

# *Tool 1:* **Quick Reference Guide & Assessment**

## Introduction

Today, more than ever before, employers are facing the growing impact of cancer in the workplace. This change is the result of several factors: an increased incidence of cancer among employees because of an aging workforce and delayed retirement; an increase in the number of employees assuming caregiving roles for family members; and reduced productivity during treatment and recovery for employees with cancer and for those caring for loved ones. With the rising direct and indirect costs associated with cancer, financial impacts also have increased. At times, too, employers must deal with the potential loss of valued employees.

Cancer casts a wide net, affecting not only those diagnosed with the disease but those who care about that individual: family members, friends, managers and co-workers. The impact on a company's culture and even its viability can be profound.

Consider the following:

- Over the course of their lives, half of men and a third of women will be diagnosed with cancer, but virtually everyone will be touched by cancer in some way.
- Because of advances made in diagnosis and treatment, cancer is increasingly becoming a chronic illness, with longer term effects on employees and on the workplace.
- The cost of cancer treatment is typically among the top three most costly conditions representing, on average, 12% of total medical expenses. What's more, the cost of treatment is rising faster than general medical costs.
- Cancer is one of the leading causes of both short- and long-term disability.
- More than 25% of employees are acting as caregivers to family members who are experiencing an illness, including cancer.



## The Need for a Comprehensive Benefits Plan

To address these growing needs, a clear, comprehensive strategy for employees with cancer and their caregivers must be considered. Through careful design and implementation of benefits and astute selection of vendors, employers can meet these needs and have a positive impact on all those affected by cancer in their workforce.

Strategies include:

- Providing access to evidence-based information about cancer;
- Motivating and rewarding employees and dependents who adopt and maintain healthy behaviors that can help reduce the risk of cancer;
- Encouraging compliance with recommended cancer screenings;
- Supporting individuals during treatment for and recovery from cancer or at end of life through appropriate medical, pharmacy, behavioral health and other benefits;
- Empowering individuals to become knowledgeable and engaged participants in their health and health care;
- Supporting employees who are caregivers for a loved one with cancer;
- Providing resources to help managers and employees cope with a co-worker's cancer;
- Retaining talented employees and optimizing productivity during cancer treatment and recovery or while employees are providing care to a loved one;
- Managing disability and leave benefits; and
- Developing evidence-based requests for proposals for vendors related to cancer in the workplace.

## Goals of the Project

This project is designed to address these issues. Over the course of three years, a comprehensive set of tools will be developed. The purpose of these tools is to help benefits managers deal effectively with the many issues about cancer that arise in the workplace. The end result will be a comprehensive document, *An Employer's Guide to Cancer Treatment and Prevention*. There is no such resource currently available.

As much as possible, the guide is intended to be a “plug and play” toolkit that can be readily applied to many aspects of the benefits life cycle, including benefit planning; budgeting and implementation; RFP development; and vendor management and plan administration. It will address issues across the continuum, including prevention and wellness; medical, pharmacy and behavioral health benefits; employee assistance programs (EAPs); and disability and family medical leave (FML). Recommendations will be supported by evidence and knowledge from a wide range of experts so that those who use the guide will be confident that their benefit dollars for cancer are invested wisely.

This project brings together two influential and respected organizations: the National Business Group on Health (Business Group) and the National Comprehensive Cancer Network® (NCCN).

The Business Group brings to the project extensive experience and credibility in developing benefit resources for its membership, and NCCN has extensive expertise and credibility in developing and communicating clinical information on cancer care. This collaboration will result in a comprehensive set of practical and usable resources to help employers offer evidence-based cancer care to employees and beneficiaries.

## **About the National Business Group on Health**

The National Business Group on Health (the Business Group) is the nation's only non-profit organization devoted exclusively to representing large employers' perspectives on national health policy issues and providing practical solutions to its members' most important health care problems.

Business Group members are primarily Fortune 500 companies, with 66 among the Fortune 100. Members also represent large public-sector employers—including the nation's most innovative health care purchasers—that provide health coverage for more than 60 million U.S. workers, retirees and their families. The Business Group fosters the development of a safe, high-quality health care delivery system and treatments based on scientific evidence of effectiveness.

## **About the National Comprehensive Cancer Network (NCCN)**

The National Comprehensive Cancer Network, a not-for-profit alliance of 21 of the world's leading cancer centers, is dedicated to improving the quality and effectiveness of care provided to patients with cancer. Through the leadership and expertise of clinical professionals at NCCN Member Institutions, NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. As the arbiter of high-quality cancer care, NCCN promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians and other health care decision-makers. The primary goal of all NCCN initiatives is to improve the quality, effectiveness and efficiency of oncology practice so that patients can live better lives.

NCCN is dedicated to improving care along the continuum of cancer screening, diagnosis, treatment and follow-up. NCCN communicates sound, evaluative clinical information to enhance the decision-making processes of patients, physicians and others who influence access to and availability of cancer care.

The NCCN Clinical Practice Guidelines in Oncology™ (NCCN Guidelines), the recognized standard for clinical policy in oncology, are the most comprehensive and most frequently updated clinical practice guidelines available in any area of medicine. Covering 97% of all patients with cancer and updated on a continual basis, the NCCN Guidelines are developed through an explicit review of the evidence integrated with expert medical judgment by multidisciplinary panels from NCCN Member Institutions. Specific treatment recommendations are implemented through performance measurement. Panels convened to review the NCCN Guidelines address cancer detection, prevention and risk reduction; workup and diagnosis; and treatment and supportive care.

## Recommendation Checklist

This resource is designed to help benefits managers during the 2012-2013 benefit cycle by providing a checklist of key benefits, such as general medical and pharmacy benefits, that can be compared to the current benefit set. It is important to note, however, that the checklist is not intended to cover all the important issues, or to cover them in detail.

### Medical Benefits – Including Behavioral Health

- ❑ Benefit plan should include access to a wide range of cancer care providers, including medical oncologists, oncology surgeons, palliative care specialists, pathologists and other specialties. Also included are providers in the community setting and in large, academic cancer centers, such as National Cancer Institute (NCI)-designated [Comprehensive Cancer Centers and Cancer Centers](#), which provide access to multidisciplinary care for rare and complex cancers.
- ❑ Out-of-pocket costs (deductible, copayment and coinsurance levels) should not differ between in-network community providers and in-network academic providers.
- ❑ Benefit plan should include access to a “Centers of Excellence” (COE) program for transplants, including bone marrow/stem cell transplants (SCT) that employ a rigorous qualification process using [transplant-specific quality criteria](#).
  - ⇒ Employers should evaluate the Transplant Centers of Excellence (COE) program(s) offered to employees to ensure that it uses specific criteria for evaluation and qualification of transplant providers.
  - ⇒ The Transplant COE program should provide access to clinical staff to help those needing a transplant make an informed decision about where to go for the procedure.
  - ⇒ Benefit plan should include travel and lodging assistance to help those who must travel to receive a transplant at a plan-designated COE, including a per diem intended to defray a substantial portion of the costs. (Up to two persons may accompany a child, defined as through 18 years of age. Adults may be accompanied by one caregiver. This benefit is outside any routine stop-loss coverage.)
- ❑ Benefit plan should cover services that are components of a second opinion for individuals with a diagnosis or suspected diagnosis of cancer. The second opinion may be for review of the diagnosis, review of the treatment plan or both. To be most valuable, the second opinion should be obtained from a large academic cancer center; in particular, an NCI-designated [Comprehensive Cancer Center or Cancer Center](#). If the employer offers a cancer COE network program, a second opinion can be obtained at a cancer center that is part of this network. At a minimum, the second opinion should be obtained from a cancer center with extensive experience and expertise and a [multidisciplinary team](#) that focuses on the patient's specific type of cancer.

- ❑ Benefit plan should provide coverage for routine costs of care when the patient is enrolled in a [qualified cancer clinical trial](#). Level of coverage should be the same as for comparable services provided outside of a clinical trial.
- ❑ Benefit plan should include hospice coverage for individuals with an estimated life expectancy of 12 months or less if their disease runs its usual course, as attested to by the primary physician treating the terminal illness.
- ❑ Benefit plan should reimburse physicians for consultation with patients and family members about all options for care during both active treatment and at end of life.
  - ⇒ Discussion topics may include evidence-based treatment options, palliative care (during active treatment and at end of life), discontinuation of treatment with curative intent and hospice enrollment.
- ❑ Benefit plan should cover initial and subsequent screening for depression (performed by oncologists and other covered providers) for all cancer patients and other beneficiaries. The screening should be conducted with a standardized instrument (e.g., PHQ-9 or PHQ-2).
  - ⇒ Surveys have found that 20%-40% of newly diagnosed and recurrent cancer patients show a significant level of distress. However, less than 10% of patients are actually identified and referred for psychosocial help. Failure to recognize and treat distress leads to several problems: difficulty making decisions about treatment and adhering to treatment; extra visits to the physician's office and emergency room; and more time spent with the patient and higher stress levels for the oncology team. Early evaluation and screening for distress leads to early and timely management of psychological distress, which in turn improves medical management (NCCN Distress Guideline).
- ❑ Employers should provide benefit coverage and ensure that providers, including oncologists and other cancer specialists, adopt the key elements of [collaborative care](#) for patients with cancer who are diagnosed with a behavioral health disorder but are principally treated in a medical setting.

## Pharmacy Benefits

- ❑ Reasonable out-of-pocket thresholds should be established so that cost is not a barrier for patients to obtain medications needed to treat their condition, including maintenance and supportive care drugs.
  - ⇒ The benefit plan should include one individual and one family out-of-pocket maximum that applies to combined medical and pharmacy expenditures.
  - ⇒ Per-prescription copayment and/or coinsurance requirements should be established at a reasonable level.
  - ⇒ Employers should provide access to information on programs that can assist patients with the costs of prescription drugs through information on their benefits website, their EAP or other resources.

- ❑ Administrators of medical plans, pharmacy benefit management (PBM) programs and other relevant organizations should ensure that their plans cover evidence-based cancer treatment, whether paid under the medical or pharmacy benefit. This includes coverage for off-label use of drugs and biologics when supported by evidence, as indicated in [NCCN Guidelines and Drugs & Biologics Compendium](#) with Category 1, 2a or 2b level of evidence.
- ❑ Benefit plan should establish parity of patient cost-sharing (copayment and/or coinsurance) between the medical and pharmacy benefit so that treatment decisions can be made without concern about which benefit will cover the treatment.

## Clinical Support and Condition Management

- ❑ Benefit plan should provide access to information and assistance related to a cancer diagnosis, including, at a minimum, a nurseline service that offers information on clinical issues and community resources and provides supportive services. Nurses and others staffing these resources should be trained and prepared to talk about important topics such as advance directives, hospice, palliative care and clinical trials.
- ❑ When contracting for case/disease management services, employers should require that oncology nurses be available to work with patients.

## Employee Assistance Programs/Work-Life

- ❑ EAP should provide counseling and/or support services to all employees and their dependents who are living with cancer. EAP should be available to provide assessment, intervention and referral services related to the psychosocial aspects of serious illnesses, including cancer.
- ❑ EAP needs to have knowledge of and referral relationships with:
  - ⇒ Wellness/preventive resources;
  - ⇒ Community resources and support groups;
  - ⇒ Transportation services;
  - ⇒ Childcare and eldercare services;
  - ⇒ Financial and legal consulting;
  - ⇒ Bereavement counseling;
  - ⇒ Advanced directives counseling; and
  - ⇒ Patient advocacy services.

- ❑ EAP should have demonstrated skills to consult with management and workplace teams about workplace issues specific to cancer, including:
  - ⇒ Assisting co-workers in understanding how to talk with those diagnosed with cancer and/or caregivers and loved ones (what to say and what not to say).
  - ⇒ Addressing co-workers' questions and concerns about cancer.
  - ⇒ Developing plans coordinated with the human resources department to stabilize the workplace and maintain productivity following a cancer-related emergency.
  
- ❑ EAP should provide managers and supervisors with accurate information and appropriate training for dealing with cancer in the workplace. The training should be tailored to the characteristics of the workforce. It also should include methods for developing a plan that is sensitive to the employee living with cancer and his/her caregivers and addresses the concerns of co-workers

## Family Medical Leave (FML)

- ❑ If appropriate EAP and support services are available, FML programs should screen employees who apply for FML for depression by using a standardized instrument (e.g., PHQ-9 or PHQ-2).
  - ⇒ FML programs should refer employees who screen positive for depression to appropriate behavioral health specialists or EAP.
  - ⇒ FML programs should provide employees with information on caregiving and depression.
  
- ❑ Employers should create a supportive work environment for employees serving as caregivers. Employers should provide reasonable accommodations to those employees, which may include:
  - ⇒ Options for reduced hours and/or workload;
  - ⇒ Modified work responsibilities and gradual return to work; and
  - ⇒ Accommodations for appointments and/or treatment plans.
  
- ❑ Employers should integrate FML with EAP, disability management and health plan benefits.
  
- ❑ Employers should include language in their FML policy that addresses common issues for employees serving as caregivers.

## Short- and Long-Term Disability

- ❑ Employers should require disability vendors to utilize protocols based on clinical information for certifying and managing cancer-related disability cases.
- ❑ Disability case managers should have knowledge of evidence-based guidelines (e.g., NCCN Guidelines) to ensure that patients are receiving appropriate care. Disability case managers should have access to an oncologist or an oncology-certified nurse (OCN) when needed for consultation.
- ❑ Disability management should evaluate barriers and motivations for returning to work following long- and short-term disability and coordinate with EAP in developing return-to-work plans.
- ❑ Disability management, in conjunction with EAP and the legal department, should establish criteria for determining reasonable accommodations for employees with cancer, which may include:
  - ⇒ Restructuring job responsibilities;
  - ⇒ Providing time off or a modified schedule;
  - ⇒ Reassigning non-essential functions to others;
  - ⇒ Transferring the employee to a different position; and
  - ⇒ Considering the psychological well-being of the employee when making return-to-work decisions.
- ❑ Short- and long-term disability policies should provide coverage for ongoing scheduled treatment after return to work as specified under the disability leave.

## Wellness/Health Promotion/Prevention

- ❑ Employers should provide access to accurate information about cancer and cancer resources, including support groups, via their employee benefits website, EAP or other resources.

- ❑ Employers should be aware of evidence-based recommendations and provide the following preventive services and resources to employees and eligible dependents:
  - ⇒ [Alcohol misuse programs](#) and [tobacco cessation programs](#), including low-cost or free state and federal programs, as well as online communities.
  - ⇒ Access to age- and risk-appropriate screenings, either on-site (e.g., mammography vans, skin cancer screenings), or in partnership with a community clinic/health plan to increase access.
  - ⇒ Information on the importance of compliance with all routine immunization recommendations for both the cancer patient and his/her family. Patients should be directed to consult with their oncologist.

- ❑ Employers should promote healthy behaviors that decrease the risk of cancer in the areas of:
  - ⇒ Nutrition: [Provide a healthy food environment](#) by, for example, offering fruits/vegetables in the dining center, using nutritional labels and including healthy options in vending machines.
  - ⇒ Environment: Minimize employee exposure to UV radiation, secondhand smoke and toxins that may be present in their environment.
  - ⇒ Obesity: [Promote the importance of a healthy weight](#) through the use of employee letters, presentations, fact sheets and other resources.
  - ⇒ Tobacco use: Establish [workplace policies](#) on such issues as smoking cessation programs and incentives for being a non-smoker.
  - ⇒ Alcohol misuse: Offer [education on the risk factors](#).

- ❑ Employers should periodically review claims data across all health plans in order to understand the impact of cancer in the workplace. An understanding of employee population characteristics can help employers focus cancer education efforts, screening programs and support services around priority cancer diagnoses and priority employee populations. When designing benefits, it can be valuable to understand the following data from the prior year and the trend over the past several years:
  - ⇒ Expenditures on cancer (malignant neoplasms) relative to other disease categories and as a proportion of total medical and pharmacy expenditures;
  - ⇒ Number of claimants by type of cancer (the 5 or 10 cancers that are most often seen and are the most expensive in the aggregate in the employee population);
  - ⇒ High-cost claimants by type of cancer (which types of cancer are the most costly on a per claimant basis); and
  - ⇒ Incidence and expenditures by state or work site location.

- ❑ Employers should evaluate their wellness programs using the [Wellness Impact Scorecard, or WISCORE<sup>SM</sup>](#) to determine best practices and identify areas of improvement.

- ❑ Employers should offer a health assessment with questions that include cancer risk factors leading to appropriate follow-up, such as disease-specific interventions and self-management techniques.

Questions addressing cancer risk factors may include the following:

- ⇒ Family history (if applicable; employer needs to remain compliant with the [Genetic Information Non-Discrimination Act](#));
- ⇒ Personal history and basic demographics; and
- ⇒ Behavioral-based factors: tobacco use, alcohol misuse, physical activity, nutrition.

## Tool 1: Quick Reference Guide & Assessment



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### About the National Advisory Committee on Employer Services for the Cancer Continuum of Care

The National Advisory Committee on Employer Services for the Cancer Continuum of Care serves as the expert advisory body for the *Employer's Guide*, ensuring that all information and recommendations are relevant to employers and their partners. The Committee helps develop recommendations for the design, quality assurance, structure, and integration of resources, programs and services around the full spectrum of employer benefits and programs. This includes the health plan, health and productivity programs and health promotion/wellness services. The Committee consists of benefit managers, clinical cancer experts, medical directors, health plan representatives, pharmaceutical representatives, health care consultants, disability managers, EAP professionals and health promotion/wellness professionals.

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SUPPORTING DOCUMENTS

## Stem-Cell Transplant Criteria

Employers should evaluate the Transplant Centers of Excellence (COE) program(s) they offer to employees, whether as part of their health plan's transplant program or through another organization. A Transplant COE program should establish and apply rigorous criteria in the evaluation and qualification of stem cell transplant (SCT)\* programs. Pediatric-specific criteria should be used to evaluate pediatric SCT programs. At a minimum, the evaluation process should include assessment of SCT programs in the following categories:

### 1. Clinical Structure

- a. Facility-related accreditations (i.e., The Joint Commission, FACT\*\*).
- b. National Marrow Donor Program (NMDP)\*\* network guidelines met if unrelated allogeneic transplants are provided.
- c. Physician credentialing, including appropriate Board certification and experience in stem cell transplantation.
- d. Clinical trial group participation.
- e. Availability of comprehensive specialty services. Pediatric SCT programs should have pediatric-specific specialists and support services.
- f. Clinical transplant coordinator(s) and patient advocate(s)/social worker(s).

### 2. Processes

- a. Established patient selection criteria and formal patient selection process.
- b. Use of treatment protocols and guidelines.
- c. Collection of data and reporting of transplant outcomes to the Center for International Blood and Marrow Transplant Research (CIBMTR).
- d. Mechanism for tracking patients post-transplant.
- e. SCT-specific clinical quality initiatives.

### 3. Volume and Outcomes

- a. Years of experience for the SCT program, clinical program leadership and individual transplant physicians.
- b. Minimum volume by type of transplant (i.e., autologous and allogeneic) and age group (i.e., adult and pediatric).
- c. Minimum survival rates by type of transplant and age group required for participation.

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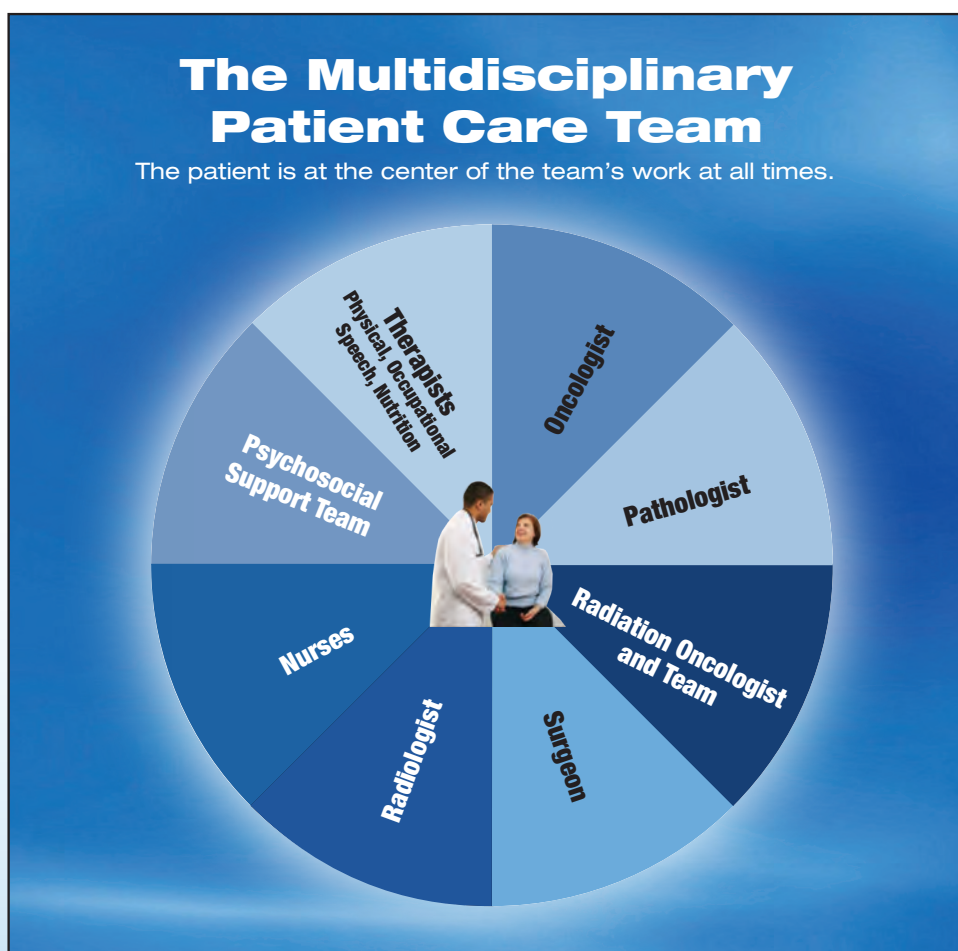
\*The term "stem cell transplant" applies to transplants using stem cells derived from bone marrow, peripheral blood or cord blood. This term is now used more than bone marrow transplant.

\*\*The Joint Commission (formerly JCAHO) is an accreditation body for several types of health care organizations, including hospitals. FACT (Foundation for the Accreditation of Cellular Therapy) accredits stem cell transplant programs and marrow and peripheral blood collection and processing centers. NMDP evaluates stem cell transplant programs that provide allogeneic (unrelated donor) transplants, services to identify potential matched unrelated donors, as well as those that arrange for transplants using stem cells from unrelated donors and offer other related services. See [www.marrow.org](http://www.marrow.org) for more information.

# Multidisciplinary Cancer Teams

In a multidisciplinary care model, the patient is at the center, with all applicable care providers and specialists coming together around the patient. The process begins with the multidisciplinary tumor board, which evaluates the individual patient's situation and treatment options and helps ensure that treatment recommendations are based on multiple perspectives, not just that of one specialist.

Participation on the tumor board by a pathologist—preferably one who specializes in the patient's type of cancer—helps ensure that treatment recommendations are made based on a precise interpretation of the pathologic diagnosis, including identification of biomarkers and the mutational status of the tumor.



In a multidisciplinary patient care team model, the primary treating physician, often the oncologist, is able to confer with subspecialists in real time to facilitate coordinated, patient-centric care. The multidisciplinary team of experts (medical and surgical specialists, palliative care specialists, nurses, therapists, the psychosocial support team, etc.) identifies and addresses problems before they become more difficult and costly to treat.

Large medical centers, particularly academic cancer centers, have a radiation oncologist, radiation physicist and dosimetrist on-site during treatment to ensure patient safety and proper calibration of equipment, as well as accurate calculation of dosage and radiation therapy technique. Large medical centers also have expert pharmacists and computerized prescription order entry to ensure accurate medication and patient safety.

Real-time collaboration between the surgeon and the pathologist during and after surgery provides important benefits in this multidisciplinary model. Real-time collaboration isn't feasible when tissue is sent out to a pathologist in a different location or to a national laboratory. Having the pathologist review intraoperative frozen sections while the patient is still in surgery helps ensure that the surgeon has obtained clean surgical margins, which can prevent local recurrence, especially in head and neck cancer, sarcoma, melanoma and breast cancer.

Participation of the pathologist during sentinel node biopsy (e.g., breast cancer or melanoma) helps ensure adequacy of node dissection to find micrometastases. Adequate lymph node dissection is also essential to ensure accurate staging (e.g., esophageal, breast, colon and rectal cancers).

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# Cancer Clinical Trial Talking Points

Self-funded employers are encouraged to cover *routine costs of care* when patients are enrolled in an *approved clinical trial* (see definitions, below). Many employers cover approved clinical trials for life-threatening conditions by including appropriate language in their Summary Plan Description (SPD). When the Plan document allows, patients who participate in a clinical trial will have coverage for routine costs of care just as they do for services that take place outside a clinical trial. Several published reports indicate that the costs of treatment in a clinical trial are, at most, only slightly higher than treatment that is not part of a clinical trial. *Estimated impact for an employer to cover routine costs of care for cancer-related clinical trials is less than \$1 per member per year.*

The purpose of clinical trials in cancer is to study promising new treatments and determine whether a new treatment is safe and effective and is better (i.e., results in improved survival or cure and/or fewer side effects) than the treatment currently in use. Coverage for clinical trials is especially important when patients are being treated at large, academic cancer centers. Since clinical research is a central aspect of the mission of academic cancer centers, they offer many high-quality clinical trials. For some individuals, treatment available in a clinical trial is the best option, and sometimes the only option. Nationwide, average clinical trial participation rate for adults is very low (about 3%). Pediatric cancer care is more often provided as part of a clinical trial, and clinical trial participation by children with cancer is estimated at more than 50%.

By including “life-threatening illness” language in the SPD, employers can ensure that Plan participants will have coverage for routine costs of care when participating in a clinical trial.

## **Costs of Care in Clinical Trials**

Routine patient care costs for clinical trials include:

1. Covered health services for which benefits are typically provided absent a clinical trial;
2. Covered health services required solely for the provision of the investigational item or service, the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
3. Covered health services needed for reasonable and necessary care arising from the provision of an investigational item or service.

Routine costs for clinical trials do not include:

1. The experimental or investigational service or item;
2. Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; and
3. Items and services provided by the research sponsors free of charge for any person enrolled in the trial.

The following definition may be included in the employer's SPD:

**An Approved Clinical Trial is a clinical trial that is funded, conducted, or supported by centers or cooperative groups that are funded by any of the following:**

1. National Institutes of Health (NIH), including the National Cancer Institute (NCI)
2. Department of Defense (DOD)
3. Department of Veterans Affairs (VA)
4. Agency for Healthcare Research and Quality (AHRQ)
5. Centers for Medicare & Medicaid Services (CMS)
6. Centers for Disease Control and Prevention (CDC)
7. Trials conducted under an investigational new drug application (IND) reviewed by the FDA

**An Approved Clinical Trial must also meet the following requirements:**

1. The subject or purpose of the trial must include the evaluation of an item or service that falls within a covered benefit category.
2. The trial must include therapeutic intent among its objectives. Some clinical trials study prevention and diagnosis.
3. The trial must enroll patients with diagnosed disease rather than healthy volunteers.

(Adapted from HHS, CMS)

### **Information on Clinical Trials from the National Cancer Institute**

The information below addresses key points about clinical trials. It has been adapted from the National Cancer Institute website: <http://www.nci.nih.gov/clinicaltrials/learning>

### **Ten Things to Know About Cancer Clinical Trials**

1. **Clinical trials** are research studies that involve people. Each study tries to answer scientific questions and to find better ways to prevent, diagnose or treat cancer. See [What Is a Clinical Trial?](#) as well as [Taking Part in Cancer Treatment Research Studies](#).
2. In **cancer research** a clinical trial is designed to show how a particular anticancer strategy—for instance, a promising drug, a gene therapy treatment, a new diagnostic test, or a possible way to prevent cancer—affects the people who receive it. A clinical trial may also compare two standard treatment options to determine which one is better. Many clinical trials, however, compare a promising new therapy to an available treatment that represents the standard of care. Providers cannot charge for any drug that has not yet received FDA approval. (See definition of routine costs, below.)
3. A clinical trial is one of **the stages of a long and careful cancer research process**. Getting promising results from testing a new drug on mice, for example, is a preliminary step to human research studies. Treatments that work well in mice do not always work well in people. See [How Is a Clinical Trial Planned and Carried Out?](#)

4. People can **benefit** from clinical trials. In treatment trials, for example, participants receive high-quality cancer care—and will be among the first to benefit if a new approach is proven to work. See [Should I Take Part in a Clinical Trial?](#)
5. **Who's eligible** to participate in a clinical trial? Each study has its own guidelines for who can participate. Generally, participants are alike in key ways—such as the type and stage of cancer, age, gender, and other factors. See [How Do I Take Part in a Clinical Trial?](#)
6. Are there **drawbacks**? New treatments under study are not always better than, or even as good as, standard care. And they may have unexpected side effects. Through a process called **informed consent**, potential clinical trial participants will learn about a study's treatments and tests, and their possible benefits and risks, before deciding whether or not to participate. See [A Guide to Understanding Informed Consent](#).
7. Do some people receive a **placebo** in clinical trials? Placebos are very rarely used in treatment trials involving people who have cancer; that is, if the current standard of care is no treatment.
8. Many treatment trials are designed to **compare a new treatment with a standard treatment**, which is the best treatment currently known for a cancer, based on results of past research. In these studies patients are randomly assigned to one group or another.
9. **Where** do clinical trials take place? They are underway all over the country—in cancer centers, other major medical centers, community hospitals and clinics, physicians' offices and veterans' and military hospitals in numerous cities and towns around the United States.
10. **Who pays for the patient care costs on clinical trials?** Health plans and managed care providers do not always cover all patient care costs in a study. What they cover varies by plan and by study. Research costs are covered by the study sponsor. See [Clinical Trials and Insurance Coverage: A Resource Guide](#).

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## Collaborative Care for Depression and Stress in Cancer Patients

Fifteen to 25% of cancer patients are affected by comorbid depression, with men and women equally affected.<sup>1</sup> Depression not only affects patients, it has a major negative impact on their families. Major depression affects approximately 25% of cancer patients. Additionally, nearly a third of cancer patients have a mood disorder other than depression (anxiety, dysthymia, adjustment disorder, significant stress).<sup>2</sup> These problems not only have an impact on quality of life for patients and their families, they also can affect adherence to treatment regimes and outcomes.

Successful interventions to improve care for depression have a number of common features, typically referred to as collaborative care. The collaborative care model focuses on treatment in general medical settings (vs. specialty behavioral health care settings) for most patients. For cancer patients, the physician and treatment team usually coordinate their care. Collaborative care includes and combines several quality improvement strategies, such as screening, case identification and proactive tracking of clinical (e.g., depression) outcomes; clinical practice guidelines and provider training; support of the primary provider treating depression by a depression care manager (e.g., a nurse, clinical social worker, or other trained staff); and collaboration with a behavioral health specialist (e.g., a psychologist or a psychiatrist).

Collaborative care interventions have two key elements. The first is case management by a nurse, social worker, or other trained staff to facilitate screening, coordinate an initial treatment plan and patient education, arrange follow-up care, monitor progress, and modify treatment if necessary. Case management can be provided in the clinic and/or by telephone. The second is consultation among the case manager, the primary provider and a consulting psychiatrist, who advises the primary treatment team about its caseload of depressed patients. This consultation is intended to maximize the cost-effectiveness of collaborative care by facilitating a process described as “stepped care.” This term refers to a treatment algorithm that starts with relatively low-intensity interventions, such as antidepressant medication prescribed by the primary provider and treatment team and telephone case management, then shifting to progressively more intensive approaches, including specialty behavioral health care, for patients who fail to respond.

More than ten large trials, in a wide range of settings, have demonstrated the feasibility of improving depression treatment and outcomes relative to usual care.<sup>3,4</sup>

The documented benefits of collaborative depression care include:

- Higher rates of evidence-based depression treatment (e.g., antidepressant medication and/or psychotherapy);
- Better medication adherence/compliance;
- Reduction in depression symptoms and earlier recovery from depression;

- Improved quality of life;
- Higher satisfaction with care; and
- Improved physical functioning.

Collaborative care has typically been found to increase direct health care costs slightly relative to usual care, mainly by increasing the use of evidence-based depression treatment. *However, this investment yields substantial improvements in patients' health status and functioning, so that collaborative care is more cost-effective than usual care for depression and has very favorable cost-effectiveness compared with other accepted medical interventions.*

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<sup>1</sup> Miaskowski C. Gender differences in pain, fatigue, and depression in patients with cancer. *J Natl Cancer Inst Monogr* (32): 139-43, 2004. [PUBMED Abstract]

<sup>2</sup> Massie MJ, Holland JC. The cancer patient with pain: psychiatric complications and their management. *Med Clin North Am* 71 (2): 243-58, 1987. [PUBMED Abstract]

<sup>3</sup> Gilbody S, Whitty P, Grimshaw J, Thomas R. Educational and organizational interventions to improve the management of depression in primary care: a systematic review. *JAMA*, 2003; 289(23): 3145-51.

<sup>4</sup> Neumeyer-Gromen A, Lampert T, Stark K, Kallischnigg G. Disease management programs for depression: a systematic review and meta-analysis of randomized controlled trials. *Med Care*, 2004; 42(12): 1211-21

## Background Information: Drugs & Biologics Compendium

### **National Comprehensive Cancer Network® (NCCN®)**

NCCN is a not-for-profit alliance of 21 of the world's leading cancer centers. NCCN is dedicated to improving the quality and effectiveness of care provided to patients with cancer. Through the leadership and expertise of clinical professionals at NCCN Member Institutions, NCCN develops resources that present valuable information to physicians, pharmacists, patients and others. The primary goal of all NCCN initiatives is to improve the quality, effectiveness and efficiency of oncology practice so that patients can live better lives.

### **NCCN Drugs & Biologics Compendium (NCCN Compendium™)**

A compendium is a concise, comprehensive compilation of a body of knowledge; it may summarize a larger work. A drug compendium lists the drugs relevant to one or more clinical areas and provides other, related information.

The NCCN Compendium is a convenient listing of recommended uses of drugs and biologics in cancer care. The NCCN Compendium recommendations are derived directly from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™). Each recommendation is designated with a Category of Evidence that reflects the quality of evidence and consensus on which the recommendation is based (see below for Categories of Evidence and Consensus).

Although other drug compendia also address cancer care, the NCCN Compendium is widely considered the most comprehensive and up-to-date oncology drug compendium available. The NCCN Compendium is important in the context of cancer care because it is widely used as the basis for coverage policy. The Centers for Medicare & Medicaid Services (CMS), Aetna, UnitedHealthcare and other managed care organizations utilize the NCCN Compendium as an authoritative reference for oncology coverage policy. It is the resource used most often by managed care medical directors, pharmacy benefits directors and other health care professionals when making decisions that impact patient access to appropriate therapy.

*Note: Although NCCN Guidelines are free of charge, a paid subscription is required to access the NCCN Compendium.*

## **NCCN Clinical Practice Guidelines in Oncology™ (NCCN Guidelines™)**

NCCN Guidelines are a comprehensive set of treatment algorithms across the continuum of cancer care (from diagnosis to end of life) that support treatment decision-making between physicians and patients. They address all treatment modalities, including chemotherapy, radiation therapy, surgery and palliative care. Guidelines can be accessed at NCCN's professional website, [NCCN.org](http://NCCN.org). They are available to all free of charge, but registration and login is required.

To date, several NCCN Guidelines have been translated into versions for patients and other non-clinicians. Patient Guidelines can be accessed free of charge at NCCN's consumer website, [NCCN.com](http://NCCN.com); no registration is required. Additional patient versions of NCCN Guidelines will be made available in the future.

NCCN Guidelines are developed through an ongoing process by 44 panels of experts from NCCN Member Institutions. Guidelines are updated based on review of clinical evidence (e.g., published reports of clinical trials) and expert consensus regarding what constitutes appropriate care. Guideline panels include physician experts in relevant fields (oncologists, surgeons, radiation oncologists and others) and may also include patient advocates, nurses or others. Each guideline panel meets at least annually, and will meet more often if important new evidence becomes available. Each recommendation in the NCCN Guidelines is identified with a category of evidence that reflects the quality of evidence available and the level of consensus (see Categories of Evidence below). Footnotes link to citations in the medical literature and other important information.

Recommendations are defined for each step in the clinical decision-making process; one treatment or a range of treatment options may be included for a specific situation. Guidelines are applicable to most but not all cancers. NCCN Guidelines cover about 98% of cancers, but do not cover rare cancers or pediatric conditions.

### **NCCN Categories of Evidence and Consensus**

**Category 1:** The recommendation is based on high level evidence (e.g., randomized controlled trials), and there is uniform NCCN consensus.

**Category 2A:** The recommendation is based on lower level evidence\*, and there is uniform NCCN consensus.

**Category 2B:** The recommendation is based on lower level evidence\*, and there is near-uniform consensus on the recommendation.

**Category 3:** The recommendation is based on any level of evidence but reflects major disagreement.

*\* Smaller randomized clinical trials, well-designed controlled trials without randomization or well-designed cohort studies*

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