EDUCATION UPDATE

Allegheny Health Network Cancer Institute

Anticancer Therapy (ACT)
Standards of Practice (SOPs)
Manual

2026

ACT Course

Table of Contents

Anticancer Therapy Overview

POL-8844166

Print Details Share Details

Overview Statement
This policy applies to the AHN entities and individuals identified in the applicability section below.

Registered Nurses (RNs), Advanced Practice Providers (APPs), Hematology/Oncology Fellows, Physicians, Pharmacists, and Pharmacy Technicians specially trained with anticancer therapy (ACT) agents follow the safety standards of practice.

Purpose:

A. To provide for the safe and effective prescribing, preparation/admixture, handling, administration, and disposal of ACT agents.

Terms and Definitions
ABBREVIATION GLOSSARY

ACT - Anticancer Therapy (this includes antineoplastic agents such as chemotherapy, anticancer therapy/antineoplastic therapy, targeted therapy, monoclonal antibodies, immunological agents, cellular therapy, photodynamic therapy) ***excludes hormonal therapy

A. Parental routes include: Intravenous (IV), Subcutaneous (SQ), Intramuscular (IM)
B. Alternate Routes - Specialized ACT administration routes (Intra-arterial, Intraperitoneal, Intrapleural, intravesical, Intrathecal, Intraventricular, intrahepatic, continuous infusion pumps), only trained licensed clinicians in these procedures may perform after being deemed competent (initially and annually) by another licensed clinician experienced in these administration procedures.
C. Solid dosage forms and oral suspensions

Advanced Practice Providers (APPs)- for the purposes of this policy, this includes Certified Registered Nurse Practitioners (CRNPs), Physician Assistants (PAs), and Hematology/Oncology Fellows.

ASCO - American Society Clinical Oncology

ASHP - American Society of Health System Pharmacists

AVS - After Visit Summary

Champion- Licensed/certified personnel trained in the ordering/prescribing, mixing/preparation, and/or administration of anticancer therapy. Designated trainers
are appointed with at least one year of practice in oncology area of practice. Champions complete annual competencies and are deemed competent annually by another licensed competent personnel with at least two years experience.

Competent- Performs the assigned task/procedure with competent application of knowledge, skills, and professionalism – not requiring champion prompting or intervention

EHR -Electronic Health Record

Hazardous Drugs: Considered hazardous by NIOSH if they meet one of the following criteria: carcinogenicity, teratogenicity, reproductive toxicity, organ toxicity at low doses, genotoxicity, and/or structure and toxicity profile of a new drug that mimics a drug that is classified as hazardous.

a. **NIOSH Table 1**: Drugs that meet the NIOSH definition of a hazardous drug contain Manufacturers Safe Handling Instructions (MSHI) and/or are classified by NTP as a 'known to be a human carcinogen' or by IARC as 'carcinogenic' or probably carcinogenic'.
b. **NIOSH Table 2**: Drugs that meet the NIOSH definition of a hazardous drug, but do not contain MSHI and are not classified by either NTP or IARC as carcinogenic or probably carcinogenic.

IP - Inpatient

Licensed Clinician - For purposes of this policy is a hematology/oncology fellow, APP, registered nurse or attending/prescribing physician.

Licensed Provider - For the purposes of this policy is a hematology/oncology fellow, APP, or attending/prescribing physician.

NIOSH - National Institute for Occupational Safety and Health

Non-Oncology ACT Inpatient OrderSets - Includes medications on the ACT Medication Policy List used for non-oncology indications in the inpatient locations. These are not Beacon Treatment Plans.

Details

Applicability
AHN Entity

Content Type
Policy

Responsible Area
Anticancer (ACT) Care

Executive Sponsor
Roberta Leinweber

Owner
Ciafre, Lisa

Former Numbers
PolicyStat ID: 8548742

Effective Date
11/1/2020

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1/15/2025

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11/30/2023

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Related Authoritative Sources

Related Content

Related Documents
Attachment A - 2016 Standards of Practice Manual.pdf
Attachment B - AHNCI Infrastructure.pdf
Attachment C - AHNCI ACT Med List.pdf
Attachment D. -AHN ACT IP Ordering-Admin Guidelines.pdf
Attachment E- ASCO -ONS Jan 2020 Standards Manual.pdf
Attachment F - AHNCI Cross Walk of Standards.pdf
Attachment G- AHNCI IP-OP OACT Procedural ACT.pdf

OACT - Oral Anticancer Therapy

OP - Outpatient

Provider - Licensed oncology attending/prescribing physicians, APPs, and Hematology/Oncology Fellows specially trained in the anticancer therapy administration process can prescribe ACT. Qualified providers include attending prescribing physicians and APPs licensed in the state of Pennsylvania and board certified or board eligible in hematology/oncology.

ONS - Oncology Nursing Society

QCP - QOPI Certification Program

QOPI - Quality Oncology Practice Initiatives

SOP - Standards of Practice

Supportive Therapy Plan - A type of therapy plan ordered only in oncology outpatient locations for medications not on the ACT List. The plans are approved and validated by the oncology team.

Therapy Plan - Includes medications on the ACT Medication Policy List used for non-oncology indications in the out-patient locations. These are not Beacon Treatment Plans.

Treatment Plan -An approved P&T ACT treatment protocol that is a planned regimen applied to a patient including the patient disease, goal of treatment, treatment of the disease, and supportive therapy. Treatment plans are only used for oncology patients by staff who receive access to the plan after completing Beacon training.

Administration
Anticancer Therapy (ACT) Council

A. A multi-disciplinary inter-facility network 'Anticancer Therapy (ACT) Council' meets monthly to develop, implement, and evaluate standards of practice (SOP) established from national anticancer/antineoplastic safety guidelines and regulatory bodies. **(Attachment A)**
    a. There are 12 scheduled meetings annually (face-to-face meetings and/or conference calls). Additional meetings as needed. Meetings may also be canceled as deemed necessary by the meeting organizer.
    b. Membership:
        i. Each facility is represented by a multidisciplinary team consisting of RNs, APPs, hematology/oncology clinical pharmacists, pharmacists, pharmacy technicians, physicians, and/or hematology/oncology fellows.
        ii. Meeting quorum consists of at least one member from each discipline (nursing and pharmacy) representing the team for their facility at each meeting. Substitute members are included in quorum.
        iii. Designated substitutes may represent the teams.
        iv. Any member or their designee missing more than two unexcused meetings in a calendar year are removed from the council.
        v. Department leaders appoint each designated representatives when necessary.
        vi. Those present at the meetings are the accountable individuals to disseminate the meeting information.
        vii. Voting occurs only when quorum is achieved at the meeting.
        viii. Chief Nursing Officers (CNOs) and Administrators are updated on discussions held and decisions made at the Council meetings, and are provided the opportunity for input.
    c. ACT council updates and changes in Standards of Practice (SOP) are reported to the Heme/Onc Subcommittee Pharmacy and Therapeutic (P&T) meetings. Once approved by Heme/Onc Subcommittee P&T, the changes are forwarded to the AHN P&T for approval and dissemination to AHN leadership **(Attachment B)**

General Overview

A. Anticancer Therapy (ACT) Medication List Criteria (which qualify medication as Anticancer Therapy) and the requirements are evaluated at least annually and updated by council **(Attachment C)**
B. Each location has designated areas with ACT trained staff.
C. A licensed provider is on-site within the facility and immediately available by phone and/or pager during any ACT administrations. For maximum resources and outcomes, it is recommended that all agents be administered following the inpatient ACT Ordering/Administration Proposed Guidelines **(Attachment D)**
D. Any unit or department that handles these medications must have access to the appropriate references available including the ONS Safe Handling of Hazardous Drugs, ONS Chemotherapy and Immunotherapy Guidelines and Recommendations for Practice 2nd Edition, and other resources as outlined below.
E. The preparation, handling, administration, and disposal of hazardous medications and related equipment are carried out in the manner recommended by industry and regulatory experts: American Society Clinical Oncology (ASCO), Occupational Safety and Health Administration (OSHA), National Cancer Institute (NCI), Oncology Nursing Society (ONS), the American Society of Health Systems Pharmacists (ASHP), and the National Institute for Occupational Safety and Health (NIOSH).
F. These standards address the American Society of Clinical Oncology (ASCO)/Oncology Nursing Society (ONS) Chemotherapy Safety Standards and are broken into the following sections: (**Attachment E and F)**
    1. Domain 1: Creating a Safe Environment - Staffing and General Policy
    2. Domain 2: Treatment Planning, Patient Consent and Education
    3. Domain 3: Ordering, Preparing, Dispensing, and Administering
    4. Domain 4: Monitoring After Chemotherapy is Given, Including Adherence, Toxicity, and Complications
G. ACT Requirements for Inpatient ACT Parenteral and/or OACT, IP OACT from home, and/or IP/OP Non-Oncology Indications and/or Procedures (**Attachment G)**

H. Non-oncology infusions treated in an AHNCI location are managed under the AHNCI's SOPs. (Exception: lab parameters are addressed in the therapy plan for non-oncology)
I. Do not prescribe, monitor, or facilitate care for ACT at non-AHN locations for the protection and safety of patients. Excluding continuous infusion ACT connected/disconnected by home health
J. AHNCI does not use or provide samples at any location

Exceptions
None

Violations
Violations of this policy or procedure may result in disciplinary action up to and including termination of employment.

Additional References

Related Policies/Procedures:

All AHN Anti-Cancer Therapy Policies

Additional References:

Connor, T.H., MacKenzie, B. A., DeBord, D. G., Trout, D. B., O'Callaghan, J. P., & Cincinnati, O. H. (2016). *NIOSH list of antineoplastic and other hazardous drugs in healthcare settings*. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH), 2016(161)- (Supersedes 2014-138). ttps://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf

Department of Health and Human Services. (2020). *NIOSH list of hazardous drug in healthcare settings 2000: Draft.* *https://www.cdc.gov/niosh/docket/review/docket233c/pdfs/DRAFT-NIOSH-Hazardous-Drugs-List-2020.pdf*

Gorski, L. A., Hadaway, L., Hagle, M. E., Broadhurst, D., Clare, S., Keidon, T., Meyer, B. M., Nickel, B. Rowley, S., Sharpe, E., & Alexander, M. (2021). *Infusion therapy standards of practice* (8th ed.). Infusion Nurses Society.

Jacobson, J. O., Polovich, M., McNiff, K., LeFebvre, K. B., Cummings, C.,Galioto, M., … McCorkle, M. R. (2009). American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards. *Oncology Nursing Forum, 36*(6), 1-8.

Jacobson, J. O., Polovich, M., Gilmore, T. R., Schulmeister, L., Esper, P.,LeFebvre, K. B., & Neuss, M. N. (2012). Revisions to the 2009 American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards: Expanding the scope to include inpatient settings. *Oncology Nursing Forum, 39*(1), 31-38.

National Comprehensive Cancer Network (NCCN, 2022). *NCCN distress thermometer and problem list for patients.* https://www.nccn.org/docs/default-source/patient-resources/nccn_distress_thermometer.pdf

National Institute for Occupational Safety and Health. (2016). *NIOSH list of antineoplastic and other hazardous drugs in healthcare settings:* 2016. https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf?id=10.26616/NIOSHPUB2016161

Neuss, M. N., Gilmore, T. R., Belderson, K. M., Billett, A. L., Conti-Kalchik, T., Harvey, B. E...Polovich, M. (2016). 2016 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology. *Journal of Oncology Practice, 12*(12), 1262-1276.

Neuss, M. N., Polovich, M., McNiff, K., Esper, P., Gilmore, T. R., LeFebvre, K. B., Schulmeister, L.…Jacobson, J. O. (2013). 2013 updated American Society of Clinical Oncology/Oncology Nursing Society chemotherapy safety standards for the safe administration and management of oral chemotherapy. *Oncology Nursing Forum, 40*(3), 225-233.

Olsen, M.M., LeFebvre, K.B., & Walker, S. L. (2023). *Chemotherapy and immunotherapy guidelines and recommendations for practice (2nd ed).* Oncology Nursing Society.

Polovich, M., & Olsen, M. M. (2018). *Safe handling of hazardous agents* (3rd ed.). Oncology Nursing Society.

People Applicability
Independent credentialed/privileged providers (including physicians, nurse practitioners, physician assistants, certified registered nurse anesthetists, and midwives); Employees (including residents and fellows); Researchers

Entity Applicability
This policy applies to Highmark Health and its subsidiaries and controlled affiliates; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Allegheny Singer Research Institute (ASRI); This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:AHN Cancer Institute; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Allegheny Clinic; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Saint Vincent Medical Group & Other Medical Offices

Contact(s)

List of Approver(s)
ROBERTA LEINWEBER - INSTITUTE VICE PRESIDENT - 1/15/2025
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regarding or requests for assistance with the information contained herein should be directed to your manager or to the subject matter contacts referenced herein.

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Anticancer Therapy Training and Staffing (1.1)

PROC-10653765

Print Details Share Details

Overview Statement
Registered Nurses (RNs), Advanced Practice Providers (APPs), Hematology/Oncology Fellows, Physicians, Pharmacists, and Pharmacy Technicians specially trained with anticancer therapy (ACT) agents follow the safety standards of practice.

Purpose:

To provide for the safe and effective prescribing, preparation/admixture, handling, administration, and disposal of ACT agents.

Details

Applicability
AHN Entity

Content Type
Procedure

Responsible Area
Anticancer (ACT) Care

Executive Sponsor
Roberta Leinweber

Owner
Ciafre, Lisa

Former Numbers

Effective Date
11/1/2020

Last Approved Date
1/8/2026

Last Revised Date
1/8/2026

Next Review Date
1/8/2027

Related Authoritative Sources

Related Content

Related Documents

The oncology attending prescribing physician ordering the treatment plan, and/or the hematology/ oncology fellow, APPS, and/ or hematology/oncology clinical pharmacists applying the treatment plan are to be knowledgeable on the disease process, treatment goals, drug classification, pharmacological indications and actions, methods of administration, rate of delivery, verification process, extravasation, hypersensitivity, and safe handling. In addition, they are responsible for checking the accuracy of the original orders as stated in the Oncology Nursing Society (ONS) Position Statement on Chemotherapy Administration.

The oncology clinical pharmacy team verifying and preparing the Anticancer Therapy (ACT) agents are to be knowledgeable on the drug classification, pharmacological indications and actions, methods of administration, rate of delivery, verification process, drug preparation/admixture, dispensing, extravasation, hypersensitivity, and safe handling.

The RN/licensed personnel administering the Anticancer Therapy (ACT) agents are to be knowledgeable on the disease process, treatment goals, drug classification, pharmacological indications and actions, methods of administration, rate of delivery, verification process, drug preparation/admixture, dispensing, extravasation, hypersensitivity, and safe handling. In addition, the licensed personnel administering ACT agents are responsible for checking the accuracy of the original orders as stated in the Oncology Nursing Society (ONS) Position Statement on Chemotherapy Administration.

ACT medications used for oncology procedures and non-oncology indications are administered by staff trained in safe handling and medical surveillance.

Terms and Definitions
ACT - Anticancer Therapy includes antineoplastic agents such as chemotherapy, anticancer therapy/antineoplastic therapy, targeted therapy, anticancer monoclonal antibodies, immunological agents, cellular therapy, photodynamic therapy. This excludes hormonal therapy. Routes of administration include: A. Parental routes include Intravenous (IV), Subcutaneous (SQ), Intramuscular (IM) B. Enteral Routes - Solid dosage forms and oral suspensions C. Alternate/Procedural Routes - Specialized ACT administration routes (Intra-arterial, Intraperitoneal, Intrapleural, intravesical, intralesional, intratumoral, Intrathecal, Intraventricular, intrahepatic, intratumoral, intralesional, and continuous infusion pumps), should only be used by licensed clinicians with advanced training in these procedures after being deemed competent (initially and annually) by another licensed clinician experienced in these administration procedures.

Advanced Practice Providers (APPs)- For the purposes of this policy, this includes Certified Registered Nurse Practitioners (CRNPs) and Physician Assistants (PAs).

Champion - Licensed/certified personnel trained in the ordering/prescribing, mixing/preparation, and/or administration of anticancer therapy. Designated champions are required to have at least one year of practice in oncology area of practice. Champions assist with initial training/validation and annual competencies.

Competency - Performs the assigned task/procedure with competent application of knowledge, skills, and professionalism – not requiring champion prompting or intervention.

OACT - Oral anticancer therapy

Licensed Clinician - Is a hematology/oncology fellow, APP, registered nurse, pharmacist, or attending/prescribing physician.

Licensed Provider- Is an APP, hematology/oncology fellow, or attending/prescribing physician.

Administration
Qualifications

A. Prescribing:

Only licensed hematology/oncology attending/prescribing physicians specially trained in the ACT administration process prescribe ACT treatment plans for patients with an oncology diagnosis. Qualified providers include attending/prescribing physicians licensed in the state of Pennsylvania and board certified or board eligible in hematology/oncology. Credentialing is maintained by the Medical Staff Office and available on-line.

APPs specialty trained and deemed competent during onboarding process may apply/prepare treatment plans for attending physician signature.

Hematology oncology fellows may apply/prepare treatment plans under the direct supervision of attending physician for attending physician signature.

Hematology/Oncology Clinical Pharmacy Specialists specially trained in the ACT process may apply/prepare, review, and verify ACT treatment plans.
B. Preparation:

Clinical Specialist Pharmacists/Licensed designees and licensed pharmacists specially trained in the ACT administration and admixture processes may review and verify ACT treatment plans and dispense ACT.

ACT is mixed, prepared, and dispensed by licensed clinicians, licensed pharmacists, and non- licensed/certified technicians in the state of Pennsylvania specially trained in the ACT administration and admixture processes.

Requirements include initial competency-based orientation and annual skills competency.

C. Administration:

Licensed clinicians specially trained in the ACT administration process administer all routes of ACT. Requirements include initial completion of the oncology ACT courses (based on experience) with simulation and checklists (based on experience) and annual skills competency.

For specialized ACT administration routes only trained licensed clinicians in these procedures may perform after being deemed competent by another licensed clinician experienced in these administration procedures.

D. Additional Requirements

At least one clinical staff member on site maintains current BLS certification from a nationally accredited course during ACT administration.

Training

Initial and annual competency checklists are revised annually based on evidence-based guidelines (available upon request).

ACT examination requirements (initial training):

Individuals pass anti-cancer therapy exams with an initial passing score of 85% or higher. Incorrect questions are retaken, then reviewed with the employee.

Individuals with less than 85%:

Incorrect questions are reviewed with the employee and study notes are taken by the employee.

The employee retakes the exam in a timeframe determined by the manager/director/ professional development team.

If the retake score is greater than or equal to 85%:

Incorrect questions are retaken, then reviewed with the employee.

If the retake score is less than 85%:

The employee retakes the course and retests upon course completion.

ACT annual competency requirements (ongoing assessment):
Incorrect response to any competency component results in:

Remediation of the staff member during the scheduled competency session.

If the remediation does not deem the employee competent:

The employee's manager is notified.

A written plan for improvement is created.

Employee signs the plan.

The employee will re-take the competency on another day.

Failure to meet pass criteria on second attempt deems employee as not passing.

Failure to successfully meet pass criteria for initial or ongoing assessments will result in:

The manager follows the AHN process with HR for assessment of employee meeting job requirements. This may include the possibility of a job transfer to an area not administering anticancer therapy agents or possible job termination.

All documentation is located in employee files.

Exceptions
None.

Violations
Violations of this policy or procedure may result in disciplinary action up to and including termination of employment.

Additional References
Hematology/Oncology Pharmacy Association. (2022). Guidelines, standards, summaries. https://www.hoparx.org/resources/guidelines-standards-summaries

Olsen, M.M., LeFebvre, K.B., & Walker, S. L. (2023). Chemotherapy and immunotherapy guidelines and recommendations for practice (2nd ed). Oncology Nursing Society.

People Applicability
Independent credentialed/privileged providers (including physicians, nurse practitioners, physician assistants, certified registered nurse anesthetists, and midwives); Employees (including residents and fellows); Researchers

Entity Applicability
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Contact(s)

List of Approver(s)
ROBERTA LEINWEBER - INSTITUTE VICE PRESIDENT - 1/8/2026
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Anticancer Therapy Treatment Planning and Documentation (1.2)

PROC-8863532

Print Details Share Details

Overview Statement
Registered Nurses (RNs), Advanced Practice Providers (APPs), Hematology/Oncology Fellows, Physicians, Pharmacists, and Pharmacy Technicians specially trained with anticancer therapy (ACT) agents follow the safety standards of practice.

Purpose:

A. To provide for the safe and effective planning and documentation of planned treatment.

Terms and Definitions
ACT - Anticancer Therapy (this includes antineoplastic agents such as chemotherapy, anticancer therapy/antineoplastic therapy, targeted therapy, monoclonal antibodies, immunological agents, cellular therapy, photodynamic therapy) ***excludes hormonal therapy

A. Parental routes include: Intravenous (IV), Subcutaneous (SQ), Intramuscular (IM)
B. Alternate Routes - Specialized ACT administration routes (Intra-arterial, Intraperitoneal, Intrapleural, intravesical, Intrathecal, Intraventricular, intrahepatic, continuous infusion pumps), only trained licensed clinicians in these procedures may perform after being deemed competent (initially and annually) by another licensed clinician experienced in these administration procedures.
C. Solid dosage forms and oral suspensions

Advanced Practice Providers (APPs)- For the purposes of this policy, this includes Certified Registered Nurse Practitioners (CRNPs), Physician Assistants (PAs), and Hematology/Oncology Fellows.

Licensed Clinician – For purposes of this policy is a hematology/oncology fellow, APP, registered nurse or attending/prescribing physician.

Licensed Provider – For purposes of this policy is a hematology/oncology fellow, APP, or attending/prescribing physician.

Administration

A. Prior to the first administration of a new ACT regimen, all required chart documentation is completed by the Licensed Provider and/or Licensed Clinician to include the following:
    1. Pathologic confirmation or verification of initial diagnosis. If original pathology report is unobtainable, a note of explanation is documented.
    2. Cancer stage at diagnosis, or current cancer status including a description of the patient's disease since diagnosis/staging (ie: recurrence, metastases).
    3. Complete medical history and physician examination that includes, at minimum:
        a. height and weight (cm and kg);
        b. treatment history;
        c. pregnancy status;
        d. assessment of organ-specific function as appropriate for the planned regimen;
        e. past and present use of tobacco, alcohol, illicit prescribed and/or over-the -counter drugs; and
        f. presence or absence of allergies and history of other hypersensitivity reactions.
    4. Documented assessment of patient's and/or caregiver's comprehension of information regarding the disease, and treatment plan
    5. Psychosocial assessment and action for support (see Monitoring and Assessment SOP).
        a. The practice offices, inpatient areas, and treatment sites maintain a listing of current psychosocial and supportive services accessible by the staff and patients in their region and/or nationally.
    6. Documented ACT regimen includes at minimum:
        a. patient diagnosis;
        b. goals of therapy;
        c. ACT drug doses;
        d. ACT anticipated duration of treatment;
        e. required monitoring for agents; and
        f. planned frequency of office visits.
    7. During the informed consent process, the provider also discusses pregnancy and fertility preservation (when applicable).
        a. Pregnancy Testing is NOT required on patients who:
            i. have prior bilateral oophorectomy, bilateral salpingectomy, or total hysterectomy
            ii. have permanent sterilization (tubal ligation or bilateral salpingectomy)
            iii. are age greater than or equal to 60
            iv. are greater than or equal to age 40 and less than 60 with amenorrhea for 12 or more months meeting one of the following two criteria:

Details

Applicability
AHN Entity

Content Type
Procedure

Responsible Area
Anticancer (ACT) Care

Executive Sponsor
Roberta Leinweber

Owner
Ciafre, Lisa

Former Numbers

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1/15/2025

Last Revised Date
12/4/2023

Next Review Date
1/15/2026

Related Authoritative Sources

Related Content

Related Documents

a. FSH and estradiol must be in post-menopausal range as defined by the ordering lab reference (AHN or other); OR
b. Absence of chemotherapy, tamoxifen, toremifene, or ovarian suppression

v. have Human Chorionic Gonadotropic (hCG) secreting tumors that require ACT (ie: ovarian germ cell tumors and trophoblastic disease)

b. Patients may decline the testing after discussion with provider, the provider documents in the medical record the rationale for the decline
c. Preferred pregnancy test is quantitative serum hCG.
d. Testing is performed within 3 days before each cycle (repeat at a minimum of 28 days during treatment unless clinically indicated sooner).
e. Positive serum hCG per facility reference ranges requires the provider to enter an order 'proceed to treat with rationale' if all parties agree to proceed with treatment with an understanding of the risks and benefits.

B. Standard and clinical trial ACT regimens by diagnosis is defined by oncology qualified physician(s), documented with references in the clinical trial protocol offices, located in the EHR system, practice ordering area, and/or physician's office.
C. **Clinical Trials**: The organization has clinical trials available to in- and out- patient populations. Clinicians are made aware of open/available trials and monitors for patient who meet eligibility. Referrals to clinical trials are made as appropriate.

Exceptions
None

Violations
Violations of this policy or procedure may result in disciplinary action up to and including termination of employment.

Additional References
Jacobson, J. O., Polovich, M., McNiff, K., LeFebvre, K. B., Cummings, C., Galioto, M., ... McCorkle, M. R. (2009). American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards. Oncology Nursing Forum, 36(6), 1-8.

Jacobson, J. O., Polovich, M., Gilmore, T. R., Schulmeister, L., Esper, P., LeFebvre, K. B., & Neuss, M. N. (2012). Revisions to the 2009 American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards: Expanding the scope to include inpatient settings. Oncology Nursing Forum, 39(1), 31-38.

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Olsen, M.M., LeFebvre, K.B., & Walker, S. L. (2023). *Chemotherapy and immunotherapy guidelines and recommendations for practice (2nd ed).* Oncology Nursing Society.

People Applicability
Independent credentialed/privileged providers (including physicians, nurse practitioners, physician assistants, certified registered nurse anesthetists, and midwives); Employees (including residents and fellows); Researchers

Entity Applicability
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Contact(s)

List of Approver(s)
ROBERTA LEINWEBER - INSTITUTE VICE PRESIDENT - 1/15/2025
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Anticancer Therapy Patient Consent (2.1; 4.2)

POL-10640914

Print Details Share Details

Overview Statement
Registered Nurses (RNs), Advanced Practice Providers (APPs), Hematology/Oncology Fellows, Physicians, Pharmacists, and Pharmacy Technicians specially trained with anticancer therapy (ACT) agents follow the safety standards of practice.

Purpose:

This policy will supplement the AHN General and Informed Consent to provide the process for obtaining informed consent specifically for the administration of Anticancer Therapy (ACT) agents.

Terms and Definitions
ACT- Anticancer Therapy (this includes antineoplastic agents such as chemotherapy, anticancer therapy/antineoplastic therapy, targeted therapy, monoclonal antibodies, immunological agents, cellular therapy, photodynamic therapy). Excludes hormonal therapy.

A. Parental routes include: Intravenous (IV), Subcutaneous (SQ), Intramuscular (IM)
B. Alternate Routes - Specialized ACT administration routes (Intra-arterial, Intraperitoneal, Intrapleural, intravesical, Intrathecal, Intraventricular, intrahepatic, intratumoral/intralesional, continuous infusion pumps), only trained licensed clinicians in these procedures may perform after being deemed competent (initially and annually) by another licensed clinician experienced in these administration procedures.
C. Solid dosage forms and oral suspensions

Advanced Practice Providers (APPs)- For the purposes of this policy, this includes Certified Registered Nurse Practitioners (CRNPs) and Physician Assistants (PAs.

EHR- Electronic Health Record

Licensed Clinician- Is a hematology/oncology fellow, APP, registered nurse, pharmacist, or attending/prescribing physician.

Licensed Provider- Is a hematology/oncology fellow, APP, or attending/prescribing physician.

OACT- Oral Anticancer Therapy.

Until Disease Progression – A specific criterion used to determine the duration of treatment to continue as long as the patient's disease does not worsen as determined by the attending provider or unacceptable toxicity.

Administration
A. Consent Process
1. Informed Consent is a process, not a form. It is the communication between the patient, a physician, or a Qualified Practitioner whereby the risks, benefits and alternatives are discussed. Consent is the exchange of this information resulting in the patient agreeing to undergo a specific intervention. The signatures on the consent form are the required documentation of that communication and consent.
2. Prior to receiving a new course or regimen of Anticancer Therapy (ACT), a written/electronic informed consent is obtained by an attending prescribing physician or hematology/oncology fellow by using the appropriate facility specific ACT Consent Form **(Attachments A,B,C),** and placed in the medical record. This includes any ACT Medication Policy List (ACT Med List.docx) for all routes requiring pharmacy dispensing.
    a. Any consent obtained by a hematology/oncology fellow is co-signed by the attending prescribing physician within 24 hours.
    b. If unable to obtain original signatures in extenuating circumstances, phone consent may be obtained following the AHN General and Informed Consent Policy.
3. **Emergencies –** Those situations where the patient is unable to consent and a delay for the purpose of obtaining consent either from the patient or a Legally Authorized Representative would expose the patient to a significant risk of death or serious bodily harm. In those circumstances, necessary care may be provided without obtaining an Informed Consent as long as the treatment/procedure is limited in scope to what is imminently exposing the patient to significant risk of death or serious bodily harm. Any treatment beyond this scope should be deferred until proper informed consent can be provided and obtained.
    a. Emergent administration of ACT is defined as delaying treatment may cause irreversible bodily harm, organ disfunction, morbidity, or mortality; includes oncologic emergencies. Refer to attachment IP ACT Planned and Emergent Treatment Planning Guidelines for procedure.
    b. In these emergent cases, the overnight covering physician or hospitalist obtains consent for the urgent dose(s) of medication(s). The oncology provider reconsents the patient within 24 hours for ongoing ACT treatment.

Details

Applicability
AHN Entity

Content Type
Policy

Responsible Area
Anticancer (ACT) Care

Executive Sponsor
Roberta Leinweber

Owner
Ciafre, Lisa

Former Numbers

Effective Date
11/1/2020

Last Approved Date
11/25/2025

Last Revised Date
11/25/2025

Next Review Date
11/25/2026

Related Authoritative Sources

Related Content
General And Informed Consent (including Pediatric / Minor Consent)

Anticancer Therapy Ordering (1.1.1; 3.1; 4.4)

Related Documents
ONC-201103-001 (R8-24) Informed Consent for the Administration of Anticancer-Immunotherapy Agents_WPH DNP.pdf
ONC-201103-002 (R8-24) Informed Consent for the Administration of Anticancer-Immunotherapy Agents_GC DNP.pdf
ONC-201103-003 (R8-24) Informed Consent for the Administration of Anticancer-Immunotherapy Agents_SVH DNP.pdf
IP ACT Planned and Emergent Treatment Planning Guidelines Nov 2025.pdf

4. Witnesses to the consent are AHN employees, not patient family members. Witness signature documents the patient's acknowledgement and signature.
5. No abbreviations are used on consents.
6. Generic and/or trade name is written on the consent (generic is preferred).
7. The consent is valid for the duration of the treatment plan discussed during the informed consent process, unless there is a material change to the risk/benefit analysis. The duration includes treating until disease progression.
8. The consent is valid from the date of the first treatment.
9. The following circumstances requires a new informed consent:
    a. The regimen adds new ACT agents from the original informed consent plan of care.
    b. Addition of cycles beyond the original planned cycles even with the same ACT agents.
    c. When switching between products/ACT medications, if the generic name is different a new consent is required.
    d. There is a material change to the risk/benefit analysis.
    e. For concurrent XRT/ACT, the consent is valid for the duration of the radiation treatment.
    f. An additional separate AHNCI ACT Consent is also required for patients on research studies and clinical trials.
        i. Research protocols and clinical trials have a separate consent and are maintained by the protocol office with a copy placed in the medical record.
        ii. The duration of treatment for patients on clinical trials/study drugs can state "See Research Consent".
10. Note: height and weight changes, dose adjustments, and/or holding agents for toxicities or organ function does not require a new consent. This is addressed in the informed risk/benefit discussion. The progress note, treatment plan, and/or treatment summary reflects the rationale for the adjusted treatment plan.
11. During the informed consent process, the provider also discusses pregnancy and fertility preservation (when applicable). Refer to Anticancer Therapy Ordering Policy for more details.
12. Signed written consent forms are scanned into the EHR.

Exceptions
None

Violations
Violations of this policy or procedure may result in disciplinary action up to and including termination of employmeNonent.

Additional References
Jacobson, J. O., Polovich, M., McNiff, K., LeFebvre, K. B., Cummings, C.,Galioto, M., … McCorkle, M. R. (2009). American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards. Oncology Nursing Forum, 36(6), 1-8.

Jacobson, J. O., Polovich, M., Gilmore, T. R., Schulmeister, L., Esper, P.,LeFebvre, K. B., & Neuss, M. N. (2012). Revisions to the 2009 American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards: Expanding the scope to include inpatient settings. Oncology Nursing Forum, 39(1), 31-38.

Informed Consent. (2002). MEDICAL CARE AVAILABILITY AND REDUCTION OF ERROR (MCARE) ACTAct of Mar. 20, 2002, P.L. 154, No. 13 40 Chapter 5, Section 504. Retrieved from https://www.health.pa.gov/topics/ Documents/Laws%20and%20Regulations/Act%2013%20of%202002.pdf

Neuss, M. N., Gilmore, T. R., Belderson, K. M., Billett, A. L., Conti-Kalchik, T., Harvey, B. E...Polovich, M. (2016). 2016 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology. Journal of Oncology Practice, 12(12), 1262-1276.

Neuss, M. N., Polovich, M., McNiff, K., Esper, P., Gilmore, T. R., LeFebvre, K. B., Schulmeister, L....Jacobson, J. O. (2013). 2013 updated American Society of Clinical Oncology/Oncology Nursing Society chemotherapy safety standards for the safe administration and management of oral chemotherapy. Oncology Nursing Forum, 40(3), 225-233.B.,

Olsen, M.M., LeFebvre, K.B., & Walker, S. L. (2023). Chemotherapy and immunotherapy guidelines and recommendations for practice (2nd ed). Oncology Nursing Society.

Polovich, M., & Olsen, M. M. (2018). Safe handling of hazardous agents (3rd ed.). Oncology Nursing Society

People Applicability
Independent credentialed/privileged providers (including physicians, nurse practitioners, physician assistants, certified registered nurse anesthetists, and midwives); Employees (including residents and fellows); Researchers

Entity Applicability
This policy applies to Highmark Health and its subsidiaries and controlled affiliates; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Allegheny Singer Research Institute (ASRI); This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:AHN Cancer Institute; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Allegheny Clinic; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Saint Vincent Medical Group & Other Medical Offices

Contact(s)

List of Approver(s)
ROBERTA LEINWEBER - INSTITUTE VICE PRESIDENT - 11/25/2025
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regarding or requests for assistance with the information contained herein should be directed to your manager or to the subject matter contacts referenced herein.

Table of Contents

Anticancer Therapy Patient Education (2.2)

PROC-8863534

Print Details Share Details

Overview Statement
Registered Nurses (RNs), Advanced Practice Providers (APPs), Hematology/Oncology Fellows, Physicians, Pharmacists, and Pharmacy Technicians specially trained with anticancer therapy (ACT) agents follow the safety standards of practice.

Purpose:

A. To provide evidence-based standardized patient education materials to the patient and caregivers on prevention, diagnosis, treatment plans, side effects, survivorship, and/or access to healthcare services and resources.

Terms and Definitions
ACT - Anticancer Therapy (this includes antineoplastic agents such as chemotherapy, anticancer therapy/antineoplastic therapy, targeted therapy, monoclonal antibodies, immunological agents, cellular therapy, photodynamic therapy) ***excludes hormonal therapy

A. Parental routes include: Intravenous (IV), Subcutaneous (SQ), Intramuscular (IM)
B. Alternate Routes - Specialized ACT administration routes (Intra-arterial, Intraperitoneal, Intrapleural, intravesical, Intrathecal, Intraventricular, intrahepatic, continuous infusion pumps), only trained licensed clinicians in these procedures may perform after being deemed competent (initially and annually) by another licensed clinician experienced in these administration procedures.
C. Solid dosage forms and oral suspensions

Advanced Practice Providers (APPs)- For the purposes of this policy, this includes Certified Registered Nurse Practitioners (CRNPs), Physician Assistants (PAs), and Hematology/Oncology Fellows.

EHR - Electronic Health Record.

Licensed Clinician - Is a hematology/oncology, APP, registered nurse, or attending/prescribing physician.

Licensed Provider - Is a hematology/oncology fellow, APP, or attending/prescribing physician.

OACT - Oral Anticancer Therapy

Administration
Patient Education Material Development

A. All patient education materials are evaluated by the AHNCI Patient Education Council prior to use.
    1. Patient education materials provided with AHN approved written literature, notebooks, pamphlets, handouts, medication information sheets, community resources, starter kits, and/or samples uses **(Attachment A)**
    2. Patient education materials provided with AHN or industry approved media uses **(Attachment B**)
    3. Patient education materials provided with an AHN, organization, or industry approved websites uses **(Attachment C)**
B. When a clinical staff member or administrator identifies the need for a particular patient education material, and confirms the need with his/her department, educator or director/supervisor, a request is submitted to the AHNCI Patient Education Council for review of the following:
    1. Determine if external sources of patient education materials exist prior to developing AHN materials. Clinical educators, other clinical experts, and library staff assist in identifying sources of patient education materials.
    2. Once the need is confirmed, the licensed health-care professional develops a draft of the education material.
    3. Material is written in a 6th grade reading level, but no higher than an 8th grade reading level.
    4. The draft material is reviewed by the licensed health-care professional knowledgeable in the requested content area.
    5. The final draft of the patient education is sent to the AHNCI Patient Education Council for review, evaluation, and approval/denial.
    6. If needed, the drafted patient education material is then sent to the communications department for editing and design.
    7. The clinical staff member then sends the material to be printed and/or placed in the EHR and AHN intranet
C. Staff access patient education materials via electronic medical record, AHN intranet and intranet, and/or approved pamphlets and handouts.

Details

Applicability
AHN Entity

Content Type
Procedure

Responsible Area
Anticancer (ACT) Care

Executive Sponsor
Roberta Leinweber

Owner
Ciafre, Lisa

Former Numbers

Effective Date
11/1/2020

Last Approved Date
1/15/2025

Last Revised Date
12/4/2023

Next Review Date
1/15/2026

Related Authoritative Sources

Related Content

Related Documents
Attachment A - Evaluation form for printed materials.pdf
Attachment B - Evaluation form for media materials.pdf
Attachment C - Evaluation form for websites.pdf
Attachment D - Pre teach education guidelines.pdf
Attachment E. - Patient Office Letter.pdf
Attachment F - General Taking Care During Treatment.pdf
Attachment G - Late and Long Term Side Effects.pdf
Attachment H - Fertility Preservation.pdf
Attachment I -Sexual Health and Intimacy.pdf
Attachment J - Immunotherapy Patient Education.pdf
Attachment K -Food Safety.pdf
Attachment L Oral Nutritional Supplements.pdf
Attachment M - Small Snacks and Meals.pdf
Attachment N- Caring for Central Line Site.pdf
Attachment O - Home Infusion Pump Education.pdf
Attachment P - Patient Guide SCT.pdf

Patient Education Material Review

A. The AHNCI Patient Education Council meets monthly, as a multidisciplinary group, to review education materials (written, media, Internet resources , etc) that are recommended for use.
B. The council is responsible for assuring the materials are up-to-date in medical content, appropriate reading level (a 6th grade reading level is recommended, but no higher than 8th grade level), and available on topics about a patients disease, treatments, side effects, survivorship, and resources to all oncology patients.
C. Team members coordinate storage and distribution of materials to each AHNCI site.
D. AHNCI developed written material and media is reviewed annually and revised every three years or sooner if deemed necessary.
E. AHNCI organization, or industry approved websites are reviewed annually or sooner if deemed necessary.

Patient Education Process

A.The licensed clinician assesses and documents the patient/family/caregiver or others on the basis of the patient's ability to manage the treatment plan.

B. The education process is tailored to the patients learning needs, abilities, preferences, and readiness to learn

C. The licensed clinician assesses and confirms patients ability to adhere to the treatment plan. This includes, but not limited to, financial, cognitive, behavioral, access to care, and support systems

D. Initial pre-teach for ACT (appointment prior to first treatment) applies to all routes – oral, intravenous, intramuscularly, subcutaneously, intraarterial, intraperitoneal, intrapleural, intravesicular, intraventricular, intrathecal, intrahepatic) (**Attachment D**). The patient and/or family/caregivers are provided verbal and written/electronic documentation about the planned treatment including:

1. Diagnosis/disease
2. Goals of treatment (cure, prolong life, palliative, etc)
3. Planned duration of ACT of administration, drug names, and supportive medications
4. Possible ACT short- and long-term side effects including fertility risks
5. Plan for monitoring and follow-up with emergency contact information (contacting the practice, reporting symptoms, who to call)
6. Drug-drug and drug-food interactions
7. Plan for missed doses
8. Symptoms requiring contact to health care setting or immediate care
9. Procedures for safe handling of medications in the home, storage, and management of unused medication
10. Handling body secretions and waste in the home
11. Follow-up plans, including laboratory and provider visits
12. Contact information for the health care setting, with availability and instructions on when and who to call
13. Missed appointment expectations (including rescheduling and cancelling)
14. Multidisciplinary resources for the patient including financial, psychosocial, and other cancer support services and resources.

E. Modified pre-teach for ACT applies to patients changing ACT medications, regardless of the route. The appointment may be prior to the first day of new treatment, the day of treatment prior to initiation, or by telehealth (**Attachment D**). The patient and/or family/caregivers are provided verbal and written/electronic documentation about the planned treatment including

1. copy of new consent

2 new ACT medication drug information

3 copy of the treatment plan with goals of therapy

4. general ACT and/or OACT education sheet

5. if the modified is for a new secondary disease diagnosis, provide disease specific teaching or notebook.

F. Educational materials are accessed in the EHR and attached to the After Visit Summary (AVS)/discharge forms when applicable (**Attachments E-P**)

G. If a patient declines the pre-teach appointment, the required materials are provided and reviewed the first day of treatment with the licensed clinician. Additional treatment chair time is provided for the pre-teach appointment day of treatment.

H. Radiation Oncology Pre-Teach:

1. Prior to receiving the first radiation oncology treatment, the patient and caregivers are provided verbal and written/electronic documentation about the planned treatment including:

a. General radiation therapy
b. Symptom management
c. Site specific radiation side effects
d. Post treatment management

I. Inpatient pre-teaches are for newly diagnosed patients receiving first treatment in an inpatient location. The patient and/or family/caregivers are provided verbal and written/electronic documentation about the planned treatment including:

1.copy of the consent

2. goals of treatment

3. treatment plan

4. disease and ACT drug information sheets

5. patients are scheduled for a full-or modified pre-teach prior to the next scheduled cycle to receive all required initial pre-teach materials.

Exceptions
None

Violations
Violations of this policy or procedure may result in disciplinary action up to and including termination of employment.

Additional References
External or Regulatory References:

Agency for Healthcare Research and Quality.(2020). *PEMAT for printable materials (PEMAT-P).* https://www.ahrq.gov/health-literacy/patient-education/pemat.html

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Neuss, M. N., Gilmore, T. R., Belderson, K. M., Billett, A. L., Conti-Kalchik, T., Harvey, B. E...Polovich, M. (2016). 2016 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology. *Journal of Oncology Practice, 12*(12), 1262-1276.

Neuss, M. N., Polovich, M., McNiff, K., Esper, P., Gilmore, T. R., LeFebvre, K. B., Schulmeister, L....Jacobson O. (2013). 2013 updated American Society of Clinical Oncology/Oncology Nursing Society chemotherapy safety standards for the safe administration and management of oral chemotherapy. *Oncology Nursing Forum, 40*(3), 225-233.

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Polovich, M., & Olsen, M. M. (2018). *Safe handling of hazardous agents* (3rd ed.). Oncology Nursing Society.

Unknown Author. (2017). *How to write easy-to-read health materials*. ttps://medlineplus.gov/ etr.html

Wittenberg, E., Ferrell, B., Kanter, E., & Bulter, H. (2018). Health literacy exploring nursing challenges to providing support and understanding. *Clinical Journal of Oncology Nursing, 22*(1), 53-61

People Applicability
Independent credentialed/privileged providers (including physicians, nurse practitioners, physician assistants, certified registered nurse anesthetists, and midwives); Employees (including residents and fellows); Researchers

Entity Applicability
This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Allegheny Singer Research Institute (ASRI); This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:AHN Cancer Institute; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Allegheny Clinic; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Saint Vincent Medical Group & Other Medical Offices

Contact(s)

List of Approver(s)
ROBERTA LEINWEBER - INSTITUTE VICE PRESIDENT - 1/15/2025
Back to List

Table of Contents

Anticancer Therapy Ordering (1.1.1; 3.1; 4.4)

PROC-10311326

Print Details Share Details

Overview Statement
Registered Nurses (RNs), Advanced Practice Providers (APPs), Hematology/Oncology Fellows, Physicians, Pharmacists, and Pharmacy Technicians specially trained with anticancer therapy (ACT) agents follow the safety standards of practice.

Purpose:

A. To ensure a safe and effective ordering process of ACT agents.
B. To provide treatment protocol, plan development, and ordering guidelines.

Details

Applicability
AHN Entity

Content Type
Procedure

Responsible Area
Anticancer (ACT) Care

Executive Sponsor
Roberta Leinweber

Owner
Ciafre, Lisa

Former Numbers

Effective Date
11/1/2020

Last Approved Date
10/22/2025

Last Revised Date
10/22/2025

Next Review Date
10/22/2026

Related Authoritative Sources

Related Content

Related Documents
Attachment A - ACT ordering formulary.pdf
Attachment B - ACT ordering nonformulary.pdf
Attachment F - Lab based hold parameters.pdf
Attachment G - Non Lab based Monitoring Parameters.pdf
ACT Med List updated 10.17.25 .pdf
Attachment C - Inpatient ACT Formulary 090825 with inpatient use criteria.pdf

Terms and Definitions
ACT - Anticancer Therapy includes antineoplastic agents such as chemotherapy, anticancer therapy/antineoplastic therapy, targeted therapy, anticancer monoclonal antibodies, immunological agents, cellular therapy, photodynamic therapy. This excludes hormonal therapy. Routes of administration include:

A. Parental routes include: Intravenous (IV), Subcutaneous (SQ), Intramuscular (IM)
B. Enteral Routes – Solid dosage forms and oral suspensions
C. Alternate Routes - Specialized ACT administration routes (Intra-arterial, Intraperitoneal, Intrapleural, intravesical, Intrathecal, Intraventricular, intrahepatic, intratumoral, intralesional, and continuous infusion pumps), only trained licensed clinicians in these procedures may perform after being deemed competent (initially and annually) by another licensed clinician experienced in these administration procedures.

Advanced Practice Providers (APPs)- For the purposes of this policy, this includes Certified Registered Nurse Practitioners (CRNPs) and Physician Assistants (PAs).

ANC - Absolute Neutrophil Count

AUC - Area Under the Curve

BSA - Body Surface Area

ECOG - Eastern Cooperative Oncology Group

EHR - Electronic Health Record

FDA - Food and Drug Administration

Licensed Clinician – For purposes of this policy is a hematology/oncology fellow, APP, registered nurse, pharmacist, or attending/prescribing physician.

Licensed Provider – For purposes of this policy is a hematology/oncology fellow, APP or attending/prescribing physician.

Non-Oncology ACT Inpatient Order Sets - Includes medications on the ACT Medication Policy List used for non-oncology indications in the inpatient locations. These are not Beacon Treatment Plans.

OACT - Oral anticancer therapy

P&T - Pharmacy and Therapeutics

Patient Specific Treatment Plans - Treatment plans for which no standard treatment protocol exists in the EHR.

Therapy Plan - Includes medications on the ACT Medication Policy List used for non-oncology indications in the out-patient locations. These are not Beacon Treatment Plans.

Treatment Plan - An ACT treatment protocol that is a planned regimen applied to a patient including the patient disease, goal of treatment, treatment of the disease, and supportive therapy. Treatment plans are only used for oncology patients by staff who receive access to the plan after completing Beacon training.

Treatment Protocol - An ACT regimen template validated by a multidisciplinary group that includes the patient disease, goal of treatment, treatment of the disease, and supportive therapy.

Administration

A. **Development and Review of Standard ACT Treatment Protocols**
    1. New treatment protocols are initiated at the request of the attending/prescribing physician or as identified as a standard-of-care by the hematology/oncology clinical pharmacy specialist.
        a. Workflows for Formulary and Non-Formulary requests **(Attachments A, B, and C)**.

2. Treatment protocols are developed by a hematology/oncology clinical pharmacy specialist (primary pharmacist reviewer) and are based on National Comprehensive Cancer Network (NCCN) category 1 and 2a recommendations and FDA approvals.
    a. Regimens with Phase II or higher data that are not NCCN Category 1 or 2a recommendations may also be developed if requested by oncology attending(s).
3. Treatment protocols are developed in the sequence that ACT is intended to be administered.
4. Treatment protocols are reviewed by a second hematology/oncology clinical pharmacy specialist then submitted to the Beacon IT team for Beacon treatment protocol build.
    a. Treatment protocols or treatment plan modifications (i.e., modified default dosing, modified supportive care recommendations, etc.) that are not included in the above sources are granted exception through multidisciplinary review.
5. Treatment protocol builds must be validated by a physician, nurse, and clinical pharmacy specialist prior to publishing in Epic production.
6. Staff Education Process for New Treatment Protocols:
    a. Education for all new protocols occurs prior to the first use of the approved agent(s).
        i. New protocols developed using previously approved medications do not require new education unless significant clinical differences (i.e., monitoring, administration) exist.
    b. The Professional Development Team (PDT) reviews industry pharmacy education, then sets up education with industry pharmacy. If not available, internal resources provide education.
    c. Industry pharmacy/internal resources obtain staff sign in sheets with non-identifying employee numbers, and the PDT maintains records of attendance.

B. **Development of Patient Specific ACT Treatment Protocol**
1. The prescribing physician sends a patient specific treatment plan note within the chart communications or enters via clinical pathways in the EHR requesting the clinical pharmacist to build the patient specific treatment plan.
2. The request note details the agents, dosing and schedule, duration of treatment, intent of treatment (ie. curative, palliative, etc) and provides references from a peer reviewed journal or published research.
3. When a patient specific treatment plan build is requested for an agent or regimen that is not P&T approved, not in clinical guidelines, or is not supported by phase II/III data for the disease state that it is intended, the request must be approved by a non-formulary/off-label review committee or reviewed by a 2nd physician specialist within the disease state being treated.
4. The 2nd reviewer notates approval in the EHR through attestation or cosign with comment.
5. The committee or 2nd reviewer physician specialist evaluates the request within 3 business days for a final decision to support timely patient care.
6. Once approved, the Patient Specific Treatment Plan Templates are generated by a heme/onc clinical pharmacy specialist. This process may take up to 3 business days.

C. **ACT Ordering**
1. Oncology Indications
    a. Residents are not permitted to order ACT no matter what the diagnosis/indication.
    b. ACT treatment plans applied to patients with oncology indications, diagnoses, and/or procedural indications include all routes.
        i. Attending prescribing physicians, hematology/oncology clinical pharmacist specialists, APPs, and/or hematology/oncology fellows specially trained in oncology may prepare the treatment plan.
        ii. When the attending does not independently apply the treatment plan, a written communication is entered by the attending prescribing physician into the patients EHR with the intended ACT regimen prior to auxiliary staff member entering the treatment plan. This includes off label/non-formulary use committee review and investigational treatment plans.
        iii. The oncology attending prescribing physician must sign all ACT plans.
        iv. Once signed by the oncology attending prescribing physician, the order is reviewed by a hematology/ oncology clinical pharmacy specialist. The dual pharmacist review process is completed once the treatment plan is released by the RN to the pharmacy for subsequent verification and mixing. **No treatment plans are released to or mixed by the pharmacy until the attending prescribing physician, hematology/oncology clinical pharmacist, and RN has reviewed the ACT Treatment Plan.**
2. ACT Requirements for Inpatient ACT Parenteral and/or OACT, IP OACT from home, and/or IP/OP Non-Oncology Indications and/or Procedures (Attachment E).

D. **ACT Treatment Plans**
1. Faxed or e-mailed ACT treatment plans are only accepted when the ordering physician and/or pharmacy clarifications is off-site from the hospital or out-patient locations without access to EPIC. Faxed orders are examined carefully by the ACT competent licensed personnel to ensure good quality/legibility of the faxed plan. If there is any question related to the faxed ACT plan, the nurse clarifies the plan with the ordering physician and documents in the medical record and orders are re-faxed.
2. New ACT treatment plans are required when the current treatment plan is discontinued and a new treatment plan is requested.
3. No verbal ACT orders are called into outside pharmacies.
4. The treatment plan lists all ACT agents by full generic name (followed by brand/trade in parentheses) and individual drug dosing parameters.
5. ACT treatment plans are written with a specified time limitation.
6. Treatment plans are developed in the sequence that ACT is intended to be administered.
7. Allergies and hypersensitivities are reviewed in the EHR.
8. A completed treatment plan contains all of the following information:
    a. Patient full name and second patient identifier (e.g. medical record number, DOB).
    b. Date the ACT order is written.
    c. Diagnosis.
    d. ACT regimen name and number of cycles/schedules.
    e. Research protocol name and number (if applicable).
    f. Date of ACT administration.
    g. Route of ACT administration.
    h. Rate of the ACT administration (when applicable).
    i. Supportive care treatments that are appropriate for the ACT regimen, including pre-medications, hydration, growth factors, and hypersensitivity medications.
    j. All medications are listed with full generic names.
    k. Drug doses are written following standards for abbreviations, trailing zeros, and leading zero.
    l. Cumulative doses are tracked in EHR for agents associated with cumulative toxicity. Cumulative doses from outside sources are entered into the EHR by the attending prescribing provider or the clinical pharmacy specialist (when data is available):
        i. Doxorubicin

ii. Epirubicin
iii. Idarubicin
iv. Daunorubicin
v. Mitoxantrone
vi. Bleomycin
vii. Mitomycin
viii. Lomustine

m. Sequence of drug administration (if applicable).

E. **Treatment Parameters**

1. Heights and Weights
   a. Record all measurements in kilograms (KG) and centimeters (CM)
   b. Patients are weighed without shoes or coats during height and weight measurements to obtain most accurate body measurement for dosing. If unable to obtain actual height and weight, care of the patient is transferred to a location that can accommodate the patient needs.
   c. Heights are obtained at initial provider encounter and annually thereafter.
      i. For patients who are unable to stand, a yard stick and/or tape measure is utilized.
   d. Weights are obtained at each provider visit and ACT encounter.
      i. Weights are rounded to nearest 10th (example 120.14 = 120.1 kg).
   e. Dual height and weight verification is required to dose ACT including any dose changes. (Exception: flat dose ACT, which is not weight-based for dosing):
      i. The double check must be by a licensed clinician and documented in the EHR.
      ii. Dual height is obtained within 30 days of ACT treatment plan initiation and annually thereafter.
      iii. Dual weight is obtained within 30 days of new ACT treatment start.
      iv. Height and weight is verified on Cycle 1, Day 1 of the treatment cycle by the releasing RN, unless ordered otherwise.
      v. A 10% or greater change in height and/or weight is:
         a. Confirm change by dual verification.
         b. Update treatment plan with new dual verified height and/or weight OR
         c. 'Proceed to treat' order required to use existing treatment plan height and/or weight that is greater than or equal to 10% of most recent height and/or weight.
      vi. The 10% weight change criterion does not apply to ACT flat doses and does not require a ‘proceed to treat’ order.
      vii. Dual verify height and weight verification is not required for active plans that add new medications, only required for new plans.

F. **Drug Dosing Guidelines**

1. Body Surface Area (BSA) Dosing:
   a. BSA = square root of (kg * cm/3600).
   b. BSA is rounded to nearest 100th (example 1.565 = 1.57).
   c. Mosteller equation is used for BSA calculation (use actual body weight unless otherwise specified by prescriber).
2. Devine Calculation for Ideal Body Weight (this is not used in cellular transplant):
   a. Females: IBW = 45.5 kg + 2.3 (inches over 60 inches)
   b. Males: IBW = 50kg + 2.3 (inches over 60 inches).
3. Creatinine Clearance (CrCl) and Carboplatin Dosing: (CrCl is used in place of Glomerular Filtration Rate (GFR):
   a. CrCl Calculations for carboplatin dosing:
      i. Use Cockcroft-Gault equation for calculation of CrCl
         a. CrCl = [(140 – age) kg / 72 x Serum Creatinine (SCr)]. Multiply this result by 0.85 for females.
      ii. CrCl is capped at a maximum value of 125 mL/min,
      iii. Consider use of SCr ≥ 0. 8 mg/dL for elderly patients (≥65 years).
      iv. Calculate Ideal Body Weight (IBW):
         a. If patient's actual weight is < 30% above Ideal Body Weight (IBW) then actual body weight is used in the Cockcroft-Gault equation.
         b. If patient's actual weight is ≥ 30% above Ideal Body Weight (IBW) then the average of actual and IBW is used in the Cockcroft-Gault equation.
            i. 0.5 (Actual BW + IBW) = weight used in Cockcroft-Gault.
   b. Carboplatin Dosing (CrCl is put into the Calvert equation for the carboplatin dose):
      i. Carboplatin (mg) = AUC [CrCl + 25].
4. Robinson Formula (Cellular Transplant Only) - this is the formula used to calculate cellular transplant 'dosing weight':
   a. Important to note, the treatment plan flags the dosing to be >10% difference from the actual body weight entered into EPIC given this is how it is set to do warnings.
      i. Always compare patient’s weight on admission to documented “actual body weight” in the treatment plan (not the treatment plan weight as this is adjusted body weight).
   b. Robinson Calculation for Ideal Body Weight (IBW):
      i. Females: IBW = 49 kg + 1.7 kg (over 60 inches)
      ii. Males: IBW = 52 kg + 1.9 kg (over 60 inches)
   c. Dosing Weight (kg):
      i. Ideal BW + 0.25 (Actual BW - Ideal BW).
      ii. If Actual BW is less than Ideal BW, use Actual BW as Dosing Weight.
5. Dose Rounding
   a. ACT doses may be rounded within 5% of the calculated dose by the verifying pharmacist or prescriber to avoid drug waste. A written order is not required as long as the ordered dose is within 5% or less of the original calculated ordered dose based on mg/m2, mg/kg, or AUC.
   b. ACT competent staff are trained to calculate/verify doses within 5% of the original calculated ordered dose.
   c. When rounding exceeds 5% of the original calculated ordered dose (not Epic-rounded dose), a proceed to treat order is required.

G. **Laboratory Parameters**

1. Lab –based and non-lab-based parameters are specified in the treatment plans or within the AHNCI ACT Lab Hold Parameters and Non-Lab Based Parameters documents. **(Attachments G and F).**
2. The standard treatment plans includes regimen-specific laboratory tests with specified time intervals determined by the medication prescribing information, NCCN guidelines, and specific disease and/or patient specific criteria (ie. hepatic and renal functions etc.).

3. General Lab Criteria for all patients: NOTE: The hematology/oncology clinical pharmacist reviews lab criteria and lifetime cumulative doses with applicable agents when reviewing the treatment plan. Additional lab criteria is reviewed prior to treatment by the verification pharmacist and treating nurse.
    a. Absolute neutrophil count (ANC) greater than 1500 u/L within 3 days is required prior to the start of each ACT treatment unless otherwise specified in the treatment plan. A repeat Complete Blood Count (CBC) is not required within 7 days of previous labs for continuation of multi-day treatment regimens unless otherwise specified in the treatment plan.
    b. Platelets greater than 100,000u/L within 3 days is required prior to the start of each ACT treatment unless otherwise specified in the treatment plan. A repeat platelet count is not required within 7 days of previous labs for continuation of multi-day treatment regimens unless otherwise specified in the treatment plan.
    c. A comprehensive metabolic profile (CMP) or basic metabolic profile (BMP) must be drawn within 7 days prior to each treatment unless otherwise specified in the treatment plan.

H. **Pregnancy Testing and Fertility Preservation**
1. During the informed consent process, the provider also discusses pregnancy and fertility preservation (when applicable).
    a. Pregnancy Testing is NOT required for patients who:
        i. have prior bilateral oophorectomy, bilateral salpingectomy, or total hysterectomy OR
        ii. have permanent sterilization (tubal ligation or bilateral salpingectomy) OR
        iii. are age greater than or equal to 60 OR
        iv. are greater than or equal to age 40 and less than 60 with amenorrhea for 12 or more months meeting one of the following two criteria:
            a. FSH and estradiol must be in post-menopausal range as defined by the ordering lab reference (AHN or other) OR
            b. Absence of chemotherapy, tamoxifen, toremifene, or ovarian suppression.
        v. have Human Chorionic Gonadotropic (hCG) secreting tumors that require ACT (ie: ovarian germ cell tumors and trophoblastic disease).
    b. Patients may decline the testing after discussion with the provider, the provider documents in the medical record the rationale for the decline.
    c. Preferred pregnancy test is quantitative serum hCG.
    d. Testing is performed within 3 days prior to each cycle.
        i. **EXCEPTION:** for oral anticancer treatment (in the absence of parenteral ACT), testing is performed within 28 days of starting treatment and repeated every 28 days thereafter unless clinically indicated sooner while on treatment.
    e. Positive serum hCG per facility reference ranges requires the provider to enter an order 'proceed to treat with rationale' if all parties agree to proceed with treatment with an understanding of the risks and benefits.

I. **Proceed To Treat**
1. When treating outside defined treatment parameters, a 'proceed to treat communication order and rationale denoting the specific parameter not met (lab value, positive HcG, treating early, etc.) is placed in the treatment plan with an associated time frame (i.e. 1 cycle, day of treatment, etc.). The following circumstances require a 'proceed to treat' order in the treatment plan with a rationale unless otherwise noted in the plan:
    a. any ECOG score greater than two and/or Karnofsky less than 50.
    b. any CTCAE toxicity greater than two.
    c. any positive findings for Immuno-effector Cell (IEC) and bispecific agents toxicity assessments set forth by the American Society for Cellular Transplant and Therapy (ASTCT):
        i. Complete neurological assessment.
        ii. Cytokine Release Syndrome (CRS).
        iii. Immune effector cell assessment neurotoxicity symptoms (ICANS).
    d. positive serum hCG per facility reference ranges.
    e. absolute neutrophil count (ANC) less than 1500 u/L within 3 days prior to the start of each treatment regimen.
    f. platelets less than 100,000u/L within 3 days prior to the start of each treatment regimen.
    g. dosing based on non-dual verified height and/or weight for weight- or BSA- based ACT.
    h. administering ACT earlier than defined frequency.
        i. Exception: treatment one day early per treatment week (ie, treating one day early with weekly regimen, two days early with every 2-week regimen, etc.) does not require a proceed to treat order.
    i. labs or non-lab parameters (ie, audiograms, pulmonary function tests, echocardiograms, etc.) that have not been resulted within the frequency defined in the treatment plan.
    j. labs or non-lab parameters that are outside of the parameters defined within the treatment plan or AHNCI ACT Lab Hold Parameters and Non-Lab Based documents **(Attachments G and F)**.
        i. NOTE: If testing does not have defined parameters within the treatment plan or AHNCI ACT Lab Hold Parameters and Non-Lab Based documents, it does not require a proceed to treat.
2. Proceed to treat orders may be placed in the treatment plan by the provider, oncology fellow, APP, or heme/onc clinical pharmacy specialist.
    a. Hematology/oncology clinical pharmacy specialist and oncology fellows may take verbal 'proceed to treat orders' from the attending physician.
    b. APPs may independently write or take verbal 'proceed to treat orders' from the attending physician.
    c. RNs do not take verbal orders for ACT or write 'proceed to treat' orders.

Exceptions
None

Violations
Violations of this policy or procedure may result in disciplinary action up to and including termination of employment.

Additional References
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People Applicability
Independent credentialed/privileged providers (including physicians, nurse practitioners, physician assistants, certified registered nurse anesthetists, and midwives); Employees (including residents and fellows); Researchers

Entity Applicability
This policy applies to Highmark Health and its subsidiaries and controlled affiliates; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Allegheny Singer Research Institute (ASRI); This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:AHN Cancer Institute; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Allegheny Clinic; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Saint Vincent Medical Group & Other Medical Offices

Contact(s)

List of Approver(s)
ROBERTA LEINWEBER - INSTITUTE VICE PRESIDENT - 10/22/2025
Back to List

Table of Contents

Anticancer Therapy Verification

POL-9627584

Print Details Share Details

Overview Statement
Registered Nurses (RNs), Advanced Practice Providers (APPs), Hematology/Oncology Fellows, Physicians, Pharmacy technicians, and Pharmacists specially trained with anticancer therapy (ACT) agents follow the safety standards of practice.

Purpose: To provide guidelines for the verification of ACT drugs in the oncology setting

Terms and Definitions

ACT - Anticancer Therapy (this includes antineoplastic agents such as chemotherapy, targeted therapy, monoclonal antibodies, immunological agents, cellular therapy) ***excludes hormonal therapy ACT medications may be administered via parental routes (including Intravenous (IV), Intrathecal (IT), Intraperitoneal (IP), Subcutaneous (SQ), Intramuscular (IM), Intrahepatic (IH), Intravesical, Intraventricular, Intraarterial, Intrapleural) or oral routes using solid dosage forms or oral suspensions. (see AHN ACT medication list and exceptions)

Advanced Practice Providers (APPs)- For the purposes of this policy, this includes Certified Registered Nurse Practitioners (CRNPs), Physician Assistants (PAs), and Hematology/Oncology Fellows.

Alternate Routes - Specialized ACT administration routes (Intra-arterial, Intraperitoneal, Intrapleural, intravesical, Intrathecal, Intraventricular, intrahepatic, continuous infusion pumps), only trained licensed clinicians in these procedures may mix/prepare after being deemed competent (initially and annually) by another licensed clinician experienced in these procedures.

ANC - Absolute Neutrophil Count

AUC - Area Under the Curve

BSA - Body Surface Area

Desensitization - Re-administration of the implicated drug in a highly controlled manner using a series of sequential steps in which the dose is gradually increased.

ECOG - Eastern Cooperative Oncology Group

EHR - Electronic Health Record

Licensed Clinician – For purposes of this policy is a hematology/oncology fellow, APP, registered nurse or attending/prescribing physician. Licensed Provider – For purposes of this policy is a hematology/oncology fellow, APP or attending/ prescribing physician.

Non-Oncology ACT Inpatient OrderSets - Includes medications on the ACT Medication Policy List used for non-oncology indications in the inpatient locations. These are not Beacon Treatment Plans.

OACT - Oral Anticancer Therapy

Patient Specific Treatment Plans - Treatment plans that are not P&T approved and/or for which no standard treatment plan exists in the EHR.

Treatment Plan - An approved P&T ACT treatment protocol that is a planned regimen applied to a patient including the patient disease, goal of treatment, treatment of the disease, and supportive therapy. Treatment plans are only used for oncology patients by staff who receive access to the plan after completing Beacon training

Administration
Dual Pharmacist Verification Review Guidelines

1. All ACT on the ACT Medication List Criteria use in treatment plans, and/or non-oncology ACT ordersets and therapy plans are independently verified by two licensed competent pharmacists. (see list of AHN ACT Drugs in Anti-cancer Therapy Administration (3.5; 3.6; 3.7; 3.8; 3.9; 4.4).
2. The following criteria is verified:
    a. Appropriateness of treatment plan notes based on the indication/diagnosis (references are provided for non-standard regimens)
    b. Patient name and two patient identifiers
    c. Date ACT order is written
    d. ACT Regimen or plan drug name(s) and number
    e. ACT Cycle number and day, when applicable
    f. Drug volume

Details

Applicability
AHN Entity

Content Type
Policy

Responsible Area
Medication Management

Executive Sponsor
Laura Mark

Owner
Peterson, Kristen

Former Numbers

Effective Date
11/1/2020

Last Approved Date
3/17/2025

Last Revised Date
3/17/2025

Next Review Date
3/17/2026

Related Authoritative Sources

Related Content
Compounded Sterile Preparation - Hand Washing And PPE

Compounded Sterile Preparations Aseptic Technique

Compounded Sterile Preparations (CSPs): Environmental Monitoring and Cleaning of the Pharmacy Cleanroom and/or Primary Engineering Control (PEC)

Related Documents
Attachment A- Lab Based Parameters.pdf
Attachment B- Non Lab Based Monitoring Parameters.pdf
Attachment L -Remote Mix Guide.pdf

g. Route of ACT administration
h. Rate of ACT administration
i. Treatment cycle and day of cycle
j. Sequence of ACT drug administration (if applicable)
k. Any patient contraindications based on known or suspected allergies or sensitivities. (this includes latex allergies)

3. Cumulative doses are tracked in EHR for agents associated with cumulative toxicity. The oncology clinical pharmacy specialist is responsible to add any outside cumulative dosing when applicable and or available
    a. Doxorubicin
    b. Epirubicin
    c. Idarubicin
    d. Daunorubicin
    e. Mitoxantrone
    f. Bleomycin
    g. Mitomycin
    h. Lomustine

Treatment parameters

1. Heights and Weights
2. Record all measurements in kilograms (KG) and centimeters (CM)
3. Patients are weighed without shoes or coats during height and weight measurements to obtain most accurate body measurement for dosing. If unable to obtain actual height and weight, care of the patient is transferred to a location that can accommodate the patient needs.
4. Heights are obtained at initial provider encounter and annually thereafter.
    a. For patients who are unable to stand, a yard stick and/or tape measure is utilized.
5. Weights are obtained at each provider visit and ACT encounter.
    a. Weights are rounded to nearest 10th (example 120.14 = 120.1 kg).
6. Dual height and weight verification is required to dose ACT (including any dose changes). (Exception: flat dose ACT which is not weight based dosing).
    a. The double check must be by a licensed clinician and signed in the EHR.
    b. Dual height is obtained within one month of ACT treatment plan initiation and annually thereafter.
    c. Dual weight is obtained within one month of new ACT treatment start.
    d. Height and weight are verified on Cycle 1, Day 1 of the treatment cycle by the releasing RN, unless ordered otherwise.
    e. A 10% change in height and/or weight is:
        i. updated in treatment plan and requires a new dual verification, or;
        ii. requires a 'proceed to treat' to use the current height and/or weight.
    f. The 10% weight change criterion does not apply to ACT flat doses and does not require a ‘proceed to treat’ order.
    g. Dual verify height and weight verification is not required for active plans that add new medications, only required for new plans.

Drug Dosing Guidelines

1. Body Surface Area (BSA) Dosing
    a. Mostellar equation is used for BSA calculation (use actual body weight unless otherwise specified by prescriber).
        i. BSA = square root of (kg * cm/3600)
        ii. BSA is rounded to nearest 100th (example 1.565 = 1.57)
2. Devine Calculation for Ideal Body Weight (this is not used in cellular transplant)
    a. Females: IBW = 45.5 kg + 2.3 (inches over 5 feet)
    b. Males: IBW = 50kg + 2.3 (inches over 5 feet)
3. Creatinine Clearance (CrCl) and Carboplatin Dosing: (CrCl is used in place of Glomerular Filtration Rate (GFR)
    a. CrCl Calculations
        i. Use Cockcroft-Gault equation for calculation of CrCl
            1. CrCl = [(140 – age)kg / 72 x Serum Creatinine (SCr)]. Multiply this result by 0.85 for females.
        ii. CrCl is capped at a maximum value of 125 mL/min
        iii. Consider use of SCr ≥ 0. 8 mg/dL for elderly patients (≥65 years).
        iv. Calculate Ideal Body Weight (IBW)
            1. If patient's actual weight is < 30% above Ideal Body Weight (IBW) then actual body weight is used in the Cockcroft-Gault equation.
            2. If patient's actual weight is ≥ 30% above Ideal Body Weight (IBW) then the average of actual and IBW is used in the Cockcroft-Gault equation.
                a. 0.5 (Actual BW + IBW) = weight used in Cockcroft-Gault
    b. Carboplatin Dosing (CrCl is put into the Calvert equation for the carboplatin dose)
        i. Carboplatin (mg) = AUC [CrCl + 25]
4. Robinson Formula (Cellular Transplant Only) - this is the formula used to calculate cellular transplant 'dosing weight'
    a. Important to note, the treatment plan flags the dosing to be >10% difference from the actual body weight entered into EPIC given this is how it is set to do warnings
    b. Robinson Calculation for Ideal Body Weight (IBW
        i. Females: IBW = 49 kg + 1.7 kg for each inch over 60 inches.
        ii. Males: IBW = 52 kg + 1.9 kg for each inch over 60 inches.
5. Dosing Weight (kg):
    a. Ideal BW + 0.25 (Actual BW - Ideal BW).
    b. If Actual BW is less than Ideal BW, use Actual BW as Dosing Weight
6. Dose Rounding
    a. ACT doses may be rounded within 5% or less by the verifying pharmacist or prescriber to the closest vial size to avoid drug waste. A written order is not required as long as the ordered dose is within 5% or less of the original calculated ordered dose based on mg/m2, mg/kg, or AUC.
    b. ACT competent staff are trained to calculate/verify doses within the 5% or less range of the original calculated ordered dose.
    c. When rounding exceeds 5% of the original calculated ordered dose, a proceed to treat order is required.

Laboratory Parameters

1. Lab –based and non-lab-based treatment parameters are specified in the treatment plans or within the AHNCI ACT Lab Hold Parameters document
2. The standard treatment plans includes regimen-specific laboratory tests with specified time intervals determined by the medication prescribing information, NCCN guidelines, and specific disease and/or patient specific criteria (ie. hepatic and renal functions etc.) (Attachments A and B)
    a. General Lab Criteria for all patients:
        i. The hematology/oncology clinical pharmacist reviews lab criteria and lifetime cumulative doses with applicable agents when reviewing the treatment plan. Additional lab criteria is reviewed on the day of treatment by the verification pharmacist and treating nurse.
        ii. Absolute neutrophil count (ANC) greater than 1500 u/L within 3 days is required prior to the start of each treatment regimen unless otherwise specified in the treatment plan. A repeat Complete Blood Count (CBC) is not required within seven days of previous labs for continuation of multi-day treatment regimens unless otherwise specified in the treatment plan.
        iii. Platelets greater than 100,000u/L within 3 days is required prior to the start of each treatment regimen unless otherwise specified in the treatment plan. A repeat platelet is not required within seven days of previous labs for continuation of multi-day treatment regimens unless otherwise specified in the treatment plan.
        iv. A comprehensive metabolic profiles (CMP) or basic metabolic profile (BMP) drawn within seven days prior to each treatment unless otherwise specified in the treatment plan.

Pregnancy Testing and Fertility Preservation:

1. During the informed consent process, the provider also discusses pregnancy and fertility preservation (when applicable).
    a. Pregnancy Testing is NOT required on patients who:
        i. have prior bilateral oophorectomy, bilateral salpingectomy, or total hysterectomy
        ii. have permanent sterilization (tubal ligation or bilateral salpingectomy)
        iii. are age greater than or equal to 60
        iv. are greater than or equal to age 40 and less than 60 with amenorrhea for 12 or more months meeting one of the following two criteria:
            1. FSH and estradiol must be in post-menopausal range as defined by the ordering lab reference (AHN or other); OR
            2. Absence of chemotherapy, tamoxifen, toremifene, or ovarian suppression
        v. have Human Chorionic Gonadotropic (hCG) secreting tumors that require ACT (ie: ovarian germ cell tumors and trophoblastic disease)
    b. Patients may decline the testing after discussion with provider, the provider documents in the medical record the rationale for the decline***
    c. Preferred pregnancy test is quantitative serum hCG.
    d. Testing is performed within 3 days before each cycle (repeat at a minimum of 28 days during treatment unless clinically indicated sooner).
    e. Positive serum hCG per facility reference ranges requires the provider to enter an order 'proceed to treat with rationale' if all parties agree to proceed with treatment with an understanding of the risks and benefits.

Proceed To Treat

1. When treating outside defined treatment parameters, a ‘proceed to treat communication order and rationale denoting specific parameter not met (, lab value, positive HcG, treating early,etc) is placed in the treatment plan with an associated time frame (ie. 1 cycle, day of treatment, etc). The following circumstances require a 'proceed to treat' order in the treatment plan with a rationale:
    a. any ECOG score greater than two and/or Karnofsky less than 50.
    b. any CTCAE toxicity greater than two.
    c. Any positive findings for Immuno-effector Cell (IEC) and BiSpecific agents toxicity assessments set forth by the American Society for Cellular Transplant and Therapy (ASTCT)
        i. Complete neurological assessment
        ii. Cytokine Release Syndrome (CRS)
        iii. Immune effector cell assessment neurotoxicity symptoms (ICANS)
    d. positive serum hCG per facility reference ranges.
    e. Absolute neutrophil Count (ANC) less than 1500 u/L within 3 days prior to the start of each treatment regimen.
    f. Platelets less than 100,000u/L within 3 days to the start of each treatment regimen.
    g. Dosing based on non-dual verified height and/or weight
    h. Administering ACT earlier than defined frequency
        i. Exception: treatment one day early per treatment week (ie, treating one day early with weekly regimen, two days early with every 2-week regimen, etc.) does not require a proceed to treat order.
    i. Labs or non-lab parameters (ie, audiograms, pulmonary function tests, echocardiograms, etc) that have not been resulted within the frequency defined in the treatment plan
    j. Labs or non-lab parameters that are outside of the parameters defined within the treatment plan or AHNCI ACT Lab Hold Parameters document. If testing does not have defined parameters within the treatment plan or AHNCI ACT Lab Hold Parameters document, it does not require a proceed to treat.
2. Proceed to treat orders may be placed in the treatment plan by the provider, oncology fellow, APP, or heme/onc clinical pharmacy specialist.
    a. Hematology/Oncology Clinical Pharmacy Specialist may take verbal 'proceed to treat orders' from the attending prescribing physician.
    b. APPs may independently write or take verbal 'proceed to treat orders' from the attending prescribing physician.
    c. RNs do not take verbal orders for ACT or write 'proceed to treat' orders.

Mixing/Preparation/Dispensing Guidelines/Procedures:

1. All ACT are mixed/prepared/dispensed by pharmacist or pharmacy technician under the supervision of a pharmacist. Both compounding and checking personnel must be appropriately trained. (Refer to AHN ACT Training and Staffing SOP; Sterile Compounding Competencies).
2. Compounding or preparation of Yellow, Orange, and Red hazardous medications is limited to facilities with a negative pressure cleanrooms unless otherwise stated in the AHN HD List. Sites include the Inpatient Pharmacies at Allegheny General, Allegheny Valley, Canonsburg, Forbes, Grove City, Jefferson, St Vincent, West Penn and Wexford Hospitals and the Cancer Institutes at Allegheny General, Beaver, Butler, Forbes, Jefferson, St Vincent and Wexford.
3. All routes including, but not limited to Intravenous (IV), Intrathecal (IT), Intraperitoneal (IP), Subcutaneous (SQ), Intramuscular (IM), Intrahepatic (IH), Intravesical. Intraventricular, Intraarterial, and Intrapleural are prepared in accordance with the AHN Compound Sterile SOP, USP 797 and USP 800 guidelines.
4. A pharmacist must verify order before mixing personnel can proceed with preparation.
5. The mixing personnel verifies the components needed for the preparation including, but not limited to:
    a. drug vials

b. concentration
c. drug volume or weight
d. diluent type and volume (when applicable)
e. administration fluid type and volume (including removal of overfill)
f. tubing and filter when applicable

6. Prior to preparation, a pharmacist verifies the components and calculations for the preparation including, but not limited to:
   a. A second review of items 4 a-f
   b. Calculates the necessary quantities or volumes of drug prior to mixing
7. Compounding checks are performed by a pharmacist. The checks include but are not limited to:
   a. Witnessing the reconstitution if applicable and verifying the volume of drug measured prior to injecting into an infusion bag.
      i. This may be done in person or electronically using IVX (see requirements in AHN Sterile Compounding Policy)
   b. Reviews final product for appropriate quantities, labeling, infusion tubing, and filter (if required), and observes for the presence of any particulate matter in the preparation.
   c. Verifies any infusions that are primed with active drug have label stating that the line is primed with 'Active Agent'.
   d. Verifies agents that are to be protected from light are covered by an opaque amber bag.
   e. Seals completed infusions in a plastic bag, tote or as required.
8. Delivery:
   a. YELLOW Hazardous Drugs are transported in a bin/tote to contain potential spills.
   b. Drugs may not be delivered via the Pneumatic Tube System if they are YELLOW or RED hazardous, liquid dosage forms of Orange or Purple hazardous drugs, drugs marked do not shake, or high cost medications. See site specific pneumatic tube procedure for more information.
   c. See the Pharmacy Remote Mix Process for transport of drugs to remote mix sites (Attachment L)
9. Drug Waste and Disposal:
   a. Patient drug waste is documented in the EHR as required
   b. See AHN medication waste policy for specific information on disposal of drugs, drug containers, compounding supplies, administration supplies, etc.

Exceptions
None

Violations
Violations of this policy or procedure may result in disciplinary action up to and including termination of employment.

Additional References
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Pharmaceutical compounding—sterile preparations (general information chapter 797). (2017). In the The United States Pharmacopeia, 40th rev., and the National Formulary, 35 ed. Rockville, MD: The United States Pharmacopeial Convention, 39-83.

Polovich, M., & Olsen, M. M. (2018). Safe handling of hazardous agents (3rd ed.). Oncology Nursing Society.

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People Applicability
Independent credentialed/privileged providers (including physicians, nurse practitioners, physician assistants, certified registered nurse anesthetists, and midwives); Employees (including residents and fellows); Contracted/embedded workforce personnel (including independent contractors and agency staff); Students; Researchers; Members of a Collective Bargaining Agreement

Entity Applicability
This policy applies to Highmark Health and its subsidiaries and controlled affiliates; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Allegheny Singer Research Institute (ASRI); This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:AHN Cancer Institute; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Allegheny Clinic; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Saint Vincent Medical Group & Other Medical Offices

Contact(s)

List of Approver(s)
LAURA MARK - VP PHARMACY - AHN - 3/11/2025,
MARK RUBINO - PHYSICIAN PRESIDENT / 74 - 3/17/2025,
ALLAN KLAPPER - PHYSICIAN PRESIDENT - 3/14/2025,
CHONG PARK - PHYSICIAN PRESIDENT / 74 - 3/11/2025,
IMRAN QADEER - PHYSICIAN PRESIDENT / 74 - 3/14/2025,
BRIAN JOHNSON - PHYSICIAN PRESIDENT / 74 - 3/14/2025,
CHRISTOPHER CLARK - PHYSICIAN PRESIDENT - 3/11/2025
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Table of Contents

Anti-cancer Therapy Administration (3.5; 3.6; 3.7; 3.8; 3.9; 4.4)

PROC-9163781

Print Details Share Details

Overview Statement
Registered Nurses (RNs), Advanced Practice Providers (APPs), Hematology/Oncology Fellows, Physicians, and Pharmacists specially trained with anticancer therapy (ACT) agents follow the safety standards of practice.

Purpose: To provide safe administration of ACT agents.

Terms and Definitions

ACT - Anticancer Therapy includes antineoplastic agents such as chemotherapy, anticancer therapy/antineoplastic therapy, targeted therapy, anticancer monoclonal antibodies, immunological agents, cellular therapy, photodynamic therapy. This excludes hormonal therapy. Routes of administration include:

A. Parental routes include Intravenous (IV), Subcutaneous (SQ), Intramuscular (IM)
B. Enteral Routes - Solid dosage forms and oral suspensions
C. Alternate/Procedural Routes - Specialized ACT administration routes (Intra-arterial, Intraperitoneal, Intrapleural, intravesical, Intrathecal, Intraventricular, intrahepatic, intratumoral/intralesional, and continuous infusion pumps), should only be used by licensed clinicians with advanced training in these procedures after being deemed competent (initially and annually) by another licensed clinician experienced in these administration procedures.

Advanced Practice Providers (APPs)- For the purposes of this policy, this includes Certified Registered Nurse Practitioners (CRNPs) and Physician Assistants (PAs).

AUC - Area Under the Curve

ANC - Absolute Neutrophil Count

BSA - Body Surface Area

CSTD – Closed System Transfer Device

CTCAE - Common Terminology Criteria for Adverse Events

CVAD - Central Venous Access Device

Desensitization - Re-administration of the implicated drug in a highly controlled manner using a series of sequential steps in which the dose is gradually increased.

ECOG - Eastern Cooperative Oncology Group

EHR - Electronic Health Record

IV - Intravenous

IT - Intrathecal

Licensed Clinician – For purposes of this policy is a hematology/oncology fellow, APP, pharmacist, registered nurse or attending/prescribing physician.

Licensed Provider – For purposes of this policy is a hematology/oncology fellow, APP or attending/prescribing physician.

Non-Oncology ACT Inpatient Order Sets - Includes medications on the ACT Medication Policy List used for non-oncology indications in the inpatient locations. These are not Beacon Treatment Plans.

OACT - Oral anticancer therapy

SOP - Standards of Practice

Time-Out - Prior to administering agent intrathecally, the licensed personnel conducts a time out to verify that the medication is for IT use only.

Therapy Plan - Includes medications on the ACT Medication Policy List used for non-oncology indications in the out-patient locations. These are not Beacon Treatment Plans.

Details

Applicability
AHN Entity

Content Type
Procedure

Responsible Area
Anticancer (ACT) Care

Executive Sponsor
Roberta Leinweber

Owner
Ciafre, Lisa

Former Numbers

Effective Date
11/1/2020

Last Approved Date
4/22/2025

Last Revised Date
4/22/2025

Next Review Date
4/22/2026

Related Authoritative Sources

Related Content

Related Documents
Attachment A - AHNCI ACT Med List.pdf
Attachment C -AHNCI IP-OP OACT Procedural ACT.pdf
Attachment D - AHNCI ACT Remote Mix Chart Prep.pdf
Attachment E - Lab based hold parameters.pdf
Attachment F - Non Lab based Monitoring Parameters.pdf
Attachment G - ACT Hazard signage.pdf
Attachment H -AHNCI ACT CSTD Guidelines.pdf
Attachment I - AHNCI ACT Intraperitoneal.pdf
Attachment J - AHNCI ACT Intrathecal - Intraventricular.pdf
Attachment K- HiPEC Alternative Route Anticancer Therapy Administration.pdf
Attachment L- TACE - Anticancer Therapy Administration.pdf
Attachment M - Intrahepatic Alternative Route ACT.pdf
Attachment N - Intravesicular ACT.pdf
Attachment O - intrathecal- ventricular labels.jpg
Attachment B IP ACT Planned and Emergent Treatment Planning Guidelines Nov 2025.pdf

Treatment Plan - An approved P&T ACT treatment protocol that is a planned regimen applied to a patient including the patient disease, goal of treatment, treatment of the disease, and supportive therapy. Treatment plans are only used for oncology patients by staff who receive access to the plan after completing Beacon training.

Patient Specific Treatment Plans - Treatment plans that are not P&T approved and/or for which no standard treatment plan exists in the EHR

Administration
Oncology

A. ACT treatment plans applied to patients with oncology indications, diagnoses, and/or procedural indications include oral, Intravenous (IV), Intrathecal (IT), Intraperitoneal (IP), Subcutaneous (SQ), Intramuscular (IM), Intrahepatic (IH), Intravesical. Intraventricular, Intraarterial. Intrapleural as listed on (Attachment A) are ordered by an oncology attending/prescribing physician applying ACT treatment plans.
B. Oncology patients receiving ACT agents on a non-oncology designated area are moved to the designated oncology areas when possible on the day that treatment is initiated.
C. In the event that the transfer cannot be accomplished, the patient's unit notifies the oncology unit so arrangements can be made for the administration of the ACT agent.
D. An oncology ACT competent licensed clinician remains assigned to the patient for administration in the designated location. Refer to the Inpatient ACT Guidelines (Attachment B)
    1. EXCEPTION: Inpatient ICU 24 hour continuous IV ACT infusions, the inpatient ACT competent RN:
        a. Hangs the infusion
        b. Provides the icu staff with an act drug sheet and oncology resource nurse contact information
        c. Physically assesses the patient in the ICU and documents a toxicity grading assessment and performance status prior to each dose administered

Non-Oncology

A. ACT Requirements for Inpatient ACT Parenteral and/or OACT, IP OACT from home, and/or IP/OP Non-Oncology Indications and/or Procedures (Attachment C)

Administration Verification Process - Step 1

A. The chart preparation process for oncology out-patient areas follows the outpatient chart preparation process.
B. Remote mix locations refer to (Attachment D) for work-flow
C. At each treatment visit, prior to initiation of the ACT administration cycle, the licensed clinician confirms with the patient the treatment plan including, but not limited to, the name of drugs, the length of infusion time, route, and review of symptoms to report for infusion-related reactions.
D. On the Outreach call or at the Infusion Center visit - prior to releasing ACT to the pharmacy for verification and mixing, the ACT competent licensed clinician verifies the following criteria:
    1. Patient's name and second unique identifier (DOB)
    2. Patient diagnosis and correct treatment plan (using approved references) of the ACT agents
    3. Planned total ACT dose and duration is indicated on the treatment plan
    4. Time, date, and schedule of intended ACT treatment plan
    5. Rate and route of ACT administration
    6. ACT drug name without using abbreviations
    7. Prior infusion-related symptoms, allergies, hypersensitivity
    8. Completed signed ACT consent
    9. Toxicity assessment, performance status, /, psychosocial distress screening, treatment parameter review
    10. Allergy review
    11. Medication review
    12. Cumulative doses are tracked in EHR for agents associated with cumulative toxicity. Cumulative doses from outside sources are entered into the EHR by the attending prescribing provider or the clinical pharmacy specialist (when data is available)
        a. Doxorubicin
        b. Epirubicin
        c. Idarubicin
        d. Daunorubicin
        e. Mitoxantrone
        f. Bleomycin
        g. Mitomycin
        h. Lomustine

Treatment Parameters

A. Heights and Weights
    1. Record all measurements in kilograms (KG) and centimeters (CM)
    2. Patients are weighed without shoes or coats during height and weight measurements to obtain most accurate body measurement for dosing. If unable to obtain actual height and weight, care of the patient is transferred to a location that can accommodate the patient needs.
    3. Heights are obtained at initial provider encounter and annually thereafter.
    4. For patients who are unable to stand, a yard stick and/or tape measure is utilized.
    5. Weights are obtained at each provider visit and ACT encounter.
    6. Weights are rounded to nearest 10th (example 120.14 = 120.1 kg).
    7. Dual height and weight verification is required to dose ACT including any dose changes. (Exception: flat dose ACT, which is not weight-based for dosing)
        a. The double check must be by a licensed clinician and signed in the EHR.
        b. Dual height is obtained within one month of ACT treatment plan initiation and annually thereafter.
        c. Dual weight is obtained within one month of new ACT treatment start.
        d. Height and weight is verified on Cycle 1, Day 1 of the treatment cycle by the releasing RN, unless ordered otherwise.
        e. A 10% change in height and/or weight is:

f. updated in treatment plan and requires a new dual verification, or;
g. requires a 'proceed to treat' to use the current height and/or weight.
h. The 10% weight change criterion does not apply to ACT flat doses and does not require a ‘proceed to treat’ order.
i. Dual verify height and weight verification is not required for active plans that add new medications, only required for new plans.

Day of treatment validation prior to releasing the ACT to the pharmacy for mixing

A. Step 1 – Compare the patients day of treatment weight to the actual dosing treatment plan dual verified weight and height to assure within 10%
B. Step 2 – If within 10% use the treatment plan weight and manually re-calculate ordered doses
C. Step 3 – if day of treatment weight not within 10% contact provider for further orders.

Drug Dosing Guidelines

A. Body Surface Area (BSA) Dosing
    1. BSA = square root of (kg * cm/3600)
    2. BSA is rounded to nearest 100th (example 1.565 = 1.57)
    3. Mostellar equation is used for BSA calculation (use actual body weight unless otherwise specified by prescriber).
B. Devine Calculation for Ideal Body Weight (this is not used in cellular transplant)
    1. Females: IBW = 45.5 kg + 2.3 (inches over 5 feet)
    2. Males: IBW = 50kg + 2.3 (inches over 5 feet)
C. Creatinine Clearance (CrCl) and Carboplatin Dosing: (CrCl is used in place of Glomerular Filtration Rate (GFR)
    1. CrCl Calculations
        a. Use Cockcroft-Gault equation for calculation of CrCl
        b. CrCl = [(140 – age)kg / 72 x Serum Creatinine (SCr)]. Multiply this result by 0.85 for females.
        c. CrCl is capped at a maximum value of 125 mL/min
        d. Consider use of SCr ≥ 0. 8 mg/dL for elderly patients (≥65 years).
    2. Calculate Ideal Body Weight (IBW)
        a. If patient's actual weight is < 30% above Ideal Body Weight (IBW) then actual body weight is used in the Cockcroft-Gault equation.
        b. If patient's actual weight is ≥ 30% above Ideal Body Weight (IBW) then the average of actual and IBW is used in the Cockcroft-Gault equation.
        c. 0.5 (Actual BW + IBW) = weight used in Cockcroft-Gault
    3. Carboplatin Dosing (CrCl is put into the Calvert equation for the carboplatin dose)
        a. Carboplatin (mg) = AUC [CrCl + 25]
D. Robinson Formula (Cellular Transplant Only) - this is the formula used to calculate cellular transplant 'dosing weight'
    1. Important to note, the treatment plan flags the dosing to be >10% difference from the actual body weight entered into EPIC given this is how it is set to do warnings
    2. Robinson Calculation for Ideal Body Weight (IBW)
        a. Females: IBW = 49 kg + 1.7 kg for each inch over 60 inches
        b. Males: IBW = 52 kg + 1.9 kg for each inch over 60 inches
    3. Dosing Weight (kg):
        a. Ideal BW + 0.25 (Actual BW - Ideal BW)
        b. If Actual BW is less than Ideal BW, use Actual BW as Dosing Weight
E. Dose Rounding
    1. ACT doses may be rounded within 5% or less by the verifying pharmacist or prescriber to the closest vial size to avoid drug waste. A written order is not required as long as the ordered dose is within 5% or less of the original calculated ordered dose based on mg/m2, mg/kg, or AUC.
    2. ACT competent staff are trained to calculate/verify doses within the 5% or less range of the original calculated ordered dose.
    3. When rounding exceeds 5% of the original calculated ordered dose, a proceed to treat order is required.

Laboratory Parameters

A. Lab –based and non-lab-based parameters are specified in the treatment plans or within the AHNCI ACT Lab Hold Parameters and Non-Lab Based Parameters documents. (Attachments G and F).
B. The standard treatment plans includes regimen-specific laboratory tests with specified time intervals determined by the medication prescribing information, NCCN guidelines, and specific disease and/or patient specific criteria (ie. hepatic and renal functions etc.).
C. General Lab Criteria for all patients:
    1. The hematology/oncology clinical pharmacist reviews lab criteria and lifetime cumulative doses with applicable agents when reviewing the treatment plan. Additional lab criteria is reviewed on the day of treatment by the verification pharmacist and treating nurse.
    2. Absolute neutrophil count (ANC) greater than 1500 u/L within 3 days is required prior to the start of each treatment regimen unless otherwise specified in the treatment plan. A repeat Complete Blood Count (CBC) is not required within seven days of previous labs for continuation of multi-day treatment regimens unless otherwise specified in the treatment plan.
    3. Platelets greater than 100,000u/L within 3 days is required prior to the start of each treatment regimen unless otherwise specified in the treatment plan. A repeat platelet is not required within seven days of previous labs for continuation of multi-day treatment regimens unless otherwise specified in the treatment plan.
    4. A comprehensive metabolic profile (CMP) or basic metabolic profile (BMP) drawn within 7 days prior to each treatment unless otherwise specified in the treatment plan.

Pregnancy Testing and Fertility Preservation

A. During the informed consent process, the provider also discusses pregnancy and fertility preservation (when applicable).
B. Pregnancy Testing is NOT required on patients who:
    1. Have prior bilateral oophorectomy, bilateral salpingectomy, or total hysterectomy
    2. Have permanent sterilization (tubal ligation or bilateral salpingectomy)
    3. Are age greater than or equal to 60
    4. Are greater than or equal to age 40 and less than 60 with amenorrhea for 12 or more months meeting one of the following two criteria:
        a. FSH and estradiol must be in post-menopausal range as defined by the ordering lab reference (AHN or other); OR

b. Absence of chemotherapy, tamoxifen, toremifene, or ovarian suppression

5. Have Human Chorionic Gonadotropic (hCG) secreting tumors that require ACT (ie: ovarian germ cell tumors and trophoblastic disease)

C. Patients may decline the testing after discussion with provider, the provider documents in the medical record the rationale for the decline
D. Preferred pregnancy test is quantitative serum hCG.
E. Testing is performed within 3 days before each cycle (repeat at a minimum of 28 days during treatment unless clinically indicated sooner).
F. Positive serum hCG per facility reference ranges requires the provider to enter an order 'proceed to treat with rationale' if all parties agree to proceed with treatment with an understanding of the risks and benefits.

Proceed To Treat

A. When treating outside defined treatment parameters, a 'proceed to treat communication order and rationale denoting specific parameter not met (lab value, positive HcG, treating early, etc) is placed in the treatment plan with an associated time frame (ie. 1 cycle, day of treatment, etc). The following circumstances require a 'proceed to treat' order in the treatment plan with a rationale:
    1. Any ECOG score greater than two and/or Karnofsky less than 50
    2. Any CTCAE toxicity greater than two
    3. Any positive findings for Immuno-effector Cell (IEC) and BiSpecific agents toxicity assessments set forth by the American Society for Cellular Transplant and Therapy (ASTCT)
        a. Complete neurological assessment
        b. Cytokine Release Syndrome (CRS)
        c. Immune effector cell assessment neurotoxicity symptoms (ICANS)
    4. Positive serum hcg per facility reference ranges
    5. Absolute neutrophil count (ANC) less than 1500 u/L within 3 days prior to the start of each treatment regimen
    6. Platelets less than 100,000u/L within 3 days prior to the start of each treatment regimen
    7. Dosing based on non-dual verified height and/or weight
    8. Administering ACT earlier than defined frequency
        1. Exception: treatment one day early per treatment week (ie, treating one day early with weekly regimen, two days early with every 2-week regimen, etc.) does not require a proceed to treat order.
    9. labs or non-lab parameters (ie, audiograms, pulmonary function tests, echocardiograms, etc) that have not been resulted within the frequency defined in the treatment plan
    10. labs or non-lab parameters that are outside of the parameters defined within the treatment plan or AHNCI ACT Lab Hold Parameters and Non-Lab Based documents (Attachments E and F).
        a. NOTE: If testing does not have defined parameters within the treatment plan or AHNCI ACT Lab Hold Parameters and Non-Lab Based documents, it does not require a proceed to treat.
B. Proceed to treat orders may be placed in the treatment plan by the provider, oncology fellow, APP, or heme/onc clinical pharmacy specialist.
    1. Hematology/Oncology Clinical Pharmacy Specialist may take verbal 'proceed to treat orders' from the attending prescribing physician.
    2. Oncology Fellows and APPs may independently write or take verbal 'proceed to treat orders' from the attending prescribing physician.
    3. RNs do not take verbal orders for ACT or write 'proceed to treat' orders.

Administration Verification Process- Chairside/Bedside Validation - Step 2

A. Verify the patient diagnosis and correct regimen of the ACT agents (using approved regimen reference)
B. Ensure the Hazardous Precaution sign is posted and dated 72 hours post completion of the ACT for all inpatients. (Attachment G)
C. Ensure antidotes are available for any vesicant agents prior to administration
D. Ensure antidotes are available for any high risk hypersensitivity/anaphylactic agents
E. Don ACT gowns and double gloves for all administration routes
    1. Mask, eye and face protection is worn when there is a possibility of splashing as warranted
F. The oncology ACT competent licensed personnel administering the ACT double checks with another licensed personnel at the chair/bed side verifying: (double check is preferred by a second ACT competent licensed personnel):
    1. Administer the ACT as sequenced in the protocol
    2. Sequence of drug administration (when applicable) with product sequence (ie. bag 1 of 2, 2of 2 etc)
    3. Sequencing divided doses with total number of products to be administered in the drug order (ie: syringe 1of 2; 2 of 2)
    4. Patient's name and second unique identifier: DOB
    5. Confirm with the patient planned treatment - cycle and day
    6. ACT drug name without using abbreviations
    7. ACT drug dose
    8. ACT drug volume(infusion and syringes)
    9. Route ACT administration
    10. Rate of ACT administration
    11. ACT expiration date and time
    12. Appearance and integrity of the ACT agent
    13. Sequencing of the ACT drug administration
        a. Administer the ACT as sequenced in the protocol
        b. Sequence the drug administration (when applicable) with product sequence (ie. Bag 1 of 2; 2 of 2, etc)
        c. Sequencing divided doses with total number of products to be administered in the drug order (ie. syringe 1 of 2; 2 of 2)
    14. Second verifier waits to verify the rate on the infusion pump then signs the medical record as second verification
G. Refer to CSTD Guidelines for infusion and flushing guidelines for sequencing single and multi-dose treatment plans using compatible solutions with appropriate ACT (ie: vesicants and multi-dose plans) (Attachment H)
    1. When a CSTD is not used, the line is labeled 'primed with active agent'
H. Use closed system device (if available) and place a disposable plastic-backed pad under work area to absorb droplets and place a piece of gauze at injection ports to catch droplets during administration

Special Notes:

A. ACT infusion are prepared on primary tubing when applicable
B. All ACT is transported in a separate tamper resistant container or container with tamper resistant seal in a leakproof plastic bin

C. ACT agents that are to be protected from light are covered with opaque amber bag
D. ACT syringe volume:
    1. Syringes dispensed containing Hazardous Drugs for IV Push or subcutaneous administration will not be filled more than 75% of the maximum capacity of syringe regardless of if that syringe is a luer-lock syringe or a closed system transfer device (CSTD) syringe (ie: Equashield).
    2. Syringes dispensed of a 60mL maximum capacity containing Hazardous Drugs for IV Push or subcutaneous administration will not be filled more than 50% (30mL) regardless of if that syringe is a luer-lock syringe or a closed system transfer device (CSTD) syringe (ex: Equashield).
        a. Exception: Syringes dispensed containing Hazardous Drugs for bladder instillation for an irrigation procedure can be filled to a maximum of 55 mL for patient comfort and ease of administration
E. Alternate Routes: Intrathecal (IT), Intraperitoneal (IP), Intrahepatic (IH), Intravesical. Intraventricular (Ommaya), Intraarterial, Intrapleural require separate training and competency validation (Attachments I, J, K, L, M, N)
F. ACT high alert titration medications: (ie: Rituximab, Daratumumab, etc)
    1. Require dual signature verification when titrated for rate and pump check
    2. The IV pumps are not pre-programmed for ACT titration
G. OACT: Crushing or manipulation is performed under the BSC
H. Vincristine:
    1. All Vincristine, Vinblastine, and Navelbine are diluted into a 50ml bag and infused via free-flow method over 5-10 minutes with the ACT competent licensed clinician at the bedside during administration. Blood return verified before and after administration
    2. The bag is labeled " FOR IV USE ONLY"
    3. Intrathecal and Intraventricular ACT:
        a. Mixed and stored separately from general ACT in preservative free solution
        b. Intraventricular for Ommaya is mixed in 3ml total volume
        c. Intrathecal for interventional radiology is mixed in 6 ml
        d. Has a separate outside auxiliary label placed on the IT bag and the syringe for delivery, after prepared (Attachment C)
        e. Are delivered immediately upon mixing or picked up from pharmacy immediately prior to administration by oncology trained licensed staff
        f. If the drug needs to be stored until delivery, it is stored in an isolated container or location clearly labeled IT ACT and delivered only with other IT medications
I. ACT Requirements for Inpatient ACT Parenteral and/or OACT, IP OACT from home, and/or IP/OP Non-Oncology Indications and/or Procedures (Attachment O)
J. Desensitization
    1. 1st desensitization occurs on the designated inpatient locations (AGH, WPH, Jefferson)
        a. Nurse: Patient ratio is 1:2
        b. Vital signs are done prior to start and at the beginning of each bag
    2. 2nd and Subsequent Desensitizations:
        a. Patients requiring desensitization receive desensitization with aliquots for all subsequent infusion of the offending agent (s)
        b. Can be inpatient (IP) or outpatient (OP) based on provider clinical decision for risk of reaction
        c. OP can only be done if the patient completed desensitization infusions inpatient without any reaction
        d. 2nd and subsequent desensitizations occurs at designated outpatient locations (ACMO AGH; ACMO Mellon; WPH MSS; ACMO AVH; ACMO Grove City; Jefferson Infusion Center)
        e. Vital signs are done prior to start and at the beginning of each bag

Special Infusion Guidelines

A. Intravenous Anticancer Therapy should be administered via a dedicated line unless otherwise specified within the medication order.
B. Peripheral IV Sites
    1. IVP vesicants require new IV if greater than 24 hours old
    2. Continuous infusion vesicants are administered through a central venous access device, not peripherally
    3. Midlines are not used for any ACT vesicants
    4. For peripheral sites, begin at the most distal area (ACT medications are not infused in the below sites):
        a. Ventral surface of the hand
        b. Joints and areas near joints (bony prominences)
        c. Lower extremities
        d. Antecubital
        e. Inner wrist area
        f. Ecchymotic or sclerosed areas
        g. Areas distal to recent venipuncture including lab draws
        h. Areas of impaired circulation
        i. Limbs with axillary node dissections, post mastectomy, post breast lumpectomy, extensive radiation therapy, or obstructive process
        j. Limbs with recent (e.g.: 30 minutes) venipunctures
        k. Areas with decreased sensation (ie: peripheral neuropathy)
    5. Only two peripheral IVs per RN are attempted. If unable to obtain access, one other RN may attempt two times (a maximum of 4 attempts). If unsuccessful, then treatment may be delayed until access can be established with a CVAD.
C. IV Push
    1. All IVP vesicant drugs are given by Free flow method sidearm to free-flowing IV fluids (with the exception of Vincristine)
        a. IVP – peripherally and centrally 1-2 ml/min
        b. Verify blood return before, during every 3-5 ml, and after each drug by:
            i. aspirate with a syringe at the lowest y-site and clamp off fluid from the bag
            ii. use gravity to check by lowering the IV bag below the patient's IV site
    2. Flush between each drug with compatible solution to avoid drug admixture and potential precipitation
D. Continuous infusion – given greater than 12 hours up to 5-7 days. Patency of CVAD is checked every eight hours or as needed
E. Blood products with ACT – do not infuse simultaneously with any first dose ACT or any other doses ACT (Exceptions: 24 hour infusions of ACT may be infused with blood or under emergent situations determined by the licensed provider)

Disconnect/Waste/Disposal/Spills/Surveillance

A. Flush with at least 10-20 ml of compatible solution to clear the line and establish patency between and upon completion of the infusion. Observe the site at this time to ensure that swelling is not occurring at the needle site and monitor for infiltration/extravasation
B. Avoid disconnecting tubing for any reason. If air needs to be removed, use a syringe at proximal y- site to remove air. Dispose of all materials in ACT bins
C. Do NOT leave empty bags of ACT hanging at the patient bedside/chairside. Immediately dispose of all tubing when completed and start new solution if ordered
D. Do not remove spikes from IV containers or reuse tubing
E. Any drug container with more than 3% of liquid remaining is disposed of in BLACK waste bin
F. Empty YELLOW hazardous drug with less than 3% drug remaining in a YELLOW HAZARD waste container
G. Patient Care Items:
    1. place contaminated patient linens into yellow designated linen bins
    2. dispose of any patient urinals, etc into YELLOW HAZARD bin
    3. for incontinence, clean with soap and water and apply protective barrier cream
    4. use disposable linen or leak proof pads to contain bodily fluids
    5. flush toilet twice (with lid down when possible)
    6. discard all contaminated materials and PPE into YELLOW HAZARD bins
H. Empty ORANGE, PURPLE, and/or Non-Hazardous glass containers with less than 3% drug into RED container
    1. Empty ORANG, PURPLE, and/or Non-Hazardous (non-glass) into regular trash after removing patient identifiers (see AHN Medication Waste Policy for additional information on disposal)
I. For any spills- exposure - medical surveillance – refer to the AHN SOP 'Medication Spills- Exposure- Medical Surveillance'
J. Labeling Guidelines are noted in the AHN "Labeling of parenteral medications in the Pharmacy and Patient Care Areas'

Documentation

A. Record actual time up and time down for all medications (even those that run over anticipated time frames).
B. Document the patient's clinical status during and upon completion of the treatment.
C. Complete the day in the EHR.

Exceptions

Violations

Additional References

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People Applicability

Independent credentialed/privileged providers (including physicians, nurse practitioners, physician assistants, certified registered nurse anesthetists, and midwives); Employees (including residents and fellows); Researchers

Entity Applicability

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Organization:Saint Vincent Medical Group & Other Medical Offices; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Chautauqua Medical Practice

Contact(s)

List of Approver(s)

ROBERTA LEINWEBER - INSTITUTE VICE PRESIDENT - 4/22/2025

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Allegheny Health Network
Anticancer Therapy (ACT) Medication Policy

Table 1. Anticancer Therapy (ACT)

Includes:

- Any FDA approved pharmacotherapy with an approved oncology indication (this includes myeloproliferative neoplasms)
- Any FDA approved pharmacotherapy with a common off label use in oncology
- Pharmacotherapies used in both oncology and either a procedural or non-oncology indications (designated with a **β** symbol)

Does NOT include:

- Hormonal and endocrine ACT (See **Sub-Table A**)

Requirements:

- Written informed consent by an oncologist
- Order entry in a treatment plan or secondary treatment plan
- Orders must be signed by an oncologist
- Must be administered by an ACT competent clinician
- Dual signoff by 2 licensed practitioners in MAR at administration
- ACT Pre-Teach appointment required for initial treatments

Exceptions:

- Agents with procedural or non-oncology indications (designated with a **β** symbol) have different requirements when used for that indication (see **Sub-table B**).
- Specific exceptions exist for continuation of home oral ACT and emergency use of certain oral ACT. See **Oral Anticancer Therapy Agents Policy** for further details.

Parenteral Agents

Ado-trastuzumab emtansine (Kadcyla®)
Alemtuzumab (Campath®) **β**
Aldesleukin (Interleukin-2, Proleukin®)
Amivantamab (Rybrevant®)
Arsenic Trioxide (Trisenox®)
Asparaginase erwinia chrysanthemi (recombinant) (Rylaze®)
Atezolizumab (Tecentriq®)
Avelumab (Bavencio®)
Axicabtagene ciloleucel (Yescarta®)
Azacitidine (Vidaza®)
Bacillus Calmette-Guerin (BCG, TheraCys®) **β**
Belinostat (Beleodaq®)
Bendamustine (Bendeka®, Treanda®)
Bevacizumab (Avastin®) **β**
Bleomycin (Blenoxane®) **β**
Blinatumomab (Blincyto®)
Bortezomib (Velcade®) **β**
Brentuximab vedotin (Adcetris®)
Brexucabtagene autoleucel (Tecartus®)
Busulfan (Busulfex®)
Cabazitaxel (Jevtana®)
Carboplatin (Paraplatin®)
Carfilzomib (Kyprolis®)
Carmustine (BiCNu®, Gliadel®)
Cemiplimab (Libtayo®)
Cetuximab (Erbitux®)
Ciltacabtagene autoleucel (Carvykti®)
Cisplatin (Platinol®) **β**
Cladribine (Leustatin®)
Clofarabine (Clolar®)
Copanlisib (Aliqopa®)
Cyclophosphamide (Cytoxan®) **β**
Cytarabine (Ara-C, Cytosar®)
Dacarbazine (DTIC-Dome®)
Dactinomycin (Actinomycin D, Cosmegen®)
Daratumumab (Darzalex®)
Daratumumab and hyaluronidase-fihj (Darzalex Faspro®)
Daunorubicin (Cerubidine®)
Liposomal Daunorubicin (DaunoXome®)
Decitabine (Dacogen®)
Denileukin Diftitox (Ontak®)
Dinutoximab (Unituxin®)
Docetaxel (Taxotere®)
Dostarlimab (Jemperli®)
Doxorubicin (Adriamycin®) **β**
Durvalumab (Imfinzi®)
Liposomal Doxorubicin (Doxil®)
Elotuzumab (Empliciti®)
Elranatamab (Elrexfio®)
Enfortumab vedotin-ejfv (Padcev®)
Epcoritamab-bysp (Epkinly®)
Epirubicin (Ellence®)
Eribulin (Halaven®)
Etoposide (VP-16, Toposar®, Vepesid®)**β**
Etoposide Phosphate (Etopophos®)
Fam-trastuzumab deruxtecan-nxki (Enhertu®)
Fluoxuridine (FUDR®)
Fludarabine (Fludara®)
Fluorouracil (5-FU, Adrucil®) **β**
Gemcitabine (Gemzar®) **β**
Gemtuzumab ozogamicin (Mylotarg®)
Glofitamab-gxbm (Columvi®)
Idecabtagene vicleucel (Abecma®)
Ibritumomab Tiuxetan (Zevalin®)
Idarubicin (Idamycin®)
Ifosfamide (Ifex®)
Inotuzumab Ozogamicin (Besponsa®)
Interferon alfa-2B *(Intron-A, etc.)* **β**
Ipilimumab (Yervoy®)
Irinotecan (Camptosar®)
Liposomal Irinotecan (Onivyde®)
Isatuximab-irfc (Sarclisa®)
Ixabepilone (Ixempra®)
Lisocabtagene maraleucel (Breyanzi®)
Loncastuximab tesirine (Zynlonta®)
Lurbinectedin(Zepzelca®)
Lutetium Lu-177 dotatate (Lutethera®) **β**
Lutetium Lu-177 vipivotide tetraxetan (Pluvicto®) **β**
Margetuximab (Margenza®)
Mechlorethamine (Mustargen®)
Melphalan (Alkeran®, Evomela®, Hepzato®) **β**
Methotrexate (Rhematrex®, Trexall®) **β**
Mirvetuximab soravtansine (Elahere®)
Mitoxantrone (Novantrone®)
Mitomycin (Mitomycin C, Mutamycin®)**β**
Mogamulizumab (Poteligeo®)
Mosunetuzumab (Lunsumio®)
Nadofaragene firadenovec (Adstiladrin®) **β**
Naxitamab (Danyelza®)
Nectimumab (Portrazza®)
Nelarabine (Ara-G, Arranon®)
Nivolumab (Opdivo®)
Nivolumab and relatlimab-rmbw (Opdualag®)
Obinutuzumab (Gazyva®)
Ofatumumab (Arzerra®)
Olaratumab (Lartruvo®)
Omacetaxine (Synribo®)
Oxaliplatin (Eloxatin®)
Paclitaxel (Taxol®)
Albumin Bound Paclitaxel (Abraxane®)
Panitumumab (Vectibix®)
Pegaspargase (Oncaspar®)
Peginterferon alfa-2a (Pegasys®)
Pembrolizumab (Keytruda®)
Pemetrexed (Alimta®)
Pentostatin (Nipent®) **β**
Pertuzumab (Perjeta®)
Pertuzumab, trastuzumab, and hyaluronidase–zzxf (Phesgo®)
Polatuzumab vedotin (Polivy®)
Porfimer Sodium (Photofrin®) **β**
Pralatrexate (Folotyn®)
Radium RA 223 dichloride (Xofigo®) **β**
Ramucirumab (Cyramza®)
Retifanlimab (Zynyz®)
Rituximab (Rituxan®) **β**
Romidepsin (Istodax®)
Ropeginterferon alfa-2b-njft (Besremi®).
Sacituzumab govitecan-hziy (Trodelvy®)
Sipuleucel-T (Provenge®)
Nanoparticle albumin bound sirolimus (Fyarro®)
Streptazocin (Zanosar®)
Tafasitamab (Monjuvi®)
Tagraxofusp-erzs (Elzonris®)
Talimogene Laherparepvec (Imlygic®) **β**
Talquetamab (Talvey®)
Tebentafusp-tebn (Kimmtrak®)
Teclistamab (Tecvayli®)
Temsirolimus (Torisel®)
Teniposide (VM-26, Vumon®)
Thiotepa (Thioplex®)
Tisagenlecleucel (Kymriah®)
Tisotumab vedotin-tftv (Tivdak®)
Topotecan (Hycamtin®)
Toripalimab (Loqtorzi®)
Trabectedin (Yondelis®)
Trastuzumab (Herceptin®)
Tremelimumab (Imjudo®)
Valrubicin (Valstar®) **β**
Vinblastine (Velban®)
Vincristine (Oncovin, Vincasar PFS®)
Liposomal Vincristine (Marquibo®)
Vinorelbine (Navelbine®)
Ziv-aflibercept (Zaltrap®)
Liposomal-encapsulated combination daunorubicin and cytarabine (Vyxeos®)

Table 1. Anticancer Therapy (ACT) – Continued

Oral and Topical Agents

Abemaciclib (Verzenio®)	Dasatinib (Sprycel®)	Lomustine (CCNU, CeeNU®)	Repotrectinib (Augtyro®)
Acalabrutinib(Calquence®)	Decitabine and cedazuridine (Inqovi®)	Lorlatinib (Lorbrena®)	Ribociclib (Kisqali®)
Adagrasib (Krazati®)	Duvelisib (Copiktra®)	Melphalan (Alkeran®, Evomela®)	Ripretinib (Qinlock®)
Afatinib (Gilotrif®)	Encorafenib (Braftovi®)	Mercaptopurine (Purinethol®) **β**	Rucaparib (Rubraca®)
Alectinib (Alecensa®)	Enasidenib (Idhifa®)	Methotrexate (Rhematrex®, Trexall®) **β**	Ruxolitinib (Jakafi®) **β**
Altretamine (Hexalen®)	Entrectinib (Rozlytrek®)	Midostaurin (Rydapt®) **β**	Selinexor (Xpovio®)
Alitretinoin - (Panretin®)	Erdafitinib (Balversa®)	Mitotane (Lysodren®) **β**	Selpercatinib (Retevmo®)
Alpelisib (Piqray®)	Erlotinib (Tarceva®)	Mobocertinib (Exkivity®)	Sonidegib (Odomzo®)
Anagrelide (Agrylin®)	Estramustine (Emcyt®)	Neratinib (Nerlynx®)	Sorafenib (Nexavar®)
Asciminib (Scemblix®)	Etoposide (VP-16, Vepesid®) **β**	Nilotinib (Tasigna®)	Sotorasib (Lumakras®)
Avapritinib (Ayvakit®) **β**	Everolimus (Afinitor®)	Niraparib (Zejula®)	Sunitinib (Sutent®)
Axitinib (Bosulif®)	Fedratinib (Inrebic®)	Nirogacestat (Ogsiveo®)	Talazoparib (Talzenna®)
Azacitidine (Onureg®)	Fluorouracil (Carac®, Efudex®, Fluoroplex®, etc.) **β**	Olaparib (Lynparza®)	Tazemetostat (Tazverik®)
Belzutifan (Welireg®)	Fruquintinib (Fruzaqla®)	Olutasidenib (Rezlidhia®)	Temozolomide (Temodar®)
Bexarotene (Targretin®)	Futibatinib (Lytgobi®)	Osimertinib (Tagrisso®)	Tepotinib (Tepmetko®)
Binimetinib (Mektovi®)	Gefitinib (Iressa®)	Pacritinib (Vonjo®)	Thalidomide (Thalomid®) **β**
Bosutinib (Bosulif®)	Gilteritinib (Xospata®)	Palbociclib (Ibrance®)	Thioguanine (6-TG)
Brigatinib (Alunbrig®)	Hydroxyurea (Hydrea®) **β**	Panobinostat (Farydak®)	Tivozanib (Fotivda®)
Busulfan (Myleran®) **β**	Ibrutinib (Imbruvica®)	Pazopanib (Votrient®)	Trametinib (Mekinist®)
Cabozantinib (Comrtriq®)	Idelalisib (Zydelig®)	Pemigatinib (Pemazyre®)	Tretinoin (ATRA, Vesanoid®)
Capecitabine (Xeloda®)	Imatinib (Gleevec®) **β**	Pexidartinib (Turalio®)	Trifluridine and tipiracil (Lonsurf®)
Capivasertib (Truqap®)	Infigratinib (Truseltiq®)	Pirtobrutinib (Jaypirca®)	Tucatinib (Tukysa®)
Capmatinib (Tabrecta®)	Ivosidenib (Tibsovo®)	Pomalidomide (Pomalyst®)	Vandetanib (Caprelsa®)
Ceritinib (Zykadia®)	Ixazomib (Ninlaro®)	Ponatinib (Iclusig®)	Vemurafenib (Zelboraf®)
Chlorambucil (Leukeran®)	Lapatinib (Tykerb®)	Pralsetinib (Gavreto®)	Venetoclax (Venclexta®)
Cobimetinib (Cotellic®)	Lenalidomide (Revlimid®)	Procarbazine (Matulane®)	Vismodegib (Erivedge®)
Crizotinib (Xalkori®)	Lenvatinib (Lenvima®)	Quizartinib (Vanflyta®)	Vorinostat (Zolinza®)
Cyclophosphamide (Cytoxan®) **β**		Regorafenib (Strivarga®)	Zanubrutinib (Brukinsa®)
Dabrafenib (Tafinlar®)			

Sub-Table A. Anticancer Therapy – Hormonal/Endocrine

Includes:

- Anticancer therapy with a primary mechanism of action involving action on hormones involved in cancer cell growth and proliferation.

Requirements:

- Requirements outlined in table 1 are waived for hormonal/endocrine agents listed in Sub-Table A (e.g. treatment plans and administration by an ACT competent clinician not required)
- ACT Pre-Teach appointment NOT required

Parenteral Agents	Oral and Topical Agents
Degarelix (Firmagon®) Fulvestrant (Faslodex® Goserelin (Zoladex®) Histrelin (Vantas, Supprelin LA®) Leuprolide (Lupron, Lupron Depot, Eligard®) Medroxyprogesterone (Depo-Provera®) Triptorelin (Trelstar, Trelstar LA®)	Abiraterone acetate (Zytiga®) Aminoglutethiamide (Cytaden®) Anastrozole (Arimidex®) Apalutamide (Erleada®) Bicalutamide (Casodex®) Darolutamide (Nubeqa®) Elacestrant (Orserdu®) Enzalutamide (Xtandi®) Exemestane (Aromasin®) Fluoxymesterone (Androxy®) Flutamide (Eulexin®) Letrozole (Femara®) Medroxyprogesterone (Provera®) Megestrol (Megace, Megace ES®) Nilutamide (Nilandron®) Raloxifene (Evista®) Relugolix (Orgovyx®) Tamoxifen (Nolvadex®) Toremifene (Fareston®)

Sub-Table B. Anticancer Therapy – Agents with Oncology & Non-Oncology or Procedural Indications

Includes:

- ACT agents used for both oncology and non-oncology indications
- ACT agents used for procedural indications (excluding intrathecal administration of ACTs – refer to intrathecal SOP for more details)

Requirements:

- Written informed consent by the attending prescribing provider
- Additional requirements vary depending on whether the agent is used for an oncology, procedural, or a non-oncology indication (see below)

Parenteral Agents	Oral and Topical Agents	Procedural agents
Alemtuzumab (Campath®) Bevacizumab (Avastin®) Bortezomib (Velcade®) Cyclophosphamide (Cytoxan®) Etoposide (VP-16, Toposar®, Vepesid®) Interferon alfa-2B (Intron-A, Roferon-A®) Methotrexate (Rhematrex®, Trexall®) Pentostatin (Nipent®) Rituximab (Rituxan®)	Avapritinib (Ayvakit®) Busulfan (Busulfex®) Cyclophosphamide (Cytoxan®) Etoposide (VP-16, Toposar®, Vepesid®) Fluorouracil (Carac®, Efudex®, Fluoroplex®, etc.) **β** Hydroxyurea (Hydrea®) Imatinib (Gleevec®) Methotrexate (Rhematrex®, Trexall®) Mercaptopurine (Purinethol®) Midostaurin (Rydapt®) Mitotane (Lysodren®) Ruxolitinib (Jakafi®) Thalidomide (Thalomid®)	Bacillus Calmette-Guerin (BCG, TheraCys®) Bevacizumab (Avastin®) Bleomycin (Blenoxane®) Cisplatin (Platinol®) Doxorubicin (Adriamycin®) Fluorouracil (5-FU, Adrucil®, etc.) Gemcitabine (Gemzar®) Irinotercan (Camptosar®) Lutetium Lu-177 dotatate (Lutethera®) Lutetium Lu-177 vipivotide tetraxetan (Pluvicto®) Melphalan (Hepzato®) Mitomycin (Mitomycin C, Mutamycin®) Nadofaragene firadenovec (Adstiladrin®) Porfimer Sodium (Photofrin®) Radium RA 223 dichloride (Xofigo®) Talimogene laherparepvec (Imlygic®)* Valrubicin (Valstar®)

Used for an Oncology Indication *(excluding procedural use)*

Additional requirements:

- Written ACT consent required prior to the administration
- Order entry in a treatment plan or secondary treatment plan for newly initiated ACT ***exception with 2 doses hydroxyurea or tretinoin for urgent doses
- OACT uses the order set "Oncology Oral Chemotherapy-Continuation from home" -valid for 30 days
- Orders must be signed by an oncologist
- Must be administered by an ACT competent clinician
- Dual signoff by 2 licensed practitioners in EHR at administration
- ACT Pre-Teach appointment required for initial treatments

Used for a Procedural or Non-Oncology Indication

Requirements for the Specialty Service Prescribing/ Attending Physician:

- Written ACT informed consent required
- DO NOT administer until validated by specialty prescribing/attending physician
- Ordering Parenteral Agents
  Outpatient – order entry in a "therapy plan"
  Inpatient – order entry in the respective "order set"
- Ordering Oral Anticancer (OACT) –
  Outpatient – order entry with standard prescription
  Inpatient – uses the "AHN IP Chemo Oral Antineoplastic" order set, that is valid for up to 30 days
- If administered IP, dual sign-off by two licensed clinicians in the EHR at the time of administration (ACT competent licensed clinician NOT required)

AHN Cancer Institute
Inpatient ACT Ordering/Administration Proposed Guidelines

Planned Routine Anticancer Therapy Admissions	New Anticancer Therapy Start and/or Emergent Treatment

• Definition:
  ○ routine planned admission for anticancer therapy (ACT) administration (OP planned not emergent)
• Scheduling:
  ○ Non-holiday weekdays only
  ○ No planned admissions on holidays or weekends
  ○ No new planned starts/first dose on holidays/weekends
  ▪ If scheduled Day 1 of the treatment plan falls on a holiday, the treatment plan is to be adjusted and admission rescheduled to align with above guidelines unless emergent or discussion with team
• Chart prep within 72 hours of admission by outpatient collaboration nurse
  ○ Includes consent, labs, orders sign and ready for release, line placement if needed
  ▪ can administer without a line with good vein access while waiting for line placement
• Bed reservations:
  ○ Evening before to reserve bed for ACT
• Patient arrival time to unit:
  ○ Recommended by 8 AM and no later than 10 AM
  ○ Reminder call the night before to patient with arrival time and bed assignment by the inpatient RN
• Chemotherapy release by 1 PM
  ○ Do not release unless all treatment parameters in the plan are met
• Chemotherapy mix turnaround time:
  ○ 2 hours premedication
  ○ 3 hours chemotherapy
	• Definitions:
	  ○ New ACT start:
	  ▪ a new diagnosis that warrants inpatient treatment but may or may not be emergent
	  ○ Emergent start:
	  ▪ delaying treatment may cause irreversible organ bodily harm, organ function, morbidity, or mortality; includes oncologic emergencies
	• Chart prep:
	  ○ consent, labs, pertinent procedures, and treatment plan (with proceed to treat if necessary) must be completed prior to release
	• Chemotherapy release:
	  ○ Optimally by 1 PM
	  ○ If patient's condition/diagnosis warrant an emergent or STAT ACT administration on weekends, holidays, or after 3 PM on weekdays:
	  ▪ A discussion among the prescribing physician, on-call pharmacist, inpatient pharmacy leadership, and oncology unit RN leader must occur to discuss the patient, resources, and staffing availably for safe ACT administration
	• Chemotherapy mix turnaround time:
	  ○ 2 hours premedication
	  ○ 3 hours chemotherapy

*Applies to all anticancer treatments even when used for non-cancer diagnosis due to nursing and pharmacy requirements for medication type

Reviewed and Revised December 2023 –AHN ACT Council & Heme/Onc P&T Subcommittee

AHN Cancer Institute
Inpatient ACT Ordering/Administration Proposed Guidelines

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	• Chemotherapy mix turnaround time:
	  ○ 2 hours premedication
	  ○ 3 hours chemotherapy

*Applies to all anticancer treatments even when used for non-cancer diagnosis due to nursing and pharmacy requirements for medication type

Reviewed and Revised December 2023 –AHN ACT Council & Heme/Onc P&T Subcommittee

INPATIENT ACT (Parenteral and/or OACT)/Procedural Guidelines

STEP 1: Determine if oncology or non-oncology indication
STEP 2: Consent is required prior to the administration of any ACT

INPATIENT NEWLY INITIATED OACT FOR ONCOLOGY INDICATIONS	**INPATIENT OACT FROM HOME - ONCOLOGY INDICATIONS**	**IP/OP PATIENTS WITH NON-ONCOLOGY INDICATIONS AND/OR PROCEDURAL ACT**
Patient is seen and evaluated by the oncology prescribing/attending physician or oncology fellow For newly initiated OACT in the hospital follow ALL AHNCI ACT AHNCI SOPs and OACT AHNCI SOPs A treatment plan is required for a newly initiated OACT Exceptions: • The overnight covering physician or hospitalist (no residents) may order a maximum of two doses of hydroxyurea or tretinoin, if urgently needed • The oncology attending may use the IP Order set to enter OACT orders without a treatment plan for emergent situations. (i.e. bridge therapy during evening or weekends) Once available, the attending hematologist/oncologist evaluates the patient, determines the need for further treatment and renews ACT orders if applicable	DO NOT administer the ACT agents until validated by the oncology prescribing/attending physician caring for the patient Oncology MUST order the continuation of the OACT If the primary admitting service is NOT the oncology prescribing/attending physician, then an oncology consult MUST be placed • If the consult is not followed up within 24 hours, reconsult the attending. If no response after reconsult within 24 hours, escalate to department head of the specialty The oncology attending provider orders as patient's supply of OACT using the order set "Oncology Oral Chemotherapy – Continuation From Home", that is valid for up to 30 days All inpatient dose modification orders are completed by the oncology prescribing/attending physician using an active medication order with a documented rationale	ACT Medications on Sub-Table B (Attachment C) - used for procedural or non-oncology services/ diagnoses/ indications includes, but is not limited to: • Rheumatology, 0B/GYN (ectopic pregnancies), Neurology, Organ Transplant Services, Operating Room, Nephrology, Gastroenterology, Cardiology, Allegheny Singer Research Institute (ASRI). DO NOT administer the ACT agents until validated by the specialty prescribing/attending physician caring for the patient The specialty MUST order the continuation of the OACT If the primary admitting service is NOT the specialty prescribing/attending physician, then a specialty consult MUST be placed • If the consult is not followed up within 24 hours, reconsult the attending. If no response after reconsult within 24 hours, escalate to department head of the specialty Parenteral Agents: • Outpatient: order entry in a "therapy plan" • Inpatient : order entry in the respective "order set"

	Patients taking OACT agents from home are instructed to bring their own supply for administration • If the patient has no family or resources to obtain the medications and when continued administration is deemed necessary by the provider, the pharmacy director and/or manager must be notified in order to approve non-formulary OACT agents • All ACTs are stored per hospital/network policy. • The procedure is outlined in the AHN "Patients Own Medication" policy is followed OACT agents from home are administered by ACT competent licensed personnel. If there are no ACT competent licensed personnel at the location, contact the unit manager/director to discuss a staffing plan	Oral Anticancer (OACT): • Outpatient: order entry with standard prescription • Inpatient: uses the "AHN IP Chemo Oral Antineoplastic" order set, that is valid for up to 30 days Administration in Inpatient • Dual sign-off by two licensed clinicians in the EHR at the time of administration (ACT competent licensed clinician NOT required) • Closed system transfer devices must be used for administration when applicable

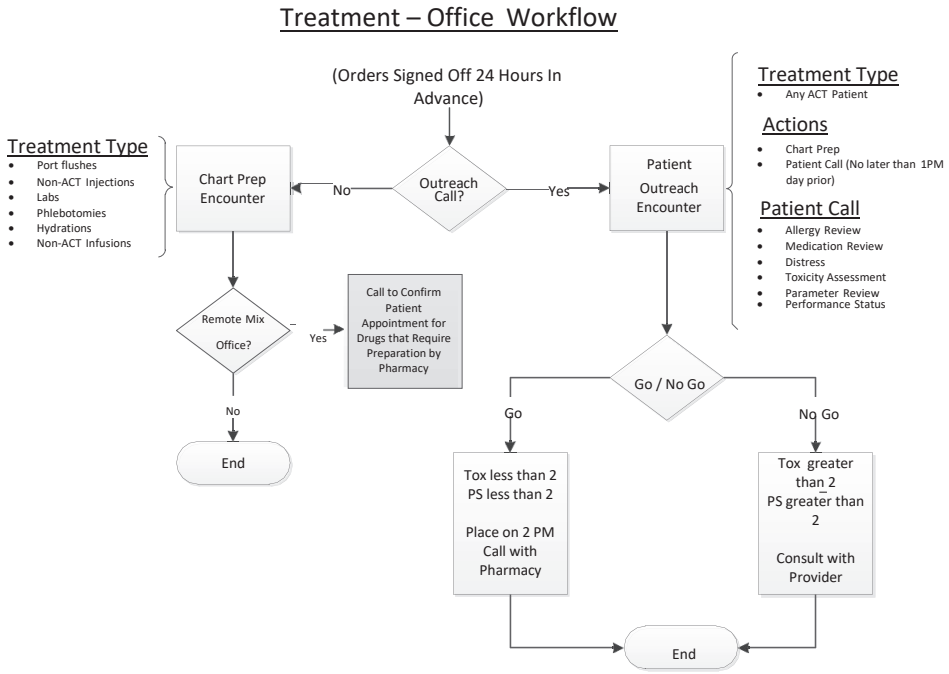
Nursing Remote-Mix Process

Purpose:

This document describes the Nursing Chart Prep process as it applies to a Cancer Institute for which medications are mixed at an off-site / remote pharmacy. The Chart Prep Encounter itself remains the same process.

However, certain types of treatments require a Patient Outreach Encounter instead prior to the patient visit. The Patient Outreach Encounter completes the 'Administration Verification Process – Step 1"

Workflow:



Nursing Remote-Mix Process

Requirements

- Route Treatment Plan to provider 1 week prior to treatment
- Process is started 2 days prior to the patient visit
- All orders must be signed off at least 24 hours in advance of patient visit
- Process is completed no later than 1PM the day prior to the patient visit

Description

'**Chart Prep Encounter'** is required for the following treatment types: o Port flushes o Non-ACT injections o Labs o Phlebotomies o Hydrations o Non-ACT infusions • As part of the Chart Prep Encounter, Nursing staff calls the patient to confirm they are coming to their appointment for any non-ACT drugs that require preparation by the Pharmacy.	Any ACT treatments requires a '**Patient Outreach Encounter'**. o The Patient Outreach Encounter includes completing the traditional Chart Prep process which is completed prior to contacting the patient as part of the Patient Outreach Encounter o Licensed clinician completes the Patient Outreach Encounter by 1PM the day prior to the patient visit. This supports verification of the patient visit at the 2PM call with pharmacy which begins the mixing process (see 2PM Pharmacy Call process for details). o **The following information is verified/documented as part of the Patient Outreach Encounter:** • Patients name and unique identifier (DOB) • Patients' diagnosis and correct treatment plan (using approved references) of ACT agents • Planned total ACT dose and duration on the treatment plan • Time, date, and schedule of intended ACT plan • Rate and route of administration • ACT drug name with abbreviations • Prior infusion related symptoms, allergies, hypersensitivity • Completed signed ACT consent • Toxicity assessment, performance statis, psychosocial distress, treatment parameter review • Allergy Review • Medication Review • If the Toxicity Assessment and Performance Status are both less than (<) 2, the patient's medications are cleared for mixing by the remote pharmacy and verified on the 2PM Pharmacy call. • If either the Toxicity Assessment or Performance Status are greater than or equal to (≥) 2, the patient's medications are held from mixing and the provider is contacted for further guidance. This may require that the patient treatment be rescheduled. • Utilize the "dot" system on the Infusion Schedule. A red "dot" means chart prep / patient outreach started and a white "dot" for Chart Prep / Patient Outreach is completed.

Table of Contents

Anticancer Therapy Oral Agent Ordering and Management (4.2; 4.3)

PROC-9163764

Print Details Share Details

Overview Statement
This policy applies to the AHN entities and individuals identified in the applicability section below. Registered Nurses (RNs), Advanced Practice Providers (APPs), Physicians, Pharmacists, and Pharmacy Technicians specially trained with anticancer therapy (ACT) agents follow the safety standards of practice for Oral Anticancer Therapy (OACT) management.

Purpose: To provide safe and effective ordering, administration, and monitoring for patients on OACT agents for both oncology and non-oncology indications.

Terms and Definitions
ACT - Anticancer Therapy includes antineoplastic agents such as chemotherapy, anticancer therapy/antineoplastic therapy, targeted therapy, anticancer monoclonal antibodies, immunological agents, cellular therapy, photodynamic therapy. This excludes hormonal therapy. Routes of administration include:

A. Parental routes include Intravenous (IV), Subcutaneous (SQ), Intramuscular (IM)
B. Enteral Routes - Solid dosage forms and oral suspensions
C. Alternate/Procedural Routes - Specialized ACT administration routes (Intra-arterial, Intraperitoneal, Intrapleural, intravesical, Intrathecal, Intraventricular, intrahepatic, intratumoral/intralesional, continuous infusion pumps), should only be used by licensed clinicians with advanced training in these procedures after being deemed competent (initially and annually) by another licensed clinician experienced in these administration procedures.

Advanced Practice Providers (APPs) - For the purposes of this policy, this includes Certified Registered Nurse Practitioners (CRNPs), and Physician Assistants (PAs).

Licensed Clinician – For purposes of this policy is a hematology/oncology fellow, APP, registered nurse, pharmacists, or attending/prescribing physician.

Licensed Provider – For purposes of this policy is a hematology/oncology fellow, APP or attending/ prescribing physician.

Cycle – For OACT and the purpose of this policy, a cycle is defined as every dispense filled.

EHR - Electronic Health Record.

OACT - Oral Anticancer Therapy.

Patient Specific Treatment Plans - Treatment plans for which no standard protocol template exists in the EHR.

REMS - Risk Evaluation and Mitigation Strategy is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

Therapy Plan – For this policy, includes medications on the ACT Medication List **[ACT Med List]** used for non-oncology indications in the outpatient locations. These are not Beacon Treatment Plans.

Treatment Plan - An ACT treatment protocol that is built into Epic as a protocol template and validated by a multidisciplinary committee. When applied to a patient, it includes the disease state, goal of treatment, treatment regimen and supportive therapy. Treatment plans are only used for oncology patients by staff who receive access to the plan after completing Beacon training.

Wet Signature – Refers to physically signing a document with ink and pen.

Administration

I. **OACT ORDERING**
A. OACT treatment plans follow the same process as outlined in the related policy: Anticancer Therapy Ordering Policy.
B. Treatment plans are written with a specified time limitation and re-validated with each new prescription.
1. During the first three cycles of therapy a prescription is written for one cycle with no additional refills:
a. Patients are re-evaluated at a provider visit with cycles 2 and 3.
2. After the first three cycles of therapy, prescriptions can be provided with refills not to exceed 90 days of total supply.
3. After the first three cycles, patients are evaluated at least once every six cycles or at the provider's discretion.
4. No refills are provided for IMIDS (lenalidomide, pomalidomide, thalidomide).
5. Wet signature may be required/requested for OACT.

Details

Applicability
AHN Entity

Content Type
Procedure

Responsible Area
Anticancer (ACT) Care

Executive Sponsor
Roberta Leinweber

Owner
Ciafre, Lisa

Former Numbers

Effective Date
11/1/2020

Last Approved Date
6/10/2025

Last Revised Date
6/10/2025

Next Review Date
6/10/2026

Related Authoritative Sources

Related Content
Anticancer Therapy Patient Consent (2.1; 4.2)

Anticancer Therapy Patient Education (2.2)

Anticancer Therapy Ordering (1.1.1; 3.1; 4.4)

Anticancer Therapy Monitoring and Assessment (1.3; 1.4; 1.5; 1.6; 4.1)

Related Documents

6. No OACT samples are provided to the patient.
7. Any refill request that is received by fax and/or EHR is discarded or refused with reason documented in the EHR.
8. If a free drug application or specialty pharmacy requires a prescription of longer duration than one-month, a longer prescription may be sent with monitoring timepoints following sections II and III of this policy by the OACT Team.

II. **OACT PATIENT MANAGEMENT BY OACT TEAM**

A. Patients on OACT agents for an oncology indication are managed by the respective OACT Team:
1. OACT patients are added onto the "OACT List".
2. The OACT RN adds self to the Care Team in the EHR.
3. Uses the OACT Encounter to communicate with the multidisciplinary team.

B. Authorizations and Financial Support:
1. Enrolls in the REMS program (if applicable).
2. Ensures authorization process is completed.

C. OACT Initiation:
1. Contact the patient to schedule the pre-teach appointment.
2. Explains process in obtaining OACT agents to the patient and/or significant other/caregiver.
3. Instructs the patient to:
a. Notify office upon OACT delivery and to NOT start taking OACT until approved by the OACT team.
b. Bring the medication to pre-teach appointment
i. If a patient is not able to bring medication to the pre-teach, a licensed clinician verifies the drug over the phone by having the patient read the medication name, dose, route, and frequency to the licensed clinician.
ii. Document in an OACT telephone encounter in the EHR.
c. Dose changes are also validated and documented at an appointment or via OACT telephone encounter.

D. Coordinates and verifies completion of baseline testing according to treatment plan.

E. Documents treatment start date (Cycle 1 Day 1 [C1D1]).

F. Completes baseline toxicity and adherence assessments:
1. The initial assessment of a patient's ability to adhere to the treatment plan is discussed during the consent process by the provider. This includes, but not limited to, financial, cognitive, behavioral, access to care, and support systems. This is also reviewed and confirmed during pre-teach and documented in the EHR.

G. Ensures consent and education is complete per anticancer therapy policies for Consent and Patient Education.

III. **OACT MONITORING AND ASSESSMENT BY OACT TEAM**

A. Laboratory testing is ordered per the treatment plan

B. Patients on OACT are assessed for drug toxicities, psychosocial/distress needs, and laboratory testing as ordered in treatment plan following the Anticancer Therapy Monitoring and Assessment Policy at the following intervals:
1. Baseline prior to initiation.
2. 1-2 weeks after initial start date.
3. At each provider visit.
4. Prior to each new prescription being sent to the pharmacy.
i. Complete at a minimum of every 3 cycles while patient is on therapy regardless of if a new prescription is sent.
5. See ACT Therapy Ordering Policy for hCG monitoring parameters.

C. The OACT nurse team is responsible for ensuring the prescribed laboratory assessment is completed and reviewed by a provider at the prescribed intervals for patients who have medication supplies issued to the pharmacy for greater than one cycle at a time.

D. Adherence to OACT treatment plan is assessed at the intervals defined above:
1. Verbal assessment/self-report and/or review of calendar, pill box, or phone app to determine adherence to treatment plan.
2. Reviews information with designated caregiver for patients unable to assume responsibility for managing medication(s).
3. Refers patient to a provider for further management when non-adherence is identified.

E. Multidisciplinary team notifies the OACT Team if treatment has been discontinued.

F. The OACT Team contacts the patient at the end of treatment to address disposal, survivorship, and any other inquiries.

G. The patient is removed from the OACT list if applicable.

IV. **INPATIENT OACT MANAGEMENT FOR ONCOLOGY INDICATION**

A. Inpatient newly initiated OACT for oncology indications.
1. Patients are seen and evaluated by the oncology prescribing/attending physician or oncology fellow.
2. For newly initiated OACT in the hospital follow Anticancer Therapy Ordering, Consent, and Patient Education Policies and steps as outlined in this policy.
3. A treatment plan is required for a newly initiated OACT except:
a. The overnight covering physician or hospitalist (no residents) may order a maximum of two doses of hydroxyurea or tretinoin via the "AHN Inpatient Chemo: Oral Antineoplastics" order set, if urgently needed.
i. Once available, the attending hematologist/ oncologist evaluates the patient, determines the need for further treatment and renews ACT orders if applicable.
b. The oncology attending may use the "AHN Inpatient Chemo: Oral Antineoplastics" order set to enter new start OACT orders without a treatment plan for emergent situations. (i.e. bridge therapy during evening or weekends).
4. Patient consent and education are provided as outlined in the Anticancer Therapy Consent and Patient Education policies.
5. Newly prescribed OACT for oncology indications must be administered by an ACT Competent Nurse following Anticancer Therapy Administration Policy for all of cycle 1.

B. Inpatient continuation from home OACT for oncology indications
1. DO NOT administer the ACT agents until validated by the oncology prescribing/attending physician caring for the patient.
2. If the primary admitting service is NOT the oncology prescribing/attending physician, then an oncology consult MUST be placed. If oncology specialists are not on staff at the inpatient facility, staff must outreach to the prescribing oncologist for direction.
3. If the consultation is not followed within 24 hours, reconsult the attending. If there is no response after a reconsult within 24 hours, escalate to department head of the specialty.
4. The oncology attending provider orders OACT as patient's supply of OACT using the order set "Oncology Oral Chemotherapy – Continuation from Home", which is valid for up to 30 days.
5. All inpatient dose modification orders are completed by the oncology prescribing/attending physician using an active medication order with a documented rationale.
6. Patients taking OACT agents from home are instructed to bring their own supply for administration:

a. Oncology MUST order the continuation of the OACT.
b. If the patient has no family or resources to obtain the medications and when continued administration is deemed necessary by the provider, the pharmacy director, oncology subcommittee of P&T physician chair, and/or manager must be notified to approve if the medication is non-formulary.
c. All ACTs are stored per hospital/network policy.
d. The procedure is outlined in the AHN "Patients Own Medication" policy is followed.

7. Administration during inpatient stay:
   a. ACT competent clinicians are NOT required to administer OACT agents continued from home.
   b. Dual sign-off by two licensed clinicians in the EHR at the time of administration.

V. **INPATIENT OACT FOR NON-ONCOLOGY INDICATIONS**

A. ACT agents used for non-oncology indications includes, but is not limited to the following specialties:
   1. Rheumatology, OB/GYN (ectopic pregnancies), Neurology, Organ Transplant Services, Operating Room, Nephrology, Gastroenterology, Cardiology, Allegheny Singer Research Institute (ASRI).

B. DO NOT administer the ACT agents until validated by the specialty prescribing/attending physician caring for the patient.

C. If inpatient continuation from home, the specialty MUST order the continuation of the OACT.
   1. If the primary admitting service is NOT the specialty prescribing/attending physician, then a specialty consult MUST be placed.
   2. If the consultation is not followed within 24 hours, reconsult the attending. If there is no response after a reconsult within 24 hours, escalateto department head of the specialty.

D. Ordering
   1. Outpatient: order entry with standard prescription.
   2. Inpatient: uses the “AHN Inpatient Chemo: Oral Antineoplastic” order set, that is valid for up to 30 days.

E. Administration during Inpatient stay:
   1. ACT competent clinicians are NOT required to administer OACT agents continued from home.
   2. Dual sign-off by two licensed clinicians in the EHR at the time of administration (ACT competent licensed clinician NOT required).)

Exceptions

None

Violations

None

Additional References

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Olsen, M.M., LeFebvre, K.B., & Walker, S. L. (2023). Chemotherapy and immunotherapy guidelines and recommendations for practice (2nd ed). Oncology Nursing Society

People Applicability

Independent credentialed/privileged providers (including physicians, nurse practitioners, physician assistants, certified registered nurse anesthetists, and midwives); Employees (including residents and fellows); Researchers

Entity Applicability

This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Allegheny Singer Research Institute (ASRI); This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Premier Medical Associates

Contact(s)

List of Approver(s)

ROBERTA LEINWEBER - INSTITUTE VICE PRESIDENT - 6/10/2025

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Table of Contents

Anticancer Therapy Extravasation (3.10)

PROC-9163780

Print Details Share Details

Overview Statement
Registered Nurses (RNs), Advanced Practice Providers (APPs), Physicians, Pharmacists, and Pharmacy Technicians specially trained with anticancer therapy (ACT) agents follow the safety standards of practice.

Purpose:

A. To provide guidelines for the management of extravasation of ACT drugs administered during treatments in the adult oncology setting.

Terms and Definitions

ACT - Anticancer Therapy (this includes antineoplastic agents such as chemotherapy, anticancer therapy/antineoplastic therapy, targeted therapy, monoclonal antibodies, immunological agents, cellular therapy, photodynamic therapy) ***excludes hormonal therapy

A. Parental routes include: Intravenous (IV), Subcutaneous (SQ), Intramuscular (IM)
B. Alternate Routes - Specialized ACT administration routes (Intra-arterial, Intraperitoneal, Intrapleural, intravesical, Intrathecal, Intraventricular, intrahepatic, continuous infusion pumps), only trained licensed clinicians in these procedures may perform after being deemed competent (initially and annually) by another licensed clinician experienced in these administration procedures.
C. Solid dosage forms and oral suspensions

Advanced Practice Providers (APPs)- For the purposes of this policy, this includes Certified Registered Nurse Practitioners (CRNPs), Physician Assistants (PAs), and Hematology/Oncology Fellows.

Antidote - A remedy to relieve or counteract the effect of an unwanted condition with ACT vesicant, vesicant-like, irritant, and non-irritant medications.

CTCAE - Common Terminology Criteria for Adverse Events

EHR - Electronic Health Record

Extravasation – The leakage of a vesicant drug into the subcutaneous or surrounding tissues that is capable of causing pain, necrosis, and/or sloughing of the tissues and/or various degrees of tissue damage.

Flare reaction - A red blush on the skin at the periphery of an urticarial lesion seen in immediate hypersensitivity reactions.

Irritants - Agents that can cause pain, inflammation, and irritation (without necrosis) at the injection site or along the vein.

Details

Applicability
AHN Entity

Content Type
Procedure

Responsible Area
Anticancer (ACT) Care

Executive Sponsor
Roberta Leinweber

Owner
Ciafre, Lisa

Former Numbers

Effective Date
11/1/2020

Last Approved Date
1/15/2025

Last Revised Date
1/19/2024

Next Review Date
1/15/2026

Related Authoritative Sources

Related Content

Related Documents
Attachment A - Extravasation recognition chart.pdf
Attachment B - AHNCI Extravasation Vesicant Algorithm.pdf
Attachment C - AHNCI Irritant and non-irritant ACT.pdf

Organization Driven Protocol: Organization Driven Protocols must meet all requirements for a Protocol outlined in 'Protocols and Standing Orders Policy'. This definition includes "nurse-driven protocols" or "pharmacy-driven protocols," but the term organization is being used to include any applicable health care practitioner and reflects the use of the Protocols at different sites and hospitals across the organization depending on their scope.

Vesicant Drugs – Agents which have the potential to cause blistering or tissue necrosis if they leak into the tissue surrounding a blood vessel or venous access device.

Administration

A. This SOP applies to all oncology patients that develop extravasation related symptoms in the AHNCI locations.
    1. Refer to - Extravasation Recognition Chart **(Attachment A)** for the signs and symptoms of extravasations, vesicants, irritants, and flare reactions.
B. Only ACT competent staff may apply the protocol (initial and annual competency required).
C. These guidelines are supported by Oncology Nursing Society (ONS), Lexicomp, Micromedix, Up-to-Date, EuropeanONS, and other extensive evidence-based literature to support the classified agents on the 'Guideline Algorithm'.
D. The AHNCI pharmacy department maintains adequate supply of ACT extravasation antidotes for admixture in the Network. A stat courier is utilized to provide antidote to remote locations when necessary.
E. In the event of an extravasation with any of the medications on the Extravasation Protocol - Implement the Organizational Driven Extravasation Protocol **(Attachment B)**
    1. Stop the infusion
    2. Immediately refer to the ACT Extravasation Algorithm Guidelines **(Attachment B)**
    3. Obtain the required compress and medication antidote (when applicable)
    4. Notify direct supervisor of extravasation and confirm with another licensed clinician that an extravasation has occurred
    5. Do not flush the line
    6. Disconnect the IV tubing from the IV device. The catheter/needle should **not** be removed immediately
    7. Attempt to aspirate fluid (3-5 mls) from the catheter/needle in the extravasated area
    8. Assess extravasation for severity using the CTCAE grading

a. Grade 1 - Painless edema
b. Grade 2 - Erythema with associated symptoms (e.g. edema, pain, induration, phlebitis)
c. Grade 3 - Ulceration or necrosis; severe tissue damage; operative intervention indicated
d. Grade 4 - Life-threatening consequences; urgent interventions indicated

9. Assess symptoms experienced by the patient (ie. pain, impairment of range of motion of extremity)
10. Mark with a permanent marker an outline of the extravasated area
11. Measure the size of the infiltration in cm (length and width)
12. Elevate the affected extremity
13. Implement extravasation orders consistent with protocol **(Attachment B)**
    a. Document the concentration and amount of drug remaining in the syringe or infusion bag.

F. **SPECIAL NOTES** - Restart new IV in opposite arm **or** ABOVE previous suspected extravasation site.
G. Apply a printed patient label with date, time and licensed personnel's initials on the affected extremity.
H. Obtain a picture (using AHN secure work phone, no personal devices may be used) of the site before the antidote treatment with the patient identification label in the picture. Ensure that the picture is sent only to an AHN email as 'PHI'.
I. Repeat picture after the antidote is administered.
J. File the photograph(s) in the patients' medical record - labeled with extravasation date and time.
K. Refer for specialized care (ie. physical therapy, plastic surgery, pain management, etc.) when indicated for any ACT extravasation.
L. Schedule follow up in the clinic by a provider 24-48 hours after the extravasation. Repeat picture at the follow-up appointment.
M. Schedule another follow-up 1-2 weeks and PRN after the extravasation. Obtain picture at the follow up appointment.
N. Complete extravasation report in AHN online reporting system and document on the IV assessment flow sheet in the EHR.
O. Use of medication antidote(s) may be limited by commercial availability.
    1. In the event where alternatives do not exist, follow the extravasation algorithm excluding the medication antidote(s).
    2. For all other irritants and non-vesicant ACT agents refer to (**Attachment C)** for treatment guidelines.
    3. Concurrent extravasation treatment, such as topical dimethyl sulfoxide (DMSO) application, should not be used, and if administered, may worsen extravasation-induced tissue injury.
P. In an event that Dexrazozane days 2 and 3 needs to be administered on a weekend, the patient is scheduled and/or admitted for administration of the antidote.
Q. **Documentation**
    1. Implement physician standing extravasation orders (**Supportive Care Plan OP and Orderset IP).**
    2. Complete IV Assessment Flow Sheet in EHR.
    3. Document in the AHN reporting solutions online system.
        a. A member of the oncology quality team receives, reviews, and follows-up errors daily.
        b. A core team of oncology directors and managers meet quarterly to review aggregate data, identify trends, and evaluate outcomes.
        c. AHNCI ACT Council reviews the aggregate data, errors, and organizational protocols at least quarterly to assess opportunities for Performance Improvement, new Standard Operating Procedures (SOPs)/policies, or other appropriate actions.

Exceptions
None

Violations
Violations of this policy or procedure may result in disciplinary action up to and including termination of employment.

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People Applicability
Independent credentialed/privileged providers (including physicians, nurse practitioners, physician assistants, certified registered nurse anesthetists, and midwives); Employees (including residents and fellows); Students; Researchers

Entity Applicability
This policy applies to Highmark Health and its subsidiaries and controlled affiliates; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates; This policy applies to Highmark Health and its subsidiaries

and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Allegheny Singer Research Institute (ASRI); This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:AHN Cancer Institute; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Allegheny Clinic; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Saint Vincent Medical Group & Other Medical Offices

Contact(s)

List of Approver(s)
ROBERTA LEINWEBER - INSTITUTE VICE PRESIDENT - 1/15/2025
Back to List

Attachment A

Signs and Symptoms of Infusion Related Venous Complications

Signs and Symptoms	Vesicant Infiltration and Extravasation		Venous Irritation	Flare Reaction
	Immediate Manifestations	Delayed Manifestations		
Blood return	Loss of blood return from IV device usually occurs.	–	Blood return should be present. If loss of blood return occurs, suspect infiltration of irritant.	Blood return is present.
Pain	Pain typically occurs and is described as burning, stinging, or a sensation of coolness at and around the vesicant administration site. However, some patients do not experience pain when a vesicant extravasates.	Pain usually increases in intensity over time.	Aching and tightness along a peripheral vein occur as the drug infuses above the administration site.	No pain occurs; the skin overlying the vein may itch.
Redness	Redness in the area of the vesicant administration site commonly occurs but is not always present or may be difficult to detect if the extravasation is occurring deeper in the tissue (e.g., as a result of needle dislodgment from implanted port).	Redness generally intensifies over time.	The vein may appear reddened or darkened.	Immediate blotches or streaks develop along the vein, which usually subside within a few minutes. Wheals may appear along the vein.
Swelling	Swelling commonly is observed and is easier to detect when extravasation is superficial (e.g., from a peripheral vein) rather than deep in the tissue (e.g., implanted ports).	Swelling typically increases over time.	Swelling does not occur.	Swelling does not occur.
Ulceration	Skin integrity is intact.	If vesicant extravasation is not treated, blistering and sloughing begins within 1-2 weeks, followed by tissue necrosis that may require surgical debridement and skin grafting or flap placement.	Ulceration does not occur.	Ulceration does not occur.

Note: Based on information from Goolsby & Lombardo (2006); Gorski et al. (2021); Sauerland et al. (2006); Wickham et al (2006)
Adapted from: Olsen, M.M., LeFebvre, K.B., & Walker, S. L. (2023). *Chemotherapy and immunotherapy guidelines and recommendations for practice (2nd ed).* Oncology Nursing Society.

ALLEGHENY HEALTH NETWORK

ANTICANCER AGENT EXTRAVASATION GUIDELINES

Vesicant/Vesicant-Like

Cabazitaxel
Cisplatin
Dacarbazine
Dactinomycin
Docetaxel
Enfortumab Vedotin*
Fluorouracil
Ibritumomab tiuxetan*
Ioncastuzumab tesirine
Liposomal doxorubicin
Lurbinectedin
Melphalan
Mitoxantrone
Mitomycin
Paclitaxel
Trabectedin

↓

Apply dry COLD compress for 20 minutes 4 times a day for 48 hours

Etoposide
Etoposide Phosphate
Mirvetuximab soravtansine gynx
Tisotumab vedotin

↓

Apply dry WARM compress for 20 minutes 4 times a day for 48 hours

Bendamustine
Mechlorethamine

↓

Apply dry COLD compress for 20 minutes 4 times a day for 48 hours

↓

SODIUM THIOSULFATE

Prepare a 4% solution:
-If a 10% (100 mg/mL): Dilute 4 mL of solution with 6 mL of sterile water
-If a 25% (250 mg/mL): Dilute 1.6 mL of solution with 8.4 mL sterile water

Administer:
Inject 2 mL subQ for each mg of suspected infiltrate and change needle with each injection.

Administer within one hour of extravasation

Ado-trastuzumab emtansine
Brentuximab vedotin
Vinblastine
Vincristine
Vinorelbine

↓

Apply dry WARM compress for 20 minutes 4 times a day for 48 hours

↓

HYALURONIDASE

Prepare a 150-200 units/mL (1 mL) solution:
-If Amphadase or Hylenex: Vial contains 150 units/mL. Do NOT dilute
-If Vitrase: Vial contains 200 units/mL. Do NOT dilute

Administer:
Inject five 0.2 mL injections subQ using a 25-G or smaller needle and change with each injection.

Administer within one hour of extravasation

Daunorubicin
Doxorubicin
Epirubicin
Idarubicin

↓

Apply dry COLD compress for 20 minutes 4 times a day for 48 hours

Withhold cooling at least 15 minutes prior to dexrazoxane and during infusion

↓

DEXRAZOXANE

Days 1 & 2:
1000mg/m^2 (max 2000 mg) IV

Day 3: 500mg/m^2 (max 1000 mg) IV.

Infuse over 1-2 hours into large unaffected vein remote from extravasation site

Begin treatment within 6 hours of extravasation

Oxaliplatin

↓

Apply dry WARM compress for 20 minutes 4 times a day for 48 hours

↓

CORTICOSTEROIDS

Dexamethasone 8 mg PO twice daily for up to 14 days

- **Stop and disconnect the infusion**
- **Attempt to aspirate 3 to 5 ml from IV/remove IV**
- **Place order set/supportive care plan for corresponding antidote and/or compress**
- **Notify provider**
- **Grade CTCAE and measure L x W**
- **Outline area with permanent marker**
- **Apply patient label above site, obtain picture, and upload into EHR**
- **Apply compress and administer antidote (if applicable)**
- **Schedule follow-up for 24 to 48 hours and 1 to 2 weeks – obtain f/u pictures and upload EHR**
- **Complete documentation (IV flowsheet and RL6)**

Reviewed and Revised December 2023– AHNCI ACT Council Heme/Onc P&T Subcommittee

ALLEGHENY HEALTH NETWORK

ANTICANCER AGENT EXTRAVASATION GUIDELINES

Irritant

Bleomycin
Bortezomib
Carboplatin
Carmustine
Cyclophosphamide
Cytarabine
Fam-trastuzumab deruxtecan
Floxuridine
Fludarabine
Gemcitabine
Gemtuzumab ozogamicin
Ifosfamide **
Irinotecan
Ixabepilone
Liposomal daunorubicin
Liposomal -encapsulated combination daunorubicin and cytarabine
Liposomal irinotecan
Methotrexate
Paclitaxel albumin-bound
Polatuzumab vedotin
Porfimer sodium
Radium 223 (dichloride)
Sacituzumab govitecan
Streptozocin
Temsirolimus
Thiotepa
Topotecan

→ Apply dry COLD compress for 20 minutes 4 times a day for 48 hours

Romidepsin

→ Apply dry WARM compress for 20 minutes 4 times a day for 48 hours

Teniposide
Vincristine liposome

→ Apply dry WARM compress for 20 minutes 4 times a day for 48 hours

→ **HYALURONIDASE**

Prepare a 150-200 units/mL (1 mL) solution:
-If Amphadase or Hylenex: Vial contains 150 units/mL. Do NOT dilute
-If Vitrase: Vial contains 200 units/mL. Do NOT dilute

Administer:
Inject five 0.2 mL injections subQ using a 25-G or smaller needle and change with each injection.

Administer within one hour of extravasation

Non-Irritant

Aldesleukin
Alemtuzumab
Amivantamab
Arsenic Trioxide
Asparaginase (Erwinia)
Atezolizumab
Avelumab
Axicabtagene ciloleucel
Azacitidine
Belantamab mafodotin
Belinostat
Bevacizumab
Blinatumomab
Brexucabtagene autoleucel
Busulfan
Carfilzomib
Cemiplimab
Cetuximab
Cladribine
Clofarabine
Copanlisib
Daratumumab
Decitabine
Dinutuximab
Dostarlimab
Durvalumab
Elotuzumab
Eribulin
Idecabtagene vicleucel
Inotuzumab ozogamicin
Interferonalfa-2b
Ipilimumab
Isatuximab
Lisocabtagene maraleucel
Margetuximab
Mogamulizumab
Mosunetuzumab
Nelarabine
Nivolumab
Nivolumab and relatlimab
Obinutuzumab
Ofatumumab
Omacetaxine
Panitumumab
Pegaspargase
Pembrolizumab
Pemetrexed
Pentostatin
Pertuzumab
Pralatrexate
Ramucirumab
Rituximab
Sipuleucel-T
Tafasitamab
Tisagenlecleucel
Trastuzumab
Tremelimumab
Ziv-aflibercept

→ Apply dry COLD compress for 20 minutes 4 times a day for 48 hours

**Use hyaluronidase if clinically warranted. Follow directions for use above
Reviewed and Revised December 2023 AHNCI ACT Council Heme/Onc P&T Subcommittee

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Table of Contents

Anticancer Therapy Hypersensitivity/ Anaphylactic Reactions (4.1)

PROC-9141244

Print Details Share Details

Overview Statement
Registered Nurses (RNs), Advanced Practice Providers (APPs), Physicians, Hematology/Oncology Fellows, Pharmacists, and Pharmacy Technicians specially trained with anticancer therapy (ACT) agents follow the safety standards of practice.

Purpose:

A. To provide guidelines in the event of hypersensitivity and/or anaphylactic reaction to medications administered during treatments in the adult population.
B. Follow the treatment plan protocol unless the manufacturer recommendations provide alternate best practice.
C. AHN clinical trials with defined hypersensitivity management protocols supersede the AHN 'organizational-driven protocol'.

Terms and Definitions
ACT - Anticancer Therapy (this includes antineoplastic agents such as chemotherapy, anticancer therapy/antineoplastic therapy, targeted therapy, monoclonal antibodies, immunological agents, cellular therapy, photodynamic therapy) ***excludes hormonal therapy

A. Parental routes include: Intravenous (IV), Subcutaneous (SQ), Intramuscular (IM)
B. Alternate Routes - Specialized ACT administration routes (Intra-arterial, Intraperitoneal, Intrapleural, intravesical, Intrathecal, Intraventricular, intrahepatic, continuous infusion pumps), only trained licensed clinicians in these procedures may perform after being deemed competent (initially and annually) by another licensed clinician experienced in these administration procedures.
C. Solid dosage forms and oral suspensions

Advanced Practice Providers (APPs)- For the purposes of this policy, this includes Certified Registered Nurse Practitioners (CRNPs), Physician Assistants (PAs), and Hematology/Oncology Fellows.

Anaphylaxis – a hypersensitivity reaction this is a systemic allergic reaction which can be life threatening.

EHR - Electronic Health Record

Hypersensitivity – Unexpected reactions mediated by the immune system

Organization Driven Protocol: Organization Driven Protocols must meet all requirements for a Protocol outlined in 'Protocols and Standing Orders Policy'. This definition includes “nurse-driven protocols” or “pharmacy-driven protocols,” but the term organization is being used to include any applicable health care practitioner and reflects the use of the Protocols at different sites and hospitals across the organization depending on their scope.

Details

Applicability
AHN Entity

Content Type
Procedure

Responsible Area
Anticancer (ACT) Care

Executive Sponsor
Roberta Leinweber

Owner
Ciafre, Lisa

Former Numbers

Effective Date
11/1/2020

Last Approved Date
1/15/2025

Last Revised Date
1/16/2024

Next Review Date
1/15/2026

Related Authoritative Sources

Related Content

Related Documents
Attachment A-AHNCI ACT Hypersensitivity Protocol Algorithm.pdf
Attachment B - AHN IP Hypersensitivity - Anaphylactic Reaction Kit.pdf
Attachment C. - AHNCI OP Emergency Drug Box Form.pdf

Administration

A. This SOP applies to all patients (oncology and non-oncology) that develop infusion related reactions in the AHNCI locations. Emergency medications are released in all oncology and non-oncology plans.
B. Only ACT competent staff may apply the protocol (initial and annual competency required).
C. All ACT drugs have the potential to cause hypersensitivity and/or anaphylactic reactions. High risk drugs include monoclonal antibodies, taxanes, platinums.
D. Patients are assessed for risk factors prior to infusion of high risk ACT medications.
E. Patients are educated on infusion related signs and symptoms to report prior to each medication infused.
F. In the event of a reaction with symptoms on **(Attachment A)**
    1. STOP drug infusion immediately
    2. Implement the Organizational-Driven Hypersensitivity Protocol **(Attachment A)**
    3. Obtain Hypersensitivity Kit
        a. IP kits are pre-made in the Omnicell **(Attachment B)**
        b. OP kits contain all emergency medications in locked box logged daily **(Attachment C)**
    4. Follow the Hypersensitivity Algorithm **(Attachment A)**
    5. Notify licensed provider
    6. Be aware that symptoms of anaphylaxis may recur hours after the initial reaction and intervention. Patients experiencing Grade 3 or 4 severe reactions are evaluated for hospitalization by the provider.
        a. If the provider determines outpatient monitoring is appropriate, the patient and/or caregiver are advised to monitor for any recurrence of symptoms within 24 hours
        b. If symptoms recur immediately, access emergency care
    7. Monitor vital signs – temperature, pulse, respirations, blood pressure, pulse ox (if available):

a. Every two minutes until the patient has stabilized;
b. Then every five minutes for 30 minutes;
c. Then every 15 minutes until emergency personnel have arrived or patient is discharged from outpatient setting.

8. Life threatening escalation of care:
   a. Procedures for responding to a life-threatening emergency are located at each AHNCI oncology location and each AHNCI facility. These are reviewed and updated annually
   b. Emergency response is either met by rapid response teams or 911 based on facility location
   c. Staff calls for assistance and also calls supervising provider
   d. CPR is initiated if warranted, and patients are maintained with supportive therapy and care until the rapid response or 911 responders arrive
   e. The person identifying the emergency initiates CPR or rapid response. Then assign tasks/roles out to obtain the emergency medications, crash cart, physician

G. **Documentation**

1. EHR hypersensitivity flow sheet
2. AHN on-line reporting system
   a. A member of the oncology quality team receives, reviews, and follows-up errors daily
   b. A core team of oncology directors and managers meet quarterly to review aggregate data, identify trends, and evaluate outcomes
   c. AHNCI ACT Council reviews the aggregate data, errors, and organizational protocols at least quarterly to assess opportunities for Performance Improvement, new Standard Operating Procedures (SOPs)/policies, or other appropriate actions

Exceptions
None

Violations
Violations of this policy or procedure may result in disciplinary action up to and including termination of employment.

Additional References
External or Regulatory References:

Boulanger, J., Boursiquot, J.N., Cournoyer, G., Lemieux, J., Masse, M.S., Almanric, K., & Guay, M.P. (2018). Management of hypersensitivity to platinum-based chemotherapy: Cepo review and clinical recommendations. *Current Oncology, 21*(4).

Bonamichi-Santos, R., & Castells, M. (2018). Diagnoses and management of drug hypersensitivity and anaphylaxis in cancer and chronic inflammatory diseases: Reactions to taxanes and monolonal antibodies. *Clinic Review Allery and Immunology, 54,* 375-385.

Cingi, C., Wallace, D., Muluk, N. B., Ebisawa, M., Castells, M., Sahin, E., Altinoprak, N. (2016). Managing anaphylaxis in the office setting. *American Journal of Rhinology & Allergy 30,* e118-e123.

Commins, S. P. (2017). Outpatient emergencies: Anaphylaxis. *Medical Clinics North America, 101,* 521-536.

Eisenberg, S. (2018). *Infusion reactions, extravasation, and transfusion reactions*. In M. Kaplan Understanding and managing oncologic emergencies: A resource for nurses (3rd ed.). Oncology Nursing Society.

Giavina-Bianchi, P., Patil, S. U., Banerji, A. (2020). Immediate hypersensitivity reactions to chemotherapeutic agents. *Journal of Allergy Clinical Immunology Practice, 5*(3), 593-599.

Olsen, M.M., LeFebvre, K.B., & Walker, S. L. (2023). *Chemotherapy and immunotherapy guidelines and recommendations for practice (2nd ed).* Oncology Nursing Society.

Note: attachment #1 "Emergency Drugs for use in case of Hypersensitivity or Anaphylactic Reaction" referenced from Chemotherapy and Immunotherapy Guidelines and Recommendations for Practice, 2nd edition (pp. 114), by M. Polovich, M. Olsen, K. Lefebvre (Eds.), 2023, Pittsburgh, PA: Oncology Nursing Society. Copyright 2023 by Oncology Nursing Society. Used with permission.

Rogers, B. B., Cuddahy, T., Briscella, C., Ross, N., Olszanski, A. J., & Denlinger, C. S. (2019). Oxaliplatin: Detection and management of hypersensitivity reactions. *Clinical Journal of Oncology Nursing, 23*(1), 68-75.

Wallace, D. (2013). Anaphylaxis in the allergists office: Preparing your office and staff for medical emergencies. *Allergy Asthma Proceedings, 34*(9), 120-131.

People Applicability
Independent credentialed/privileged providers (including physicians, nurse practitioners, physician assistants, certified registered nurse anesthetists, and midwives); Employees (including residents and fellows); Students; Researchers

Entity Applicability
This policy applies to Highmark Health and its subsidiaries and controlled affiliates; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Allegheny Singer Research Institute (ASRI); This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:AHN Cancer Institute; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Allegheny Clinic; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Saint Vincent Medical Group & Other Medical Offices

Contact(s)

List of Approver(s)
ROBERTA LEINWEBER - INSTITUTE VICE PRESIDENT - 1/15/2025
Back to List

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Adult Hypersensitivity Protocol Algorithm

Patient change in condition during therapy

STOP INFUSION AND DISCONNECT

OBTAIN VITAL SIGNS

CONNNECT NSS IV WIDE OPEN

PLACE PATIENT SUPINE

OBTAIN EMERGENCY KIT AND NOTIFIY PROVIDER

Initiate Hypersensitivity Protocol

Organ System & Symptoms	Grade	Grade Criteria	Management & Sequence		
Grade I & II Symptoms: **Cutaneous:** • Hives • Itching • Redness/flushed • Fever • Chills/rigors **Conjunctival** • Any eye symptom **Gastrointestinal:** • Nausea • Vomiting • Diarrhea • Abdominal pain **Musculoskeletal:** • Cramps • Back pain **Respiratory :** • SOB with RR less than 25 bpm • Rhinitis	**Grade I (MILD)**	Involves **ONE** organ system: • Cutaneous • Conjunctival • Gastrointestinal • Musculoskeletal • Respiratory	**Diphenhydramine** 50 mg IV Push over 2 min. x1 (if already given as premed, give 25 mg IV push x1) **AND** **Famotidine** 20 mg IV over 5 min. x1 (20 mg in 50 mL infusion bag)	**If Progression to Grade II**	
	Grade II (MODERATE)	Involves **TWO** organ systems: • Cutaneous • Conjunctival • Gastrointestinal • Musculoskeletal • Respiratory	**Diphenhydramine** 50 mg IV Push over 2 min. x1 (if already given as premed, give 25 mg IV push x1) **AND** **Famotidine** 20 mg IV over 5 min. x1 (20 mg in 50 mL infusion bag) **AND** **Hydrocortisone** 100 mg IV Push over 30 sec. x1	**Add:** **Hydrocortisone** 100 mg IV Push over 30 sec. x1	**If Progression to Grade III**
Grade III Symptoms: **Cutaneous:** • Swelling of the lips, face or tongue **Respiratory:** • Wheezing • SOB with RR greater than or equal to 25 bpm • Stridor • Bronchospasm-chest tightness/chest pain • Cough • Hoarseness **Cardiovascular:** • Dizziness • Syncope • Hypotension (SBP less than 80 mmHg or 20 mm Hg decrease from baseline) • Loss of consciousness	**Grade III (SEVERE)**	**Grade III Symptom:** • Cutaneous • Respiratory • Cardiovascular	**GIVE FIRST—Epinephrine** 0.3mg IM in lateral thigh—may repeat every 5 min. up to 3 doses **AND** **Diphenhydramine** 50 mg IV Push over 2 min. x1 (if already given as premed, give 25 mg IV push x1) **AND** **Famotidine** 20 mg IV over 5 min. x1 (20 mg in 50 mL infusion bag) **AND** **Hydrocortisone** 100 mg IV Push over 30 sec. x1 **PRN** **Oxygen 2-6 L nasal cannula or 6-8 L face mask** to maintain saturations greater than or equal to 92%		**Add:** **Epinephrine** 0.3mg IM in lateral thigh—may repeat every 5 min. up to 3 doses **PRN** **Oxygen 2-6 LnNasal cannula or 6-8 L face mask** to maintain saturations greater than or equal to 92%

Consult provider for patient disposition and/or re-initiation of infusion

YES

Symptoms Resolved?

NO

Provide Basic Life Support and transition patient to higher level of care

Albuterol MDI or Albuterol 2.5 mg via nebulizer for persistent bronchospasm after 2 doses of epinephrine to be ordered by the provider when available

Reviewed and Revised December 2023 –AHN ACT Council & Heme/Onc P&T Subcommittee

Table of Contents

Anticancer Therapy Monitoring and Assessment (1.3; 1.4; 1.5; 1.6; 4.1)

PROC-10645875

Print Details Share Details

Overview Statement
Registered Nurses (RNs), Advanced Practice Providers (APPs), Physicians, Hematology/Oncology Fellows, Pharmacists, and Pharmacy Technicians specially trained with anticancer therapy (ACT) agents follow the safety standards of practice.

Purpose:

To provide safe administration and treatment guidelines related to patient monitoring with ACT treatment.

To provide a consistent process facilitating the management of out-patient phone calls with a mechanism to effectively triage calls that meets individual needs 24 hours a day 7 days per week and escalation of care during emergency situations

Terms and Definitions
ACT - Anticancer Therapy includes antineoplastic agents such as chemotherapy, anticancer therapy/antineoplastic therapy, targeted therapy, anticancer monoclonal antibodies, immunological agents, cellular therapy, photodynamic therapy. This excludes hormonal therapy. Routes of administration include:

A. **Parental Routes -** Intravenous (IV), Subcutaneous (SQ), Intramuscular (IM)
B. **Enteral Routes** - Solid dosage forms and oral suspensions
C. **Alternate Routes** - Specialized ACT administration routes (Intra-arterial, Intraperitoneal, Intrapleural, intravesical, Intrathecal, Intraventricular, intrahepatic, intratumoral, intralesional, and continuous infusion pumps), only trained licensed clinicians in these procedures may perform after being deemed competent (initially and annually) by another licensed clinician experienced in these administration procedures.

Advanced Practice Providers (APPs) - For the purposes of this policy, this includes Certified Registered Nurse Practitioners (CRNPs) and Physician Assistants (PAs).,

BLS – Basic Life Support

CTCAE - Common Terminology Criteria for Adverse Events

Licensed Clinician – For purposes of this policy is a hematology/oncology fellow, APP, registered nurse, pharmacist, or attending/prescribing physician.

Licensed Provider – For purposes of this policy is a hematology/oncology fellow, APP, or attending/ prescribing physician.

OACT - Oral Anticancer Therapy

PHQ 2/9 - Patient Health Questionnaire 2/9 questions

Administration

I. **Clinical Provider and Treatment Encounter Assessment**
   A. ACT competent licensed clinician may complete performance status and toxicity assessments. A non-ACT competent licensed clinician completing the assessments requires review with cosign by the ACT competent licensed clinician.
   B. On each ACT clinical provider or treatment encounter, the staff performs and documents a patient assessment including:
      1. Performance status
         a. A baseline assessment is completed by a licensed clinician prior to the initiation of ACT treatment regimen.
         b. Patients actively receiving ACT with an active treatment plan are assessed for performance status by an ACT licensed clinician prior to the administration of each ACT treatment using ECOG or Karnofsky Performance Assessment Tool. The licensed clinician will:
            i. Report ECOG score greater than two and/or Karnofsky less than 50 to the licensed provider to evaluate the treatment plan.
            ii. A 'proceed with treatment' order is required for any ECOG score greater than two or Karnofsky less than 50.
         c. Licensed Providers will assess and document performance status at each visit but does not require the use of ECOG or Karnofsky assessment tools.
      2. **Toxicity Grading**
         a. A baseline toxicity assessment is completed by a licensed clinician prior to the initiation of ACT Treatment regimen.
         b. Patients actively receiving ACT with an active treatment plan are assessed for toxicities by an ACT licensed clinician on each treatment day prior to the administration of ACT treatment using CTCAE Toxicity Assessment Tool **(Attachment A)**. The licensed clinician will:
            i. Report any patient with a toxicity greater than two to the licensed provider to evaluate the treatment plan.
            ii. A 'proceed with treatment' order is required for any toxicity greater than two.
         c. Licensed Providers will assess and document toxicity status at each visit but does not require the use of the CTCAE assessment tool.

Details

Applicability
AHN Entity

Content Type
Procedure

Responsible Area
Anticancer (ACT) Care

Executive Sponsor
Roberta Leinweber

Owner
Ciafre, Lisa

Former Numbers

Effective Date
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11/25/2025

Last Revised Date
11/25/2025

Next Review Date
11/25/2026

Related Authoritative Sources

Related Content
Occurrence Reporting for Patients and Visitors

Related Documents
Attachment A -AHNCI CTCAE 5-0 Toxcity Grading.pdf
Attachment B -AHNCI Patient Office Letter.pdf
Attachment C - AHNCI Triage Management.pdf
ONC-201121-004 (9-25) Neurotoxicity Handwriting Assessment Log.pdf

d. Any positive findings for Immuno-effector Cell (IEC) and Bispecific T-cell engager agents' toxicity assessments set forth by the American Society for Cellular Transplant and Therapy (ASTCT):
    i. Complete neurological assessment.
    ii. Cytokine Release Syndrome (CRS).
    iii. Immune effector cell assessment neurotoxicity symptoms (ICANS) will be assessed prior to each dose through a handwriting assessment **(Attachment B):**
        1. Patients writes the sentence "Our national bird is the bald eagle."
        2. Scan document to media using document type "ICANS writing sample".
        3. For subsequent assessments, the nurse will search media for the last document, print, and have the patient write the sentence on the next line and re-upload to media.
e. Dose modifications related to toxicities are communicated in the treatment plan and/or the provider notes.

3. **Psychosocial Assessment**
    a. A baseline psychosocial assessment is completed by a licensed clinician prior to the initiation of ACT Treatment regimen.
    b. Patients actively receiving ACT with an active treatment plan are assessed for psychosocial needs by an ACT licensed clinician prior to each cycle. When using PHQ-2/9 and distress assessment tools, the licensed clinician will:
        i. Report a PHQ-9 score greater than or equal to ten to the social worker and /or provider for further evaluation and follow up.
        ii. Report a distress score greater than or equal to four to the social worker and/or provider for further evaluation and follow up.
    c. Licensed Providers will assess and document psychosocial assessment at each visit but does not require the use of the PHQ-2/9 or distress assessment tools.
    d. Information is provided to patients on psychosocial and supportive services.
4. **Nutrition** – A nutritional assessment is performed by a licensed clinician prior to each cycle using the Malnutrition Screening Tool (MST). The licensed clinician will:
    a. Report an MST score greater than or equal to two to dietitian for further evaluation and follow up.
5. **Medication Reconciliation** - Patient medications (prescribed, over the counter, complementary and alternative) are updated at every visit by licensed clinicians and reviewed by the licensed provider as per the AHN Medication Reconciliation Policy.
6. **Vital Signs** - are assessed at every visit.
7. **Height and weight** – height is assessed prior to initiating ACT Therapy and then once per calendar year. Weight is assessed at every visit. The licensed clinician will:
    a. Report any patient with a 10% change to the provider to evaluate the treatment plan.
    b. A 'proceed with treatment' order is required for any weight change greater or equal to 10%.
8. **Allergies** - are assessed at every visit.
9. **Pain** - is assessed at every visit.

II. **Missed/Canceled Appointments/Labs/Treatments (Attachment B)**
A. A designated staff member will contact any patient with missed provider, lab, or infusion appointments.
B. The contact method may include telephone, mail, or electronic medical record (EMR) pathways. Note: if EMR pathway is chosen, staff member must ensure patient utilization of this pathway by verifying patient has accessed their EMR electronically within the past 6 months.
C. The timeframe for contacting patients to reschedule missed/cancelled appointments is as follows:
    1. Established Missed Appointments:
        a. 1st attempt - within 5 business days.
        b. 2nd attempt - within 10 business days.
        c. After 2nd failed attempt without evidence of patient contact - a letter is sent via regular mail.
    2. Non-established Missed Appointments:
        a. 1st attempt – within 5 business days.
        b. After failed first attempt without evidence of patient contact a letter is sent via regular mail and notify the referring physician.
    3. Staff documents this interaction in the no show follow up report.

III. **24/7 triage**
A. All patients are provided with the office phone number where they are an established oncology patient **(Attachment B).**
B. Calls received during open office hours:
    1. Office staff member receives calls from patients.
    2. Staff members inquire regarding if the call is urgent or non-urgent (if there is a question of urgency, the call is considered urgent). **(Attachment C)**
        a. Non-urgent calls:
            i. A message is taken (may be a note or voice mail)
            ii. Non-urgent calls are returned by office staff within 24 hours.
        b. Urgent calls:
            i. Are given directly to a licensed clinician for immediate attention.
            ii. A telephone encounter is created to document the call in the EHR.
C. Messages received during open office hours:
    1. Patients will be informed that messages will be reviewed and returned within one business day. A business day is defined as Monday through Friday from 8:00 am to 4:00 pm.
D. Calls during closed office hours:
    1. Office calls are forwarded to answering service.
    2. Answering service takes a message and arranges immediate notification of the on-call oncology provider.
    3. Answering service has a list of oncology providers who are on call.
    4. Answering service contacts on-call oncology provider with message.
    5. On-call oncology provider reaches out directly to the patient to triage the problem.
E. Life- Threatening Emergencies - Escalation of Care
    1. Procedures for responding to a life-threatening or imminent emergency condition are located at each AHNCI oncology office and each AHNCI facility.
    2. Staff calls for assistance including the onsite supervising provider, and initiates emergency response team.
        a. Emergency response team is described as internal code team, transport team, or community response by calling 911.
        b. BLS is initiated if warranted, and patients are supported until appropriate transition of care occurs.

Exceptions

None

Violations
None.

Additional References
Common Terminology Criteria for Adverse Events (CTCAE). (2017). https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_8.5x11.pdf

ESMO Oncology Pro. (2022). Performance scales: Karnofsky & ECOG scores. https://oncologypro.esmo.org/oncology-in-practice/practice-tools/performance-scales

National Comprehensive Cancer Network (NCCN, 2020). NCCN distress thermometer and problem list for patients. https://www.nccn.org/patients/guidelines/content/PDF/distress-patient.pdf

Olsen, M.M., LeFebvre, K.B., & Walker, S. L. (2023). Chemotherapy and immunotherapy guidelines and recommendations for practice (2nd ed). Oncology Nursing Society

People Applicability
Independent credentialed/privileged providers (including physicians, nurse practitioners, physician assistants, certified registered nurse anesthetists, and midwives); Employees (including residents and fellows); Students; Researchers

Entity Applicability
This policy applies to Highmark Health and its subsidiaries and controlled affiliates; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Allegheny Singer Research Institute (ASRI); This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:AHN Cancer Institute; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Allegheny Clinic; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Saint Vincent Medical Group & Other Medical Offices

Contact(s)

List of Approver(s)
ROBERTA LEINWEBER - INSTITUTE VICE PRESIDENT - 11/25/2025
Back to List

TOXICITY GRADING

	Grade 1 Mild	Grade 2 Moderate	Grade 3 Severe	Grade 4 Life Threatening
Constitutional				
Fever	38.0-39.0 degrees C (100.4-102.2 degrees F)	>39.0-40.0 degrees C (102.3-104.0 degrees F)	>40.0 degrees C (>104.0 degrees F) for <= 24 hours	>40.0 degrees C (>104.0 degrees F) for > 24 hours
Febrile Neutropenia			ANC <1000/mm3 with a single temperature of >38.3 degrees C (101 degrees F) or a sustained temperature of >38.0 degress C (100.4 degrees F) for more than one hours	Life threatening consequences; urgent interventions indicated
Fatigue	Relieved by rest	Not relieved by rest; limiting instrumental ADL	not relieved by rest; limiting self-care ADL	
Weight Gain/Loss	5-10% from baseline; intervention not indicated	10-20% from baseline	>20% from baseline	
Blood and Lymphatic				
Anemia	Hgb <LLN- <10.0 g/dl; <6.2 mmol/L; <100g/L	Hgb <10.0 – 8.0 g/dL; <6.2 – 4.9 mmol/L; <100 – 80 g/L	Hgb <8.0 g/dl; <4.9 mmol/L; < 80g/L; transfusion indicated	Life-threatening consequences; urgent intervention indicated
Neurosensory				
Sleep/Insomnia	Mild difficulty falling asleep. Staying asleep or waking up early	Moderate difficulty falling asleep, staying asleep, or waking up early	Severe difficulty in falling asleep, staying asleep, or waking up early	
Neuropathy- Sensory-Motor	Asymptomatic; clinical or diagnostic observations only	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self-care ADL	Life-threatening consequences; urgent interventions indicated
Musculoskeletal				
Arthralgia (joint)	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self-care ADL	----------
Myalgia (muscle)	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self-care ADL	----------
Integumentary				
Rash/ Acne/ Acneiform	Papules and/or pustules covering <10% BSA, which may or maynot be associated with symptoms of pruritus or tenderness	Papules and/or pustules covering 10-30% BSA, which may or may not be associated with symptoms of pruritus or tenderness; associated with psychosocial impact; limiting instrumental ADL; papules and or pustules covering >30% BSA with or without mild symptoms	Papules and/or pustules covering >30% BSA with moderate or severe symptoms; limiting self-care ADL; associated with local superinfection with oral antibiotics indicated	Life threatening consequences; papules and/or pustules covering any % BSA, which may or may not be associated with symptoms of pruritus or tenderness and associated with extensive superinfection with IV antibiotic indicated
Palmer-plantar erythrodyses-thesia (PPE) Hand/Foot Syndrome	Minimal skin changes or dermatitis (e.g. erythema. Edema, hyperkeratosis without pain	Skin changes (e.g. peeling, blisters, bleeding, fissures, edema, hyperkeratosis) with pain limiting instrumental ADL	Severe skin changes (e.g. peeling, blisters, bleeding, fissures,edema, hyperkeratosis) with main; limiting self-care ADL	_____
Nail Changes	Present; asymptomatic separation of the nail bed from the nail plate or loss	Symptomatic separation of the nail bed from the nail plate or nail loss; limiting instrumental ADL		
Pruritus	Mild or localized; topical intervention indicated	Widespread and intermittent; skin changes from scratching (e.g. edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL	Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroids or immunosuppressive therapy indicated	----------
Respiratory				
Cough	Mild symptoms; non-prescription intervention indicated	Moderate symptoms; medical intervention indicated; limiting instrumental ADL	Severe symptoms; limiting self-care ADL	----------
Dyspnea	Shortness of breath with moderate exertion	Shortness of breath with minimal exertion; limiting instrumental ADL	Shortness of breath at rest; limiting self-care ADL	Life-threatening consequences; urgent intervention indicated
Hiccups	Mild symptoms; intervention not indicated	Moderate symptoms; medical intervention indicated; limiting instrumental ADL	Severe symptoms; interfering with sleep; limiting self-care ADL	----------

Cardiac/PV				
Hypertension	Systolic BP 120-139 mm Hg or diastolic BP 80-89 mm Hg	Systolic BP 140-159 mm HG or diastolic BP 90-99 mm Hg if previously WNL; change in baseline medical intervention indicated; recurrent or persistent (>=24 hours); symptomatic increase by >20mm Hg (diastolic) or to >140/90 mm Hg; monotherapy indicated initiated	Systolic BP >160 mm Hg or diastolic BP >100 mm Hg; medical intervention indicated; more than one drug or more intensive therapy the previously used indicated	Life-threatening consequences (ie malignant HTN; transient or permanent neurologic deficit; HTN crises); urgent intervention indicated crises)
Hypotension	Asymptomatic, intervention not indicated	Non-urgent medical intervention indicated	medical intervention indicated; hospitalization indicated	life threatening consequences; urgent intervention)
Edema	1+ noted on exam; localized to dependent areas; no disability or functional impairment	Moderate localized edema; limiting instrumental ADL; intervention indicated	Severe localized edema; intervention indicated; limiting self-care ADLs;	life threatening consequences
Gastrointestinal				
Anorexia	Loss of appetite without alteration in eating habits	Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated	Associated with significant weight loss or malnutrition (ie. Inadequate oral caloric and/or fluid intake); tube feedings, or TPN indicated	Life-threatening consequences; urgent interventions indicated
Diarrhea	Increase of <4 stool per day over baseline; mild increase in ostomy output compared to baseline	Increase of 4-6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental ADL	Increase of ≥7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL	Life-threatening consequences; urgent interventions indicated
Constipation	Occasional or intermittent symptoms; occasion use of stool softeners, laxatives, dietary modification, or enema	Persistent symptoms with regular use of laxative or enemas indicated; limiting instrumental ADL	Obstipation with manual evacuation indicated; limiting self-care ADL	Life-threatening consequences; urgent intervention indicated
Dehydration	Increased oral fluids indicated; dry mucous membranes; diminished skin tugor	IV fluid indicated	Hospitalization indicated	Life-threatening consequences; urgent interventions indicated
Nausea	Loss of appetite without alteration in eating habits	Oral intake decrease without significant weight loss, dehydration malnutrition	Inadequate oral caloric or fluid intake; tube feedings, TPN, or hospitalization indicated	Life-threatening consequences; urgent interventions indicated
Vomiting	intervention not indicated	Outpatient IV hydration; medical intervention indicated	Tube feeding, TPN, or hospitalization indicated	Life-threatening consequences
Mucositis	Asymptomatic or mild symptoms; interventions not indicated	Moderate pain or ulcer that does not interfere with oral intake; modified diet indicated	Severe pain; interfering with oral intake	Life-threatening consequences; urgent interventions indicated
Esophagitis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered eating/swallowing; oral supplements indicated	Severely altered eating/swallowing; tube feeding, TPN, or hospitalization indicated	Life-threatening consequences; urgent operative intervention indicated
Reproductive				
Sexual/Libido	Decreased in sexual interest not adversely affecting relationship	Decrease in sexual interest adversely affecting relationship		
Pregnancy Test Complete (HCG)	yes	no		
Ocular				
Yes/no 0 = no change previous assessment 1 = new onset 2= worsening symptoms	• photophobia • blurred visions • dry eyes • periorbital edema • watery eyes • decreased vision			
Oral Adherence	yes	no		
Immune Effector Cell				
Neuro Symptoms	Check any that apply			
ICE (CAR-TOX 10-pt)				
ICANS	0-2	3-6	7-9	10
ASTCT CRS Consensus Grading	Fever - yes	Fever – no		

Graded Oncology Symptom Management Phone Triage Guidelines

Grade 1 Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
Grade 2 Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL.
Grade 3 Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL.
Grade 4 Life-threatening consequences; urgent intervention indicated.

Symptoms	Green - Grade 1	Yellow – Grade 2-3		Red – Grade 4
Constipation	Occasional: symptoms, use of stool softeners, laxatives, dietary modification, or enema	Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL	Obstipation with manual evacuation indicated; limiting self-care ADL	Severe acute abdominal pain
Diarrhea	Increase of less than 4 stools per day over baseline; mild increase in ostomy output compared to baseline	Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental ADL		With or without severe acute abdominal pain. Increase of greater than/equal to 7 stools per day overbaseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL
Dehydration	Increased oral fluids indicated; dry mucous membranes; diminished skin turgor	Dizziness; dizziness with standing; light-headed; unable to tolerate oral fluids for up to 12 hours (span of 2 meals)		Rapid heart rate; severe and persistent dizziness; lightheaded at rest
Nausea and/or Vomiting	Loss of appetite without alteration in eating habits (Nausea only); Screen for symptoms of dehydration	Nausea and/or vomiting greater than 4x per day; Loss of appetite with alteration in eating habits; uncontrolled with current medications (anti-medics); able to tolerate fluids with vomiting; Screen for symptoms of dehydration		Greater than 5x per day; patient demonstrates criteria for dehydration
Mouth Sores	-	Mouth sores but can still eat; Screen for dehydration		Severe – difficulty eating or swallowing; screen for dehydration symptoms
Fever	Less than 100.4 F	Greater than 100.4 Non-neutropenic		Greater than 100.4 Neutropenic
Chills	Mild sensation of cold; shivering; chattering of teeth	Moderate tremor of the entire body; narcotics indicated – Non-neutropenic – Send to Answering Line On-Call MD		Severe or prolonged, not responsive to narcotics - Neutropenic
Pain/Tumor Pain	Mild pain; less than 4 (Scale: 1-10)	Moderate pain; limiting instrumental ADL Measuring 4-7		Severe, uncontrolled pain less than 7; limiting self-care ADL
Cardiac	-	Symptomatic at rest or with minimal to moderate activity or exertion; intervention indicated; new onset of symptoms; lower extremity pitting edema		Fluttering in chest, racing heart, feel heart beating, pounding heart and/or sudden onset of severe shortness of breath
Vascular	-	Pain, redness, swelling, syncope, phlebitis/cellulitis, thromboembolism		Peripheral ischemia
Neurological	-	Tingling pins and needles sensation in hands or feet – sharp jabbing, throbbing, burning pain, syncope		Inability to walk – loss of feeling in extremities
Respiratory	-	Mild to moderate shortness of breath; difficulty breathing during exertion; chronic in nature		Lips or fingernails turning blue; Progressive change in baseline shortness of breath; acute sudden onset shortness of breath
Headache	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self-care ADL	Assess for F.A.S.T. (stroke) criteria: **F**acial drooping, **A**rm weakness, **S**peech difficulties, **T**ime
Cutaneous	Papules and/or pustules covering less than 10% BSA, which may or may not be associated with symptoms of pruritus or tenderness – Faint erythema or dry desquamation	Papules and/or pustules covering 10-30% BSA, which may or may not be associated with symptoms of pruritus or tenderness; associated with psychosocial impact; limiting instrumental ADL; papules and or pustules covering >30% BSA with or without mild symptoms – Moist desquamation confined to skin folds – Moderate to brisk erythema	Papules and/or pustules covering >30% BSA with moderate or severe symptoms; limiting self-care ADL; associated with local superinfection with oral antibiotics indicted – Moist desquamation other than skin folds - bleeding	Life threatening consequences; papules and/orpustules covering any % BSA, which may or may not be associated with symptoms of pruritus or tenderness and associated with extensive superinfection with IV antibiotic indicated
Mood	-	Mood change with no impact to ADL		Severe – inability to cope ; New onset of hallucinations; suicidal tendencies
Weight Gain/Loss	5 to less than 10% from baseline; intervention not indicated	10 to less than 20% from baseline; nutritional support indicated for weight loss	Greater than 20% from baseline; tube feeding or TPN indicated for weight loss	-
Fatigue	Fatigue relieved by rest	Fatigue not relieved by rest; limiting instrumental ADL (Call office next morning) - Not sleeping as well as usual		Unable to sleep for 2-3 nights

National Cancer Institute. Common Terminology Criteria for Adverse Events (CTCAE) v5.0. https://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm. Accessed August 8th, 2018.

Call Triage Pathway:

- Once you identify the symptom(s) and their grade, please refer to the below triage pathway forassistance.
- You must medically triage/understand the patient's symptoms to ID what level of action or escalation isneeded.

New Patient Call during Office Hours:

- Establish Care – Schedule patient appointment
- Establish Care – Schedule patient appointment
- Seek emergent care

Established Patient Call during Office Hours:

- Establish Care – Schedule patient appointment
- Re-direct to providing office → Leave amessage
- Re-direct to Providing Office → if no answer, call back line *AND/OR* Call 911/Emergent care needed

New Patient Call After-Hours:

- Establish Care – Schedule patient appointment
- Establish Care – Schedule patient appointment *AND/OR* Re-direct to last known established care provider/Emergent care if symptoms justify
- New Patient Call → Seek emergent care

Established Patient Call After-Hours:

- Create CRM
- Direct to Physician Office Answering Service *OR* Emergent care if symptoms justify
- Re-direct to Providing Office → if no answer, call back line *AND/OR* Call 911/Emergent care needed

Reviewed and Revised December 2023 –AHNCI ACT Council & Heme/Onc P&T Subcommittee

Neurotoxicity Handwriting Assessment Log

Staff Directions: Prior to each dose of an Immuno-effector Cell or Bispecific T-cell engager agent, the patient will write the sentence ***"Our national bird is the bald eagle."*** The document is scanned into media using "Nursing Assessment as the document type with ICANS Writing Sample" as the description. For, subsequent assessments, the nurse will search media for the last document, print, and have the patient write the sentence on the next line and re-upload to media. Note: In-patient units will scan in the document upon to discharge.

Patient Directions: Write the sentence, "Our national bird is the bald eagle," when instructed by your healthcare team.

Patient Name: _____ **Date of Birth:** _____

MRN#: _____ **Medication:** _____

Date	Time	RN initials	Sentence	Patient initials

AHN
Allegheny Health Network

201121

Neurotoxicity Handwriting Assessment Log

Patient Identification

Date	Time	RN initials	Sentence	Patient initials

Signature Key Please print and sign your name and add your initials in the spaces below. Use your initials where indicated on the form.

Print Name	Signature	Initials

Allegheny Health Network

201121

Neurotoxicity Handwriting Assessment Log

Patient Identification

Table of Contents

Safe Handling of Hazardous Drugs

POL-10313853

Print Details Share Details

Overview Statement

This policy applies to the AHN entities and individuals outlined in the policy applicability section below.

It is the intent of the Allegheny Health Network to establish practice and quality standards for handling hazardous drugs in healthcare settings and help promote patient safety, worker safety, and environmental protection.

This policy has been developed to establish standard operating procedures to promote safe work practices and ensure the protection of all employees, licensed independent Practitioners, and embedded contract employees from the potential adverse effects to the of hazardous drugs.

Details

Applicability
AHN Entity

Content Type
Policy

Responsible Area
Medication Management

Executive Sponsor
Laura Mark

Owner
Peterson, Kristen

Former Numbers

Effective Date
1/19/2024

Last Approved Date
9/29/2025

Last Revised Date
9/29/2025

Next Review Date
9/29/2026

Related Authoritative Sources

Related Content

Related Documents
Attachment A - shipping between facilities.pdf
AHN HD List (official).xlsx

Terms and Definitions

Hazardous (NIOSH) Drug: Defined by the 2020 version of the NIOSH hazardous drugs list. A drug which exhibits one or more of the following characteristics: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity, or structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the other criteria.

Hazardous (EPA) Drug: Drugs that considered hazardous to the environment and require special disposal instruction.

Biosafety: Safety precautions that reduce the risk of exposure to a potentially infectious microbe and limit contamination of the work environment.

- BSL 1: are microbes that are not known to consistently cause disease in healthy adults and present minimal potential hazard to employees and the environment.
- BSL 2: are microbes that pose moderate hazards to employees and the environment. The microbes are typically indigenous and associated with disease of varying severity.

Anti-cancer (ACT) Drug: Drugs that have oncology indications (See ACT Drug list: Anti-Cancer Therapy Administration)

The Program Administrator: AHN Pharmacy Regulatory Department and the Designated Persons at each location

Administration

Responsibilities:

1. Leadership Duties:
    - AHN Leadership is responsible for providing the resources required to ensure that the Hazard Communication Plan (HCP) can be executed in order to stay in compliance with the latest mandates.
2. Program Administrator Duties:
    - The Program Administrator will be made up of the Pharmacy Regulatory Department and the facility Designated Person(s). (AHN Designated Person)
    - The Pharmacy Regulatory Department will oversee the AHN HD list, policy review, provide educational materials and assist with environmental monitoring and regulation issues. They will also aid the facility designated person(s) through regular communications and routine meetings.
    - Each facility will be appointed a designated person on site who is qualified and trained on the appropriate procedures of handling hazardous drugs found on the NIOSH list. They are responsible for keeping their facility up to date on the most current regulations, laws, and standards pertaining to the handling of hazardous drugs.
    - The designated person(s) is also responsible for overseeing the facility and maintaining any reporting, testing/sampling performed and taking the necessary steps to act on the results. (See designated person policy)
3. Management Duties:
    - It is the responsibility of the management staff in each department to ensure that the requirements for the handling of hazardous drugs are being followed. Annual education and the demonstration of knowledge is also required to be managed for each department.
    - Some of their other duties are to include, but aren't limited to:
        - Ensuring the availability of task specific PPE.
        - Being aware of tasks requiring the use of PPE.
        - Enforcing the proper use of PPE and counseling employees when deviations are observed.
        - Continually monitoring work areas and operations to identify new or changed hazards.
        - Coordinate with the Program Administrator on how to address concerns regarding the program.
4. Employee Duties:
    - All employees that handle hazardous drugs on a regular basis must ensure that they are following the policies and procedures related to the handling of hazardous drugs. This includes, but is not limited to:
        - Ensuring that the proper personal protective equipment (PPE) is worn properly for each specific instance when handling hazardous drugs
        - Handling hazardous drugs according to the network risk assessment document.
        - Ensuring that spills are handled properly according to the policy
        - Completing all training and acknowledgements are completed annually
        - Reporting any exposures to potential hazardous drugs to their management and employee health
        - Informing management or the facilities Designated Person of any hazards that they feel may not be adequately addressed in the work place and of any other concerns that they have regarding the program.

Procedures:

1. Annual Education and Acknowledgement

- All new employees will be required to complete hazardous drug education upon hire during their initial orientation and annually thereafter. An acknowledgement of risk will also be required from each employee to document their understanding of the risks involved with handling hazardous drugs in the workplace.
- Employees that handle hazardous drugs must be trained based on their job functions. For clinical and non-clinical groups regularly exposed to hazardous drugs, an annual in-depth training will be provided in addition to the annual education.

2. Identifying a hazardous drug

- The AHN Hazardous Drug List will be created from our purchase history and the NIOSH list of Hazardous Drugs used in the healthcare setting published in 2024. The AHN HD List must be reviewed annually by AHN network pharmacy leadership to verify all AHN formulary drugs in use are being properly managed according to the hazardous drug listing.
- There are two groupings of hazardous drugs:
    - Group 1: Drugs that meet the NIOSH definition of a hazardous drug
        - Contain MSHI in the package insert
        - And/or are:
            - Classified by the NTP as ‘known to be a human carcinogen’
            - Classified by IARC as ‘carcinogenic’ or ‘probably carcinogenic’
    - Group 2: Drugs that meet one or more of the NIOSH definition of a hazardous drug.
        - Do NOT contain MSHI in the package insert
        - And are NOT classified by the NTP as ‘known to be a human carcinogen’ or classified by IARC as ‘carcinogenic’ or ‘probably carcinogenic’
- The designated person at each facility will work assist the Regulatory Department to conduct a hazard assessment on each new drug to ensure the proper procedures are in place for any potential exposures.
- If there is insufficient information available to categorize the drug properly or until NIOSH determines hazard level, it must be considered a hazardous drug until more information is available to determine.
- Investigational Drugs are not included in the AHN HD list. Handling requirements are determined by the Investigational Drug Service department
- Link to AHN HD List:
    - AHN HD List - 2024 (official).xlsx
    - AHN Sharepoint --> select pharmacy from departments --> guidelines --> AHN HD list.

3. Protection from hazardous drugs

- Additional PPE may be required for handling hazardous drugs found on the AHN HD List for situations such as treating a patient or cleaning a spill. Guidance on the proper PPE to use will be found on the listing for each drug. (See AHN HD list)
- Appropriate PPE must be worn when the following activity is occurring:
    - Receipt
    - Storage
    - Transport
    - Compounding (sterile and non-sterile)
    - Administration
    - Deactivation/decontamination, cleaning, and disinfecting
    - Spill control
    - Waste disposal

4. Labeling of a hazardous drug

- All hazardous drugs that require special handling must be clearly labeled at all times.

5. External Shipping (i.e. Fedex, UPS):

- Labeling must be compliant with the proper standards that are documented in accordance with applicable federal, state, and local regulations. All hazardous drug labels will have the following included:
    - Signal word - The signal word, such as “Danger,” or “Warning,” is used to indicate the hazard level. Danger indicates the most serious hazard level, while Warning indicates a lower level of risk. Pictograms - A pictogram, or GHS hazard symbol, is a visual representation of hazardous products.
    - Pictograms are used to group products according to risk level, including health risks, chemical/physical risks, and environmental risks.
    - Manufacturer Information - GHS labels must include the manufacturer’s name, as well as contact information including an address and phone number.
    - Precautionary Statements - Precautionary statements are phrases included with a hazard statement that provide information about preventative, response, storage, and disposal precautions that should be taken when handling or using the hazardous material.
    - Hazard Statements - Hazard statements are used to describe the degree of hazard and the nature of the hazardous material.
    - Product Identification - A product identifier is used to disclose the chemical’s or product’s name. If additional identifiers are needed beyond the product name, these identifiers can be placed to the right of the manufacturer’s information on a GHS label.
        - A representative from the Pharmacy will ensure that all hazardous drugs and any specific transport containers are appropriately labeled and in compliance with regulations.
- If a hazardous drug must be shipped to locations outside of the facility, the safety data sheet must be reviewed to identify transport information.
- Drugs will not be transported in biohazard labeled containers/bags unless the drug is listed as a biohazard.

5. Dispensing of a hazardous drugs

- Hazardous drugs should be packaged to prevent possible contamination of drug residue or from potential spill or leak
- Liquid hazardous (includes oral solutions, topicals, IVs – items that can spill or leak)
    - Purple – dispense in a sealed drug container in a manner to prevent leaks or contamination similar to non-hazardous drugs.
    - Orange – Place in sealed zip closure bag
    - Yellow – Item to be double bagged in zip closure bags (outer bag labeled clearly as hazardous drug) or item to be placed in zip-closure bag, then placed in impervious plastic bin(bin labeled clearly as hazardous drug)

- Solid hazardous dosage forms - dispense in a sealed unit dose packaging or prescription bottle in a manner to prevent leaks or contamination similar to non-hazardous drugs.
- Use of Patient's own hazardous meds (from home) –
    - Seal patient own medication container in zip closure bag for storage in pharmacy or in ADS. Epic label for scanning to be placed on the outside of the bag
        - See Patient Own Med Policy for guidance about what home medications may be used.
    - May include Investigational drug, oral medications and topicals (See Investigational Drug Policy)
    - Patient's meds received through an AHN Pharmacy may be dispensed following the same procedures as standard inventory

7. Transport of a hazardous drug
    - To another AHN facility
        - See Appendix A for shipment of remote mix hazardous drugs
    - Within a department or facility
    - Hazardous drugs that need to be transported must be labeled, stored, and handled in accordance with applicable federal, state, and local regulations. They must be transported in containers that minimize the risk of breakage or leakage such as a impervious, plastic bin. The computerized tube system will not be used in order to transport such drugs.

7. External Shipping (i.e. Fedex, UPS):
    - Labeling must be compliant with the proper standards that are documented in accordance with applicable federal, state, and local regulations. All hazardous drug labels will have the following included:
        - Signal word - The signal word, such as "Danger," or "Warning," is used to indicate the hazard level. Danger indicates the most serious hazard level, while Warning indicates a lower level of risk. Pictograms - A pictogram, or GHS hazard symbol, is a visual representation of hazardous products.
        - Pictograms are used to group products according to risk level, including health risks, chemical/physical risks, and environmental risks.
        - Manufacturer Information - GHS labels must include the manufacturer's name, as well as contact information including an address and phone number.
        - Precautionary Statements - Precautionary statements are phrases included with a hazard statement that provide information about preventative, response, storage, and disposal precautions that should be taken when handling or using the hazardous material.
        - Hazard Statements - Hazard statements are used to describe the degree of hazard and the nature of the hazardous material.
        - Product Identification - A product identifier is used to disclose the chemical's or product's name. If additional identifiers are needed beyond the product name, these identifiers can be placed to the right of the manufacturer's information on a GHS label.
            - A representative from the Pharmacy will ensure that all hazardous drugs and any specific transport containers are appropriately labeled and in compliance with regulations.
    - If a hazardous drug must be shipped to locations outside of the facility, the safety data sheet must be reviewed to identify transport information.
    - Drugs will not be transported in biohazard labeled containers/bags unless the drug is listed as a biohazard.

8. Storage of a hazardous drug
    - All hazardous drugs must be stored properly to prevent spillage or breakage if the container falls. Hazardous drugs should not be stored on the floor.
    - Final dosage forms of Hazardous drugs may be stored in an ADS if clearly labeled as hazardous. Liquid forms of Hazardous drugs must also be stored in a sealed, leakproof plastic bag or container.
    - NIOSH Table 1 Antineoplastic drugs that require manipulation and any active pharmaceutical ingredient (API) must be stored in a separate area from non-HDs to avoid contamination and exposure to employees. These drugs must be stored in a negative pressure room which has an external ventilation system with at least 12 air changes per hour.
    - Sterile and non-sterile hazardous drugs may be stored together, but drugs that are used for non-sterile compounding should not be stored in the same areas used for sterile compounding.
    - A dedicated refrigerator must be used to store hazardous drug and kept in a negative pressure area such as the storage room, buffer room, or containment segregated compounding area.
    - Refer to storage policy

9. Disposal of a hazardous (NIOSH) drug
    - All employees who are responsible for the removal and cleaning of hazardous (NIOSH) drug materials must protect themselves with the proper PPE and comply with all appropriate procedures related to federal, state, and local regulations.
    - Materials used for handling hazardous (NIOSH) drugs must be disposed of in the designated color bins to comply with proper disposal.
        - Black Bin: Used for the disposal of non-hazardous and Hazardous (NIOSH) medication waste (>3% of the final container). Some drugs must be segregated during disposal. See Medication waste policy for more information.
        - Yellow hard sided Bin: Used for 'sharps' that were used to compound or administer NIOSH Table 1 antineoplastics (Yellow Hazardous Drugs per AHN HD List) and may have trace contamination (i.e. empty Equashield syringes, empty chemotherapy vials/bags, etc,)
        - Yellow soft sided Bins: Used for to dispose of items that may have been contaminated with NIOSH Table 1 antineoplastics (Yellow Hazardous Drugs per AHN HD List) (i.e. used PPE, used cleaning wipes, etc.)
    - This policy does not fully describe the medication waste program. See the Medication waste policy for more information.

10. Safety Data Sheets
    - Safety Data Sheets (SDS) will be maintained for all hazardous drugs in order to provide important manufacturer information and properties of the substance.
    - SDS will be maintained online on the AHN Sharepoint site: (https://www.3eonline.com/EeeOnlinePortal/DesktopDefault.aspx?tabid=90).
    - For AHN facilities that do not have access to the online database, hard copies of the SDSs will be maintained at each facility. You can contact the assigned designated person at your location in order to obtain information.

11. Program Evaluation:
    - The Program Administrator will conduct an annual evaluation of the Hazard Communication Plan to ensure that all aspects of the program meet the most current requirements. The Program Administrator will also ensure that the plan is being implemented effectively to protect employees from hazardous exposures.
    - Program evaluation will include, but is not limited to:
        - A review of the written program.
        - Completion of a program evaluation checklist based on observations of workplace practices.
        - A review of feedback obtained from employees that will be collected during the annual training session.
    - The Program Administrator will revise the program elements as necessary. Records of revisions will be documented and kept on file. Any procedural changes that are implemented as a result of program evaluation will be communicated to the employees and reinforced by the management staff and included in education materials.

Exceptions

None

Violations

Violations of this policy or procedure may result in disciplinary action up to and including termination of employment.

Additional References

People Applicability

Independent credentialed/privileged providers (including physicians, nurse practitioners, physician assistants, certified registered nurse anesthetists, and midwives); Employees (including residents and fellows); Contracted/embedded workforce personnel (including independent contractors and agency staff); Students; Members of a Collective Bargaining Agreement

Entity Applicability

This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates

Contact(s)

List of Approver(s)

LAURA MARK - VP PHARMACY - AHN - 9/23/2025,
MARK RUBINO - PHYSICIAN PRESIDENT / 74 - 9/29/2025,
ALLAN KLAPPER - PHYSICIAN PRESIDENT - 9/26/2025,
CHONG PARK - PHYSICIAN PRESIDENT / 74 - 9/23/2025,
IMRAN QADEER - PHYSICIAN PRESIDENT / 74 - 9/26/2025,
BRIAN JOHNSON - PHYSICIAN PRESIDENT / 74 - 9/26/2025,
CHRISTOPHER CLARK - PHYSICIAN PRESIDENT - 9/23/2025

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Table of Contents

Medication Spills in Pharmacy and Patient Care Areas

POL-10499350

Print Details Share Details

Overview Statement

The purpose of this policy is to minimize exposure and protect employees during the mitigation and cleanup of hazardous medication spills.

The policy outlines the required training, clean up procedures, personal protective equipment, and supplies to be used when attending to a hazardous medication spill. Guidance for how to clean up spills in the home is also included.

Terms and Definitions

EHS - Employee Health Services

PAPR - Powered Air Purifying Respirator

PPE - Personal Protective Equipment

Hazardous Drugs: Hazardous drugs are considered hazardous by NIOSH if they meet one of the following criteria: carcinogenicity, teratogenicity, reproductive toxicity, organ toxicity at low doses, genotoxicity, and/or structure and toxicity profile of a new drug mimic a drug that is classified as hazardous.

NIOSH Table 1: Drugs that meet the NIOSH definition of a hazardous drug, contain Manufacturer's Safe Handling Instructions (MSHI), and/or are classified by NTP as a 'known to be a human carcinogen' or by IARC as 'carcinogenic' or 'probably carcinogenic'

NIOSH Table 2: Drugs that meet the NIOSH definition of a hazardous drugs, but do not contain MSHI and are not classified by either NTP or IARC as carcinogenic or probably carcinogenic

Biosafety: Safety precautions that reduce the risk of exposure to a potentially infectious microbe and limit contamination of the work environment.

BSL 1: are microbes that are not known to consistently cause disease in healthy adults and present minimal potential hazard to employees and the environment.

BSL 2: are microbes that pose moderate hazards to employees and the environment. The microbes are typically indigenous and associated with disease of varying severity.

Administration

Medications at AHN are categorized by NIOSH hazardous rating and AHN Assessment of Risk. Categories include

- General – non-hazardous
- Purple – low risk
- Orange – medium risk
- Yellow – high risk

1. General Medication Spills

a. General Medications are drugs that are not on the AHN HD List or NIOSH

b. Employees that work in the area and are familiar with the handling of medications or cleanup where medications are stored or handled may address a spill.

c. Personal Protective Equipment: Employees must wear a single pair of HD resistant gloves when cleaning up a medication spill. Additional PPE is optional.

d. Procedure for clean up **(Attachment A)**

e. Medical Follow up – see Section G

f. Cleanup: Clean and affected area using approved cleaning wipes and solutions. Wipes and towels may be disposed of in the standard trash.

g. Remove gloves and any other PPE and wash hand after cleanup is complete.

2. Purple Handling Medication Spill

i. Staff who are pregnant, trying to become pregnant (male or female) or breastfeeding should refrain from cleaning up hazardous drugs.

a. Purple Hazardous Drugs are low risk hazardous drug. See AHN HD List

b. Employees that work in the area and are familiar with the handling of medications or cleanup where medications are stored or handled may address a spill.

c. Personal Protective Equipment: Employees must wear a single pair of HD gloves when cleaning up a medication spill. A face shield, gown or other PPE is optional.

d. Procedure for cleanup **(Attachment A)**

e. Medical Follow up – see Section G

f. Cleanup: Clean and affected area using approved cleaning wipes and solutions. Wipes and towels may be disposed of in the standard trash.

g. Remove gloves and any other PPE and wash hand after cleanup is complete.

3. Orange Handling Medication Spill

i. Staff who are pregnant, trying to become pregnant (male or female) or breastfeeding should refrain from cleaning up hazardous drugs.

a. Orange Hazardous Drugs are medium risk hazardous drug. See AHN HD List

b. Employees that work in the area and are familiar with the handling of medications or cleanup where medications are stored or handled may address a spill.

c. Personal Protective Equipment: Employees must wear a two pair of HD resistant gloves, goggles, a N95/N100 mask, a HD resistant gown and shoe covers when cleaning up medication spill in this category. A PAPR may be used instead of goggles and N95/N100 mask if available and staff has been trained.

Details

Applicability
AHN Entity

Content Type
Policy

Responsible Area
Medication Management

Executive Sponsor
Laura Mark

Owner
Peterson, Kristen

Former Numbers

Effective Date
11/1/2020

Last Approved Date
12/11/2025

Last Revised Date
12/11/2025

Next Review Date
12/11/2026

Related Authoritative Sources

Related Content

Related Documents
Appendix B Spill Kit Expiration Checklist.pdf
Attachment A - Spills color grid front and back (1).pdf
D PAPR TR600 donnng checklist.pdf
C PAPR TR600 cleaning checklist.pdf

d. Procedure for cleanup **(Attachment A)**

e. Medical Follow up– see Section G

f. Cleanup: Clean and affected area using approved cleaning wipes and solutions. Wipes and towels may be disposed of in the standard trash.

g. Remove gloves and any other PPE and wash hand after cleanup is complete.

4. Yellow Hazardous Medication Spill

i. Training includes PAPR training and Spill Cleanup Training

ii. Staff who are pregnant, trying to become pregnant (male or female) or breastfeeding should refrain from cleaning up hazardous drugs.

i. **Reminder:** dispose partial hazardous medication containers (those that contain >3% of original volume) shall be disposed of in the BLACK Stericycle bin. Do NOT return to Pharmacy for disposal.

a. Yellow Hazardous Drugs are high risk hazardous drug. See AHN HD List

b. Employees must receive special training prior to cleaning up a spill in this category. These employees may include Registered Nurses (RNs), Advanced Practice Providers (APPs), Hematology/Oncology Fellows, Physicians, Pharmacy Technicians, and Pharmacists.

c. Personal Protective Equipment: Employees must wear a two pair of HD resistant gloves, PAPR 600 series**, (Attachments C and D**), a HD resistant gown and shoe covers when cleaning up medication spill in this category.

d. Procedure for cleanup **(Attachment A)**

e. Medical Follow up – see Section G

f. Cleanup: Clean and affected area using approved decontaminating wipes and solutions. Wipes and towels must be disposed in the Yellow trash.

g. Remove PPE disposing in the Yellow trash. Wash hands after cleanup is complete.

5. BSL-II drugs Spills

a. Follow the spill clean up procedure for Yellow Hazardous medications (4)

6. Spills in the PEC/C-PEC of the Pharmacy

i. Training may include PAPR training, N95/N100 mask fit testing, PEC/C-PEC cleaning and/or Spill Cleanup Training

ii. Staff who are pregnant, trying to become pregnant (male or female) or breastfeeding should refrain from cleaning up hazardous drugs.

a. Pharmacy employees must receive special training prior to cleaning in the compounding area.

b. Do NOT turn off the C-PEC or PEC

c. Personal Protective Equipment:

1. Inspect PPE immediately after spill. Change immediately if tears, rips or contamination is detected.

2. Additional PPE, such as N95/N100 mask or PAPRs is required for clean up if spill contaminates the area below the workbench of the hood.

d. Medical Follow up – see Acute Exposures section

e. Cleanup:

i. Non-hazardous or Purple: Clean and affected area using approved wipes and solutions.

ii. Orange or Yellow: Clean and affected area using approved decontaminating wipes and solutions. Wipes and towels must be disposed in the Yellow trash.

iii. Refer to the CSP cleaning policy for more information.

f. Remove PPE and perform hand hygiene after cleanup is complete and before continuing to compound.

g. Report all spills to manager/director.

h. Document hazardous drug spills in RL and complete an employee occupational exposure report.

i. Obtain SDS Sheet

Exceptions

None

Violations

Violations of this policy or procedure may result in disciplinary action up to and including termination of employment.

Additional References

National Institute for Occupational Safety and Health. (2016). NIOSH list of antineoplastic and other hazardous drugs in healthcare settings. Retrieved from https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf

National Institute for Occupational Safety and Health. (2020). Hazardous drug exposures in healthcare. Retrieved from https://www.cdc.gov/niosh/docket/review/docket233c/pdfs/DRAFT-NIOSH-Hazardous-Drugs-List-2020.pdf

Olsen, M.M., LeFebvre, K.B., & Walker, S. L. (2023). Chemotherapy and immunotherapy guidelines and recommendations for practice (2nd ed). Oncology Nursing Society.

Oncology Nursing Society. Polovich, M., & Olsen, M. M. (2018). Safe handling of hazardous agents (3rd ed.). Oncology Nursing Society

People Applicability

Independent credentialed/privileged providers (including physicians, nurse practitioners, physician assistants, certified registered nurse anesthetists, and midwives); Employees (including residents and fellows); Contracted/embedded workforce personnel (including independent contractors and agency staff); Students; Researchers; Members of a Collective Bargaining Agreement

Entity Applicability

This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Allegheny Singer Research Institute (ASRI); This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:AHN Cancer Institute; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Allegheny Clinic; This policy applies to Highmark Health and its subsidiaries and controlled affiliates:This policy applies to Allegheny Health Network and its subsidiaries and controlled affiliates:Physician Organization:Saint Vincent Medical Group & Other Medical Offices

Contact(s)

List of Approver(s)

LAURA MARK - VP PHARMACY - AHN - 11/24/2025,
MARK RUBINO - PHYSICIAN PRESIDENT / 74 - 11/28/2025,
ALLAN KLAPPER - PHYSICIAN PRESIDENT - 12/1/2025,
CHONG PARK - PHYSICIAN PRESIDENT / 74 - 11/24/2025,
IMRAN QADEER - PHYSICIAN PRESIDENT / 74 - 11/28/2025,
BRIAN JOHNSON - PHYSICIAN PRESIDENT / 74 - 11/28/2025,
CHRISTOPHER CLARK - PHYSICIAN PRESIDENT - 12/11/2025

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Steps for PURPLE Medication Spills

- Clear area of people, if possible, to prevent exposure.
- Perform necessary First Aid – remove soiled clothing, cleanse exposed skin with soap and water, rinse eyes with isotonic saline for at least 15 minutes.
- Obtain cleaning supplies (absorbent wipes/towels, cleaner, wipes,) and PPE.
- Don 1 pair of HD gloves. Additional PPE, such as goggles, face shields, and gowns are optional.
- For each step: Clean spill area thoroughly from least contaminated to most contaminated (outer to inner), using at least three (3) separate cloths with the standard solution below for each step. Be sure to clean the spill from all items, including, but not limited to IV poles, beds, chairs, furniture, walls, and floors.

STEP 1

- Wipe up liquids using absorbent pads or towels
- Wipe up solids using wet absorbent pads or towels
- Pick up glass fragments using a dust pan, scoop, or utility gloves and place in hard sided waste container (BLACK medication waste or RED sharps container)

STEP 2

- DO NOT DIRECTLY SQUIRT SPRAY CLEANER DIRECTLY ONTO THE SPILL AREA
- Pour cleaner onto towels or wipes or use premoistened wipes
- Wipe all surfaces

STEP 3

- If necessary, Call Environmental Services or Cleaning staff to mop the floors

Additional Steps

- Obtain the SDS (Safety Data Sheet) to determine if any additional cleaning or first aid steps are required. Send to Emergency Room/Employee Health follow up if follow up is required.
- Place any contaminated materials (i.e. cleaning supplies, linens) into a general trash bag.
- Place the sealed bag inside another general trash bag. Leave the outer bag open.
- Remove PPE and place in general trash bag.
- Perform hand hygiene.
- Report spill to a manager and complete RL for the spill **and** the employee exposure.

Steps for ORANGE Medication Spills

- Clear area of people, if possible, to prevent exposure.
- Perform necessary First Aid – remove soiled clothing, cleanse exposed skin with soap and water, rinse eyes with isotonic saline for at least 15 minutes.
- **Obtain Spill kit from the pharmacy**. If spill kit not available, obtain absorbent pads/towels, approved cleaner, lint-free wipes.
- Don 2 pair of HD gloves, disposable HD gown, shoe covers, N95/N100 mask and goggles
- For each step: Clean spill area thoroughly from least contaminated to most contaminated (outer to inner), using at least three (3) separate cloths with the standard solution below for each step. Be sure to clean the spill from all items, including, but not limited to IV poles, beds, chairs, furniture, walls, and floors.

TURN THIS SHEET OVER FOR CLEANING STEPS 1, 2, 3

Additional Steps

- Obtain the SDS (Safety Data Sheet) to determine if any additional cleaning or first aid steps are required. Send to Emergency Room/Employee Health follow up if follow up is required.
- Place any contaminated materials (i.e. cleaning supplies, linens, etc.) into a general trash bag.
- Remove outer pair of gloves and place in trash bag.
- While still wearing single pair of gloves, place the sealed bag inside another general trash bag. Leave the outer bag open.
- Remove remaining PPE and place in general trash bag. Start with the face shield or goggles, gown, shoe covers and mask.
- Perform hand hygiene.
- Report spill to a manager and complete RL for the spill **and** the employee exposure.

Steps for YELLOW Medication Spills

- Clear area of people, if possible, to prevent exposure.
- Perform necessary First Aid – remove soiled clothing, cleanse exposed skin with soap and water, rinse eyes with isotonic saline for at least 15 minutes.
- **Call Oncology to address the spill.**

TURN THIS SHEET OVER FOR THE FULL SET OF CLEANING STEPS AND INSTRUCTIONS

INITIAL STEPS FOR YELLOW HAZARDOUS MEDICATION SPILLS

A. **STEP 1 - Open the 'CONTAIN' materials from the spill kit** and use the absorbent pads to contain the spill
B. Obtain the PAPR and spill kit
C. Don 2 pairs of gloves, disposable gown, and booties, place PAPR respirator on (if no PAPR, use eye protection and N95 from spill kit)
D. Clean all spill areas thoroughly from least contaminated to most contaminated areas, using at least three separate cloths with the standard solutions below for each step (outer to inner)
    - Wipe up liquids using absorbent pads or spill-control pads
    - Wipe up solids by using wet absorbent pads
    - Pick up glass fragments using a scoop or utility gloves -place in YELLOW hard sided disposal bin.

STEP 2 – DECONTAMINATION/DEACTIVATION/ DISINFECTING PROCESS

- **Peridox:**
  Obtain the bag labeled STEP 2
  1. **STEP 2A - DO NOT SQUIRT THE CLEANER DIRECTLY ONTO THE SPILL AREA.**
     - Pour the PeridoxRTU into a bag with the lint free pads/cloths and gently shake the bag until thoroughly dampened but not dripping
     - Wipe down all surfaces thoroughly. Change pads/cloths frequently.
  2. **STEP 2B**
     - Repeat Step 2A with fresh pads/cloths. Use enough Peridox RTU to ensure the surfaces remain wet for at least 3 minutes. After 3 minutes, move to Step 3.
- **Decontaminating Agent may vary depending on availability**
  - Other products may include Surface Safe or WipeDown 1-2-3 (or similar)
  - Follow directions on the product for steps.
  - Use as many wipes as needed for the spill

STEP 3 – Residue Removal

- **Remove residue from decontamination step with cleaning solution.**
  - Clean or wipe area with soap and water solution or isopropyl alcohol
- **EVS (or equivalent) to do clean the area as soon as possible.**

Additional Steps

A. Dispose of any items that cannot be cleaned or wiped down such as linens, supplies, PPE, etc.
B. Clean any items in the spill zone, including but not limited to IV poles, chairs, and bed frame.
C. Place any contaminated materials (items from A and cleaning supplies) into a YELLOW Hazardous Waste Bag.
D. Seal the bag, then place the sealed bag inside a second Yellow Hazardous Waste Bag leaving the outer bag open.
E. Remove outer gloves and dispose of them in unsealed hazardous bag.
F. Remove the remaining PPE including the PAPR hood, gown, shoe covers.
   - Place disposable items in the unsealed hazardous bag.
   - Reusable items (PAPR motor/blower, battery and hoses) should be placed in a plastic bag temporarily until they can be properly decontaminated and disinfected.
G. Dispose of partially used bottles of PeridoxRTU in Yellow Hazardous Waste Bag.
H. Seal the outer Yellow Hazardous Waste Bag.
I. Remove gloves and perform hand hygiene.
J. Complete the RL: one for the spill **AND** one for employee exposure.
K. Obtain the SDS safety sheet with manager/director to determine if any additional cleaning guidelines are required.
   Highmark Health SharePoint → AHN home page (Our Company dropdown)→ SDS online link under Tools and Resources dropdown
L. Seek medical attention as needed
M. See Medication Spills – Exposure – Medical Surveillance Policy for complete instructions.

Reviewed and Revised 5/2025