POLICY AND PROCEDURE MANUAL

Policy Title: Acute and Chronic Opioid Therapy	**Policy Number: M50.58**
Primary Department: Clinical Operations **Affiliated Department(s):** Customer Experience, Operations	**NCQA Standard:** N/A **URAC Standard:** N/A
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Medicare:	☐SNP ☐MMAI ☐MA ☐PDP	☐SNP ☐MMAI ☐MA ☐PDP		☐SNP ☐MMAI ☐MA ☐PDP	☐SNP ☐MMAI ☐MA ☐PDP
Medicaid:	☐TANF ☐SPD ☐SCHIP	☐TANF ☐SPD ☐SCHIP		☐TANF ☐SPD ☐SCHIP	☐TANF ☐SPD ☐SCHIP
Commercial:	☐Exchange ☐Employer ☐Private	☐Exchange ☐Employer ☐Private	☐CMC	☐Exchange ☐Employer ☐Private	☐Exchange ☐Employer ☐Private
State/Program					
Medicare:	☐SNP ☐MMAI ☐MA ☐PDP	☐SNP ☐MMAI ☐MA ☐PDP	☐SNP ☐MMAI ☐MA ☐PDP	☐SNP ☐MMAI ☐MA ☐PDP	☐SNP ☐MMAI ☐MA ☐PDP
Medicaid:	☐TANF ☐SPD ☐SCHIP	☐TANF ☐SPD ☐SCHIP	☐TANF ☐SPD ☐SCHIP	☐TANF ☐SPD ☐SCHIP	☐TANF ☐SPD ☐SCHIP
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I. PURPOSE

i. To define the conditions under which opioids will be covered when the duration of use exceeds 7 days for the treatment of pain.

II. FOCUS

i. The focus of the policy is to ensure safe and evidence-based utilization of opioids for the treatment of pain and to promote member access to safer, more effective chronic pain treatment through implementation of opioid use criteria aimed at reducing the risks associated with the use of chronic opioids.

III. SCOPE

i. The following criteria applies to Michigan and Illinois Medicaid.

IV. KEY WORDS/DEFINITIONS

i. **Centers for Disease Control and Prevention (CDC)**
ii. **Federal Drug Administration (FDA)**
iii. **Pharmacy Benefit Manager (PBM)**
iv. **Urinary Drug Screen (UDS)**
v. **Activities of Daily Living (ADL)**
vi. **Prior Authorization (PA)**
vii. **Quantity Limit (QL)**
viii. **Utilization Management (UM)**
ix. **Point of Sale (POS)**
x. **Drug Utilization Review (DUR)**
xi. **Schedule II Controlled Substances (CII)**
xii. **Morphine Milligram Equivalents or Morphine Equivalent Dose (MME or MED)**
    i. Milligram Morphine Equivalent (MME) is a value assigned to opioids to represent their relative potencies. MME is determined by using an equivalency factor to calculate a dose of morphine that is equivalent to the ordered opioid. Daily (MED) is the sum of the MME of all opioids a patient is likely to take within 24 hours, and that total is used to determine if the patient is nearing a potentially dangerous threshold.
xiii. **Morphine Milligram Equivalents (MME) Threshold**
    i. The MME threshold is the MME above which certain limitations may apply.
xiv. **Prescription Drug Monitoring Program (PDMP)**
    i. Patient safety tool developed by the state to facilitate the collection, analysis, and reporting of information on the prescribing and dispensing of controlled substances.
xv. **Pain Medication Agreement/Contract**
    i. Use of a written informed consent and treatment agreement for long-term chronic opioid therapy that outlines the joint responsibilities of the clinician and patient, including the patient's agreement to periodic and unannounced drug testing for opioids and other medications when deemed appropriate by the clinician with potential for substance use disorder, as well as, discussion with the patient on how and when the PDMP will be reviewed as part of the patient's care.

V. POLICY

i. MeridianRx utilizes an opioid use policy to promote the appropriate, safe, and effective utilization of opioid medications for the treatment of pain and management of chronic pain, guided by the most current CDC recommendations for the prescribing of opioids, as follows:
    i. Before initiating opioid therapy, clinicians should perform an initial assessment to determine if opioids are clinically indicated and to determine risks associated with their use in a particular individual with pain, as well as establish treatment goals with all patients, including realistic goals for pain and function, and defining the responsibilities of both the patient and physician for managing therapy.
    ii. If the decision to use opioids is made, clinicians should prescribe the lowest effective dose, and they should be combined with non-pharmacologic therapy and non-opioid pharmacologic therapy, as appropriate.
    iii. Non-pharmacologic and non-opioid therapies should be optimized at all times.
    iv. When initiating opioid therapy for chronic pain, immediate-release or short-acting opioids should be prescribed instead of long-acting opioids.
    v. Prior to beginning chronic opioid therapy and at least every 3 months thereafter, clinicians should review the patient's history of controlled substance prescriptions using state PDMP data to assess opioid risk.
    vi. A UDS should be performed before the initiation of chronic opioid treatment and should be repeated AT LEAST once every 365 days. Patients deemed as moderate to high risk for opioid abuse may need to be tested more frequently based on the provider's discretion.

vii. Clinicians should use risk stratification tools such as the Opioid Risk Tool (ORT), Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R), and Brief Risk Interview to gauge the patient's risk for opioid abuse prior to starting a chronic opioid therapy.
viii. Clinicians and patients should regard initial treatment with opioids as a therapeutic trial to determine whether chronic opioid therapy 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.
ix. 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.
    1. A ***soft edit*** reject will occur at POS for members prescribed greater than 90 MME/day up to 200 MME/day.
        a. This edit will require review by the dispensing pharmacist to assess medical necessity of the medication
        b. The dispensing pharmacist will be required to input the appropriate overrides at POS in order to process the prescription
    2. A ***hard edit*** reject will occur at POS for members prescribed greater than or equal to 200 MME/day
        a. This edit will require submission of a prior authorization with supporting documentation by the prescribing physician for medical necessity review
x. Clinicians should continue chronic opioid treatment for pain only if there is clinical evidence that the improvement in pain and function outweighs the potential risks to patient safety.
xi. When risks of opioid use begin to outweigh patient improvement in quality of life, a taper plan should be implemented with the goal of dose reduction or discontinuation.
xii. Avoid the concomitant use of opioids with benzodiazepines, whenever possible.
xiii. 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

ii. Nothing in this policy shall preclude the prescribing health care professional from prescribing another drug covered by the plan that is medically appropriate for the consumer, nor shall anything in this section be construed to prohibit generic drug substitutions.
iii. Lastly, this policy does not encourage the prescribing of opioids over other means of treatment (pharmacological and non-pharmacological), but rather recognizes the need to view pain management as essential to quality of medical practice and to the quality of life for our members who suffer from pain.

VI. COVERAGE CRITERIA

i. **Opioid Coverage Criteria**

Opioid Naïve Patients: Initial fill is determined by a 90-day lookback for the same or similar medication as indicated by ETC classification.

i. **Treatment Duration ≤ 7 Days**
    1. Request within the maximum QL will automatically adjudicate at POS in absence of potential limitations (i.e. DUR Rejects or other UM restrictions).
ii. **Treatment Duration >7 Days**
    1. Request will reject at POS and require submission of PA with supporting documentation for extended-use therapy
        a. Exceptions or conditional approvals for **acute** use >7 days may be made on a case by case basis when involving:
            i. Post-operative pain requiring opioid therapy expected to last longer than 7 days
            ii. Exceptions are subject to all other policy conditions
        b. Exceptions or conditional approvals for **chronic** use >7 days may be made on a case by case basis when:

i. Submission of current clinical documentation provides evidence of diagnoses of sickle cell disease, active cancer, cancer related pain, hospice and/or end-of life or palliative care management
ii. Members new to plan or not identified by the adjudicating system to meet the lookback conditions, however, clinical documentation shows member is currently on chronic opioid therapy for documented pain conditions.
iii. Submission of a diagnosis code of cancer or sickle cell disease by the pharmacy at POS
iv. Exceptions are subject to all other policy conditions

c. *Refills*
i. Up to a 30 day supply will be allowed
ii. Fills remain subject to all utilization management requirements (i.e. QLs, PA restriction or criteria) and other policy conditions
iii. Any refill will reject if <90% of the previous prescription has been used

ii. **Prior Authorization Criteria**

In circumstances where a PA is required for extended use, the following requirements must be met:

i. Requesting prescriber must be board certified in Pain Management, Anesthesiology, and/or Oncology
ii. Recent clinical documentation must be provided and include the following information:
1. Medical history and physical examination targeted to the pain condition and diagnosis
2. Nature and intensity of the pain
3. Current and past treatments, including interventional treatments, non-pharmacological treatments and pharmacological treatments (including name of medication(s), dates of use, and duration of treatment(s)), with response to each treatment
4. Underlying or co-existing diseases or conditions, including those which could complicate treatment (i.e. obesity, renal disease, sleep apnea, COPD, etc.)
5. Effect of pain on physical and psychological functioning
6. Personal history of substance use disorder
7. Medical indication(s) for use of opioids
8. Completion of PDMP by the prescriber
9. Urine Drug Screen test results
iii. Treatment agreement outlining the joint responsibilities of the clinician and patient which should include:
1. Treatment goals in terms of pain management, restoration of function and safety
2. Patient's responsibility for safe medication use (not taking more than prescribed; combination with alcohol or other substances like benzodiazepines, unless closely monitored by the prescriber, etc.)
3. Secure storage and safe disposal
4. Patient's responsibility to obtain prescribed opioids from only one clinician or practice
5. Patient's agreement to periodic drug testing
6. Clinician's responsibility to be available or to have a covering clinician available to care for unforeseen problems and to prescribe scheduled refills.
iv. Documentation or attestation of the following:
1. Pain contract or an informed consent and treatment agreement for chronic opioid therapy
2. Urine Drug Screen results from within the last 12 months that are consistent with patient's prescribed regimen
3. Prescriber is monitoring the state prescription drug monitoring program at each visit
v. The prescribing of dual short-acting or dual long-acting opioid medications is not permitted.
vi. No dual therapy with opioid addiction treatment, including buprenorphine products or methadone will be permitted. (These products may still be used as single long-acting opioids for the treatment of chronic pain).

vii. Meperidine is only indicated for the treatment of acute pain and therefore is will not be permitted for chronic opioid therapy.
viii. Inconsistent UDS results will require clinical documentation showing medical rationale for the discrepancy. If medical rationale is not provided and provider deems continuation of opioid therapy appropriate a subsequent UDS will be required at the patient's next follow-up appointment.
    1. >1 consecutive UDS resulting in inconsistencies with prescribed medications will require UDS testing to be performed at every appointment for 3 consecutive appointments.
    2. >2 consecutive inconsistent results may result in increased limitations or denial of requested medication.
ix. Chronic use of co-prescribed opioids and benzodiazepines requires clinical documentation explaining the medical rationale for their concomitant use.

Long-Acting Opioid Use

i. Member must meet PA criteria requirements as stated above.
ii. Severity of pain requires daily, around the clock management of chronic pain.
iii. Adequate trial and failure of short-acting opioid(s), with any non-opioid medications optimized along with non-pharmacological treatment modalities.
    1. Requested strength and quantity of the long-acting opioid being initiated, or transitioned to, should be clinically appropriate when compared to the patient's diagnosis, severity of pain, frequency of pain, history of opioid use, and current total MME, when evaluating the appropriateness of starting a long-acting opioid.
iv. Only **ONE** long-acting opioid can be prescribed at a given time for the treatment of chronic pain**.**
v. Members with clinical documentation showing evidence they are stable on a long-acting opioid, who meet PA criteria, are exempt from trial and failure with a short-acting opioid.
vi. Opioid doses and/or frequencies greater than the standard approved by the FDA require both of the following:
    1. Documented trial and failure of the standard FDA approved dose and frequency.
    2. Written medical justification as to why greater than the FDA approved dose and/or frequency is required.

iii. **Initial Authorization**

i. Minimum of 3 months or as requested by physician based on the criteria listed above.
    1. Authorizations for patients not from board certified providers, as stated above, with a calculated MME of ≥200 will be subject to taper requirement for continuation of care requests post initial approval

iv. **Re-Authorization**

i. Up to 12 months
ii. An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective for pain.
iii. For a diagnosis of chronic non-cancer pain, the following must also be documented:
    1. Objective progress towards treatment plan goals with chronic opioid therapy. Patient should show both functional improvement and pain relief.
    2. Medication records (including date(s) written, name of medication, dosage, and quantity prescribed) that correspond with medical reasons for continuing or modifying opioid therapy.
    3. Physical, behavioral, and non-opioid therapies (i.e. physical therapy. exercise. cognitive behavioral therapy, NSAIDs, antidepressants, anticonvulsants, etc.) are used as indicated in combination with chronic opioid therapy.
    4. A UDS has been performed within the past 12 months of request.
    5. A review of PDMP results for the patient has been performed within the past 3 months of request.

6. Prior authorization requests for patients subject to taper requirement, without documented plan for taper, may be subject to denial of request and/or referral to pain management specialist

VII. SPECIAL INSTRUCTIONS

i. Coverage criteria applies to ALL FORMULARY OPIOIDS. Non-formulary alternatives are still subjected to the same criteria, but only after the medication is deemed medically necessary.

ii. This policy recognizes that there are unique clinical situations not covered by these criteria in which certain restrictions and limitations may not be clinically appropriate to apply to a member's case. These instances will be evaluated based on current best practices and standards of care, as they arise.

iii. ***NOTE for Illinois Medicaid Members:***

i. Documentation detailing clinically adequate trial and failure of preferred formulary medications ***OR*** showing contraindication to all preferred alternatives must be provided when requesting a non-preferred formulary agent.

ii. Non-preferred extended- and immediate- release medications are to be used in a step-wise fashion based on their formulation and guidelines for use. Members may not receive approval for a medication unless documentation detailing clinically adequate trial and failure of medications is provided showing evidence of step criteria being met. See Appendices 1 and 2 for complete list of agents and step requirements.

REFERENCES

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Appendix 1. Immediate-Release Opioids

Step 1 Agents: Two (2) or more of the following agents must be adequately tried and failed before moving on to step 2	
Agent	**Strength**
Acetamin-Caff-Dihydrocodeine Tablet	325-30-16mg
Apadaz Tablet Benzydrocodone-Acetaminophen Tablet	4.08-325 mg, 6.12-325mg, 8.16-325mg
Dilaudid Tablet and Liquid	2mg, 4mg, 8mg, 5mg/5mL
Dvorah Tablet	325-30-16mg
Lortab Elixer	10-300mg/15mL
Meperidine HCL Tablet and Solution	50mg, 100mg, 50mg/5mL
Nalocet Tablet	2.5-300mg
Norco Tablet	5-325mg, 7.5-325mg, 10-325mg
Oxycodone HCL-Aspirin Tablet	4.8355-325mg
Oxycodone HCL-Ibuprofen Tablet	5-400mg
Tramadol HCL-Acetaminophen Tablet Ultracet Tablet	37.5-325mg
Ultram Tablet	50mg
Step 2 Agents: Two (2) or more of the following agents must be adequately tried and failed before moving on to step 3	
Agent	**Strength**
Butorphanol Tartrate Spray	10mg/mL
Nucynta Tablet	50mg, 75mg, 100mg
Opana Tablet	5mg, 10mg
Oxaydo Tablet	5mg, 7.5mg
Oxymorphone HCL Tablet	5mg, 10mg
Percocet Tablet	2.5-325mg, 5-325mg, 7.5-325mg, 10-325mg
Primlev Tablet	5-300mg, 7.5-300mg, 10-300mg
Roxicodone Tablet	5mg, 15mg, 30mg
Step 3 Agents:	
Agent	**Strength**
Abstral Sublingual Tablet	100mcg, 200mcg, 300mcg, 400mcg, 600mcg, 800mcg
Actiq Lozenge	200mcg, 400mcg, 600mcg, 800mcg, 1200mcg, 1600mcg
Fentanyl Citrate Buccal Tablet	100mcg, 200mcg, 400mcg, 600mcg, 800mcg
Fentanyl Citrate OTFC	200mcg, 400mcg, 600mcg, 800mcg, 1200mcg, 1600mcg
Fentora Buccal Tablet	100mcg, 200mcg, 400mcg, 600mcg, 800mcg
Lazanda Nasal Spray	100mcg, 300mcg, 400mcg
Levorphanol Tablet	2mg, 3mg

Appendix 2. Extended-Release Opioids

Step 1 Agents: One (1) or more of the following agents, or preferred formulary agent(s), must be adequately tried and failed before moving on to step 2	
Agent	**Strength**
Arymo ER Tablet	15mg, 30mg, 60mg
Belbuca Film	75mg, 150mg, 300mg, 450mg, 600mg, 750mg, 900mg
Buprenorphine Patch	5mcg/hr, 7.5mcg/hr, 10mcg/hr, 15mcg/hr, 20mcg/hr
Butrans	
Conzip Capsule	100mg, 200mg, 300mg
Diskets Dispersible Tablet	40mg
Dolophine HCL Tablet	5mg, 10mg
Embeda ER Capsule	20-0.8mg, 30-1.2mg, 50-2mg, 60-2.4mg, 80-3.2mg, 100-4mg
Methadone HCL Tablet and Solution	5mg, 10mg, 5mg/5mL, 10mg/mL, 10mg/5mL
Methadone Intensol	10mg/mL
Methadone Dispersible Tablet	40mg
Morphine Sulfate ER Capsule	10mg, 20mg, 30mg, 40mg, 45mg, 50mg, 60mg, 75mg, 80mg, 90mg, 100mg, 120mg
MS Contin Tablet	15mg, 30mg, 60mg, 100mg, 200mg
Tramadol ER Tablet and Capsule	100mg, 200mg, 300mg
Step 2 Agents: Two (2) or more of the following agents must be adequately tried and failed before moving on to step 3	
Agent	**Strength**
Hydromorphone ER Tablet	8mg, 12mg, 16mg, 32mg
Hysingla ER Tablet	20mg, 30mg, 40mg, 60mg, 80mg, 100mg, 120mg
Kadian ER Capsule	10mg, 20mg, 30mg, 40mg, 50mg, 60mg, 80mg, 100mg 200mg
Morphabond ER Tablet	15mg, 30mg, 60mg, 100mg
Oxycodone ER Tablet	10mg, 15mg, 20mg, 30mg, 40mg, 60mg, 80mg
Xtampza ER Capsule	9mg, 13.5mg, 18mg, 27mg, 36mg
Zohydro ERCapsule	10mg, 15mg, 20mg, 30mg, 40mg, 50mg
Step 3 Agents:	
Agent	**Strength**
Duragesic	12mcg/hr, 25mcg/hr, 50mcg/hr, 75mcg/hr, 100mcg/hr
Fentanyl Patch	12mcg/hr, 25mcg/hr, 37.5mcg/hr, 50mcg/hr, 62.5mcg/hr, 75mcg/hr, 87.5mcg/hr, 100mcg/hr
Nucynta ER Tablet	50mg, 100mg, 150mg, 200mg, 250mg
Oxycontin Tablet	10mg, 15mg, 20mg, 30mg, 40mg, 60mg, 80mg
Oxymorphone ER Tablet	5mg, 7.5mg, 10mg, 15mg, 20mg, 30mg, 40mg