

Tool 3, Part I: Request for Proposal (RFP) Questions and Requested Evidence for Vendors

This tool is intended to be used in creating an RFP that will be sent to current and/or potential medical and pharmacy plan vendors. The tool can be used in two ways: to determine the extent to which current vendors are meeting or can meet your benefit specifications and to evaluate potential vendors to determine which are able to implement your benefit plan in a way that is consistent with your specifications. This tool translates benefit recommendations from the [Plan Design & Assessment Tool](#) (Tool 2) into Benefit or Practice statements so that vendors will clearly understand your requirements. Vendors are then asked to respond to a series of questions about their ability to implement these benefits according to your requirements.

Vendor responses can be evaluated using *Tool 3, Part II: Request for Proposal (RFP) and Response Evaluation* and then scored and ranked using *Tool 3, Part III: Request for Proposal (RFP) Scoring Tool*.

After each benefit and objective, questions are listed (noted in the document) that can be used if other vendors are in place for:

- A transplant Centers of Excellence program (if offered and not provided by the medical plan vendor);
- A cancer Centers of Excellence program (if offered and not provided by the medical plan vendor);
- Specialty pharmacy (SP) program (if offered and not provided by the pharmacy plan vendor);
- Nurseline and/or care management program (if not provided by the medical plan vendor); and
- Stop-loss or Reinsurance carrier (if stop-loss reinsurance is purchased).

For most mid- to large-size self-funded employers, medical and pharmacy plan vendors should be able to implement each benefit or practice according to your specifications. If there are certain aspects of the benefit specifications that vendors are not able to implement, they should indicate what they are. If a vendor can only partially implement the benefit or practice, the response should describe the vendor's limitations. If the vendor will charge an additional premium to implement the benefit or practice, the vendor should indicate that and state what the additional premium will be. The vendor should also define any additional time needed to implement the benefit or practice.



For smaller self-funded employers and employers purchasing a fully insured medical plan, vendors should indicate if their standard plan is consistent with the benefits or practices as described in your requirements. If a vendor's standard plan is not fully consistent with your requirements, the response should indicate areas where the benefit or practice cannot be implemented as written. If the vendor will charge an additional premium to implement the benefit or practice, the vendor should indicate that and state what the additional premium will be. The vendor should also define any additional time needed to implement the benefit or practice.

1.0: General Medical & Behavioral Health

Medical Benefit 1.1

Recommended Benefit or Practice

Benefit plan should include access, within the available provider network, to a wide range of cancer care providers, including medical oncologists, hematologists, pediatric hematologist-oncologists, radiation oncologists, surgeons who specialize in cancer, 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.

Objective(s)

- To ensure that beneficiaries have access to the expertise needed to accurately diagnose and appropriately treat their cancer.

RFP Questions & Evidence

RFP - Q 1.1

Do you offer a network that provides access to a wide range of cancer care providers, including medical oncologists, hematologists, pediatric hematologist-oncologists, radiation oncologists, surgeons that specialize in cancer, palliative care specialists and pathologists, both in the community setting and in large, [academic cancer centers](#), including National Cancer Institute (NCI)-designated [Comprehensive Cancer Centers and Cancer Centers](#)?

If yes:

1. Do you offer a national network that includes academic medical centers/cancer centers, including National Cancer Institute (NCI)-designated Comprehensive Cancer Centers and Cancer Centers?
[Yes/No]

If yes:
(Continued)

- a) List the NCI-designated Cancer Centers included in the network.
- b) Provide evidence that the network provides comprehensive access and wide geographic distribution of medical oncologists, hematologists, pediatric hematologist-oncologists, radiation oncologists, surgeons that specialize in cancer, palliative care specialists and pathologists in the community and in academic centers by including a directory of providers or a link to your online provider network listing and/or a geoaccess map.

OR

2. Do you offer a regional network that includes academic medical centers/cancer centers, including National Cancer Institute (NCI)-designated [Comprehensive Cancer Centers and Cancer Centers](#)? [Yes/No]
 - a) Provide evidence of the extent of medical oncologists, hematologists, radiation oncologists, oncology surgeons, palliative care specialists and pathologists in your regional network both in the community and in academic cancer centers.
 - b) Define the network's geographic region.
 - c) Provide evidence that your network provides comprehensive access and geographic distribution within the region to medical oncologists, hematologists, pediatric hematologist-oncologists, radiation oncologists, surgeons that specialize in cancer, palliative care specialists and pathologists in the community and in academic centers by including a directory of providers, a link to your online provider network listing and/or a geoaccess map.
 - d) Does your network include at least two academic medical centers/cancer centers and at least one NCI-designated Comprehensive Cancer Center or Cancer Center in the region? [Yes/No]
 - i) If yes, list the academic medical centers/cancer centers and the NCI-designated Cancer Center(s).
 - ii) If no, do you provide access to academic medical centers/cancer centers and NCI-designated Comprehensive Cancer Centers or Cancer Centers outside your region as in-network providers? [Yes/No]

If yes:
(Continued)

- e) Do you require beneficiaries to obtain prior authorization to receive services at academic medical centers/cancer centers and NCI-designated Cancer Centers outside the region in order to obtain network benefits? [Yes/No]
If yes:
 - i) What criteria are used to determine approval? What is the review and decision-making process that ensures that beneficiaries who need specialized cancer care can access qualified providers?
 - ii) What is the actual average turnaround time to respond to requests? What is the average turnaround time for emergency oncologic conditions?

3. Do you utilize a restrictive pathway program, which limits and/or favors certain cancer treatment options and includes financial incentives so that physicians choose these options for the majority of patients? If so, is the program offered by an external vendor or was it developed internally?

- a) What process is used to select the options from among the entire range of nationally recognized, evidence-based treatment options?
- b) Who participates in selecting the pathway options?
- c) What is the process for evaluating and updating the pathway options as new treatments become available?
- d) Are effectiveness and/or toxicity considered? If so, how are they taken into consideration?
- e) What is the target (i.e., a specific percent) for provider compliance with the selected options?
- f) What is the process for approval, if any, if the treating physician chooses a treatment that is not included in the pathway options?
- g) What incentives are provided to physicians for participating in and meeting objectives and targets of the pathway program?

OR

4. Do you preferentially contract with physicians that have adopted a restrictive pathway program?
- a) What process does the physician group use to select the options from among the entire range of nationally recognized, evidence-based treatment options?
 - b) Who participates in selecting the pathway options?

If yes:
(Continued)

- c) What is the process for evaluating and updating the pathway options as new treatments become available?
- d) Are effectiveness and/or toxicity considered? If so, how are they taken into consideration?
- e) Has the physician group defined a target (i.e., a specific percent) for compliance with the selected options?
- f) What is the process for approval, if any, if the treating physician chooses a treatment that is not included in the pathway options?
- g) What incentives do physicians have for meeting targets for the pathway program?

If you answered yes to either #3 or #4, please also answer the following questions (5-7):

5. Are potential conflicts of interest of the panel or physician group choosing the options tracked and made available on an ongoing basis?
 - a) If the information is publicly available, where can it be found?
 - b) If the information is not publicly available, can this information be obtained? If so, how?
6. Is information about the pathway program and its effect on treatment options given to patients or made available to them upon request? How are patients informed about other appropriate treatment options (i.e., non-pathway options)?
7. In the interest of transparency, is there a clearly defined process for interested and authoritative constituencies (e.g., patient advocacy groups, clinical organizations, experts, governmental bodies) to comment on the pathway recommendations?

Medical Benefit 1.2

Recommended Benefit or Practice

1. Benefit plan should include access to a Centers of Excellence (COE) program for transplants, including bone marrow/stem cell transplants (SCT) that employs a rigorous qualification process using [transplant-specific quality criteria](#).
 - Employers should evaluate the Transplant COE program offered to employees to ensure that it uses specific criteria for evaluation and qualification of transplant providers.

Recommended Benefit or Practice (Continued)

- Transplant COE contracts should include inpatient and outpatient behavioral health/psychosocial services at the transplant center as a component of the global set of services.
 - 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.
2. In addition to covering pre-transplant, transplant and post-transplant care as recommended by the transplant center, the benefit plan should cover donor search and typing costs, including:
- Full cost of biological sibling typing;
 - Full cost of unrelated donor search, including typing and testing of potential donors, through the National Marrow Donor Program (NMDP) or other approved registry;
 - Full cost of related donor procurement, including travel and lodging of the selected related donor for the donation process; and
 - Full cost of donor cell product procurement for the unrelated donor.

Objective(s)

- To provide beneficiaries with access to high-quality stem cell transplant providers with the experience and expertise needed to treat the individual's condition in a competent, cost-effective way.
- To provide access to information and guidance that will enable beneficiaries to choose the transplant center that best meets their needs.
- To provide coverage for donor search, testing and acquisition to ensure that transplant candidates requiring donor stem cells/bone marrow are not prevented from proceeding to transplant.

RFP Questions & Evidence

Medical plan or Transplant COE program vendor may respond to this question.

RFP Q 1.2-a

Does your COE program employ a rigorous qualification process using transplant-specific criteria? [Yes/No]

If yes:

Provide the following information:

1. A list and description of criteria used to evaluate transplant programs. If not available, provide a statement indicating that criteria are used to evaluate transplant programs with as much information as possible about the criteria.

If yes:
(Continued)

2. A policy defining the frequency of reevaluation of transplant centers. If a written policy is not available, provide a statement indicating frequency of transplant center reevaluation.
3. Criteria for removal of a transplant COE, including a policy defining the reasons for and process followed to remove a transplant center that no longer meets the evaluation criteria. If a written policy is not available, provide a statement that includes as much information as possible about the reasons for and process used to remove a transplant center that no longer meets the evaluation criteria.

RFP Q 1.2-b

Are your transplant COE contracts all-inclusive of hospital services and all applicable physicians, ancillary and other health care professionals (including behavioral medical specialists) that provide care during the transplant period? [Yes/No]

If yes:

Describe what is included in transplant COE contracts:

1. Scope of services included in the contracted rates.
2. Duration of contract (time period covered by the contract's global rate and post-transplant period if covered outside the global rate).
3. Providers, by specialty.
4. Payment model(s) used.

If no:

Describe providers and/or services specifically excluded from transplant COE contracts.

RFP Q 1.2-c

Does your transplant COE program provide access to nurses to guide patients in understanding their condition and choosing an appropriate transplant center? [Yes/No]

If yes:

Provide the following information:

1. Evidence that your transplant COE program ensures that nurses with transplant expertise are available to identify and support candidates for transplant.
2. Describe minimum qualifications of nurses (e.g., RN or BSN; 3-5 years of clinical experience in transplantation or oncology).
3. Documentation that a physician with transplant expertise supports nurses. Medical director with appropriate qualifications (physician with experience in transplantation or oncology, or at least 2 years experience supporting a transplant COE program).

Medical Benefit 1.3

Recommended Benefit or Practice

Benefit plan includes access to a cancer COE program that uses a rigorous qualification process. The cancer COE network should be available, in particular, for individuals with complex, aggressive, and rare cancers, those that are difficult to diagnose and those that require complex treatment.

- Employers should evaluate the cancer COE program offered to employees. Employers should require that the cancer COE program use specific criteria for evaluation and qualification of cancer centers. Criteria may be cancer-specific, apply to overall attributes of the cancer center or both.
- The cancer COE programs should ensure that participating cancer centers have physicians available from all relevant specialties, as well as other clinical staff needed for each patient's multidisciplinary treatment team. These physicians and other clinical staff should be contracted network providers.
- The cancer COE program should provide access to clinical staff to help individuals who need cancer care make an informed decision about where to go for care.
- The cancer COE program should include access to network behavioral medical providers for inpatient and outpatient behavioral medical/psychosocial services at the cancer center.

Objective(s)

- To provide beneficiaries access to high-quality cancer providers with the subspecialty experience and expertise to diagnose and treat the individual's cancer in an appropriate, cost-effective way.
- To provide access to information and guidance that enables beneficiaries to choose the cancer center that best meets their needs.

RFP Questions & Evidence

Medical plan or Transplant COE program vendor may respond to this question.

RFP Q 1.3-a

Does your cancer COE program use specific criteria for evaluation and qualification of cancer centers? [Yes/No]

If yes:

Provide the following information:

1. A list and description of criteria used to evaluate cancer centers. If not available, provide a statement indicating that criteria are used to evaluate cancer centers with as much information as possible about the criteria.

If yes:
(Continued)

2. A policy defining the frequency of reevaluation of cancer centers. If a written policy is not available, provide a statement indicating frequency of cancer center reevaluation.
3. Criteria for removal of a cancer COE, including a policy defining the reasons for and process followed to remove a cancer center that no longer meets the evaluation criteria. If a written policy is not available, provide a statement that includes as much information as possible about the reasons for and process used to remove a cancer center that no longer meets the evaluation criteria.

RFP Q 1.3-b

Are your cancer COE contracts all-inclusive of hospital services and all applicable physicians, ancillary and other health care professionals (including behavioral health specialists) that provide care? [Yes/No]

If yes:

- Describe what is included in cancer COE contracts:
1. Scope of services included in the contracted rates.
 2. Duration of contract, including whether there is any limitation on the time period covered by the contract.
 3. Providers, by specialty.
 4. Payment model(s).

If no:

Describe providers or services specifically excluded from cancer COE contracts.

RFP Q 1.3-c

Does your cancer COE program provide access to clinical staff to guide patients in understanding their diagnosis and treatment options and choosing an appropriate cancer center? [Yes/No]

If yes:

- Provide the following information:
1. Description of the role of nurses who are available to assist patients participating in the cancer COE program.
 2. Nurses with appropriate qualifications (Minimum qualifications: RN or BSN with 3-5 years of clinical experience in oncology).
 3. Documentation that nurses are supported by a physician/medical director with oncology experience and expertise.

If no:

Describe how you will support the needs of cancer patients who participate in the program.

Medical Benefit 1.4

Recommended Benefit or Practice

Benefit plan should include travel and lodging assistance to help those who must travel to receive a transplant or cancer treatment at a plan-designated COE.

Objective(s)

- To ensure that lack of funds for travel to a selected transplant or cancer treatment center or for lodging near that center does not prevent cancer patients from choosing treatment at the center most qualified to provide care.

RFP Questions & Evidence

Medical plan or Transplant and/or Cancer COE program vendor may respond to this question.

RFP Q 1.4

Do you currently administer a travel and lodging (T&L) assistance program? [Yes/No]

If yes:

Describe how you administer your T&L program (for transplant, cancer or both) and the standard reimbursement criteria.

If no:

If not currently administering a T&L program, can you implement a program consistent with the eligibility criteria and level of coverage the employer has established? If so, how?

Medical Benefit 1.5

Recommended Benefit or Practice

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.

Objective(s)

- To validate the accuracy of the cancer diagnosis.
- To ensure that the proposed treatment plan is evidence-based and most appropriate for treatment of the specific individual.

RFP Questions & Evidence

RFP Q 1.5

Do you cover services that are components of a second opinion (for review of the diagnosis, review of the treatment plan or both) at standard reimbursement levels for individuals with a diagnosis or suspected diagnosis of cancer? [Yes/No]

Components of a second opinion are defined as follows: Evaluation and management (E&M) services, pathology review, diagnostic radiology services and laboratory tests even if equivalent services were previously billed by other providers and claims were paid.

If yes:

1. Provide documentation that specifically states that claims are paid at standard reimbursement levels for services that are components of a second opinion.

OR

2. Provide documentation that specifically states that, with prior authorization for a second opinion and confirmation that a second opinion is sought from a large, academic cancer center or other large cancer center, that you pay the claims at standard reimbursement levels for services that are components of a second opinion.

- a) What is the actual average turnaround time for non-urgent cases? For urgent/emergency oncologic conditions?
- b) For what services (i.e., diagnostic radiology or lab tests) is prior authorization required?

If no:

Describe how you can ensure that second opinion coverage is consistent with the specifications described above.

Medical Benefit 1.6

Recommended Benefit or Practice

Benefit plan should provide coverage for [routine costs of care](#) when the patient is enrolled in an approved cancer clinical trial. Level of coverage should be the same as for comparable services provided outside of a clinical trial.

An “approved clinical trial” is one that is funded, conducted or supported by centers or cooperative groups that are funded by any of the following:

Recommended Benefit or Practice
(Continued)

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 a diagnosed disease rather than healthy volunteers.

Objective(s)

- To provide access, without financial penalty, to individuals who choose to participate in quality cancer clinical trials.
- To provide access, without financial penalty, to those individuals for whom cancer clinical trials are the only available option.

RFP Questions & Evidence

RFP Q 1.6-a

Does your standard benefit plan cover [routine costs of care](#) when the patient is enrolled in an approved cancer clinical trial that is comparable to coverage for services provided outside of a clinical trial? [Yes/No]

If yes:

Provide the following documentation:

1. Medical policy or other documentation stating that routine costs of care are covered when a beneficiary is enrolled in an approved clinical trial as defined in this recommendation.

OR

2. Medical policy or other documentation stating that routine costs of care are covered when a beneficiary is enrolled in an approved clinical trial, which is defined more narrowly than in this recommendation. Provide the definition you use.

If no:

Describe how payment of routine costs of care will be implemented in a way that is consistent with the specifications described above.

RFP Q 1.6-b

Is prior notification to the medical plan required by the treating physician, who indicates a patient's intent to participate in a clinical trial and confirms that it is an approved clinical trial? [Yes/No]

If yes:

What is the turnaround time to provide coverage determination?

Medical Benefit 1.7

Recommended Benefit or Practice

1. Benefit plan should include hospice coverage for individuals with an estimated life expectancy of 12 months or less. Hospice coverage should include up to five days of inpatient respite care (care provided in a Medicare-approved facility to alleviate the burden on the primary caregiver) per three-month period.
2. While obtaining hospice services, beneficiaries should continue to have coverage for participation in approved clinical trials on the same basis as when not obtaining hospice services. Reimbursement for routine costs of care when part of a clinical trial should be paid to providers separate from the hospice per diem.
3. Residential services should be a covered benefit when:
 - a) A beneficiary is eligible for and enrolled in a hospice program;
 - b) 24/7 care is needed but hospitalization is not required; and
 - c) Family and/or volunteer caregivers are not available/able to provide necessary care.Services include care in a residential hospice, skilled nursing facility or assisted living facility. Services may also be provided by home health aides or other qualified staff in the beneficiary's home during hours when hospice staff, family or volunteer caregivers are not available. Residential care is paid in addition to the hospice per diem.
4. Medical plan should include access to care management nurses with training in palliative care and end-of-life issues to assist individuals who may be eligible for hospice and their families. The care manager should evaluate available options to ensure that the beneficiary receives hospice services in the most cost-effective and medically appropriate setting.
5. Medical plan administrators should contract only with hospice providers that have appropriate certification and meet quality standards.

Objective(s)

- To ensure that patients are informed about and can choose hospice services in a timely manner when a cure is no longer likely.
- To minimize barriers to hospice enrollment.
- To provide care management support to individuals with limited life expectancy and their families and caregivers.
- To ensure that hospice programs available to patients through their health plan network have appropriate qualifications.
- To minimize hospital admissions and emergency room visits when patients are receiving appropriate hospice services and supportive care, including residential care if indicated.

RFP Questions & Evidence

RFP Q 1.7-a

Do you offer a hospice benefit as described in this recommendation for individuals with an estimated life expectancy of 12 months or less? [Yes/No]

If yes:

Provide the medical policy or other documentation stating that you cover hospice services based on eligibility that is consistent with this recommendation.

If no:

Describe how the hospice benefit will be implemented in a way that is consistent with specifications described above.

RFP Q 1.7-b

Do you cover routine costs of care for individuals enrolled in an approved clinical trial while also enrolled in hospice, and are these costs paid separately from the hospice per diem? [Yes/No]

If yes:

Provide the medical policy or other documentation stating that you cover routine costs of care for individuals enrolled in an approved clinical trial while also enrolled in hospice.

If no:

Describe how you will implement the hospice benefit in a way that is consistent with specifications described above.

RFP Q 1.7-c

Do you cover residential services (in a residential hospice, skilled nursing or assisted living facility or when provided by in-home aides) when a beneficiary is eligible for and enrolled in a hospice program and meets other criteria described in this recommendation? [Yes/No]

If yes:	Provide the medical policy or other documentation stating that you cover residential services consistent with the options and eligibility criteria described in this recommendation.
If no:	Describe how you will implement this benefit in a way that is consistent with the specifications described above.
RFP Q 1.7-d	Do you provide care management support for individuals who have a diagnosis of cancer, an advanced illness and/or who are terminally ill? [Yes/No]
If yes:	<ol style="list-style-type: none"> 1. Provide a description of the program, its objectives and the patient populations served: <ol style="list-style-type: none"> a) Is the program focused on this patient population or does it serve this patient population as part of a general care management program? b) Is the program focused on meeting the needs of individuals who have a diagnosis of cancer, an advanced illness and/or who are terminally ill? c) Are the services provided part of a general care management program that has multiple objectives, including meeting the needs of individuals who have a diagnosis of cancer, an advanced illness and/or who are terminally ill? 2. Do nurses who staff the care management program have specific training and experience with these conditions? <ol style="list-style-type: none"> a) If yes, provide minimum required qualifications and type (or types) of required training programs. 3. Are nurses supported by a physician/medical director with expertise in cancer, palliative care and/or hospice care? <ol style="list-style-type: none"> a) If yes, describe the qualifications of the physician/medical director or provide a biosketch.
RFP Q 1.7-e	Do you employ a qualification process for hospice programs to ensure that they have appropriate certification and meet quality standards? [Yes/No]
If yes:	Describe the criteria used to evaluate hospice programs.
If no:	Describe any plans to evaluate hospice programs for network participation.

Medical Benefit 1.8

Recommended Benefit or Practice

Benefit plan should reimburse network physicians for consultation with patients and family members about all options for care, both during active treatment and at end of life. Discussion topics may include evidence-based treatment options, palliative care (when needed during active treatment as well as at end of life), discontinuation of treatment with curative intent, and hospice.

Objective(s)

- To ensure that patients and their loved ones are aware of all appropriate options when making decisions about treatment or discontinuation of treatment when one or the other option may no longer be appropriate or consistent with the patients' preferences.

RFP Questions & Evidence

RFP Q 1.8

Do you cover consultation by a network physician with patients and family members about options for care at standard reimbursement rates? [Yes/No]

If yes:

Provide the medical policy or other documentation indicating that you pay claims for evaluation & management (E&M) or consultation services when applicable CPT codes are used, even if equivalent services were previously billed by other providers and claims were paid.

If no:

1. Describe how you will implement this benefit in a way that is consistent with the specifications described above.
2. Indicate what CPT codes are accepted for reimbursement of these services.

Medical Benefit 1.9

Recommended Benefit or Practice

Benefit plan should provide coverage for nutrition counseling and medical nutritional therapy for individuals with a diagnosis of cancer.

Provider network should include registered dietitians, including registered dietitians that are Board-certified specialists in oncology (CSO).

- Objective(s)**
- To improve tolerance to treatment, help maintain quality of life and ability to function during and following cancer treatment, and enhance recovery.

RFP Questions & Evidence

RFP Q 1.9-a Do you cover nutrition counseling and medical nutrition therapy in conjunction with a diagnosis of cancer? [Yes/No]

- If yes:**
1. Indicate nutrition counseling and medical nutrition therapy services that are covered when provided by registered dietitians.
 2. Is prior authorization required?
 - a) If yes, what is the actual average turnaround time for prior authorization for nutrition counseling and medical nutrition therapy provided by registered dietitians?

If no: Describe how you will implement this benefit in a way that is consistent with the specifications described above.

RFP Q 1.9-b Does your network include registered dietitians within its provider network, including dietitians that are Board-certified in oncology (CSO)? [Yes/No]

If yes: Do you use an accreditation process to ensure that participating dietitians have required qualifications? [Yes/No]
If yes, provide evidence of the extent of the network by including a network directory or geoaccess map.

If no: Describe how you will implement this benefit in a way that is consistent with the specifications described above.

Medical Benefit 1.10

Recommended Benefit or Practice Benefit plan should provide coverage for dental prevention services and treatments in the medical plan when such services are required prior to, during or after cancer treatment or stem cell transplantation, and when not otherwise covered by the dental benefit. Specialized treatments such as maxillofacial surgery (as direct treatment of the cancer or to repair cancer surgery-related defects) should be covered when provided at a cancer center with the necessary expertise.

Recommended Benefit or Practice
(Continued)

Provider network should include dentists and oral surgeons (DDS and MD/DDS) on faculty at academic medical centers and cancer centers.

Objective(s)

- To ensure that patients are not prevented from receiving needed medical treatment due to dental and oral health problems.
- To minimize the detrimental effects of cancer treatment on oral structures, dental function and overall dental health.
- To restore essential functions (speaking, eating and swallowing) and improve appearance to an acceptable level following treatment to the head and neck area.
- To ensure that overall health is not negatively affected by oral disease and/or infection.

RFP Questions & Evidence

RFP Q 1.10-a

Do you cover dental preventive services and treatments when required prior to, during and after cancer treatment or stem cell transplantation when they are not otherwise covered by dental benefits in a way that is consistent with this recommendation? [Yes/No]

If yes:

Provide the following:

1. Medical policy or other written documentation that states you cover dental services in a way that is consistent with this recommendation.

OR

2. Documentation that outlines the level to which you cover dental preventive services and treatments to a more limited extent than defined here and/or with narrower eligibility criteria for coverage.
 - a) Include eligibility criteria.
 - b) Provide detail of coverage of dental preventive services and treatments provided through out-of-network benefits.

If no:

Describe how you will implement this benefit in a way that is consistent with this recommendation.

RFP Q 1.10-b

Does your provider network include dentists and oral surgeons, as well as maxillofacial surgeons (MD/DDS or DDS), on faculty at academic medical centers and cancer centers? [Yes/No]

If yes:

Provide documentation that states:

1. The network includes dentists and oral surgeons and uses an accreditation process to ensure that participating dentists have required qualifications.

OR

2. The network includes dentists and oral surgeons but does not use an accreditation process to ensure they have required qualifications.

Medical Benefit 1.11

Recommended Benefit or Practice

Benefit plan should provide coverage for [molecular and biomarker testing](#) based on recommendations in NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®).

Objective(s)

- To determine appropriate diagnosis and treatment for an individual patient.

RFP Questions & Evidence

RFP Q 1.11

Does your standard benefit plan cover molecular/biomarker testing based on recommendations in NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)? [Yes/No]

If yes:

1. Indicate the process used when evaluating new lab vendors that provide molecular and biomarker testing and when evaluating existing lab vendors that provide such testing.
2. Describe processes used to determine how these labs submit claims for molecular and biomarker testing.
3. Describe the data analytics used to retrospectively determine what molecular and biomarker testing has been paid for on behalf of clients.
4. Describe what processes or protocols have been implemented and/or are planned for the future to ensure appropriate utilization based on results of molecular or biomarker testing.

Medical Benefit 1.12

Recommended Benefit or Practice

Benefit plan should provide coverage for [genetic testing and counseling](#) as recommended by the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®).

Coverage for genetic counseling services should be limited to professionals qualified to provide genetic counseling and clinical genetic services. The medical plan network should provide access to qualified genetic counselors for services provided in person and telephonically.

Qualified professionals must meet criteria specified by the NCI: <http://www.cancer.gov/cancertopics/genetics/directory/criteria>

Objective(s)

- To determine if early screening and/or preventive care is appropriate for those with a significant family history of cancer.

RFP Questions & Evidence

RFP Q 1.12-a

Do you cover genetic testing and counseling for risk assessment of individuals with significant family history or personal cancer history based on recommendations in NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)? [Yes/No]

If yes:

Provide the medical policy or other documentation indicating that you cover genetic testing and counseling consistent with these standards.

If no:

Describe how you will implement this benefit in a way that is consistent with the specifications described above.

RFP Q 1.12-b

Do you cover genetic counseling services only when provided by professionals certified to provide genetic counseling and medical genetic services; that is, Board-certified or Board-eligible genetic counselors or medical geneticists (physicians)? [Yes/No]

If yes:

Describe the process used to ensure that counseling is covered only when provided by certified genetic counselors and other qualified providers.

If no:

Describe how you will implement this benefit in a way that is consistent with the specifications described above.

RFP Q 1.12-c	Does your network provide access to Board-certified or Board-eligible genetic counselors and medical geneticists? [Yes/No]
If yes:	Provide the following: <ol style="list-style-type: none"> 1. Describe the accreditation process used to ensure that the network includes Board-certified or Board-eligible genetic counselors with required qualifications. 2. Geoaccess mapping or comparable evidence to demonstrate adequacy of certified genetic counselors in the network.
If no:	Describe how you will implement this benefit in a way that is consistent with the specifications described above.
RFP Q 1.12-d	Does the health plan network cover genetic counseling services when provided in person and/or telephonically? [Yes/No]
If yes:	Describe the process used to ensure that genetic counseling services are covered whether provided in person or telephonically.
If no:	Describe how you will implement this benefit in a way that is consistent with the specifications described above.

Medical Benefit 1.13

Recommended Benefit or Practice	Benefit plan should provide coverage for standard fertility preservation treatments when a medically necessary cancer treatment (surgery, chemotherapy, radiation therapy) may directly or indirectly cause infertility. Standard fertility preservation treatments are those identified as such by appropriate professional societies, such as the American Society for Reproductive Medicine (ASRM) or the American Society for Clinical Oncology (ASCO).
Objective(s)	<ul style="list-style-type: none"> • To ensure that individuals likely to become infertile as a result of treatment for cancer (iatrogenic infertility) have access to fertility preservation therapies that are standard of care.

RFP Questions & Evidence

RFP Q 1.13 Does your standard policy provide coverage for standard fertility preservation treatments for iatrogenic infertility (infertility caused by medically necessary cancer treatment) when treatments have been identified as appropriate by applicable professional societies? Has any requirement to demonstrate attempts to conceive before infertility benefits become available been waived? [Yes/No]

If yes: Provide documentation of the process used to confirm that the patient is at risk of infertility related to a planned cancer treatment.

If no: Describe how you will administer this benefit in a way that is consistent with the specifications described above.

Medical Benefit 1.14

Recommended Benefit or Practice

Benefit plan should cover home health visits under the following conditions:

- When the beneficiary must be confined to the home or when leaving the home for required services would involve considerable effort or expose the patient to undesirable risk;
- When the services are clinically appropriate for the home setting;
- When the services are prescribed by the attending physician as part of a written plan of care; and
- When authorized by the health plan as clinically appropriate.

Objective(s)

- To support cost-effective and patient-centered care in the home setting.

RFP Questions & Evidence

RFP Q 1.14 Does your standard benefit plan cover home health visits in a way that is consistent with this recommendation? [Yes/No]

If yes: Provide documentation of the number of home health visits or hours of home health services (if the number is limited) and conditions under which services are covered in a way that is consistent with this recommendation.

If no:

Describe how you will administer this benefit in a way that is consistent with this recommendation.

Medical Benefit 1.15

Recommended Benefit or Practice

If purchased, stop-loss insurance should apply benefits in a way that is consistent with the company's health care plan, including coverage of clinical trials and off-label use of drugs, as defined in Pharmacy Benefit Recommendation 2.2. Approved clinical trials (as defined in Medical Benefit Recommendation 1.6) should not be excluded under the experimental and investigational language.

Objective(s)

- To ensure that stop-loss insurance provides employers with the expected financial protection and is consistent with benefits described in the health care plan regarding: (1) coverage for the routine costs of care in clinical trials and (2) evidence-based coverage for off-label use of drugs in cancer care that is consistent with the recommendations in the NCCN Drugs & Biologics Compendium (NCCN Compendium®).

RFP Questions & Evidence

Stop-loss carrier will respond to this question.

RFP Q 1.15

Does your contract with the employer clearly state that you cover claims for services consistent with the employer's SPD and plan document language in regard to clinical trials and off-label use of drugs? [Yes/No]

If yes:

Provide contract language indicating that you cover claims when the individual has received or is receiving care as part of an approved clinical trial or is receiving or has received treatment that includes off-label use of drugs if such use is consistent with the recommendations in the NCCN Drugs & Biologics Compendium.

If no:

Describe how you will implement coverage consistent with the employer's SPD language.

Medical Benefit 1.16

Recommended Benefit or Practice

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).

Objective(s)

- To identify individuals with cancer and other beneficiaries (e.g., spouse, children) who could benefit from a timely diagnosis of depression and effective treatment.
- To minimize the cost impact for patients with cancer and comorbid depression through quicker diagnosis.

RFP Questions & Evidence

RFP Q 1.16-a

Do you cover depression screening (performed by oncologists and other covered providers) for all cancer patients and other beneficiaries? [Yes/No]

If yes:

Indicate the method(s) used to support this recommendation (select all that apply):

1. Specific provisions contained in an approved provider contract (e.g., reference to standardized screening instruments such as Emotional Health Inventory or the Patient Health Questionnaire).
2. Provider communication materials that clearly address this Practice Recommendation, including whether non-behavioral health specialists are to be reimbursed.
3. Provider compliance is assessed as part of the provider evaluation methodology (e.g., chart of claims audit).

RFP Q 1.16-b

Do you reimburse depression screening procedures as a unique lab test? [Yes/No]

If yes:

List applicable CPT codes supported by the plan and covered providers eligible to perform this screening.

If no:

Describe how you will administer this benefit in a way that is consistent with the specifications described above.

Medical Benefit 1.17

Recommended Benefit or Practice

Oncologists and other approved health providers should be reimbursed for screening, assessing and diagnosing behavioral health conditions as a primary or secondary health condition.

Objective(s)

- To support and encourage adequate documentation of the incidence, prevalence, treatment and outcomes of common behavioral health conditions in the general medical environment.
- To provide the information necessary to correct missing or inaccurate clinical/diagnostic information that potentially impedes plan administrators' ability to monitor and improve network performance, provider quality and patient outcomes.
- To minimize the cost impact of a comorbid depression condition through quicker diagnosis and effective treatment.

RFP Questions & Evidence

RFP Q 1.17

Do you reimburse approved providers, including oncologists, for screening, assessing and diagnosing behavioral health conditions as a primary or secondary health condition? [Yes/No]

If yes:

1. If yes, indicate the type(s) of services addressed by these policies and procedures (select all that apply):
 - a) Depression screening.
 - b) Behavioral health assessment and diagnostic services.
 - c) Behavioral health treatment services.
2. Indicate the method(s) used by the plan to support this Practice Recommendation (select all that apply):
 - a) Specific provisions contained in approved provider contract(s).
 - b) Provider communication materials that clearly address the Practice Recommendation, including whether non-behavioral health specialists are to be reimbursed for treatment services for behavioral health conditions (e.g., administrative or clinical practice manual, training or related materials).
 - c) Provider compliance is assessed as part of the provider evaluation methodology (e.g., chart or claims audit).

If no:

Describe how you will administer this benefit in a way that is consistent with the specifications described above.

Medical Benefit 1.18

Recommended Benefit or Practice

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.

Objective(s)

- To ensure that patients with cancer who have behavioral health conditions, particularly depression and anxiety, receive effective, evidence-based care.
- To increase the coordination of behavioral health treatment with cancer treatment when a physician who is not a behavioral health specialist diagnoses a mental health or substance abuse condition.

RFP Questions & Evidence

RFP Q 1.18

Do you cover consultation between an approved provider, a behavioral health specialist and/or a condition management specialist to provide collaborative care for patients with cancer who are diagnosed with a behavioral health disorder but are principally treated in a medical setting? [Yes/No]

If yes:

Indicate the components in support of collaborative care:

1. Screening for behavioral disorders to identify the symptoms associated with a behavioral health diagnosis.
2. Assessment to confirm a behavioral health diagnosis.
3. Patient education to help patients select treatment options.
4. Treatment.
5. Face-to-face and telephonic care management by a qualified professional who works with and is supervised by a primary care provider (PCP).
6. Clinical consultation provided by a qualified specialty behavioral health provider to the PCP and/or care manager.

If no:

Describe how you will administer this benefit in a way that is consistent with the specifications described above.

Medical Benefit 1.19

Recommended Benefit or Practice

Medical plan should contract with behavioral health providers at network cancer centers and children's hospitals.

Objective(s)

- To make all evidence-based interventions readily accessible and effective for all plan members diagnosed with cancer.
- To ensure that there are in-network behavioral health providers with knowledge and skills to deliver evidence-based treatment options for individuals with cancer and their beneficiaries, including children.

RFP Questions & Evidence

RFP Q 1.19

Do you credential and contract with behavioral health providers at network cancer centers and children's hospitals? [Yes/No]

If yes:

1. What is your accreditation/credentialing process for behavioral health providers in cancer centers and children's hospitals?
2. Does your quality assurance program include behavioral health metrics that measure patient outcomes?

If no:

Describe how you will ensure access to behavioral medical providers at network cancer centers and children's hospitals.

2.0: Pharmacy Benefit

Pharmacy Benefit 2.1

Recommended Benefit or Practice

Reasonable out-of-pocket thresholds should be established so that cost is not a barrier for patients to obtain the medications they need 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.

Specialty Pharmacy (SP) programs should implement programs to counsel individuals who are prescribed oral oncology drugs or self-injectables to reduce the prescription abandonment rate. SP programs should also monitor patients on long-term treatment regarding failure to fill or refill prescriptions.

SP programs and 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 employee assistance programs (EAP) or other resources.

- To help ensure adherence to prescribed medications required to treat cancer, the side effects of their treatment and maintenance drugs.
- To prevent prescription abandonment due to unaffordable out-of-pocket costs.

RFP Questions & Evidence

Pharmacy plan, Medical plan and SP vendors may respond to this question.

RFP Q 2.1-a

Does your plan include a reasonable out-of-pocket threshold consistent with this recommendation? [Yes/No]

If yes:

1. Provide documentation of your standard out-of-pocket cost structure and out-of-pocket maximum.

If yes: <i>(Continued)</i>	2. Out-of-pocket requirements for beneficiaries should be consistent with the pharmacy benefit cost-sharing structure, but not greater than \$100 per prescription fill and/or an aggregate of \$200 out-of-pocket maximum per month. Special consideration is given for high-deductible health plans.
If no:	Provide evidence of current practice or ability to implement copayments in a way that is consistent with this recommendation.
RFP Q 2.1-b	Do you currently work together to implement a single out-of-pocket maximum for medical and pharmacy expenditures? [Yes/No]
If yes:	Provide examples of how the collaboration has been successfully implemented.
If no:	How will you work together to implement a single out-of-pocket maximum?
RFP Q 2.1-c	Does your SP program provide counseling services to individuals obtaining oncology medications? [Yes/No]
If yes:	<ol style="list-style-type: none"> 1. Describe the objectives of the counseling services. 2. Describe the qualifications of staff that counsel individuals obtaining oncology medications.
If no:	Describe how the SP program will administer this benefit.
RFP Q 2.1-d	Does your SP program provide access to information about programs to assist patients with the costs of prescription drugs? [Yes/No]
If yes:	Describe the resources used to assist patients and the resources patients are referred to for assistance with the costs of prescription drugs.
If no:	Describe how you will administer this benefit.

Pharmacy Benefit 2.2

Recommended Benefit or Practice

1. Administrators of medical plans, pharmacy benefit management (PBM) programs, Specialty Pharmacy (SP) benefit plans and any 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 the [NCCN Guidelines®](#) and the [NCCN Drugs & Biologics Compendium](#) (NCCN Compendium®) with Category 1, 2A or 2B level of evidence.
2. In regard to cancer treatment, employers should adopt the NCCN Drugs & Biologics Compendium in its entirety.

Objective(s)

- To ensure that patients receive evidence-based treatment when diagnosed with cancer.

RFP Questions & Evidence

Medical plan, Pharmacy plan and SP vendors may respond to this question.

RFP Q 2.2

Can you ensure that plans cover evidence-based cancer treatment, whether paid under the medical or pharmacy benefit based on [NCCN Guidelines and Drugs & Biologics Compendium®](#) recommendations for products with Category 1, 2A or 2B level of evidence? [Yes/No]

If yes:

Provide medical policy or other documentation that NCCN Drugs & Biologics Compendium® recommendations with Category 1, 2A or 2B level of evidence are used as the basis of coverage determination for drugs and biologics in cancer care.

If no:

Describe current criteria for coverage determination and indicate how you will customize your practices to determine coverage for drugs and biologics in cancer care based on NCCN Compendium® recommendations with Category 1, 2A or 2B level of evidence.

Pharmacy Benefit 2.3

Recommended Benefit or Practice

Benefit plan should establish parity of patient cost sharing between the medical and pharmacy benefit.

Objective(s)

- To help ensure that treatment decisions can be made without regard to whether the treatment is covered by the medical or pharmacy benefit.

RFP Questions & Evidence

Pharmacy plan, Medical plan and SP vendors may respond to this question.

RFP Q 2.3

Do you have a process to work together to establish parity of patient cost sharing between the medical and pharmacy benefit? [Yes/No]

If yes:

Describe the current process in place to establish parity.

If no:

Describe how will you work together to establish parity consistent with the specifications described above.

3.0: Clinical Support & Condition Management

Clinical Support & Condition Management Benefit 3.1

Recommended Benefit or Practice

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.

Objective(s)

- To provide access to evidence-based information on a wide range of topics relevant to individuals with questions about a suspected or confirmed diagnosis of cancer, concerns or questions about cancer risk, prevention and treatment.

RFP Questions & Evidence

Medical plan or Care Management program vendor may respond to this question.

RFP Q 3.1-a

Do you provide assistance related to a cancer diagnosis via a nurseline service that offers information on cancer-related clinical issues and community resources? [Yes/No]

If yes:

1. Provide documentation about the scope of information used by the nurseline program, including topics of relevance to individuals with questions about cancer risk, their own or a family member's cancer diagnosis, cancer treatments and community resources.
2. Describe the sources of information used by the program and the process used to ensure that the information is credible, evidence-based, current and relevant.

If no:

Describe how you will provide this type of service.

RFP Q 3.1-b

Do you employ appropriately trained nurses and/or others to staff the nurseline program? [Yes/No]

If yes:

- Indicate qualifications and training provided to staff:
1. What are the minimum requirements for nurses and/or others that staff the nurseline program?
 2. Describe the initial and ongoing training program for nurseline staff, including training in oncology-related issues as described in this recommendation.

Clinical Support & Condition Management Benefit 3.2

Recommended Benefit or Practice

Employers should contract for case management services and require that oncology nurses be available to work with patients and are supported by a physician or physicians with oncology expertise.

Alternatively, employers should consider purchasing a cancer-specific case management/care management program staffed by oncology nurses who are supported by a physician or physicians with oncology expertise.

Objective(s)

- To provide comprehensive support to individuals with a diagnosis of cancer by offering them education about their diagnosis, decision support related to evidence-based treatment options and strategies to prevent or reduce symptoms and side effects.
- To address options when cure is no longer possible, including hospice. Support provided by oncology nurses can mitigate treatment costs, help ensure that patients are receiving evidence-based care (consistent with NCCN Guidelines) from providers with appropriate expertise, help prevent emergency room visits and admissions, increase completion of advance directives, increase hospice utilization and earlier enrollment in hospice, and provide psychosocial support to both patients and caregivers.

RFP Questions & Evidence

Medical plan or Care Management program vendor may respond to this question.

RFP Q 3.2-a

Do you offer a cancer case management/disease management program? [Yes/No]

If yes:

Describe the following aspects of the program:

1. Is this a cancer-specific case management program or is it a general case management program that serves individuals with a range of complex conditions, including cancer?
 - a) Describe minimum qualifications for nurses who staff the program.
 - b) Describe initial and ongoing training programs for nurses that staff the program.
2. Are the nurses who staff the program supported by a physician/medical director with oncology expertise? Describe the qualifications of the physician/medical director.
3. Do patients have one nurse assigned to support them for the duration of their time in the program?

RFP Q 3.2-b

Does your case management program include social workers with oncology experience to support patients and their families? [Yes/No]

If yes:

1. Describe minimum qualifications for the program's social workers.
2. Describe initial and ongoing training program for social workers.

Tool 3, Part I: **Request for Proposal (RFP) Questions and Requested Evidence for Vendors**



**National
Business
Group on
Health**



National
Comprehensive
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Written by:

National Business Group on Health: Ron Finch, Ed.D., Vice President and Principal Investigator; Demian Kendall, Program Associate; Brenna Shebel, MS, CHES, Assistant Director and Project Manager.

National Comprehensive Cancer Network: Elizabeth Danielson, MHA, Director of Payor Relations; Patricia Goldsmith, Executive Vice President/Chief Operating Officer

Please contact healthservices@businessgrouphealth.org for more information.

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.

National Business Group on Health

National Business Group on Health
20 F Street, N.W., Suite 200 • Washington, D.C. 20001
Phone (202) 558-3000 • Fax (202) 628-9244 • www.businessgrouphealth.org
Helen Darling, President and CEO, National Business Group on Health

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

Len Lichtenfeld, M.D., **American Cancer Society**, Wayne Burton, M.D., **American Express**, Michelle Martin, **CBS Corporation**, Rick Heine, **Consultant**, Jack Mahoney, M.D., **Medical Consultant**, Lynn Zonakis, **Delta Air Lines, Inc.** Thomas D'Amico, M.D., **Duke Comprehensive Cancer Center**, Scott Howell, M.D., **Genentech, Inc.**, Arthur Small, M.D., **Genentech, Inc.**, Angela Cafferillo, **General Electric Company**, Bryan Loy, M.D., **Humana Inc.**, Daniel Conti, Ph.D., **JPMorgan Chase**, Jill Berger, **Marriott International, Inc.**, Jane Barlow, M.D., **Medco Health Solutions**, Milayna Subar, M.D., **Medco Health Solutions**, Michael Schoenbaum, Ph.D., **National Institute of Mental Health**, Mary Bradley, **Pitney Bowes, Inc.**, Duane Putnam, **Pfizer Inc.**, Don Weber, **PricewaterhouseCoopers**, Michael Rosen, M.D., **OptumHealth**, Mary Lou Smith, J.D., **Research Advocacy Network**, Shelly Wolff, **Towers Watson**, Samuel Silver, M.D., Ph.D., **University of Michigan Medical School**, Robert Jacob, **Unum**, Bruce Sherman, M.D., **Wal-Mart Stores, Inc.**, Alan Rosenberg, M.D., **Wellpoint, Inc.**, Ken Mitchell, Ph.D., **WorkRx Group**

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SUPPORTING DOCUMENTS

Cancer Diagnoses for Referral to Centers of Excellence (COEs)

This listing is intended as general guidance for the types of cancer that can benefit from diagnosis, evaluation and/or treatment at a large, academic cancer center. It is not intended to be all-inclusive or to suggest that all such cancers require referral to a COE.

For any Type of Cancer

- Access to multimodality programs, where a team representing several areas of expertise is required to meet the patient's need, such as for head and neck cancer surgery requiring special skill/expertise (e.g., pancreatectomy, skull base surgery, pelvic exenteration, extrapleural pneumonectomy)
- Specialized radiation therapy interventions
- Intensive chemotherapy requiring maximal support
- Pathology review that requires special expertise/experience
- Patients at high surgical risk due to comorbidities

Head and Neck Cancers

- Stage III-IV or recurrent disease
- Cancer of larynx, Stage II or greater
- Skull base tumors

Esophageal Cancer

- Any stage if non-metastatic; upon diagnosis or local recurrence

Stomach (Gastric) Cancer

- Any stage upon diagnosis if non-metastatic; for surgery

Colon Cancer

- History of familial polyposis
- Locally advanced or recurrent disease
- *Solitary* hepatic metastasis and/or other organ involved

Rectal Cancer

- Refer for surgery upon diagnosis, lesion below 6 cm, distal 1/2 or 2/3
- Any local recurrence, or other organ involved

Liver and Bile Duct Cancers

- Any stage upon diagnosis; for surgery

Kidney Cancer

- Advanced renal cell cancer or metastatic disease

Pancreatic Cancer

- Any stage upon diagnosis, excluding patients with Eastern Cooperative Oncology Group (ECOG) performance status > 3 with liver metastases
- After failure of first-line therapy and for surgery

Lung and Other Respiratory Cancers

- Stage III (multimodality therapy needed)
- Endobronchial obstruction
- Mesotheliomas and thymomas

Sarcoma (Soft Tissue, Bone and Connective Tissue Cancers)

- Upon initial diagnosis or suspicion of diagnosis of sarcoma (prior to biopsy)
- All stages for consideration of all treatment options, especially if potential for limb salvage

Brain and Central Nervous System (CNS) Malignancies

- Primary brain and CNS cancers, upon initial diagnosis or suspicion of diagnosis
- Refer all patients for pathologic examination
- After failure of frontline therapy

Ovarian and Other Gynecologic Cancers

- All ovarian cancers, upon diagnosis, for surgery or evaluation for participation in a clinical trial
- Other Stage III-IV gynecologic cancers

Leukemia – Acute and Chronic

- All acute leukemias upon diagnosis
- Any chronic leukemia upon relapse

Lymphoma (includes Hodgkin and non-Hodgkin's Lymphoma)

- For confirmation of pathologic diagnosis
- Mantle cell lymphoma, high-grade lymphoma (e.g., Burkitt's lymphoma)
- All Hodgkin lymphoma

Breast Cancer

- Advanced (stage IIIB or IV)
- Breast cancer during pregnancy
- Male breast cancer

Malignant Melanoma

- After failure of first-line therapy
- Ocular melanoma and other rare melanomas

Pediatric Cancers

- Leukemia and lymphoma in infants or upon recurrence
- Hodgkin and non-Hodgkin's lymphoma, upon recurrence
- Brain tumors, except medulloblastoma
- PNET (primitive neuroectodermal tumor)
- Retinoblastoma
- Neuroblastoma, stage IV
- Wilms' tumor, metastatic or poor risk morphology
- Bone tumors, including Ewing's sarcoma and osteogenic sarcoma
- Any recurrent solid tumor

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Complex Cancer Surgery: Volume Outcome Correlation

Selected Citations

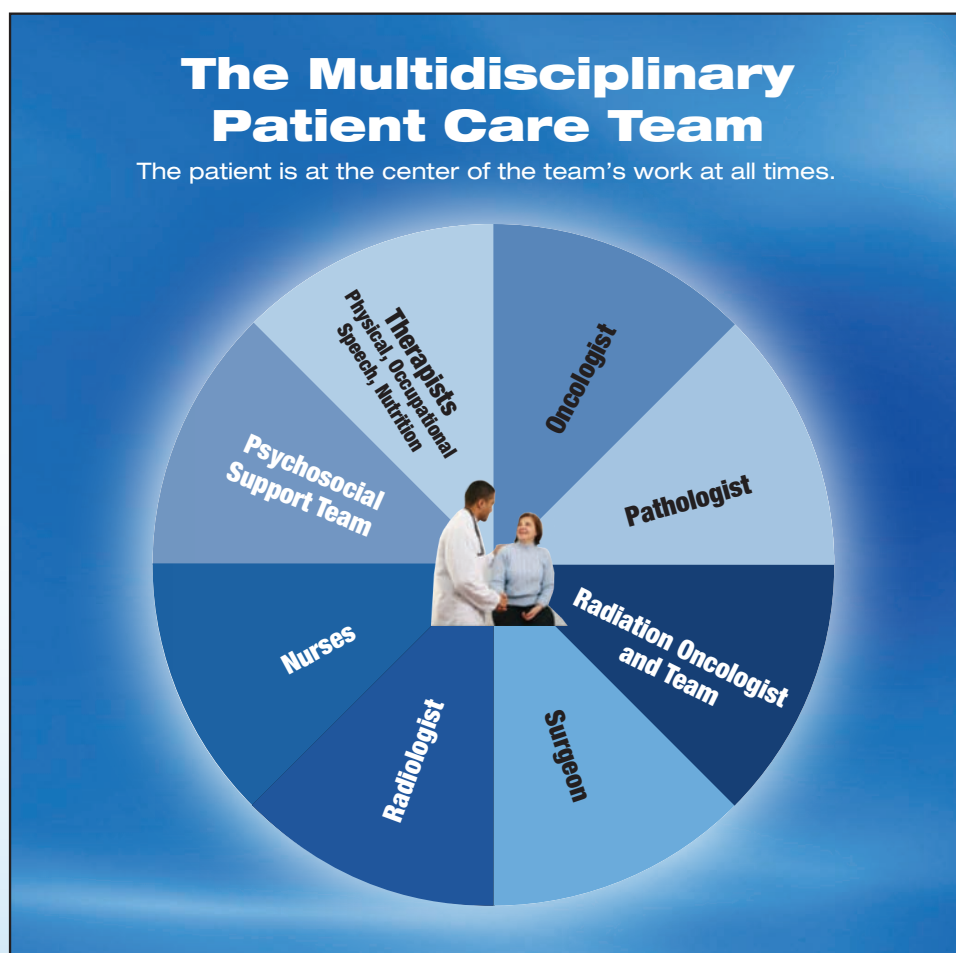
1. Higher volume was linked with lower mortality for pancreatectomy, esophagectomy, liver resection and pelvic exenteration, but most strikingly for esophagectomy and pancreatectomy. Low volume was strongly associated with excess mortality. For esophagectomies, there was a fourfold decrease, and for pancreatectomies, a twofold decrease. The data support the hypothesis that when complex surgical oncologic procedures are provided by surgical teams in hospitals with specialty expertise, mortality rates are lower. (Begg et al. Impact of hospital volume on operative mortality for major cancer surgery. *JAMA*. 1998; 280: 1747-1751)
2. Five years post-surgery, 44% of patients who had lung cancer resection at the highest volume hospitals were alive, compared to 33% who had the operation at the lowest volume hospitals. Post-operative complications were also lower at the highest volume hospitals (20%), compared to the lowest volume hospitals (44%). (Bach et al. The influence of hospital volume on survival after resection for lung cancer. *NEJM*. 2001; 3: 181-188)
3. This study of 46,951 lung resections found that overall, odds of death were reduced by 17% at teaching hospitals versus non-teaching hospitals, except for the highest volume institutions. (Meguid et al. Are surgical outcomes for lung cancer resections improved at teaching hospitals? *Ann Thorac Surg*. 2008; 85: 1015-24)
4. Both hospital- and surgeon-specific procedure volume predict outcomes following colon cancer resection, but hospital volume may exert a stronger effect. The study concludes that efforts to “optimize the quality of colon cancer surgery should focus on multidisciplinary aspects of hospital care” rather than solely on surgical technique. (Schrag et al. Surgeon volume compared to hospital volume as a predictor of outcome following primary colon cancer resection. *J Surg Oncol*. 2003; 83: 68-78)
5. Review of imaging studies by a multidisciplinary tumor board resulted in changes in interpretation for 45% of patients and changes in surgical management for 11%. Review of pathology resulted in changes for 29%. Overall, second evaluation of patients by a multidisciplinary tumor board led to changes in surgical management for 52% of patients evaluated. (Newman et al. Changes in surgical management resulting from case review at a breast cancer multidisciplinary tumor board. *Cancer*. 2006; 107: 2346-51)

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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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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 for more information.

Criteria for Cancer Centers of Excellence (COEs) Network Programs

Criteria used to assess cancer centers for designation as a cancer center of excellence vary among existing models. The criteria listed below are commonly used.

Cancer COE Network Criteria

1. Multidisciplinary tumor boards that meet at least monthly, evaluate patients and make treatment recommendations in complex cases (should include specialized pathologist).
2. Multidisciplinary treatment team that includes all appropriate disciplines, which vary by type of cancer. Each tumor-specific team should include the following specialties, as appropriate for the type of cancer:
 - a. Medical oncologist or hematologist
 - b. Radiation oncologist
 - c. Surgeon with expertise appropriate to the diagnosis
 - d. Pharmacist
 - e. Pathologist with subspecialty expertise
 - f. Palliative care specialist
 - g. Nurses, including advance practice nurses
 - h. Social worker
 - i. Therapists, as needed (PT, OT, speech)
 - j. Nutritionist
 - k. Rehab services
 - l. Spiritual support staff
 - m. Other specialists as needed (infectious disease, cardiologist, nephrologist, etc.)
 - n. For pediatric patients, child-family life specialist and teacher should be available, as well as appropriate pediatric specialists
3. Dedicated patient care units
4. Multidisciplinary outpatient clinics
5. Radiation oncology program that includes Board-certified radiation oncologists, medical physicist and dosimetrist on-site.
6. Joint Commission accreditation
7. Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathology lab certification
8. Completion of advance directive consistently encouraged.
9. Pain and palliative care programs available and consistently offered when appropriate.
10. Hospice program as part of the cancer center's programs or by referral and consistently offered when appropriate.

11. Patient and family resources (via library, computer lab and website) readily available.
12. Sufficient patient volume to ensure expertise is maintained, especially in surgical areas.
13. Electronic Medical Record system and computerized physician order entry (CPEO) system in place or in process.
14. Communication and coordination processes in place with referring physician or physician to whom patient will be transitioned.
15. Comprehensive discharge planning processes in place.
16. Participation in cancer clinical trial cooperative groups appropriate to areas of clinical expertise.
17. Use of NCCN Guidelines® (reporting of concordance with NCCN Guidelines® is not available for most providers at this time and is not a requirement).
18. System and process in place for tracking clinical outcomes.

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Diagnostic Errors

Pathology Expertise: Key Points

- Many publications describe discrepancies in diagnosis when a subspecialist pathologist conducts a “second read.”
- Change of diagnosis that affects treatment choice can occur in as many as 20% of cases, depending on the type of cancer.
- NCCN Member Institutions report that errors are most common in central nervous system (CNS) and hematologic malignancies, sarcoma, and skin, prostate and breast cancers. Changes from benign to malignant or vice versa, though rare, are especially significant.
- Correlates of accurate diagnosis and staging include:
 - pathologists with subspecialty boards;
 - consensus conferences;
 - robust QA/QI programs;
 - expertise in IHC, FISH, flow cytometry, molecular diagnostics, and cytogenetics; and
 - adequacy of tissue fixation.

Selected Citations Regarding Pathology Discrepancies

1. *Leukemia*: 18% major discordance. (DeLima et al. Comparison of referring and tertiary cancer center physicians’ diagnoses in patients with leukemia. *Am J Med.* 1998; 104: 246-251)
2. *Central nervous system (CNS) cancers*: 8.8% “major disagreement” plus 19.2% “less serious but substantial” disagreement in diagnosis. A neuropathologist at a large, academic cancer center may review 50 times as many brain/CNS tumor cases as a pathologist in a community hospital. (Bruner et al. Diagnostic discrepancies and their clinical impact in a neuropathology referral practice. *Cancer.* 1997; 79: 796-803)
3. *Immunohistochemistry*: 18.3% “significant change in diagnosis.” (Wetherington et al. Clinical significance of performing immunohistochemistry on cases with a previous diagnosis of cancer coming to a National Comprehensive Cancer Center for treatment or second opinion. *Am J Surg Pathol.* 2002; 26:1222-1230)
4. *Bladder cancer*: 18% discrepancy rate; five radical cystectomies avoided; estimated savings: \$658 per specimen reviewed. (Coblentz et al. Impact of second opinion pathology in the definitive management of patients with bladder carcinoma. *Cancer.* 2001; 1284-1290.)
5. *Prostate cancer*: Seven of 535 outside needle biopsies were reclassified as benign. Surgical avoidance saved two times the cost of all 535 biopsy reviews. (Epstein et al. Clinical and cost impact of second-opinion pathology: Review of prostate biopsies prior to radical prostatectomy. *Am J Surg Path.* 1996; 20: 851-857)

6. *Breast*: 9% change in surgical management after second pathology review. (Newman et al. Changes in surgical management resulting from case review at a breast cancer multidisciplinary tumor board. *Cancer*. 2006; 2346-2351)
7. *Head and neck cancer*: 7% change in diagnosis, including malignant to benign and benign to malignant. (Westra et al. The impact of second opinion surgical pathology on the practice of head and neck surgery: A decade of experience at a large referral hospital. *Head & Neck*. 2002; 684-93)
8. *Liver and gastrointestinal cancers*: 6.8% major discrepancy for liver cancer and 7.2% major discrepancy for gastrointestinal cancers, with clinical significance that changed treatment or prognosis. (Hahm et al. The value of second opinion in gastrointestinal and liver pathology. *Arch Path Lab Med*. 2001; 736-739)
9. *Pancreatic cancer*: Change of diagnosis in 3.4% of cases when histologic slides are read by pancreatic pathologists. (Pawlik et al. Evaluating the impact of a single-day multidisciplinary clinic on the management of pancreatic cancer. *Ann Surg Onc*. Posted online, May 2008)

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Cancer Clinical Trials 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.

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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.
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.
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](#).

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. 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; 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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Molecular and Biomarker Testing: Their Role in Cancer Diagnosis and Treatment

Molecular and biomarker tests have a variety of clinical uses: confirmation of diagnosis, identification of cancer subtype, estimation of prognosis, prediction of the effectiveness of a particular kind of therapy, prediction of side effects of a treatment, and monitoring of the disease's progression while the patient is on therapy.

One example that may be familiar is testing for the HER2 biomarker in breast cancer. HER2 testing is part of the workup for all breast cancer patients, as described in the NCCN Breast Cancer Guideline. It is important to identify those patients whose tumors have this marker because they then become eligible for therapy using a medication called Herceptin. Only breast tumors that are positive for HER2 are sensitive to this therapy.

More recently, a molecular test has been approved for melanoma. Mutations referred to as "BRAF mutations" are found in 30% - 60% of patients with melanoma. One specific BRAF mutation is sensitive to the drug vemurafenib. Both the package insert for this drug and the NCCN Melanoma Guideline specify that the mutation test must be done to determine which patients can benefit from vemurafenib treatment.

These tests are critical tools in the practice of oncology. However, new tests are being developed that, while of research interest, do not yet have a proven role in patient management. Like the NCCN Drugs & Biologics Compendium, the NCCN Molecular Testing Compendium, which will be available in 2012, will provide recommendations for the appropriate use of molecular tests and biomarkers to help oncologists provide effective care for their patients. The NCCN Molecular Testing Compendium will help differentiate between those tests that comprise standard treatment and those that are not yet ready for routine use.

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The Importance of Genetic Testing/Counseling

A number of cancers have a genetic component in their risk profiles. Genetic testing and counseling should be available for individuals whose family history includes several members with cancers that have a known genetic risk. Testing for specific genetic mutations can identify people who are at a much higher risk of developing cancer than the general population. These individuals can even be targeted before the onset of the disease.

Based on this information, individuals can make informed choices about whether to undergo more aggressive screening for cancer to help ensure it is diagnosed at an early, potentially curable stage, or possibly undergo risk reduction therapy. Therapy may include drug therapy or surgery to remove the part of the body at highest risk of cancer, such as undergoing a prophylactic mastectomy. Genetic testing can also help identify other family members who might benefit from this kind of testing and counseling.

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