patients at greater risk for potentially fatal overdose.
   a. Hawaii Senate Bill 505 includes language to providers to limit initial concurrent opioid and benzodiazepine prescriptions to a maximum of 7 days.

4. Clinicians must obtain informed consent, a treatment agreement, and have an opioid management plan:
   a. UHA expects providers to comply with Hawaii Senate Bill 505 which includes language to implement an opioid therapy informed consent process agreement between patient and prescriber of opioids in cases where the patient is at increased risk for developing dependency.
      i. Prescribers are expected to be familiar with Hawaii regulations regarding prescribing of controlled substances. Act 066/Senate Bill 505 (Effective 07-01-18) State of Hawaii has a requirement for policy or and written agreements to engage in an informed consent process between the prescribing provider and qualifying opioid therapy patient.
      ii. Related Resource: Hawaii Department of Health, Patient Informed Consent Form; also the Hawaii Revised Statute (HRS) 329.38-5
   b. Prior to writing an opioid prescription for ≥30 day supply, providers should establish and discuss treatment goals with patients. Providers seeing new patients already receiving opioids should establish treatment goals for continued opioid therapy.
      i. Providers should discuss with patients known risks and realistic benefits of opioid therapy and patient and provider responsibilities for managing therapy.
      ii. Informed consent should be accompanied by a Treatment Agreement clearly stating the expectations and obligations of both the treating physician and the patient for monitoring and compliance, and to assure the patient has been informed of the risk and limitations of opioids for treatment of chronic pain. Time must be available for discussion and answering any questions the patient may have regarding opioid treatment and any appropriate alternatives.
   c. UHA has a pain management consent form (Long Term Opioid Therapy Consent and Medication Agreement) online that you may download from the provider portal at uhahaalth.com.

5. Initiation and Titration of COT:
   a. Providers should review the patient’s history of controlled substance prescriptions using The Hawaii Prescription Drug Monitoring Program (HI-PDMP) data to determine whether the patient is receiving high opioid dosages or dangerous combinations that put him or her at high risk for overdose. Providers should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain.
      i. System access can be found at: hawaii.pmpaware.net.
ii. Prescribers are expected to be familiar with Hawaii regulations regarding prescribing of controlled substances (note that these requirements are not restricted to COT). State of Hawaii Act 153/Senate Bill 2646 (Effective 07-01-18) Pertains to practitioner utilization requirements of the PDMP and reads (in part) as follows:

- No prescriber shall prescribe a schedule II, III, or IV controlled substance without first requesting, receiving, and considering records of the ultimate user from the state electronic prescription accountability system as needed to reduce the risk of abuse of or addiction to a controlled substance, as needed to avoid harmful drug interactions, or as otherwise medically necessary; provided that this subsection shall not apply to:
  - Any prescription for a supply of three days or less that is made in an emergency situation, by an emergency medical provider, or in an emergency room; and
  - Any prescription written while the state electronic prescription accountability system is nonfunctional

b. Clinicians and patients should regard initial treatment with opioids as a therapeutic trial to determine whether COT is appropriate. Opioid selection, initial dosing, and titration should be individualized according to the patient’s health status, previous exposure to opioids, attainment of therapeutic goals, and predicted or observed harms.

c. When starting opioid therapy for chronic pain, providers should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids. ER/LA opioids should be reserved for severe, continuous pain and should be considered only for patients who have received immediate-release opioids daily for at least 1 week. When changing to an ER/LA opioid for a patient previously receiving a different immediate-release opioid, providers should consult product labeling and reduce total daily dosage to account for incomplete opioid cross-tolerance.

d. When opioids are started, providers should prescribe the lowest effective dosage. Providers should use caution when prescribing opioids at any dosage, should implement additional precautions when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should generally avoid increasing dosage to ≥90 MME/day.

i. Experts agreed that, in general, increasing dosages to 50 or more MME/day increases overdose risk without necessarily adding benefits for pain control or function. Experts also agreed that additional precautions should be taken when patients are prescribed daily opioid dosages of ≥50 MME/day and that opioid dosages generally should not be increased to ≥90 MME/day.

ii. Providers should explain in a nonjudgmental manner to patients already taking high opioid dosages (≥90 MME/day) that there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages. Providers should empathically review benefits and risks of continued high-dosage opioid therapy and should offer to work with the patient to taper opioids to safer dosages or safely wean patients off opioids.

6. Clinicians may consider initiating COT for patients with chronic non cancer pain and history of alcohol or drug abuse, psychiatric conditions, or serious aberrant drug related behaviors only if they are able to implement frequent and stringent monitoring parameters. In such situations,
clinicians should strongly consider consultation with a mental health or addiction specialist, restructuring of therapy, or aborting the initiation of COT.

7. Providers should use urine drug testing (UDS) before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
   a. Refer to UHA’s Urine Drug Screening policy for criteria and guidelines for testing to avoid causing an inadvertent high financial burden on patients.
   b. Providers should be familiar with the drugs included in urine drug testing panels used in their practice and should understand how to interpret results for these drugs.

B. After initiation of COT, the following guidelines apply:

1. Providers should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Providers should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, providers should work with patients to reduce opioid dosage and to discontinue opioids.
   a. Monitoring should include documentation of pain intensity and level of functioning, assessments of progress toward achieving therapeutic goals, presence of adverse events, and adherence to prescribed therapies.

2. Providers prescribing opioids should identify treatment resources for pain management and opioid use disorder in the community and consider consultation with a physician specializing in psychiatry, neurology, addiction medicine, physical medicine and rehabilitation, or pain medicine within the following guidelines:
   a. Ongoing pain symptoms with no improvement in function despite treatment with opioids
   b. Patients with preexisting psychiatric diagnosis or new symptoms of mood, anxiety, and psychotic disorders, patients on psychiatric or mood altering medications, or patients with history of substance abuse.
   c. Patients requesting more than 90mg MED (Morphine Equivalent Dose) of opioid daily for pain control. Equianalgesic tables and online calculators can aid the clinician in determining MED.
   d. UHA may mandate consultation within above guidelines and will assist in coordinating the consultation.

C. Consider discontinuation of therapy within the following guidelines:

1. No documented improvement in pain level or function in patients compliant with COT
2. Opioid therapy produces significant adverse effects
3. Patient exhibits drug seeking behaviors or diversion such as selling or forging prescriptions, aggressive demands for opioids, unsanctioned use of opioids, getting opioids from multiple prescribers including ER visits, or failing Urine Drug Screening (failing screening is defined as the lack of prescribed medication in UDS or the presence of opioids in UDS other than those prescribed).
   a. Experts agree that providers should not be quick to dismiss patients from their practice on the basis of suspected or overt aberrant behaviors. Doing so can adversely affect patient safety, could represent patient abandonment, and could result in missed opportunities to provide potentially lifesaving information (e.g., about risks of opioids and overdose prevention) and interventions (e.g., safer prescriptions,
nonopioid pain treatment, naloxone, and effective treatment for substance use disorder.)

4. If therapy is discontinued, dosage should be tapered cautiously using current practice guidelines for safety and efficacy. Providers should discuss with patients undergoing tapering the increased risk for overdose on abrupt return to a previously prescribed higher dose.

D. Methadone is characterized by complicated and variable pharmacokinetics and should be initiated and titrated cautiously, by clinicians familiar with its use and risks. Clinicians must be diligent in their awareness that Methadone does not titrate to effect like other opioids.

NOTE:

This UHA payment policy is a guide to coverage, the need for prior authorization and other administrative directives. It is not meant to provide instruction in the practice of medicine and it should not deter a provider from expressing his/her judgment.

Even though this payment policy may indicate that a particular service or supply is considered covered, specific provider contract terms and/or members’ individual benefit plans may apply, and this policy is not a guarantee of payment. UHA reserves the right to apply this payment policy to all UHA companies and subsidiaries.

UHA understands that opinions about and approaches to clinical problems may vary. Questions concerning medical necessity (see Hawaii Revised Statutes §432E-1.4) are welcome. A provider may request that UHA reconsider the application of the medical necessity criteria in light of any supporting documentation.

III. Administrative Guidelines

A. Prior authorization is not required, however, providers are encouraged to be aware of the pharmacy benefit restrictions on long term opioids. These limitations are managed by the UHA pharmacy benefits manager.

1. UHA’s pharmacy benefits manager restricts dose changes, early refills, lost medications, and vacation overrides for opioid prescriptions.

   a. Members can request UHA medical director review of denials, however, such review may require submission of documentation from providers and/or members. Required documentation may include medical records and/or travel itineraries. Standard review time is up to 15 calendar days. Members should remain cognizant of these requirements and plan appropriately when requests for review are time sensitive.

B. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record and must be made available to UHA upon request. UHA reserves the right to perform retrospective review using the above criteria to validate if services rendered met payment determination criteria and to ensure proper reimbursement is made.

IV. Policy History

Policy Number: MPP-0080-120515
Current Effective Date: 07/03/2019
Original Document Effective Date: 05/15/2012
Previous Revision Dates: 10/05/2016, 12/01/2016, 06/12/2018
PAC Approved Date: 05/15/2012
References:
CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016
http://www.guidelines.gov/content.aspx?id=16165
And the American Society of Regional Anesthesia and Pain Management
www.agencymedicaldirectors.wa.gov : Interagency Guideline on Opioid Dosing for Non-cancer Pain

<table>
<thead>
<tr>
<th>Drug, delivery route</th>
<th>Dosage by route</th>
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<tbody>
<tr>
<td>Morphine sulfate, parenteral</td>
<td>60 mg IM, SC, IV</td>
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<tr>
<td>Morphine sulfate, oral</td>
<td>180 mg PO (chronic use)</td>
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<td>Methadone</td>
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<td>50-100 mcg/h patch (change q72h)</td>
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<td>1200 mg PO</td>
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<tr>
<td>Hydrocodone</td>
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