Introduction

The proven effectiveness of Comprehensive Pediatric Hematology/Oncology Programs has demonstrated the need for a multidisciplinary team approach. The Children's Oncology Group (COG) has implemented this policy because of the unique nature of the disorders as well as the special medical and psychosocial requirements of children, adolescents and young adults with cancer.

Policy Statement

A COG Member Institution must meet the general criteria and guidelines for pediatric cancer centers established and published by the Section on Hematology-Oncology of the American Academy of Pediatrics and the American Society of Pediatric Hematology/Oncology.

Purpose

The purpose of this policy is to provide the personnel and service requirements for a Comprehensive Pediatric Hematology/Oncology Program.

Note: This policy does not imply the need for all personnel and services to necessarily be on-site. In many situations, although initial diagnosis and treatment planning may be done by a Comprehensive Pediatric Hematology/Oncology Program, it will be desirable to develop outreach services to bring much of the care as close to the patient’s home as is possible while maintaining state-of-the-art medical care.

Scope

This policy applies to all COG Member Institutions.
Member institutions are independently administered hospitals, medical centers or research institutes with which one or more qualified individual members are affiliated. However, when members function in more than one hospital or institution under the scientific and administrative purview of a single director of pediatric hematology/oncology, these eligible hospitals and institutions comprise a single member institution with one Institutional Review Board (IRB) per the Clinical Trials Monitoring Branch definitions of an institution. Community Clinical Oncology Program (CCOP) institutions may have more than one IRB per the National Cancer Institute (NCI) guidelines but must identify one local administrative contact for the COG.

Separate entities must be able to stand alone as hematology/oncology centers, as defined in this policy; though it is recognized that not all COG Member Institutions have all care and support facilities in one location, but certain minimum requirements are expected (as described in this policy).

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The following personnel are required to be on-site at the facility:

- Board certified/eligible or equivalent pediatric hematologist/oncologist
- Board certified pathologist(s) committed to handling specimens according to COG protocols
- Nurses with additional training in the management of children and adolescents with cancer and blood disorders, and documented in-house training in chemotherapy administration
- Clinical research associates trained in data management support of cooperative research
- Respiratory therapists with expertise in pediatrics
- Anesthesiologist
- Radiologist
- Pharmacist with expertise in chemotherapy
- Social worker with additional training in the management of children and adolescents with cancer and blood disorders
On-site Services

The following services are required to be on-site at the facility:

- Pediatric unit (i.e., personnel trained in taking care of children even if beds are in an adult unit)
- Intensive care unit with the ability to treat critically ill children
- Outpatient clinic for the acute and chronic care and treatment of children and adolescents with cancer
- Computed axial tomography
- Ultrasonography
- Pharmacy with capability of storage, accurate preparation, dispensing, and accounting for investigational drugs, and other antineoplastics
- Anatomic pathology services necessary for the immediate handling of specimens:
  - Ability to perform and interpret rapid frozen sections
  - Ability to rapidly freeze specimens for storage
- Laboratory services necessary for the care of critically ill children that must be available 24 hours a day:
  - Ability to perform routine blood gas, clinical chemistry, hematology and coagulation assays on small samples
  - Availability of therapeutic apheresis
  - Immediate interpretation of organism stains
- Capabilities to provide appropriate isolation for patients with severe immunosuppression
- Expertise available to determine the need to deliver and monitor total parenteral nutrition for critically and chronically ill children and adolescents
- Pain management and sedation guidelines
- Long term follow-up services for survivors of pediatric cancer
- Internet connectivity and readily accessible workstations
Personnel - Readily Accessible

The facility must be able to document that they have the following, readily available and accessible personnel with expertise in the management of children and adolescents with cancer and blood disorders:

- Board certified/eligible or equivalent surgeon with expertise in the general surgical management of children and adolescents with cancer and blood disorders
- Radiation oncologists with special expertise in the treatment of children and adolescents with cancer and blood disorders
- Orthopedic surgeons
- Urologic surgeons
- Neurosurgeons
- Ophthalmologist
- Otolaryngologist
- Plastic surgeon
- Nuclear medicine physician
- Board certified pathologist with special training and/or certification in pediatric pathology
- Board certified pathologist with special training and/or certification in hematopathology
- Board certified pathologist with special training and/or certification in neuropathology
- Nutritionist(s) with expertise in the dietary requirements of children and adolescents
- Physical therapist(s)
- Pediatric psychologist(s)
- Occupational therapist(s)
- Child Life specialist
- Nephrology
- Pulmonology
- Cardiology
- Dentistry
- Gastroenterology
- Neurology
- Infectious disease
- Endocrinology
- Psychiatry
The facility must be able to document that they have the following services available and readily accessible:

- Radiation therapy equipment designed for state-of-the-art treatment of children and adolescents including rotational linear accelerator dedicated
- Diagnostic imaging and radiation oncology equipment and services, including:
  - Magnetic resonance imaging
  - PET Scan
  - Nuclear medicine
  - Angiography
  - Interventional radiology
  - Rotational linear accelerator
  - Dedicated radiation simulator or CT simulator
  - Treatment planning system capable of doing multiple point calculations on irregular fields
  - Adequate physics support for calibration, dosimetry, and regular quality assurance
  - Anesthesia resources to meet the sedation/anesthesia needs of pediatric patients
  - Agree to be surveyed by the RPC (Radiologic Physics Center) and to submit data including benchmarks to QARC
- CLIA approved (or equivalent) Clinical laboratories with expertise in the assessment and diagnosis of pediatric hematologic/oncologic disorders offering:
  - Cell marker studies
  - Bone marrow aspirate and biopsy analysis
  - Histopathology
  - Cytogenetic analysis
  - Immunohistochemistry for tumor diagnosis
  - Comprehensive microbiology and virology
  - Clinical chemistry expertise in monitoring antibiotic and methotrexate levels
  - Note: Laboratory services necessary for the care of critically ill children that must be available 24 hours a day:
    - Transfusion service that can supply leukocyte reduced, irradiated cellular products appropriate for immunocompromised patients
    - Therapeutic apheresis
    - Transfusion program for the efficient and safe administration of blood products to ambulatory patients
- Services for dialysis of children and adolescents
- Rehabilitation
Other Requirements

- Comprehensive Pediatric Hematology/Oncology Programs should have regularly scheduled multidisciplinary tumor boards as well as case conferences designed to discuss children and adolescents with serious hematologic problems. The outpatient clinic should ensure the long-term follow-up of successfully treated patients and those with lifelong chronic disorders.

- Comprehensive Pediatric Hematology/Oncology Programs must be affiliated with or part of a hospital and laboratory approved for the care of children and adolescents by the JCAHO or equivalent.

Related Policies & Procedures

- COG’s Constitution and Bylaws
- Conduct of Clinical Research for Member Institutions

Who Should Be Knowledgeable About This Policy

Those who are responsible for following the guidelines/performing the procedures that implement this policy, those who have the oversight and/or supervisory responsibility for these guidelines/procedures, and those who have the responsibility to authorize this policy and its related guidelines/procedures should be knowledgeable about this policy.

Policy Maintenance Responsibility

- Policy Owner – Children’s Oncology Group
- Policy Contact – Group Chair, Children’s Oncology Group

Policy Authorization

Approval Indicator: Approved by the Executive Committee on 12/11/12
COG Executive Committee

Version/Revision History

Reassessment of this policy will occur once every 24 months; interim revisions will be incorporated as needed. The table below documents the version/revision history for this policy. A cumulative history for this document is maintained for seven years.

<table>
<thead>
<tr>
<th>Approval Date</th>
<th>Version</th>
<th>Version/Revision Summary</th>
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<tbody>
<tr>
<td>05/2002</td>
<td>V1.0</td>
<td>Initial documentation/publication of Admin Sections 3.1.1 and 3.1.2.</td>
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<tr>
<td>06/2008 &amp; 12/2007</td>
<td>V2.0</td>
<td>Re-assessments/revisions to Admin Sections 3.1.1 and 3.1.2.</td>
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<tr>
<td>12/11/12</td>
<td>V3.0</td>
<td>Re-assessment and republication. Top portion of Admin Section 3.1.1 and all of Admin Section 3.1.2.</td>
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