Department:	Pharmacy	**Original Approval:**	09/12/2007
Policy #:	PM508	**Last Approval:**	03/13/2019
Title:	Pharmaceutical Management Procedures		
Approved By:	Medical Management Leadership Team		
Dependencies:	*Clinical Guidelines Development* policy (QM600)		

Purpose

This Community Health Plan of Washington (CHPW) policy documents goals and responsibilities for the review and approval of pharmaceutical management programs for the Medicaid line of business.

Policy

The primary goal of pharmaceutical management programs is to ensure appropriate utilization. CHPW's independent Pharmacy and Therapeutics (P&T) & DUR Committee is responsible for the review and approval of CHPW pharmaceutical management programs. The CHPW Pharmacy department is responsible for the development and implementation of pharmaceutical management programs.

This Community Health Plan of Washington (CHPW) policy describes the decisions regarding the selecting of pharmaceutical management procedures and the different types of pharmaceutical restriction programs.

SELECTING PHARMACEUTICAL MANAGEMENT PROCEDURES

In its decisions regarding pharmaceutical management procedures, the Pharmacy Department and Pharmacy and Therapeutics (P&T) Committee strive to:

Meet identical medication coverage, age/dose/quantity limitations and coverage criteria policies as directed by the Washington State Healthcare Authority (HCA) for medications included on the Single Preferred Drug List.

Develop a Drug Formulary which favors drugs that have been determined to be the most clinically appropriate, safe, and cost-effective drugs for the diagnosis and treatment of disease and promotion of health.

Set Quantity Limits based on treatment duration or maximum dosing limits as approved by the Food and Drug Administration (FDA) or as reflected in current authoritative sources to ensure patient safety.

Implement Step Therapy protocols when there is a recognized first-line drug that should be used before a second-line drug to foster safe and effective treatment while reducing the cost of treatment.

Recommend Prior Authorization requirements for drugs and drug classes with the potential for significantly increasing costs without a commensurate improvement in efficacy or health status.

Adhere to contractual requirements including, but not limited to, benefit exclusion or age restriction of drugs used for cosmetic purposes. In addition, ensuring adherence to coverage requirements of FDA approved contraceptive drugs, including emergency contraceptives, without any limitations.

Control adverse utilization trends of high cost drugs which include, but are not limited to, the availability of less expensive drugs and price parity between different strengths of the same drug.

Make process improvements to help improve access and outputs. The Committee reviews quarterly denial reports to ensure that there are no unnecessary barriers or possible interventions needed.

NARCOTIC REVIEW

In addition to the CHPW P&T committee, CHPW participates in the HCA Pharmacy and Medical Director meetings to develop a process to identify and manage enrollees with a diagnosis of chronic, non-cancer pain taking opioids at a combined daily dose of greater than listed as the maximum in the Agency Medical Director's Group Opioid Guidelines.

Starting in 2017, CHPW is following the HCA's Opioid Clinical Policy. See Appendix A. In addition, requests for opioids that exceed current quantity limitations are referred to the CHPW Patient Review and Coordination (PRC) Program. See Policy *PM 563 – PRC Policy* for further details.

CONTINUITY OF CARE

To ensure continuity of care, members new to Community Health Plan of Washington will receive transition fills for non-formulary medications until the first of the following occurs:

- The member's prescription expires
- A participating provider examines the member to evaluate the continued need for the prescription or if the member refuses an evaluation by a provider.

These members will receive a notification of transition fill that includes an instruction to obtain exceptions from Community Health Plan of Washington. Transition fills are applied to non-formulary medications. Edits on benefit exclusions and designed for patient safety, such as quantity limit will still apply during the transition fill.

Members currently started on atypical antipsychotics, antidepressants, anti-epileptics, and ADHD medications will be grandfathered indefinitely for continuity of care per HCA Mental Health Benefit

Policy. The submission review ensures that it meets identical mental health coverage, age/dose/quantity limitations and generics first policy as directed by the HCA. CHPW's policy is to dispense a one-month supply of a formulary medication at a time. Additional circumstances including but not limited to an emergency supply of medication needed when a delay in authorization would interrupt a drug therapy regimen or pose a threat to the member's health and safety, may require an override. See *Policy PM515 – Transition Process* for further details.

MEDICATION THERAPY MANAGEMENT (MTM)

CHPW reimburses pharmacists and other qualified providers for providing comprehensive medication management services to targeted individuals. Targeted individuals are enrollees who have undergone a transition of care that may create a high risk medication-related problem, including:

1. Takes four or more prescribed medications (including OTC and dietary supplements)
2. Takes any "high risk" medications as defined by NCQA for the measure: Use of High Risk Medications in the Elderly
3. Has two or more chronic diseases from the list of conditions measured by CMS as part of the Multiple Chronic Condition initiative.

The MTM services are provided to the HCA in an annual report. The report includes patient clinical outcomes and total health care costs, including reduction in emergency department utilization, hospitalization, and drug costs. See *DP – 152 HCA Reporting Process* for further details on submission.

TYPES OF PHARMACEUTICAL RESTRICTION PROGRAMS

Prior Authorization (PA)

Age Restriction

Step Therapy

Quantity Limits

1. Prior Authorization (PA)

The goal of PA is to promote the most appropriate utilization for selected high-risk or high-cost drugs. The drug selection and criteria for PA are determined by the CHPW P&T Committee.

- Prior Authorization is recommended by CHPW's Pharmacy department for drugs and drug classes with the potential for significantly increasing costs without a commensurate improvement in efficacy or health status.

CHPW pharmacists research clinical evidence and refer to current clinical practice guidelines to develop the PA criteria.

CHPW pharmacists present their recommendations, including thorough clinical evaluations of the evidence that supports the PA and its associated criteria, for the P&T Committee.

The P&T Committee makes the following decisions:

- If a PA should be put in place for the identified drug(s).
- If the recommended criteria are clinically sound. The P&T Committee may amend the criteria if it is deemed necessary.

See *Policy PM 504 – Non Formulary Drug Requests* for further details.

2. Age Restrictions

Age restrictions apply to selected drugs. These drugs are covered without prior authorization for specific age ranges, but otherwise require prior authorization.

- CHPW's pharmacists research the clinical evidence regarding age restrictions.

CHPW's pharmacists present their recommendations, including thorough clinical evaluations of the evidence regarding age restrictions to the P&T Committee.

The P&T Committee determines if age restrictions should be put into effect for the identified drugs.

Second Opinion for Children Prescribed Mental Health Medications

As mandated by Washington State law, psychotropic medications are restricted for Apple Health (AH) members who are under the age of eighteen. Any claim, that is not a refill of the same drug/strength/daily dose, or meets duplication or polypharmacy limits being processed at the point-of-dispensing with respect to psychotropic drugs for AH members exceeding the age/dose limits set by the State will be rejected with the message of "second opinion required" (SON). The provider/designee must call the PBM at 1-844-605-8168 (24 hours a day, 365 days a year) for a 90 day fill if therapy is a continuation for the member. These medication requests will be authorized for 90 days to allow for continuation pending SON review. For Enrollees who have NOT previously filled prescriptions at the same daily dosage, CHPW shall deny authorization of psychotropic medications exceeding these review thresholds until receipt of written report containing treatment recommendations from the SON.

No later than one business day after a denial of any psychotropic medication for a child under 18, CHPW shall request relevant clinical information and chart notes from all prescribers of requested medications. The chart notes must be received by CHPW within ten business days. No later than one business day after obtaining all documentation CHPW shall send notification of authorization denial and all documentation to applehealthpharmacypolicy@hca.wa.gov for SON review. Notifications shall include the following:

- Enrollee name
- Enrollee date of birth
- Enrollee ProviderOne ID
- Denied drug NDC
- Prescribed quantity
- Prescribed days supply
- Prescriber NPI
- Prescriber name
- Prescriber phone and/or fax number
- Pharmacy NPI
- Pharmacy name
- Pharmacy phone and/or fax number
- Date of denial
- Reason for denial

Upon written receipt from the HCA, CHPW will approve or deny medications according to the SON recommendations within 2 business days. If a medication is approved up to a specific dosage, all lower strengths of the same medication will also be authorized without the need for another SON review. Upon notification by HCA that a prescriber has failed to provide documentation to support a prescription which exceeds HCA defined review thresholds, or that the prescriber has failed to participate in an SON consultation, CHPW shall deny all medications exceeding thresholds within five (5) business days.

The CHPW Provider Relations department notifies the provider network that the HCA provides access to consultation with a child psychiatrist.

The HCA will provide definitions of age and dose based review thresholds which will be implemented. Changes to these thresholds will be communicated to CHPW by the HCA 60 calendar days prior to required implementation.

3. Step Therapy

Step Therapy is a program that requires that one or more "**first-line**" drugs must be tried before the requested drug will be covered. The "first-line" drugs have been determined by the CHPW P&T Committee to be effective in treating the same medical condition as the requested drug. All programs of Step Therapy are supported by supplemental PA criteria to ensure that members have adequate access to their medications in situations excluded from the step therapy algorithm.

The procedure for determining if a drug is subject to Step Therapy is as follows:

- Step therapy is recommended by CHPW's Pharmacy Department when there is a recognized first-line drug that should be used before a second-line drug to foster safe and effective treatment while reducing the cost of treatment.

CHPW pharmacists research the clinical evidence regarding the step therapy algorithm and any supplemental PA criteria which are relevant.

CHPW's pharmacists present their recommendations, including thorough clinical evaluations of the evidence regarding the step therapy algorithm and any relevant supplemental PA criteria to the P&T Committee.

The P&T Committee makes the following determinations:

- If a program of Step Therapy should be put in place for the identified drug(s).
- If the recommended step therapy algorithm is clinically sound. The Committee may amend the algorithm if it is determined to be inadequate or unsafe.
- If the recommended supplemental PA criteria are clinically sound. The Committee may amend the supplemental PA criteria if they are determined to be insufficient to meet the goal of the proposed therapy.

See *Policy PM507 – Step Therapy* for further details.

4. Quantity Limit

Quantity limits are based on maximum dosing limits as approved by the FDA or as reflected in current authoritative sources to ensure patient safety.

- Quantity limits are recommended by CHPW's Pharmacy Department based on maximum dosing limits as approved by the FDA or as reflected in current authoritative sources to ensure patient safety.

CHPW pharmacists research, clinical evidence to support placement of a quantity limit.

CHPW pharmacists present their recommendations, including thorough clinical evaluations of the evidence that supports the quantity limit to the P&T Committee.

The P&T Committee makes the following decisions:

- If the quantity limit should be put in place for the identified drug(s).
- If the recommended quantity limits are clinically sound. The P&T Committee may amend the quantity limit if it is deemed necessary.

See *Policy PM506 – Quantity Limits* for further details.

List of Appendices

A. HCA Opioid Clinical Policy

Citations & References

CFR		
WAC		
RCW		
Contract Citation	☒ WAH	
	☒ IMC	
	☐ MA	
Other Requirements		
NCQA Elements	2018 NCQA UM 11	

Revision History

Revision Date	Revision Description	Revision Made By
09/12/2007	Original	Rachel Koh
04/25/2008	Added contract citation	Rachel Koh
01/08/2009	Review for style and formatting	Sunny Otake
06/25/2009	Content Update	Eric Guyette
05/28/2010	Review and no change	Maria Chan
06/08/2010	Approval	MMLT
01/07/11	Inserted Continuity of Care	Eric Guyette
05/27/2011	Content Update	Maria Chan
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04/16/2014	Content Update	Steven Zona
04/23/2014	Approval	MMLT
4/2/2015	Updated Citation Table, and changed dates	Nonye Connor
04/27/2015	Approval	MMLT
07/07/2015	Added Health Benefit Exchange LOB	Mary Eckhart
07/22/2015	Approval	MMLT
03/04/2016	Updated citations table. Minor text additions.	Mary Eckhart
03/18/2016	Approval	MMLT
08/24/2016	Updated SON process	Mary Eckhart; Fran McGaugh
08/31/2016	Approval	MMLT
01/30/2017	Updated to new template; added contraceptive section and updated SON section	Mary Eckhart
02/03/2017	Approval	MMLT
07/17/2017	Updated MTM and narcotic review section. Added appendix A.	Mary Eckhart

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11/27/2017	Added additional management procedures	Mary Eckhart
11/28/2017	Approval	MMLT
03/02/2018	Moved to new template. Added HCA Opioid Policy. Removed Exchange LOB. Updated SON process.	Mary Eckhart; Fran McGaugh
03/13/2018	Approval	MMLT
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03/12/2019	Reviewed, no changes	Erin Riddle
03/13/2019	Approval	MMLT

Opioid Clinical Policy—Medicaid

Updated September 11, 2017; Effective November 1, 2017

Acute use of opioids for the treatment of non-cancer, non-palliative care, non-hospice, non-end of life pain (applies to both short-acting and long-acting formulations):

1) Grandfathering a) Patients who have a history of opioid use (other than methadone) for ≥ 90 calendar days in the previous 120 days. No consultation or attestation needed. i) The dose, quantity, and 42-day supply limits do not apply.
ii) These patients may be identified by either electronically looking back at claims data or by establishing an authorization with no expiration date, prior to November 1, 2017.

b) Methadone has its own coverage criteria. Patients taking methadone are exempt from this policy
c) Buprenorphine has its own coverage criteria. Patients taking any buprenorphine products are exempt from this policy.

2) In general, only short-acting opioids will be approved for acute use. Long-acting opioids for acute use will be approved only under the exception criteria listed in (4) below.

3) All short and long-acting opioid prescriptions are covered without prior authorization to treat non-cancer, non-palliative care, non-hospice, and non-end of life related pain when the limits listed in (3a) and (3b) below are followed or when one of the exceptions listed in (4) applies. Limits apply as follows: a) For short acting opioids only: i) A quantity limit of 18 dosages per prescription for children (≤20 years of age); [Note: Prescriber indicating EXEMPT overrides quantity limit] **OR**
ii) A quantity limit of 42 dosages per prescription for adults (≥21 years of age); [Note: Prescriber indicating EXEMPT overrides the quantity]; **AND**

b) For both long and short acting opioids: i) No more than 42 calendar days of opioid use within a rolling 90-day period. Use of any opioid for more than 42 days within a 90-day period is considered chronic use of opioids and requires prior authorization. See the **chronic use of opioids section** below; **AND**

4) **Exceptions** (Quantity and Dose Limits in Table 1 below apply) (4a and 4b require separate codes): a) Patient with a diagnosis or pharmacy claim for active cancer treatment, hospice, palliative care, or end-of-life care and pharmacy submitted the claim with an **expedited authorization code;** [Note: Day supply limits do not apply]; **OR**

b) Provider wrote/typed "EXEMPT" on the prescription or the pharmacist has contacted the provider and the provider confirmed the patient had an "EXEMPT" medical condition. i) By indicating "EXEMPT" the provider is attesting that the patient has a medically necessary need that requires the prescribed long or short acting opioid (other than pain related to active cancer, hospice, palliative care, or end-of-life care) and it is documented in the medical record

ii) The pharmacy may submit the claim with an **expedited authorization code**
iii) Prescriber indicating EXEMPT overrides the dosage limit]; **OR**

c) New members are exempted for the first 120 days of enrollment.

i) If your system cannot identify new members automatically when the claim is submitted, you may implement as follows: (1) Reject the claim, with messaging to call pharmacy help desk if a chronic opioid user. Pharmacy Help Desk must be able to enter an override when the pharmacy calls and the pharmacist attests that the patient is a chronic opioid user at the prescribed dose.
(2) Expedited Authorization code submitted by the pharmacy where the pharmacist attests that the patient is a chronic opioid user at the prescribed dose, even if over the dosage limits per prescription.

ii) Documentation from the pharmacist or prescriber is not required
iii) Quantity limits and 42 day supply limit do not apply.

d) Current prior authorization on file.

5) Opioid prescriptions exceeding the limits in (3a) and (3b) that do not have an exception listed in (4) are not authorized unless provider submits attestation.

Chronic use of opioids for the treatment of non-cancer pain (applies to both short-acting and long-acting formulations)

6) Use of opioids for more than 42 days may be authorized in 12 month intervals when the prescriber signs the attestation below. Dose limits **do not apply** for existing chronic users; these are considered "grandfathered" as above, and do not require prior authorization or dose restriction at this time.

Attestation:
"I [Doctor's Name] attest that all of the below criteria are met, or there is documentation in the chart for why one or more are not applicable:
a) The patient has an on-going clinical need for chronic opioid use at the prescribed dose (more than 42 days per 90 day calendar period) that is documented in the medical record.
b) The patient is using appropriate non-opioid medications, and/or non-pharmacologic therapies; OR
c) The patient has tried and failed non-opioid medications and non-pharmacologic therapies for the treatment of this pain condition; AND
d) For long-acting opioids**,** the patient must be using or had trials of short-acting opioid therapy for at least 42 days; OR i) The reason for inadequate response to short-acting opioid therapy is documented in the medical record; OR
ii) Justification of beginning an opiate naïve patient on a long-acting opioid is documented in the medical record;

e) The provider has recorded baseline and ongoing assessments of measurable, objective pain scores and function scores. These should be tracked serially in order to demonstrate clinically meaningful improvements in pain and function; AND

f) The patient has been screened for mental health disorders, substance use disorder, naloxone use; AND
g) The provider will conduct periodic urine drug screens; AND
h) The provider has checked the PDMP for any other opioid use and concurrent use of benzodiazepines and other sedatives; AND
i) The provider has discussed with the patient the realistic goals of pain management therapy and has discussed discontinuation as an option during treatment; AND

j) The provider confirms that the patient understands and accepts these conditions and the patient has signed a pain contract or informed consent document.

By signing this attestation, I hereby certify that the above information is true, accurate and complete. That the requested treatment is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical record. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to recoupment upon an audit.

Definitions:

• **Short-acting opioid:** an opioid that is FDA-approved to manage pain severe enough to require opioid treatment and for which alternative treatment options are inadequate (includes tramadol and tapentadol; excludes trans-mucosal fentanyl and all buprenorphine products).
• **Long-acting opioid:** an extended release opioid that is FDA-approved to manage pain severe enough to require daily, around-the-clock, long-term opioid treatment for opioid-tolerant patients and for which alternative treatment options are inadequate (includes fentanyl patches and tramadol ER; excludes methadone and buprenorphine patches).
• **Dosage:** One dosage equals one tablet, one capsule, one suppository, or 5 ml.
• **Opioid:** Drugs containing the following ingredients
- Codeine
- Fentanyl
- Hydrocodone
- Hydromorphone
- Meperidine
- Morphine
- Oxycodone
- Oxymorphone
- Tapentadol
- Tramadol

• **MED:** Morphine equivalent doses per the calculator published on the Washington State Agency Medical Directors' Group website (http://agencymeddirectors.wa.gov/opioiddosing.asp)