Standard Operating Procedure	Medication Administration	CHPS SOP

PURPOSE: To provide administration guidelines for investigational and non-investigational medications given on CHPS units as well as during CHPS Scattersite visits [on non-CHPS units].

SCOPE: CHPS RNs and Clinical Study Teams (CSTs)

RESOURCES:

1. Medication Administration: HUP & CPUP Policy 4B-03-01.
2. Investigational Drug Policy: HUP & CPUP Policy 01-12-04.
3. Chemotherapy: Medication Use: HUP & CPUP Policy 01-12-49.
4. Control of Schedule I-V Medications (Controlled Substances): HUP & CPUP Policy 1-09-14
5. Minimal and Moderate Sedation for Diagnostic or Therapeutic Interventions: HUP & CPUP Policy: 01-12-11
6. Laboratory Point of Care Testing: HUP & CPUP Policy 1-12-54

PROCEDURE:

1. Hospital Policy
    a. CHPS staff follows hospital policy regarding medication administration including but not limited to the policies above.
2. Ordering Medications
    a. All medications, both investigational and non-investigational, administered during a CHPS visit need signed orders in the Electronic Medical Record (EMR). The Clinical Study Team (CST) is responsible for placing medication orders in the EMR or finding a qualified practitioner to do so. A Principal Investigator or Sub-Investigator is required to sign orders for Investigational Products (IPs); it is the responsibility of the CST to ensure that this requirement is followed.
    b. Beacon Treatment Plans
        i. Medication Given on a CHPS Unit (PCAM 4 South, Ravdin 6NE, and/or Mutch)
            1. A Beacon Treatment Plan is required for all medication administered on a CHPS unit. For exceptions regarding home medications, see Section 5c.
                a. For guidance on creating and submitting Beacon Treatment Plans, please visit the EPIC/BEACON Information page on the CHPS website.

b. **Please note: The Beacon Treatment Plan must be reviewed by CHPS prior to submission for build.**

ii. Medication Given on Non-CHPS Units

1. Inpatient Oncology Units

a. Beacon Treatment Plan is required.

2. Inpatient Non-Oncology Units

a. Beacon Treatment Plans are not utilized on non-oncology units. Instead, an Order Set must be created. Please email Geeti Ahmadzai from the PennChart Research Team to create an Order Set.

b. CHPS must also review Order Sets prior to finalization.

3. Releasing Medications
   a. **CST members are not permitted to release medications that will be administered at CHPS.**
   b. CHPS Staff will release medications from the Beacon Treatment Plan only after the following parameters have been collected and reviewed:
      i. Height and weight
         1. A height and weight must be collected on oncology patients every 7 days per the American Society for Clinical Oncology (ASCO).
         2. Some medications are weight-based or based on body surface area (BSA); BSA is calculated using both height and weight.
         3. For consistency, **height and weight will be collected on both oncology and non-oncology patients at every treatment visit.**
            a. If there is a physical limitation for a particular patient (ex. a patient with fibrodysplasia ossificans progressiva) to collect a height, it may be skipped for non-oncology patients if the treatment does not require a height.
      ii. Vital Signs
      iii. Nursing Assessment
      iv. Pregnancy Status
      v. Clinical lab results (if applicable)
   c. Any concerning parameters above or signs or symptoms that could impact the participant's ability to get treated must be escalated to the CST prior to release of medications.
   d. Releasing medications in the Beacon Treatment Plan signals to the pharmacy to begin preparing the medications.
      i. Sometimes medications are prepared independently from the CHPS RNs releasing them from the Beacon Treatment Plan. This process is known as Advanced Prep and is only utilized in select situations. Medications will not show up on the MAR until they have been released by the CHPS RN from the Beacon Treatment Plan. CST is not permitted to release Advanced Prep orders from the Beacon Treatment Plan.
4. Drug Preparation
   a. Drugs administered by CHPS RNs are prepared by Investigational Drug Services (IDS), PCAM Infusion Pharmacy, and/or Inpatient Pharmacy. Sometimes drugs are sourced from a combination of pharmacies for the same research study.

b. Drugs must be prepared, verified, and labelled in a pharmacy according to institutional policy. Medications must not be administered before they are verified by pharmacy, except in an emergency. Labels must be scannable through the Bar Code Medication Administration (BCMA) system. If there is an issue with the bar code for a particular medication, pharmacy must be contacted by CHPS staff. The issue should be resolved prior to medication administration, if possible.

5. Drug Administration
    a. Who Gives What?
        i. CHPS RNs must administer any medications being given on the CHPS unit, unless the route is 1) out of their scope of practice OR 2) requires specific training from the sponsor. In either of these cases, another appropriately credentialed and trained personnel will administer the medication.
            1. Routes of administration that are <u>within scope</u> for a CHPS RN include:
                a. Oral
                b. Subcutaneous
                c. Intramuscular
                d. Intravenous
            2. Routes of administration that are <u>out of scope</u> for a CHPS RN include:
                a. Nebulized
                b. Intrabuccal
                c. Intra-Parotid Gland
                d. Intrapleural
                e. Intrathecal
                f. Intratumoral
            3. Examples
                a. PI or HUP Respiratory Therapist would administer a nebulized treatment.
                b. PI or another medical provider would administer an intrathecal IP.
        ii. Time Outs
            1. Some routes of administration will require a Time Out prior to being performed on the CHPS unit. A Time Out requires the participation of the person performing the procedure as well as a CHPS RN. The following routes of administration would require a Time Out (list is non-exhaustive):
                a. Intrabuccal
                b. Intra-Parotid Gland
                c. Intrapleural
                d. Intrathecal
                e. Intratumoral
    b. Pregnancy Testing
        i. At CHPS, a person of child-bearing potential is defined as a person with a uterus between 18-65 years old who has not undergone menopause.
            1. Menopause is the permanent cessation of menses resulting from estrogen deficiency and is diagnosed when a person of child-bearing potential has not had a period for 12 consecutive months (Peacock et al., 2023).
        ii. A pregnancy test must be performed for persons of child-bearing potential prior to administration of any IP or any non-investigational chemotherapy or immunotherapy by CHPS RNs and/or on the CHPS unit. Therefore, a pregnancy test must also be performed when:

1. **Non-CHPS personnel** administers the above medication types **on a CHPS unit**.
2. **A CHPS RN** administers the above medication types **on a non-CHPS unit** (such as during a Scattersite visit).

iii. If the study involves more than one visit per week and the IP is oral, a pregnancy test only needs to be performed prior to the first administration of the IP and weekly thereafter.

iv. The CHPS department typically utilizes Point of Care (POC) urine pregnancy tests to determine pregnancy status. A urine HCG or serum HCG test analyzed by the Penn lab may be substituted if desired, although it is important to note that the results will take longer to receive than the POC test. Both a POC urine pregnancy test and a Penn lab pregnancy test can be performed if desired.

v. The POC urine pregnancy test is approved and under the jurisdiction of the University of Pennsylvania Health System (UPHS) Point of Care Testing (POCT) Oversight Committee which is in turn under the CLIA license holder of the hospital. This is outlined in the Laboratory Point of Care Testing hospital policy. Please also see the CHPS SOP: Point of Care Testing for more information.

vi. CHPS does not accept sponsor-provided and/or study coordinator-performed urine pregnancy test results on days IP is being administered. This is because CHPS is unaware of 1) the urine pregnancy tests' quality control checks and test timing requirements and 2) if the CST member has completed the mandated education, user competencies, and necessary documentation for the test.

vii. If a specific pregnancy test is required by the study, CSTs can complete the sponsor-provided test. However, CHPS will also perform the test on our hospital-approved POC urine pregnancy tests and document that result in EPIC. The CST is not permitted to put the results of the sponsor-provided test in EPIC.

c. Oral Medication

i. Dose Administration

1. If a patient is receiving their first dose of an oral IP on the CHPS unit:
    a. A Beacon order must be placed by the CST.
    b. The CHPS RN must administer the dose to the participant and document the administration on the Medication Administration Record (MAR).
2. Subsequent doses of the same IP can be self-administered by the participant on the CHPS unit, and a Beacon order is not needed. The administration will be recorded on the CHPS Nursing Worksheet instead.
    a. This is true even if the patient received their first dose of the oral IP in a non-CHPS area. In other words, if a participant receives the first dose of their oral investigational medication outside of the CHPS unit and thereafter takes it as a home medication, subsequent doses on the CHPS unit can be self-administered and do not require a Beacon order unless new bottles are being dispensed (see next section for more information). The self-administration will be recorded on the CHPS Nursing Worksheet.

ii. Dispensing New Bottles of Oral IP

1. If a patient is on the CHPS unit when they receive a new bottle of oral IP and is receiving a dose from the bottle while on the CHPS unit:
    a. CHPS staff will follow the usual procedures for dual medication check and mark the IP as "Given" on the MAR.
2. If a patient is on the CHPS unit when they receive a new bottle of oral IP but is not receiving a dose from the new bottle while on the CHPS unit:
    a. The CHPS RN will release the order from the Beacon Treatment Plan

b. The CHPS RN will utilize the "Investigational Dispense" option on the MAR after confirming that the bottle matches the order.
c. The study team is responsible for the patient education related to the oral IP such as timing of dosing, food intake, side effects, and hold parameters.

3. Informational Purposes only: If a patient is not on the CHPS unit when they receive a new bottle of oral IP:
    a. Oncology teams release orders from **Beacon Treatment Plans** and give oral IP bottles to participants once prepared
    b. Non-oncology teams utilize **e-Fax** and give oral IP bottles to participants once prepared

iii. Oral IP Dose Reductions

1. Dose reductions that DO NOT require IDS dispense:
    a. In these scenarios:
        i. There is no order in Epic
        ii. IDS is not dispensing IP
        iii. Patient is self-administering the IP from existing supply
    b. Required actions by the CST:
        i. Educate the patient on the dose reduction
        ii. Document in Epic that the patient was educated on the dose reduction
2. Dose reductions that do require IDS dispense:
    a. In these scenarios:
        i. There is an order in Epic.
        ii. IDS is dispensing a new supply of IP
        iii. CHPS is administering the IP
    b. Required actions by the CST:
        i. Update the order in Epic to reflect the new dose
        ii. Notify IDS and the CHPS RN of the new dose
        iii. Educate the patient on the dose reduction
        iv. Document in Epic that the patient was educated on the dose reduction

d. Intravenous Medication

i. Unless otherwise directed, CHPS RNs will administer the full volume of IP dispensed. A flush of the IV medication tubing is usually required to ensure the full volume is delivered. Please see the CHPS SOP: Flushing Medications for more information on this topic.

1. In the event of an Infusion-Related Reaction (IRR), the full dose of IP may be withheld following the guidance of the CST.

ii. Infusion-Related Reactions (IRRs)

1. In the event of an IRR on the CHPS unit, the CHPS RN will stop the infusion and assess the patient. A Rapid Response or a Code may be called depending on the clinical status of the participant. The CHPS staff will communicate with the CST to inform them of the situation. The PI or covering provider may be asked to come assess the patient on the unit and provide clinical guidance.
2. In the interest of patient safety, all Beacon Treatment Plans created for use on CHPS will include the Emergency Medication Order Set (Group 210), which correlates with the HUP Hypersensitivity Algorithm. These medications can be used in case of emergency.

7. Accountability and Disposal
    a. The MAR documentation serves the chain of custody demonstrating that the IP has been received by the CHPS team and administered to the participant.
    b. Unused IP and non-investigational medications
        i. If IP or a non-investigational medication is delivered to the CHPS unit but not administered, it must be returned to the pharmacy that it came from.
            1. For example, if a participant withdraws their consent from their research study after the IP has been delivered to CHPS, the IP must be returned to IDS.
        ii. If a participant is on an oral IP study with a bottle that is dispensed for home use, and the participant does not finish all the doses in the bottle, the CST must collect the IP from the participant and discuss next steps with IDS. The unused IP must not, under any circumstances, be left on the CHPS unit, as this does not allow for proper accountability of IP.

REFERENCES:

Peacock K, Carlson K, Ketvertis KM. Menopause. [Updated 2023 Dec 21]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK507826/

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