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Section:	Clinical Care/Patient Rights

Ordering and Administering of Anti-Neoplastic Agents/Chemotherapy

Purpose:

To ensure that antineoplastic therapy is safely ordered, prepared, and administered to patients with malignancies.

Definition:

Antineoplastic agents can be administered through an oral, subcutenaous, intramuscular, intra-arterial, intravesical, intrathecal or parenteral routes and are drugs administered with the intent of treating malignant neoplasms. Antineoplastic agents include but are not limited to cytotoxic chemotherapy, small molecule inhibitors, monoclonal antibodies, and drug conjugates. Hormonal agents are not included in the definition of antineoplastic therapy for the purposes of this policy. Some drugs used as antineoplastics may also be used for non-neoplastic indications; when used for other indications they are not covered by this policy.

Anti-neoplastics maybe classified as a Hazardous medication per the National Institute for Occupational Safety and Health (NIOSH) and United States Pharmacopeia 800 (USP 800) guidelines, please refer to Policy #13.03.013 *Hazardous Drug Handling* (Appendix A) for appropriate handling of these agents.

Application:

All orders for antineoplastic therapy at Boston Medical Center

Privileged practitioners to order antineoplastic therapy

a. Practitioners must be privileged during the credentialing process to order antineoplastic therapy. Privileged practitioners may include MDs and DO's. Nurse practitioners and physician assistants may also be privileged to order antineoplastic therapy, with the following exceptions:
   1) Nurse practitioners and physician assistants may not order antineoplastic therapy for stem cell transplantation.
b. Fellows in approved training programs may write chemotherapy orders but orders must be signed by a credentialed physician before they are available to nursing and pharmacy.
c. In emergent situations, a single dose of tretinoin or hydroxyurea may be ordered by a house officer or fellow without attending co-signature.
d. Interns, residents, pharmacists, and others may not write orders for antineoplastic therapy with the following exceptions:
   1) Pharmacists may re-order antineoplastic therapy for densitization protocols and when a dose of antineoplastic therapy requires separation into multiple bags, syringes, etc.
   2) Pharmacists may place antineoplastic orders on hold with consent of the ordering provider.

Exceptions:

None

Procedure:

1. **ANTINEOPLASTIC ORDERS:**

1.1. Antineoplastic orders must be written within the computerized order entry system (EPIC) as part of an approved treatment plan. Treatment plans must be approved by designated representatives from pharmacy, nursing, and physician leadership.

1.2. Specific directions, including dose guidelines for both intravenous and oral antineoplastics will be included in the treatment plan.

1.3. Doses for antineoplastics that are based on weight or body surface area must be calculated based on a weight obtained within 24 hours.

1.4. Treatment parameters must be based on laboratory values obtained within 24 hours of administration.

1.5. Orders for oral neoplastics will be referred to the specialty pharmacy upon signature of the treatment plan. Pharmacy will draft specific oral antineoplastic orders based on the directions in the treatment plan. Oral antineoplastic orders drafted by pharmacy will then be sent back to the ordering provider for signature prior to oral chemotherapy being dispensed. Oral antineoplastics will not be dispensed without final provider signature.

1.6. Initial antineoplastic orders for any given regimen must be accompanied by a treatment note. The treatment note must contain the following elements:

1.6.1. Names of the drugs being administered

1.6.2. Dosing guidelines for the drugs being administered (i.e the doses described in mg/m2 or mg/kg) and the associated dose schedule of the drugs. Specific dose calcluations based on body surface area or weight are not required in the treatment note

1.6.3. Indication for treatment

1.6.4. Description and reason for any dose adjustments from the standard regimen made in the treatment plan.

1.7. A subsequent treatment note describing dose modifications and reason for modifcations must be written for patients undergoing dose modifications,

1.8. A new treatment note must be written and signed for any inpatient receiving antineoplastic therapy during each inpatient admission.

1.9. All treatment notes must be signed by a credentialed attending physician. Nurse practitioners and physician assistants may not sign treatment notes.

1.10. For inpatients, if the provider signing the antineoplastic orders and treatment note is not the inpatient attending of record, the inpatient attending of record must document concurrence with administering chemotherapy in the patient chart prior to the administration of antineoplastic therapy.

1.11. Nursing and pharmacy will not dispense antineoplastics if there is not a valid order by a credentialed provider, an initial treatment note for the regimen signed by an attending physician, and a subsequent treatment note for patients requiring dose modifications on subsequent cycles or for inpatients during a new admission, as described above.

2. **SPECIAL CONSIDERATIONS FOR ORAL ANTINEOPLASTICS**

2.1. Prior to dispensing oral antineoplastics, the pharmacist will provide counseling to the patient confirming handling/dispending, directions of use, clinically relevant side effects, and contact information for their health care provider in the event of questions.

2.2. Patients receiving oral antineoplastics should be evaluated by their provider at a minimum of 3 month intervals. Oral antineoplastics will not be refilled for patients who have not seen their provider in more than 6 months.

3. **SPECIAL CONSIDERATIONS FOR INTRA-ARTERIAL AND INTRAVESICAL ANTINEOPLASTICS**

3.1. Intra-arterial chemotherapy must be administered under the direction of an interventional radiologist. All safety checks as described for other routes of administration must be performed. following the same safety checks described for chemotherapy administered via other routes.

3.2. Intravesicle chemotherapy can be prescribed and administered under the direction of an urology physician in an appropriate setting (i.e., staffing, equipment, etc.). All safety checks as described for other routes of administration must be performed. following the same safety checks described for chemotherapy administered via other routes.

4. **SPECIAL CONSIDERATIONS FOR INTRATHECAL ANTINEOPLASTICS**

4.1. Intrathecal antineoplastics can only be administered by a properly privileged LIP, or by a hematology/oncology fellow under the supervision of an attending physician. All safety checks as described for other routes of administration must be performed. In addition, a Universal Protocol (Time Out) is required before this procedure. (see *Policy #03.60.000 – Universal Protocol (Time Out))*

5. **CONSENT:**

5.1. Written informed consent must be obtained in accordance with *Policy #03.02.000 – Patient Consent* prior to **administration of drugs for antineoplastic indications**. Informed consent is required for each regimen, even if the drugs have been used earlier in the course of disease in a different combination. Desensitization protocols for drugs that have been administered previously are considered a new regimen. Consent is required for all routes of administration. The signed copy of the consent (either ink-signed paper consent or electronic signature) should be stored in the medical record, and a copy of the consent given to the patient. If paper, a copy must be sent to HIM for scanning into the patient's EHR. The original consent can be used for patients who are subsequently admitted to the inpatient setting but either the original consent or a copy should be available in the patient's medical record. If the consent is not available, a new consent for the current treatment plan must be obtained prior to antineoplastic administration. This policy applies for both standard regimens and for investigational drugs and research protocols.

5.2. **Hormonal Agents:** Hormonal agents used in the treatment of cancer do not require a written informed consent.

5.3. **Hydroxyurea:**

5.3.1. When Hydroxyurea is administered for treatment of malignant conditions (i.e. cytoreduction for leukemia) , the same policies and procedures used for other antineoplastics apply, with the exception of a single dose which may be ordered in emergent situations (i.e hyperleukocytosis).

5.3.2. When Hydroxyurea is administered for treatment of non-malignant conditions (i.e. sickle cell disease, myelofibrosis), informed consent is not required.

5.4. **All-trans retinoic acid (ATRA):** When ATRA is administered for the treatment of acute promyelocyctic leukemia (APL), the same policies and procedures for chemotherapy apply, with the exception of a single dose which may be ordered by a licensed independent provider (LIP) in emergent situations.

6. **NURSING PROCEDURES:**

6.1. Refer to *Nursing Policy #10.03.010 - Medication Administration*. And Hazardous Drugs and Chemotherapy waste and spill Policy #06.17.000.

6.2. Only RNs who have demonstrated competence (per BMC standards) in antineoplastic drug administration will administer antineoplastics.

6.3. Nurses in Urology may administer intravesical chemotherapy after requird competency obtained.

6.4. Oral anti-neoplastic agents) may not be be split or crushed; capsules may not be opened by RN at bedside/medication room for administration. If a patient is unable to swallow, the ordering provider and the Hematology Oncology Pharmacy Specialist should be informed for extemporaneous compounding of oral liquid dosage formulation or alternative drug delivery method for the anti-neoplastic agent.

6.5. Prior to administration, the following assessments and checks will be made by RN:

6.5.1. Review the antineoplastic treatment plan; assess the patient's understanding of treatment goals, the antineoplastic regimen prescribed, potential side effects, and patient self-care measures. The RN should provide and document the appropriate individualized teaching.

6.5.2. Complete pre-chemotherapy administration assessment:

6.5.2.1. Confirm that the signed consent is in the medical record (see section 3.1 for applicability).

6.5.2.2. Where appropriate, check all drug dosage and weight calculations and validate with an independent double check performed by a second RN, LIP, or pharmacist.The calculated dose must be within 10% of the ordered dose.

6.5.2.3. Check that a signed treatment note is in the chart. As noted above, a new treatment note is required for any new inpatient admission and for any dose modifications from the standard regimen.

6.5.2.4. Check that the orders contain all the components listed in Clinical Policy.

6.5.2.5. Confirm that lab results are within the parameters for administering treatment, as documented in the antineoplastic orders and treatment plan. Lab results must be from labs drawn within 24 hours of antineoplastic administration.

6.5.2.6. For antineoplastic orders based on weight or BSA, confirm that weight has been obtained within 24 hours.

6.5.3. Verify route and determine patency of intravenous ACCESS. For patients receiving intravesical chemotherapy, insert Foley as ordered.

6.5.4. Verify that the prepared antineoplastic label is independently double-checked by the administering RN and another RN, pharmacist or LIP against the written order. Both verifiers enter their signatures in EHR.

6.5.5. Compare patient name or name/medical record number (inpatient) or name/date of birth (outpatient) on name band with medical label on chemotherapy bag, syringe, or tablet/capsule packet.

7. **PHARMACY PROCEDURES:**

7.1.1. Only pharmacy technicians trained to compound chemotherapy may do so (exceptions include leucovorin and mesna or other non-hazardous compounds). If no chemotherapy

trained pharmacy technician is available, for planned inpatient chemotherapy, arrangements will be made by the inpatient pharmacy clinical specialist for preparation and delivery.

7.1.2. Patients continuing oral antineoplastics on the inpatient service may use their own home supply which will be stored on the respective floor's Pyxis machine. *See Policy #13.16.030 - Patient-Supplied Medication/Alternative Therapies* for procedure. Only nurses with demonstrated competency in antineoplastic procedures and policy may administer oral antineoplastics.

7.1.3. Clinical pharmacy specialists reserve the right to withhold dispensing treatment in situations where patients are not monitored in accordance with standard guidelines.

7.1.4. Antineoplastic doses , whenever applicable, will be rounded to the nearest vial size or concentration in order to ensure accurate measurement or minimize drug waste. The verifying pharmacist should ensure that the difference between the originally ordered and the rounded dose is within 10%.

7.1.5. All antineoplastic orders require two independent checks for verification prior to dispensing. The first check must be completed by a chemotherapy trained pharmacist.

7.1.6. Second verification may be completed by a chemotherapy trained pharmacist or a pharmacy resident that has completed a previous oncology learning experience (e.g. rotation).Order verification includes checking the medication name, dose, route and indication against the approved treatment plan or approved oral regimen. The pharmacists will also review laboratory parameters to ensure they are met, appropriateness for the disease state, and potential drug-drug interactions.

8. ADMINISTRATION PROCEDURE:

8.1. Handling Guide: All medications have been assessed for the risk of exposure as low, moderate or high risk. This list is continually reviewed and updated by the pharmacy department. See PPE section for link to BMC Hazardous Drug Handling Guide Chart.

8.2. Patients receving antineoplastic/High Risk Hazardous drugs are placed on Hazardous Drug Excreta Precautions. Staff must don Personal Protective Equipment (PPE) when handling drugs and/or patient excreta during and for 48 hours after IV drug administration. PPE consists of front closed, non-permeable, lint-free disposable gown with tight fitting cuffs, gloves, and a face shield if splashing is anticipated. Gowns are single use and should not be reused. The used gown and gloves should be disposed of in a yellow chemotherapy precaution trash bag or yellow bucket located in patient's room. Patients receiving oral or injectable anti-neoplastic agents excretions are continuously hazardous, based on the half-life of the agent.

8.2.1. Excreta from urinals/commodes shall be discarded in regular toilet facilities on the unit, with the lid down to prevent splash. For toilets with no lid, a disposable chuck can be placed over the opening to contain any splashes. Pour the waste gently to minimize splashing, and dispose of the chuck and all PPE in the yellow chemotherapy bucket. There is no evidence that double flushing is necessary. When yellow bucket is full, place in dirty utility room on the unit and call Environmental Health and Safety (EHS) at 617-638-8830 for pick up.

8.2.2. USP 800 Hazardous Drug Safety guidelines have classified some chemotherapy/targeted agents as hazardous. Refer to the alert on medication administration record, or on the BMC Nursing Department website, for the appropriate personal protective equipment (PPE) that must be worn when administering or handling hazardous agents.

8.2.3. Closed system transfer device (CSTD) must be used when preparing or administering high risk hazardous agents. Please refer to BMC website's inpatient pharmacy link to hazardous drug handling chart.

8.3. In the event of exposure to chemotherapy agents, refer to the Safety Data Sheet (SDS) for immediate treatment recommendations. Obtain the SDS for the chemotherapy drug that caused contamination through Lexicomp for possible decontamination procedures. To access Lexicomp from BMC intranet > click on Clinical > under CLINICAL RESOURCES, click on Drug Information (Lexicomp) > From menu at top of page, click on "Toxicology" > Under "Explore by General Category:", click on MSDS > search Drug Trade Name for SDS. Report event to the department supervisor and complete Accident Report Form (ART) as soon as possible (see *Policy #07.27.000 – Work Related Injuries*).

8.4. A RN/Pharmacist may take verbal orders from the hematology-oncology attending to hold the chemotherapy treatment only.

8.5. The RN, LIP and/or pharmacist will ensure that all appropriate protectants and possible rescue agents have been ordered and are available before administration of any anti-neoplastic agent.

8.6. Vesicant drugs will be administered as the first agent when more than one drug is being administered. It will be administered using a side-arm Intra Venous Push (IVP) and or bolus into a compatible running intravenous solution.

8.7. Continuous infusion vesicants or Irritants can only be administered via a central line.

8.8. Only antineoplastic drugs prepared by BMC Pharmacy that are properly labeled with the date, patient's name, medical record number, generic drug names, dose, expiration and pharmacist verification initials will be administered by the RN. Antineoplastics prepared by an outside pharmacy cannot be administered. Inpatients that bring in oral antineoplastics when difficult to obtain by pharmacy, will be kept in PYXIS, and administered from there.

8.9. If an antineoplastic is known to have an increased risk of allergic reaction, a LIP will be immediately available. Emergency medications and equipment will be available.

8.10. During intravenous push administration of vesicant drug, the RN will continually assess for signs and symptoms of infiltration and confirm a blood return after each 3cc of administered drug.

8.11. Continuous infusions of vesicants (which may be administered via a central line only) will be administered piggybacked into a compatible flush line. A blood return will be checked and documented every 4 hours. The central access site will also be checked and documented every 4 hours or as needed for signs or symptoms of infiltration. All nurses at BMC, even those not IV chemotherapy competent are responsible to assess central line site, patency and presence of blood return every 4 hours while patient is receving continuous IV infusion of chemotherapy agent.

8.12. When administering intravenous bolus infusions of antineoplastics the tubing must be pre-primed with a compatible solution. This chemotherapy or targeted therapy infusion is then piggybacked into a compatible main line at the port closest to the IV site, unless otherwise indicated.

8.13. When an antineoplastic agent requires non-PVC tubing, the chemotherapy line becomes the main line and the compatible flush line is piggybacked into the non-PVC tubing.

8.14. Complete an Adverse Drug Event (ADE) form A) only if antineoplastic toxicity is unexpected or the toxicity manifestation requires intervention and/or a change in the treatment plan; and B) when giving biotherapy, for any adverse event.

8.15. When RNs are administering an oral or injectable antineoplastic agent they must wear gloves, and dispose of empty syringe in sharps' container. Please see *Policy #06.17.000 - Chemotherapy Waste and Spill Response* if you have any questions, and the Drug handling chart on the medication administration record. .

8.16. All IV tubing luer lock injection ports must have an alcohol impreganated cap applied when not in use.

8.17. The travel of Inpatients with hazardous drugs infusing is prohibited. Stop infusion of hazardous drug if patient has to travel for emergency scan/procedure. If patients must travel to another area within the hospital with a hazardous medication infusing, a spill kit should accompany the patient. Otherwise, if a spill occurs, the transport worker will restrict the area and call the charge nurse of the sending unit, who will send nursing personnel with a spill kit to manage the spill, if spill is large and call x4-6666 for chemical spill safety assistance.

9. **SPECIAL CONSIDERATIONS FOR BROCKTON**

9.1. All oral anti-neoplastic taken by a Brockton patient will be verified by admitting provider with the prescribing oncologist, Drug/dose/route/frequency and administration instructions will be documented in electronic medical record in a Treatment note by the Oncologist. Consent will be in the electronic medical record.

9.2. Pharmacy will verify patient's supply and follow medication policy to secure oral medications.

9.3. A nurse will administer oral anti-neoplastic agents practicing safe handling (PPE) and an independent double check with another nurse confirming correct patient/drug/dose/route and frequency, then administer to patient practicing the "five rights" (i.e., right medication, right dose, right time, right route, and right patient), and document administration on the Medication Administration record in the electronic medical record.

9.3.1. Brockton nurses must be competent to administer oral chemo. The nuse will:

9.3.1.1. Complete the oral chemotherapy competency

9.3.1.2. Read and follow this policy, as well as Policy #06.17.000- Hazardous Drugs and Chemotherapy Waste and Spill.

9.3.1.3. Use the appropriate PPE (personnel protective equipment) when administering oral anti-neoplastic agents and handling hazardous excreta.

9.3.1.4. Review and understand resources available to administer oral anti-neoplastic.

9.3.1.5. Safely administer oral anti-neoplastic agents.

Responsibility:

Physicians, Nurse Practitioners,Physician Assistants, Pharmacists, RNs

Other Related Policies:

03.00.700 - Methotrexate for Early Ectopic Pregnancy
03.02.000 - Patient Consent
03.49.000a - Credentialing/ Privileging for Chemotherapy and Targeted Therapy for Non-Malignancy
03.60.000 - Universal Protocol (Time Out)
05.03.030 - Protective/Neutropenic Care
06.17.000 – Hazardous drugs and Chemotherapy Waste and Spill Response
07.27.000 - Work Related Injuries
10.03.010 - Medication Administration

10.03.110 - Management of IV Infiltrations and Extravasations
10.03.11a - Extravasation Addendum
13.03.013 - Hazardous Drug Handling
13.14.020 - Non-Formulary Medications
13.16.030 - Patient-Supplied Medication/Alternative Therapies

References:

Kienle, P. C. (2020) The Chapter <800> Answer Book. American Society of Health-System Pharmacists.
Goldspiel BR, DeChristoforo R and Daniels CE (2000) A continuous-improvement approach for reducing the number of chemotherapy-related medication errors Am J Health-Syst Pharm 57 (Suppl 4): S4-S9

Olsen M, LeFebvre K. B., Brassil K.J. (Eds)(2019) Chemotherapy and Immunotherapy Guidelines and Recommendations for Practice, Pittsburgh, PA: ONS.

Neuss, M.N, et al(2016) 2016 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards Including Standards for Pediatric Oncology. *Oncology Nursing Forum, 44(1)):January 2017, A1-A13*..

Initiated by: Nursing

Contributing Departments:
Pharmacy
Hematology/Oncology

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Section:	Safety

Hazardous Drugs and Chemotherapy Waste and Spill Response

Purpose:
To establish procedures for the handling and disposal of hazardous waste materials, including Hazardous Drug and Chemotherapy spills in accordance with the National Institute for Occupational Safety and Health (NIOSH) and United States Pharmacopeia (USP 800) guidelines.

Policy Statement:
It is the policy of Boston Medical Center (BMC) to manage hazardous wastes to minimize impacts on staff and the environment and to comply with applicable chemical waste disposal regulations. All hazardous waste material generated during its preparation, use or from spill clean-up operations must be disposed of in specifically designated containers in accordance with applicable regulations and standards. All hazardous spills will be handled immediately according to the procedures described below.

NIOSH and the U.S. Pharmacopeia (USP) have published standards to prevent possible exposure to all involved health care workers.

Application:
All staff at BMC who handle hazardous drugs and/or wastes.

Exceptions:
Any medication not identified on the NIOSH hazardous drug list, per USP 800 Guidelines.

Definitions:

1. A hazardous /chemotherapy drug is any agent for which pharmacy, NIOSH, or the manufacturer has defined special guidelines for preparation, storage and disposal. The term hazardous drug (HD)/chemotherapy drug is defined as a drug having any of the following properties: carcinogenicity, teratogenicity, or other developmental toxicity, reproductive toxicity, organ toxicity at low doses, and/or genotoxicity.

2. Black Bucket Waste are hazardous drugs listed on the BMC Hazardous Waste Pharmaceutical training available on BMC online training, listed on the side of the Black Bucket, Product Label or indicated on the Pyxis Machine. All waste associated with these drugs must be collected in the Black Bucket.

3. Yellow Bucket is for trace Chemotherapy waste only. This could include, but not limited to, PPE associated with prepping, administering and cleaning a Chemotherapy drug spill, or soiled linen from a patient receiving Chemotherapy.

4. Handling Guide: All medications have been assessed for the risk of exposure as low, moderate or high risk. This list is continually reviewed and updated by the pharmacy department. See PPE section for link to BMC Hazardous Drug Handling Guide Chart.

5. An "empty" container is one from which all wastes have been removed that can be removed using "commonly employed practices" for that type of container AND one of the following is true:
   No more than 1 inch of residue remains on the bottom of the container or liner OR no more than 3% by weight of the total capacity of the container.

6. A "non-empty" container is any Hazardous /Chemotherapy drug container that has more than 1-inch residue remaining in the container or greater than (>) 3% by weight of the total capacity of the container. If you are unsure whether the container is "empty," then assume it is non-empty.

7. EHS- Environmental Health and Safety.

8. EVS- Environmental Services.

9. OEM – Working Well Occupational and Environmental Medicine (OEM) Clinic

Procedure:

1. Personal Protective Equipment (PPE) for Medium and High-Risk Hazardous Drugs, refer to pharmacy or nursing website for Hazardous Drug Handling Chart.

   1.1. Patients receiving medium/high risk hazardous medications are placed on Hazardous Drug /Excreta Precautions. Staff must don PPE when handling patient excreta during and for 48 hours after IV. SQ or IM drug please check the half-life of the drug for how long it is in a patient's system. PPE consists of front closed, non-permeable, lint-free disposable gown with tight fitting cuffs, double pair of gloves, and a face shield if splashing is anticipated. Gowns are single use and should not be reused. The used gowns and gloves should be disposed of in a Yellow Bucket located in the patient's room. Oral hazardous medications are eliminated continuously via patient's excreta, use PPE when handling or disposing of all excreta.

   1.2. PPE required for patients receiving low risk hazardous drug are a single pair of gloves only.

   1.3. Excreta from urinals/commodes shall be discarded in regular toilet facilities on the unit. For toilets with no lid, a disposable chuck can be placed over the opening to contain any splashes. Pour the waste gently to minimize splashing, and dispose of the chuck and all PPE in the Yellow Bucket (trace Chemotherapy

waste) or if applicable the Black Bucket. There is no evidence that double flushing is necessary.

2. Waste Disposal

2.1. **UNUSED** sharps containing hazardous drugs **MUST** be returned to the pharmacy. Syringes and needles (sharps) that contained hazardous drugs must **NEVER** be placed in the Yellow or Black Buckets. They **MUST** be empty and placed in a red biological waste sharps container. If a syringe with needle is not empty and not able to safely separate needle to dispose into sharps container and syringe into Black Bucket, then please call pharmacy for disposal instructions.

2.2. Black Bucket Waste:

2.2.1. Left-over or unused (unable to return to Pharmacy) Black Bucket drugs.

2.2.2. All non-empty IV bags, tubing, and containers which held or carried Medium or high risk hazardous drugs.

2.2.3. Any material used to clean up a spill of medium or high risk hazardous drugs (Place in sealed plastic bag before placing into the Black Bucket).

2.2.4. According to federal regulations, some drugs are "acutely toxic" and therefore all containers which held this material must go into the Black Bucket, including IV bags and tubing even if empty. Please refer to medication label on the Black Bucket, or pharmacy warning.

2.2.5. Materials placed into a Black Bucket must be in closed containers. IV bags and tubing are considered closed containers.

2.2.6. Medications disposed of in the Black Bucket must be checked off on the outside label or written in the space provided.

2.3. Yellow Bucket:

2.3.1. Gowns, gloves, masks, wipes, chucks and any other PPE which were used during the preparation or administration of Chemotherapy drug(s).

2.3.2. Empty IV bags, tubing and containers which held or carried Chemotherapy drug.

2.3.3. Liquid hazardous agent in a urinary (Foley) catheter (e.g. intravesical) must first be emptied in toilet before disposal of (Foley) catheter into the Yellow Bucket following protocol for excreta disposal described in below in section 2.3.4.

2.3.4. Excreta from urinals/commodes shall be discarded in regular toilet facilities on the unit. For toilets with no lid, a disposable chuck can be placed over the opening to contain any splashes. Pour the waste gently to minimize splashing, and dispose of the chuck and all PPE in the Yellow Bucket (trace Chemotherapy waste) or if applicable, the Black Bucket. There is no evidence that double flushing is necessary.

2.3.5. Linen and supplies contaminated with bodily fluids (stool, urine, blood, emesis, sputum) from patients receiving medium and high risk hazardous drugs (IV- for 48hrs, oral -all the time while receiving drug, SQ/IM check

the half-life of the drug for how long it is in a patient's system) must be put in Yellow Bucket.

3. Container Placement

3.1. Inpatients receiving Chemotherapy are required to have individual Black and/or Yellow waste container(s) placed in their room. Black and Yellow Buckets are also centrally located on floors/units (dirty utility rooms) where hazardous drugs are administered and/or stored. Nursing Staff shall ensure hazardous wastes generated during hazardous drug administration are segregated into the appropriate bucket.

4. Container Management

4.1. **Yellow Buckets** are provided by the Supply Chain Operations (SCO). Yellow Buckets are collected by EVS. Pickups are scheduled by EVS. If additional pickup is needed, email EVS at DG-EVS@bmc.org and request a pick up.

4.1.1. Full Yellow Bucket containers shall be removed from patient rooms and stored in dirty utility rooms while awaiting pickup from EVS.
4.1.2. Yellow Buckets must be closed at all times

4.2. Black Buckets are provided by EHS. Pickups are requested by calling EHS at (617) 638-8830.

4.2.1. Black Buckets must be closed at all times.
4.2.2. Black Buckets must have a "Hazardous Waste Label" affixed at all times. As wastes are added to the bucket, check off the appropriate box on the label or if a hazardous drug is not listed on the pre-printed label you must write the name of the drug in the space provided. The label is required to reflect the bucket's contents. When the Black Bucket becomes full, the date must be written on the label.
4.2.3. Full Black Bucket containers shall be removed from patient rooms and stored in dirty utility rooms while awaiting pickup from EHS.
4.2.4. Black Buckets are periodically monitored to ensure that they are being managed properly, including closure, labeling, and replacement when full.

5. Training

5.1. All personnel who handle hazardous pharmaceutical wastes must complete the *Electronic online learning module* Hazardous Waste Pharmaceutical Training Annually, or receive an annual in-service training session conducted by EHS.

6. Spills

6.1. If spill is Small and within your control follow steps 6.1 – 6.12:

6.1.1. Obtain a hazardous drug Spill Kit. Hazardous drug spill kits are available either in the unit supply room or from central supply. The kit is a Medegen #9258 Chemotherapy or hazardous drug spill kit. If more cleaning material is needed obtain or request an additional kit.

6.1.2. Restrict access to the immediate area, place caution sign (included in kit) near spill location.

6.1.3. Don the appropriate PPE, including a plastic gown, eye protection and a properly fitted BMC issued N95 (not the mask provided in the kit) to protect against splashes, and double disposable *Nitrile* gloves.

6.1.4. If there is a hazardous drug spill on the patient's gown or bed linens, the contaminated items should be placed in the Black Bucket for disposal as hazardous waste. Carefully wash the patient's skin with soap and water to remove any product and limit exposure to the spilled hazardous drug. If required contact EHS through the Control Center at 617-414-6666 for additional Black Buckets. At the conclusion of the spill cleanup complete an online incident report in accordance with policy 04.01.000 Online Incident Reporting.

6.1.5. Using the absorbent pads, wipe up liquids and/or solids. If more pads are needed, obtain another kit.

6.1.6. Any broken glass should be scooped up using the included plastic scoop and hand tool, and put into the plastic hazardous drug bag (included with the kit).

6.1.7. If there is residual liquid in the yellow hazardous waste bag (included with kit), add package of solidifier (white powder included in the kit) to the bag.

6.1.8. Wash the area three (3) times with detergent (can use purple wipes) and rinse with water. Dispose additional materials including your PPE in a Black Bucket waste container.

6.1.9. Place all contaminated cleaning materials in plastic, seal it, and place it in Black Bucket waste container.

6.1.10. **AFTER** you complete step 6.1.9**:** Contact EVS 617-414-5183 to request the area be cleaned. The area should be considered dirty until EVS has finished cleaning the spill area.

6.1.11. If additional assistance with the spill is needed, contact EHS through the control center 617-414-6666.

6.1.12. If personal contamination occurs, the individual will:

6.1.12.1. Immediately remove gown and gloves, and/or contaminated clothing.

6.1.12.2. Wash affected area with soap and water. For eye contact, flush eyes with water or isotonic eye wash for at least 15 minutes.

6.1.12.3. Notify employee's manager of contamination and if applicable, seek immediate medical attention at Working Well/OEM (normal business hours) or the Emergency Department (after hours).

6.1.12.4. Obtain the Safety Data Sheet (SDS) for the Chemotherapy drug that caused contamination from the Pharmacy for possible decontamination procedures.

6.1.12.5. Complete an employee accident report for employee exposures.

6.2. If the spill is complex or out of your control follow steps 6.2.1 – 6.2.4:

6.2.1. Obtain a hazardous drug Spill Kit. Hazardous drug spill kits are available either in the unit supply room or from central supply. The kit is a Medegen #9258 Chemotherapy or hazardous drug spill kit.

6.2.2. Restrict area and place caution sign; notify EHS through the Control Center at 617 414-6666. When notifying EHS via control center include:

6.2.2.1. Location of spill,

6.2.2.2. Reporting person's name and contact information,

6.2.2.3. Product name, estimated quantity, potential complications associated with spill,

6.2.2.4. Are additional spill kits or supplies needed?

6.2.3. If there is a hazardous drug spill on the patient's gown or bed linens, the contaminated items should be placed in the Black Bucket for disposal as hazardous waste. Carefully wash the patient's skin with soap and water to remove any product and limit exposure to the spilled hazardous drug. If required contact EHS through the Control Center at 617-414-6666 for additional Black Buckets. At the conclusion of the spill cleanup complete an online incident report in accordance with policy 04.01.000 Online Incident Reporting.

6.2.4. Once EHS has cleaned the spill they will ask unit/department to call EVS 617-414-5183 to complete final cleaning of the area. The spill area should be considered dirty until EVS has finished cleaning the affected area.

6.2.5. If personal contamination occurs, the individual will:

6.2.5.1. Immediately remove gown and gloves, or all contaminated clothing.

6.2.5.2. Wash affected area with soap and water. For eye contact, flush the eye with water or isotonic eye wash for at least 15 minutes.

6.2.5.3. Notify employee's manager of contamination and if applicable, and seek immediate medical attention at Working Well/OEM (normal business hours) or the Emergency Department (after hours).

6.2.5.4. Obtain the Safety Data Sheet (SDS) for the Chemotherapy drug that caused contamination from the Pharmacy for possible decontamination procedures.

6.2.5.5. Complete an employee accident report for employee exposures.

7. Responsibility:

7.1. Nursing and Pharmacy are responsible for appropriately segregating Hazardous Drug waste in the designated waste containers. In addition, they are responsible for cleaning up hazardous drug spills (BMC Hazardous Drug list). Or contacting EHS for hazardous drug spills out of their control.

7.1.1. The travel of Inpatients with hazardous drugs infusing is prohibited. Stop infusion of hazardous drug if patient has to travel for emergency scan/procedure. If patients must travel to another area within the hospital with a hazardous medication infusing, a spill kit should accompany the patient. Otherwise, if a spill occurs, the transport worker will restrict the area and call the charge nurse of the sending unit, who will send nursing personnel with a spill kit to manage the spill.

7.1.2. Spills within their control, follow spill response guidance in Section 6.1

7.1.3. For out of control or complex spills, follow spill response guidance in Section 6.2

7.1.4. Notify EHS at 617-358-8830 when Black Buckets are full and EVS at DG-EVS@bmc.org for full Yellow Bucket's.

7.2. EVS is responsible for picking up and replacing Yellow Buckets and for mopping affected area after spill cleanup is complete.

7.3. EHS is responsible for assisting staff with hazardous drug spills that are out of staff's control or too complex for an individual to clean up. When notified, EHS will help with coordinating the pickup of Black Buckets.

Forms:

"Pharmaceutical Waste Disposal in BMC Pharmacies" - Placard is posted in all pharmacy locations in waste areas and is available through EHS.

"Pharmaceutical Hazardous Waste Satellite Accumulation Area" - Placard is posted in all Black Bucket locations and is available through EHS.

Other Related Policies:

03.49.000 – Chemotherapy & Targeted Therapy
04.01.000 –Online Incident Reporting
07.27.000 - Work Related Injuries
13.03.010 - Chemotherapy Orders
13.03.013 - Chemotherapy/Hazardous Drug Handling
Respiratory Protection Program Available through EHS

Initiated by: Nursing

Contributing Departments:

1. Pharmacy
2. Environmental Health and Safety
3. Nursing

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Management of Chemotherapy and Biological Infusion Reactions

Note: This guideline was developed using scientific data and expert opinions available at the time of its last review. The clinician may choose to deviate from the guideline based on clinical judgment and assessment of a specific patient's clinical condition and needs.

Purpose:

To standardize the management of infusion reactions, in patients receiving chemotherapy and/or biological agents, including therapeutic monoclonal antibodies. .

Background:

A. *Characteristics of infusion reactions and anaphylaxis*

Chemotherapeutic and biological agents utilized in the treatment of malignancies have an increased potential to cause infusion reactions. These infusion reactions can range in severity from mild to life-threatening. Infusion reactions usually occur during their administration but can occur up to a few hours after the end of their infusion. Infusion reactions are more likely to occur during the first or second infusions but can occur during subsequent infusions as well.

Potential signs and symptoms of infusion reactions are:

- Itching
- Scratchy Throat
- Chest tightness
- Difficulty breathing
- Difficulty speaking or swallowing
- Agitation or restlessness
- Dizziness or tunnel vision
- New onset of nausea and/or vomiting
- Back, abdominal, muscle pain
- Anxiety or sense of impending doom
- Fever and/or chills
- Need to urinate or defecate
- Flushing
- Hot Flashes
- Various skin rashes (e.g., urticarial)
- Respiratory distress with/without stridor or wheezing
- Swelling of face (lips/tongue), neck, hands or feet

- Cyanosis
- Alterations in heart rate and blood pressure

Anaphylaxis is a serious reaction that is rapid in onset and may cause death. The diagnosis is based on clinical signs and symptoms, which include:

- Respiratory compromise
- Hypotension or symptoms of end-organ dysfunction
- Skin/mucosal manifestations

Differentiating between anaphylaxis and an infusion reaction are difficult due to an overlap of many clinical features. There are certain signs and symptoms that are highly suggestive of anaphylaxis reactions: urticarial, repetitive cough, wheeze, throat tightness, and hypotension. Infusion reactions have several signs and symptoms that are not prominent in anaphylaxis. Fever and muscular pain symptoms seen in infusion reactions but not in anaphylaxis.

B. *Grading of infusion reactions*

GRADE 1	**GRADE 2**	**GRADE 3**	**GRADE 4**	**GRADE 5**
Mild transient reaction; infusion interruption not indicated; intervention not indicated	Therapy or infusion interruption indicated but responds promptly to symptomatic treatment; prophylactic medication indicated for less than 24 hours	Prolonged (e.g., not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for other clinical sequelae	Life-threatening consequences; urgent intervention indicated	Death

Reproduced from: Common Terminology Criteria for Adverse Events (CTCAE), Version 5.0, November 2017, National Institutes of Health, National Cancer Institute. Available at: https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_8.5x11.pdf.

C. *Risk stratification*

The following table provides EXAMPLES (NOT Inclusive) of some commonly-used medications, stratified according to high, moderate or low risk of initiating an infusion reaction.

HIGH RISK (>10%)	**MODERATE RISK (3-10%)**	**LOW RISK (<3%)**
IVIG	IV iron	Carmustine
ATG	Bleomycin	Gemcitabine
Monoclonal antibodies – e.g. Rituximab, obinutuzumab, daratumumab, cetuximab, trastuzumab	Carboplatin Cisplatin	Daunorubicin Doxorubicin Idarubicin
Paclitaxel	Docetaxel	Irinotecan

	Etoposide	Melphalan
Asparaginase (after several doses)	Oxaliplatin	Methotrexate
		Procarbazine

Infusion Reaction Treatment Plan:

A. *Infusion reaction orders with the treatment plan*

During the development and revision of treatment plans in EPIC, regimens that are associated with a high risk (>10%) of infusion reaction will incorporate standing infusion reaction medication orders as part of the treatment plan, to allow immediate intervention by the RN if symptoms occur without waiting for the clinician.

In the Moakley Infusion Clinic, a virtual "Hypersensitivity Kit" is built in the Pyxis, allowing for albuterol, dexamethasone (IV) and diphenhydramine (IV) to be overridden for quick access. Additional pharmacologic agents for the management of infusion reactions can be overridden through the treatment plan reaction order. Supplemental IV fluids, oxygen, and/or IM epinephrine maybe be required and ordered by the provider.

B. *Nursing management*

1. If any of the above signs/symptoms occur, STOP the infusion of the suspected medication immediately and:
   - Maintain IV access with normal saline
   - Outpatient setting: Notify the provider (this may be the patient's NP/PA or the late APP on for the evening) AND the patient's attending physician.
   - Inpatient setting: Notify the House Staff, and Resource Nurse and the hematology-oncology provider (this may be the fellow or attending).
   - Monitor vital signs (including O2 saturation) and mentation every 5 minutes
   - Perform an electrocardiogram (ECG) if patient is complaining of chest pain
   - Administer 2L supplemental oxygen by nasal cannula if the oxygen saturation is <90% and/or 10% lower than baseline
   - If the infusion reaction is severe (Grade 3 or higher) or there are signs/symptoms of anaphylaxis, call a Proceed Out (in the outpatient setting) or Rapid Response (in the inpatient setting)

2. RN may administer the following pharmacologic agents for management of the infusion reaction before the provider arrives and performs their own clinical assessment:
   - Diphenhydramine 25 mg IV x 1 for hives, itching, or anaphylaxis. If no response, may repeat 25 mg x 1 at 15 minutes after first dose for a total of 50 mg
   - Famotidine 20 mg IV x 1 for itching, hives, or anaphylaxis (administer with diphenhydramine)
   - Dexamethasone 8mg IV x 1 for shortness of breath, respiratory distress, or wheezing

- Acetaminophen 650mg oral x 1 for back pain or muscle spasm
- Albuterol 0.5 mL of 0.5% solution /2.5 mL saline by nebulizer for wheezing or stridor if ordered in the treatment plan
- Normal saline IV bolus if blood pressure is 20% less than patient's baseline if ordered in the treatment plan.
- Meperidine 25mg IV x 1 for rigors and/or chills. If no response, may repeat 25mg x 1 at 30 minutes after first dose for a total of 50 mg .

3. After resolution of the acute event, the decision to attempt retreatment depends upon the specific agent, severity of the reaction, and clinical situation:
    - For mild/moderate (Grade 1 and 2) infusion reactions lacking signs/symptoms of anaphylaxis, the RN may be instructed by provider to restart the infusion after repeating premedication at 50% of the infusion rate at time of reaction with close monitoring, and then slowly titrate up as tolerated, at the provider's (hematology-oncology fellow, APP or attending provider) discretion.

    - For severe (Grade 3 or higher) infusion reactions or any reactions with anaphylaxis, infusion should be stopped and retreatment should not be attempted. Call a Proceed out (outpatient, may require transfer to ED) or Rapid Response (inpatient- may require transfer to the ICU). Treatment may require permanent discontinuation, but sometimes may be attempted at a future occasion after additional premedication and infusion at a slower rate, at the discretion of the provider, and/or desensitization Protocol.

    - Epinephrine injection is available via override from the automated dispensing system and may be administered following assessment by a licensed independent practitioner pursuant to a verbal or written order.

Other Related Guidelines or Policies:

Section: Pharmacy

Medication Guideline #:

Title: Management of Chemotherapy and Biological Infusion Reactions

Initiated by: Adrian Zobniw, PharmD, BCOP, Diane Sarnacki, RN, MSN, AOCN 10/2022

Approved by: Pharmacy and Therapeutics Committee

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