

Michigan Working Group to Improve Cancer Outcomes
*Consensus Guidelines for Healthcare Coverage of
Routine Patient Care Costs Associated with Oncology Clinical Trials*

Introduction

The American Cancer Society's *Cancer Facts & Figures 2001* estimates that 45,300 people from Michigan will be diagnosed with cancer this year. Michigan ranks in the top ten (8th) among all states for overall cancer deaths. Cancer clinical trials offer patients the opportunity to obtain new treatments and may be the only therapeutic options available for seriously ill cancer patients.

Acknowledging that the major advancements in cancer prevention and treatment are the result of quality clinical research and recognizing that patients and providers are reluctant to participate in clinical trials without assurance of health plan coverage, Senator John J.H. Schwarz, M.D. convened a meeting of cancer care providers, payers and their accounts, patient advocates and legislators on November 3, 1999 to discuss and resolve this important health care issue. This assembly recommended that a collaborative voluntary solution to this patient care issue should be formulated by those most involved in the process.

The Michigan Working Group to Improve Cancer Outcomes is a consortium of the major stakeholders in the care of Michigan's cancer patients. An Executive Committee from this group was established on February 23, 2000 and empowered to draft a voluntary agreement that would provide the framework for third party payer coverage of patient care costs for those enrolled in clinical trials within the scope of the individual's benefit plan. (*Appendix 1*)

The Michigan Working Group to Improve Cancer Outcomes believes this agreement would improve research study recruitment and Michigan's cancer patients' access to clinical trials as a treatment option without risk of personal financial burden. Cancer clinical trials provide outcomes data necessary to assess medical practice and build on evidence based, value driven health care. Scientific oversight helps to focus rational decision making within these studies. Michigan healthcare payers could benefit from the advancement in science, avoidance of useless treatment and continuous quality improvement in cancer care clinical research provides. The goal of this agreement is to increase participation in select cancer-related clinical trials by making payment for services provided within the context of clinical trials predictable. After serious consideration of these concerns and discussion of the rationale for supporting clinical research efforts in Michigan, the Group agreed that health plans* should be willing to provide coverage for the routine care costs of patient participation in approved clinical trials.

**For the purpose of this agreement, a health plan includes any corporation that (a) directly or indirectly provides payment for health care services on behalf of its employees, subscribers or enrolled members through a licensed or registered product (e.g. fully insured commercial product, pre-paid health plan,*

Medicaid or Medicare product, participating ASO products, etc.) and (b) agrees to participate in the clinical trials program of the Michigan Working Group to Improve Cancer Outcomes as described herein.

The work of this committee addresses the coverage of best medical practices in the investigational treatment of cancer patients who are enrolled in quality clinical research studies. This document includes basic information about clinical trials, qualifications for “approved” or “deemed” clinical trials, and definitions of the costs associated with clinical trials. This consensus document is limited to oncology and cancer clinical trials and is not meant to include other illnesses or areas of medicine. This agreement is restricted to clinical trials being performed in Michigan

I. Cancer Clinical Trials Definitions

- 1.1 The group agreed to adopt the American Society of Clinical Oncology’s definition of patient oriented research:
“Clinical investigation in oncology is hypothesis-driven research that employs measurements in whole patients or normal human subjects, in conjunction with laboratory measurements as appropriate, on the subjects of clinical biology, natural history, prevention, screening, diagnosis, therapy or epidemiology of neoplastic disease”.

- 2.1 After careful laboratory testing for safety and effectiveness, new therapies are evaluated in people during three phases.
 - 2.1.1 Phase I trials determine toxicities through a continuum of modest dosing to determine safe levels for human subjects.
 - 2.1.2 Phase II trials begin to evaluate the effectiveness of the treatment.
 - 2.1.3 Phase III trials compare two or more appropriate treatments to evaluate relative efficacy and therapeutic value.

The guidelines in this document are applicable to Phase II and Phase III clinical trials.

- 3.1 Only those studies that have the potential of therapeutic benefit for patients will be considered for coverage.

II. Qualifications Required For “Approved” or “Deemed Status” Clinical Trial Classification

A clinical research study will be considered worthy of support if all of the following apply:

- 1.1 The institution/investigator/team performing the cancer clinical trial adheres to accepted Office of Human Research Protection (OHRP)/National Institute of Health (NIH)/Food and Drug Administration (FDA) procedural and ethical standards pertaining to conflict of interest and consistent protection of human subjects including:
 - 1.1.1 Thoroughness of an independent peer review for scientific validity,
 - 1.1.2 Review and approval by an Institutional Review Board (IRB),
 - 1.1.3 Processes to identify, avoid and disclose conflicts of interest,
 - 1.1.4 Policies prohibiting payment for patient recruitment beyond reasonable reimbursement for administrative costs incurred and
 - 1.1.5 Policies that prohibit any actions intended to inappropriately influence the review process.

- 2.1 The IRB/institution has written policies to preclude investigators and team members directly responsible for patient selection in a clinical trial, the informed consent process and/or clinical management of a trial from any influence by material enrichment.
 - 2.1.1 These policies shall include review, oversight and appropriate disclosure of potential conflicts of interest that may interfere with appropriate attention to patient care.

- 3.1 The institution shall have policies that would prohibit censorship of clinical trial results by the industry sponsor.
 - 3.1.1 These policies prohibit the industry sponsor reviewer to change, amend or otherwise modify the published outcomes.
 - 3.1.2 These policies prohibit industry sponsor influence on the clinical trial's publication.

- 4.1 Treatment is provided with therapeutic intent

- 5.1 Treatment is being provided pursuant to an oncologic or malignant hematologic clinical trial sponsored or approved by one or more of the following:
 - 5.1.1 One of the National Institutes of Health (NIH),
 - 5.1.2 A NIH cooperative group, or a NIH center;
 - 5.1.3 At, or under the auspices of, an NCI designated Comprehensive Cancer Center
 - 5.1.4 The Food and Drug Administration (FDA) in the form of an investigational new drug (IND) or new device (IDE) exemption
 - 5.1.5 The Department of Defense (DOD)
 - 5.1.6 The Department of Veterans Affairs (VA)
 - 5.1.7 Health Care Financing Administration (HCFA),
 - 5.1.8 Agency for Healthcare Research and Quality (AHRQ),

- 5.1.9 Center for Disease Control (CDC);
- 5.1.10 A qualified non-governmental research entity as identified in guidelines issued by individual NIH Institutes for center support grants;
- 6.1 The facility and personnel providing the treatment are capable of doing so by virtue of their experience or training.
- 7.1 The available clinical or pre-clinical data provide a reasonable expectation that the protocol treatment will be at least as efficacious as non-investigational therapy.
- 8.1 Coverage applies to therapeutic Phase II and Phase III trials meeting these criteria.
- 9.1 Coverage applies to those enrolled in deemed clinical trials. Patients receiving ad hoc investigational treatment are not covered under the terms of these guidelines.

III. Health Plan Discretion

- 1.1 Health plans may grant “deemed status” to investigators or institutions when it determines that the investigator or institution follows and is committed to the principles represented in this document.
- 2.1 Health plans may revoke “deemed status” to an investigator or institution when it determines that the investigator or institution has abused its privileges or violated principles represented in this document.
- 3.1 Clinical trials related to cancer prevention and/or performed at institutions not listed above may be covered outside the scope of this agreement by individual health plans according to their individual policies and procedures.

IV. Costs Associated With Cancer Clinical Trials

Funding for cancer clinical trials, which covers the cost of protocol development and data collection traditionally comes from a variety of sources including pharmaceutical companies, research institutions and government agencies. (Hereafter referred to as “sponsors”) Support for patient care provided in cancer clinical trials is not generally included in this funding.

There are five components of costs associated when conducting clinical trials.

- 1.1 **The administrative costs of the study** are borne by the sponsoring organizations and include:
 - 1.1.1 Data gathering,
 - 1.1.2 Statistical study,
 - 1.1.3 Regulatory requirements,
 - 1.1.4 Contractual agreements,
Meetings and travel.

- 2.1 **The routine patient care costs** (conventional care) shall be provided by the patient's health plan.
 - 2.1.1 Routine patient care costs are items or services that are typically covered benefits when provided outside a clinical trial.
 - 2.1.2 "Routine" services include services that would be approved for coverage under the policy, even when delivered within the context of a clinical trial.
 - 2.1.3 Health plans shall provide coverage for routine patient care costs incurred for drugs and devices provided to the member during the clinical trial provided that those drugs or devices have been approved for sale by the FDA, whether or not the FDA has approved the drug or device for use in treating the member's particular condition, and to the extent those drugs or devices are not provided or paid for by the sponsor of the clinical trial, or the manufacturer, distributor, or provider of that drug or device.

- 3.1 **The costs associated in the delivery of the investigational agent** shall be borne by the health plan.
 - 3.1.1 Services required solely for the provision of the investigational item shall be provided in accordance with the benefits of the patient's health plan Coverage would include procedures, drugs or devices approved for coverage for any medical indication.
 - 3.1.2 The clinically appropriate monitoring of the effects of the item or service should be considered routine patient care costs.
 - 3.1.3 The prevention of complications of the item or service should be considered routine patient care costs.
 - 3.1.4 This coverage shall include payment for reasonable and medically necessary services necessary to administer the drug or use the device under evaluation in the clinical trial.

- 4.1 **Costs incurred for patient care generated specifically by the cancer clinical trial** shall be borne by the clinical trial sponsor.
 - 4.1.1 Examples of these are costs for additional medication, laboratory studies, or diagnostic imaging.

- 4.1.2 The health plan's coverage of "routine costs" would *not* include non-FDA approved drugs or devices or unapproved medical procedures.
 - 4.1.3 Coverage would *not* include diagnostic tests that are performed for investigative purposes but not necessary for the patient's medical management.
 - 4.1.3 It would also not include services beyond the scope of the subscriber's contract.
- 5.1 **Costs of treating adverse side effects** experienced during treatment should be borne by the health plan. The health plan would be expected to cover medical care needed to treat any complications arising from the investigational service, when the medical services provided are otherwise covered under the subscriber contract.
- 5.1.1 It is recognized that while quality trials are designed with the utmost attention to patient safety, complications can occur when patients are participating in a clinical trial.
 - 5.1.2 It is reasonable to expect that in the event of an adverse reaction, the payers' commitment to offer their members treatment for any medically necessary treatment would apply.

V. Out of network services are not covered, unless approved in advance by the health plan.

Conclusions

Approved cancer clinical trials are carefully designed treatment protocols that require external scientific oversight and Institutional Review Board (IRB) approval. In contrast to the continuum of clinical trials, there is widespread "ad hoc" treatment that is uncontrolled, single patient oriented and based on the chance occurrence that a given regimen will work. By not covering the routine patient care costs for participation in cancer clinical trials, there is unwitting support for ad hoc care that may have no value or may be futile. This construct results in great expense and provides no answers to pressing current questions regarding treatment for patients whose cancer has failed to respond to standard therapy or for which no effective standard therapy exists.

While regulatory and legislative proposals have been promulgated in a number of states, Michigan is seeking instead to address these issues through a voluntary cooperative effort. Accordingly, the major stakeholders in the care of Michigan's cancer patients have created the Michigan Working Group to Improve Cancer Outcomes. This is a voluntary group consisting of leaders from the Michigan Department of Community Health, health plans, health care providers, the research community, voluntary health associations, the pharmaceutical industry and patient consumers. The purpose of this Working Group is to improve the quality of care and provide much greater access for Michigan citizens to clinical trials in general, decrease the overall cost of care, increase patient participation in cancer trials in particular, improve the research climate in

Michigan and develop a fair and equitable mechanism for coverage of routine patient care costs when an enrollee or subscriber participates in approved cancer clinical trials.

Our joint goal is to advance cancer care and increase enrollment in clinical research studies by making appropriate coverage available through payers for Michigan citizens with cancer who are eligible for scientifically approved cancer clinical trials.

**Michigan Working Group to Improve Cancer Outcomes
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Routine Patient Care Costs Associated with Oncology Clinical Trials**

This document represents an agreement by the undersigned to provide Michigan’s cancer patients with access to high-quality, peer-reviewed cancer clinical trials, with appropriate coverage and payment for routine patient care services by their health care plans. The purpose of this agreement is to assure patient access to cancer clinical trials in a manner that is both fiscally responsible and medically appropriate.

The undersigned agree to adhere to the principles as defined in this document in developing policies for coverage of the routine patient care costs associated with cancer clinical trials:

(Signature)

(Signature)

(Print/Type Name)

(Print/Type Name)

(Title)

(Title)

(Date)

(Date)

Representing:

(Organization/Institution)

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Appendix 1

Michigan Working Group to Improve Cancer Outcomes Executive Group

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