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Owner **Mike Skafi:**
Executive
Director System
Pharmacy
Operations

Policy Area **Pharmacy**

Applicability **Providence
Systemwide**

PSJH-PHARM-1316 Inpatient Provision of High Dollar Antineoplastics and Monoclonal Derivatives Policy

Executive Sponsor:	Elie Bahou, Chief Pharmacy Officer
Policy Owner:	Mike Skafi, Executive Director Clinical Operations and Regulations, System Pharmacy
Contact Person:	Michael Dalious, Senior Program Manager, System Pharmacy

Scope:

This policy applies to the not-for-profit, non-profit entities of Providence and its Affiliates [\[i\]](#) (collectively known as "Providence") and their workforce members (caregivers, volunteers, trainees, interns, apprentices, students), independent contractors, vendors and all other individuals working at the ministry, whether they are paid by or under the direct control of the facility; employees of affiliated organizations (collectively, "workforce members"). Where an organization is not wholly or majority owned, exceptions may apply.

☐ Yes ☒ No Is this policy applicable to Providence Global Center (PGC) caregivers?

This is a management level policy reviewed and recommended by the Clinical Operations Council and the Policy Advisory Committee (PAC) to consider for approval by senior leadership which includes vetting by Executive Council with final approval by the President, Chief Executive Officer, or appropriate delegate.

Purpose:

To detail a policy and process for the provision of high dollar antineoplastics and monoclonal derivatives

in the inpatient setting.

Definitions:

- 340B refers to federal legislation that requires pharmaceutical manufacturers to provide front-end discounts on covered outpatient drugs purchased by specified providers or delivery systems, called "covered entities," that serve the nation's most vulnerable patient populations. The purpose of the 340B program is to enable covered entities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."
- A covered entity may have associated sites and off-site ambulatory facilities that may also be eligible for discounts under the 340B program. For non-hospital covered entities, associated sites that are listed in the covered entity's scope of grant, project, or contract may be eligible to register as child sites.
- Providence refers to the Providence Health System including all affiliates.

Policy:

Antineoplastics are most commonly administered in an ambulatory environment. Many of these facilities qualify as 340B eligible covered entities. Provision of antineoplastics at outpatient 340B sites, rather than inpatient environments, enables Providence to optimize financial stewardship of resources. This not only includes 340B savings but also reimbursement from payers. Provision of high dollar antineoplastics and monoclonal derivatives in the inpatient environment offers no additional reimbursement nor 340B savings.

In order to maintain the financial health of Providence, it is necessary to restrict the provision of high dollar antineoplastics and monoclonal derivatives to the ambulatory environment or other appropriate outpatient setting whenever possible. Every effort will be made to administer high-cost biologicals and chemotherapeutic agents in the ambulatory setting to reduce treatment cost and length-of-stay for patients.

Provision of high dollar antineoplastics and monoclonal derivatives in the inpatient hospital setting is restricted to the clinical indications and scenarios outlined within this policy including the attached Use Criteria and Drug List. Prescribing and/or administration of inpatient chemotherapy and monoclonal derivatives at Providence must be performed under the authority of a Licensed Independent Practitioner (LIP) whose credentialing and/or scope of practice includes the prescribing and/or administration of these medications.

Provision of high dollar antineoplastics and monoclonal derivatives administered on a clinical trial protocol are exempt from the provisions of this policy.

Decision to Provide Inpatient High Dollar Antineoplastics and Monoclonal Derivatives

Provision of high dollar antineoplastics and monoclonal derivatives in the inpatient hospital setting is restricted to the clinical indications and scenarios outlined within this policy including the attached Use Criteria and Drug List. Patients who do not meet the criteria described herein may be eligible to receive treatment in an ambulatory oncology infusion center or other outpatient setting.

Patient care circumstances that do not meet the criteria to receive inpatient antineoplastics and monoclonal derivatives may be referred to the Medical Director of Oncology Services (or equivalent) for additional review if warranted.

Provision of antineoplastics and monoclonal derivatives for non-oncology applications will require the same "huddle" process to review the inpatient acute care need, explore therapeutic alternatives, and assess resources required to provide prescribed therapy.

An ad hoc "huddle" may be requested by the Administrator on Duty (or equivalent) if warranted and/or at the request of Oncology Services, Pharmacy Services, or Nursing.

The following stakeholders should be included in the huddle:

- A. Administrator on Duty (or equivalent)
- B. Prescribing LIP
- C. Administrative Nursing Supervisor (or equivalent)
- D. Area Pharmacy Manager/Director (or equivalent)
- E. Area Director Oncology Services (or equivalent)
- F. Oncology RN (if available)
- G. Oncology Pharmacist (if available)

The ad hoc "huddle" will determine the following:

- A. Clinical appropriateness of the prescribed therapy
- B. Acute need for therapy to be given in the inpatient setting
- C. Other solutions available to meet the patient need(s)
- D. Clinical resources needed to provide prescribed therapy (medication(s), pharmacy staff and equipment, nursing staff and equipment, educational materials, etc.)
- E. Communication to additional stakeholders such as Finance, Case Management, and/or Administration

Cases deemed to be inappropriate for inpatient provision of high dollar antineoplastics and monoclonal derivatives may be referred to the peer review process by the prescribing LIP if so desired.

All patient cases where high dollar antineoplastics and monoclonal derivatives were provided in the inpatient setting will be sent to the Utilization Review Committee (or equivalent) to validate that the processes outlined in this policy were followed including appropriateness of the care delivered and stewardship of resources. Cases not conducted in accordance with this policy and/or deemed to be inappropriate will be referred to the peer review process.

Applicability:

[i] For purposes of this policy, "Affiliates" is defined as any not-for-profit or non-profit entity that is wholly owned or controlled by Providence, Providence St. Joseph Health (PSJH), Providence Health & Services,

St. Joseph Health System, Western HealthConnect, Kadlec, Covenant Health Network, Grace Health System, Providence Global Center*, NorCal HealthConnect, or is a not-for-profit or non-profit entity majority owned or controlled by Providence or its Affiliates and bears the Providence, Swedish Health Services, St. Joseph Health, Covenant Health, Grace Health System, Kadlec, or Pacific Medical Centers names (includes Medical Groups, Home and Community Care, etc.). *Policies and/or procedures may vary for our international affiliates due to regulatory differences.

Attachments

[Inpt Provision High Dollar Antineoplastics and Monoclonal Derivatives - Use Criteria Drug List.pdf](#)

Approval Signatures

Step Description	Approver	Date
PSJH President/CEO	Cynthia Johnston: Senior Compliance Specialist	03/2023
PSJH Executive Council	Cynthia Johnston: Senior Compliance Specialist	03/2023
PSJH Policy Advisory Committee	Cynthia Johnston: Senior Compliance Specialist	03/2023

Standards

No standards are associated with this document