

Tool 3, Part II: Request for Proposal (RFP) and Response Evaluation for Employers

The purpose of this tool is to provide guidance on evaluating vendor RFP responses for the benefits outlined in the *Benefit Design & Assessment Tool* (Tool 2). To make it easier to follow the RFP guidance information, each benefit is listed here as well. Evaluation criteria are provided for each recommendation.

Not all responses can be scored using a clear-cut “meets” or “does not meet” rating. The rating of some responses may be subjective and may vary among employers. The information provided here gives you enough background to assess the nuances of the RFP materials. For additional help, refer to *Tool 3, Part III: The Request for Proposal (RFP) Scoring Tool*.

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.



Benefit Plan Recommendation

- **Applicable Plan:** General Medical
- **Benefit or Practice Definition:** Adequacy of number of specialists and a sufficient number of providers in the network for cancer care.
- **Recommended Cost Sharing:** Should not differ between network providers in the community and those in academic medical center settings.
- **Recommended Copayment / Coinsurance Level:** Should not differ between network providers in the community and in academic medical center settings.
- **Covered Providers:** In addition to documented adequacy of network providers, the plan should have no restrictions on a beneficiary's ability to choose and access any network provider.

Administrative Guidance

An estimated 15% of cancer patients have been diagnosed with uncommon, complex, difficult-to-diagnose cancers and/or require complex medical or surgical interventions. These include subsets of common cancers as well as complex cancers. While most cancers can be treated effectively in the community setting, individuals with these more complex cancers may benefit from or require access to expertise that is only available at large, academic cancer centers. These individuals should have access to physicians with the needed expertise as well as cancer centers within their health plan network. In addition, individuals should not be penalized by having to pay a greater share of costs for those services.

Individuals who need to or choose to be treated at an academic cancer center should not be penalized by having to pay a greater share of the cost than those who can receive care in a community setting.

An individual with an uncommon or complex cancer, a cancer that is difficult to diagnose or requires complex medical or surgical treatment should not be prohibited from receiving care from a non-network subspecialist physician with extensive expertise. This practice should be followed even if a network physician or surgeon is available, unless the network physician has comparable experience and expertise. The utilization review process should take the unique needs of the individual into consideration while evaluating a request to be seen outside the plan network and should be fully documented.

Supporting Documents

- [Cancer Diagnoses for Referral to COEs](#)

RFP Assessment & Vendor Scoring

RFP - Q 1.1

Does the medical plan 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](#)? [Yes/No]

Suggested Follow-up

1. Does the medical plan 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]
OR
2. Does the medical plan 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) If the network does not include at least two academic medical centers/cancer centers and at least one NCI-designated Comprehensive Cancer Center or Cancer Center in the region, does the medical plan provide access to academic medical centers/cancer centers and NCI-designated Comprehensive Cancer Centers or Cancer Centers outside its region with in-network benefits? [Yes/No]
 - i) If prior authorization (PA) is required to access these centers, what criteria are used to determine approval? What review and decision-making processes are in place to ensure that beneficiaries who need specialized cancer care are able to access qualified providers?
 - ii) What is the actual average turnaround time to respond to requests? (*Note: 72 hours used as standard unless an emergency oncologic condition requires immediate treatment and same day turnaround*)
3. Does the medical plan 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?

**Suggested Follow-up
(Continued)**

- 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. Does the medical plan 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?
 - 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?
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?

Suggested Follow-up (Continued)

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?

RFP Evaluation Criteria

- The response should address and provide evidence regarding:
1. Geographic extent of network (i.e., national or regional).
 2. Comprehensiveness of hospital and physician network, including specialists listed in the recommendation for Medical Benefit 1.1.
 3. Inclusion of academic medical centers/cancer centers (both hospitals and physicians), including NCI-designated Comprehensive Cancer Centers and Cancer Centers, within its network.
 4. Any beneficiary requirements (e.g., prior authorization) to access out-of-network specialists with in-network level of benefits.
 5. If applicable, turnaround time to receive a decision and timeliness of the prior authorization process.
 6. If contracted with physician groups that utilize pathway programs, practices are established to ensure transparency about how pathways are selected, physician incentives, process for choosing a non-pathway treatment option and availability of information for patients.

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.
 - 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.

Recommended Benefit or Practice (Continued)

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.

Benefit Plan Recommendation

- **Applicable Plan:** General Medical
- **Benefit or Practice Definition:** Transplant COE program offered as part of the General Medical Plan or through a separate vendor relationship.
- **Recommended Benefit Coverage Limits:** At a minimum, consistent with [Affordable Care Act](#).
- **Recommended Cost Sharing:** Out-of-pocket maximum should apply. Employer should require higher cost-sharing if the patient chooses a transplant center this is not a designated COE for the specific type of transplant the patient is receiving.
- **Recommended Copayment / Coinsurance Levels:** There should not be a separate coinsurance requirement or out-of-pocket maximum for transplant services.
- **Covered Providers:** Transplant COE providers, including hospitals, all applicable physicians and other health care professionals that provide care during the contracted transplant period.

RFP Assessment & Vendor Scoring

RFP - Q 1.2-a

Does the transplant COE program vendor or medical plan that offers the program employ a rigorous qualification process using transplant-specific criteria? [Yes/No]

Suggested Follow-up

If yes, indicate the method(s) used to support this recommendation:

1. *Evaluation Criteria*

a) List and description of criteria used to evaluate transplant programs.

OR

b) Statement indicating that criteria are used to evaluate transplant programs, but criteria are not provided.

2. *Reevaluation*

a) Policy defining frequency of at least every two years for reevaluation of transplant centers.

OR

b) Statement indicating the frequency for transplant center reevaluation of at least every two years.

3. *Criteria for Removal of a Transplant COE*

a) Policy defining the reasons for and process followed to remove a transplant center that no longer meets the evaluation criteria.

OR

b) Statement indicating the reasons for and process used to remove a transplant center that no longer meets the evaluation criteria.

RFP Evaluation Criteria

The response should address and provide evidence regarding:

1. Comprehensiveness of evaluation criteria (compared to supporting documentation from [Tool 2: Plan Design & Assessment Tool](#)). Transplant center evaluation occurs at least every two years.
2. Policy and procedures are in place to remove transplant centers that no longer meet the evaluation criteria; reasons for removal are defined.

RFP - Q 1.2-b

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

Suggested Follow-up

- 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 Evaluation Criteria

The response should demonstrate that the COE contracts are inclusive of comprehensive programs and services, including behavioral health providers.

RFP Q 1.2-c

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

Suggested Follow-up

- If yes, supporting documentation should include:
1. Evidence that the transplant COE program ensures that nurses with transplant expertise are available to identify and support candidates for transplant.
 2. Nurses with appropriate qualifications (Minimum qualifications: RN or BSN; 3-5 years of clinical experience in transplantation or oncology).
 3. Documentation that nurses are supported by a physician with transplant expertise. Medical director with appropriate qualifications (physician with experience in transplantation or oncology, or at least 2 years experience supporting a transplant COE program).

RFP Evaluation Criteria

- The response should address:
1. Appropriate qualifications for nurses.
 2. Availability and qualifications of medical director/physician.

Medical Benefit 1.3

Recommended Benefit or Practice

Benefit plan should include 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.
- 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.
- Cancer COE programs should include access to network behavioral health providers for inpatient and outpatient behavioral health/ 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.

Benefit Plan Recommendation

- **Applicable Plan:** General Medical – Cancer COE program as part of General Medical Plan or through a relationship with a separate vendor.
- **Benefit or Practice Definition:** Cancer COE program
- **Recommended Benefit Coverage Limits:** At a minimum, consistent with Affordable Care Act.
- **Recommended Cost Sharing:** Out-of-pocket maximum should apply.
- **Recommended Copayment / Coinsurance Levels:** Should not differ from normal cost sharing.
- **Covered Providers:** Cancer COE providers, including hospitals, all applicable physicians and other health care professionals providing services along the continuum of care.

Administrative Guidance

Substantial differences exist among cancer centers in terms of their experience, capabilities and outcomes, especially for cancers that are complex, aggressive or rare; difficult to diagnose; and require complex treatment. Cancer centers with extensive experience and expertise in the patient's specific diagnosis and type of treatment generally have better outcomes.

Careful evaluation of cancer centers is important to help ensure that patients have access to information about services, credentials and quality to help them make informed choices about where to go for care. In addition, an evaluation helps ensure that cancer care expenditures are well spent.

A Cancer COE network should include, but not necessarily be limited to, NCI-designated [Comprehensive Cancer Centers and Cancer Centers](#). Organizations that develop cancer COE programs consider not only clinical program attributes, but also employer/payer requirements, geographic location and contractual issues.

Guidance from knowledgeable professionals about choosing a cancer center is an important component of a cancer COE program. A cancer COE program should have nurses available who are knowledgeable about cancer, cancer treatments and attributes of cancer centers and can provide information to help individuals make an informed decision about where to go for care.

RFP Assessment & Vendor Scoring

RFP Q 1.3-a

Does the cancer COE program vendor or medical plan that offers the cancer COE program use specific criteria for evaluation and qualification of cancer centers? [Yes/No]

Suggested Follow-up

If yes, indicate the method(s) used to support this recommendation:

1. *Evaluation Criteria*

- a) List and description of criteria used to evaluate cancer centers. (Criteria may be cancer-specific, apply to overall attributes of the cancer center or both.)

OR

- b) Statement indicating that criteria are used to evaluate cancer centers, but the criteria are not provided.

2. *Reevaluation*

- a) Policy defining frequency of at least every two years for reevaluation of cancer centers.

OR

- b) Statement is made indicating that reevaluation of cancer centers takes place at least every two years.

3. *Criteria for Removal as COE*

- a) Policy defining the reasons for and process followed to remove a cancer center that no longer meets the criteria.

OR

- b) Statement is made indicating the reasons for and process followed to remove a cancer center that no longer meets the criteria.

RFP Evaluation Criteria

The response should address:

1. Comprehensiveness of evaluation criteria (compare to supporting documentation from [Tool 2: Plan Design & Assessment Tool](#)).
2. Cancer center evaluation occurs at least every two years.
3. Policy and procedures are in place to remove cancer centers that no longer meet the criteria; reasons for removal are stated.

RFP Q 1.3-b

Are 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]

Suggested Follow-up	<p>If yes, describe what is included in cancer COE contracts:</p> <ol style="list-style-type: none">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). <p>If no, describe providers or services specifically excluded from cancer COE contracts.</p>
RFP Evaluation Criteria	<p>The response should demonstrate that the COE contracts are inclusive of comprehensive programs and services, including behavioral health providers.</p>
RFP Q 1.3-c	<p>Does the 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]</p>
Suggested Follow-up	<p>If yes, supporting information should include:</p> <ol style="list-style-type: none">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.
RFP Evaluation Criteria	<p>The response should address:</p> <ol style="list-style-type: none">1. Appropriate qualifications for nurses.2. Availability and qualifications of medical director.

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.

Benefit Plan Recommendation

- **Applicable Plan:** General Medical – Transplant COE program and/or Cancer COE program as part of General Medical Plan or through a relationship with a separate vendor.
- **Benefit or Practice Definition:** Travel and lodging assistance applies only when the patient is being evaluated for or receiving a stem cell transplant or cancer treatment at a plan-designated COE that has met the criteria for the patient's specific transplant or type of cancer. Travel and lodging assistance is typically offered when the transplant or cancer COE is at least 50 miles from the patient's home. The employer covers travel costs (coach air, train or mileage at IRS level for travel by car) for patient plus one companion if the patient is an adult (> 18 years old) or up to two companions if the patient is a child (under age 18). The employer covers a per diem intended to defray a substantial portion of lodging and living expenses near the transplant or cancer center.
- **Recommended Benefit Coverage Limits:** Travel reimbursed at actual cost for modes of travel described above; the maximum amount is optional. Employers may offer a per diem at their discretion. Travel and per diem payments may be deemed taxable under IRS rule.
- **Recommended Cost Sharing:** Beneficiary is responsible for travel and lodging costs not covered by the employer.
- **Recommended Copayment / Coinsurance Levels:** N/A
- **Covered Providers:** N/A

Administrative Guidance

- Since patients may have to travel some distance to be treated at a transplant or cancer center with the most relevant experience and expertise, it is important that the cost of travel and lodging not be a major impediment to choosing the most appropriate center.
- When a cancer COE program is offered, travel and lodging assistance should be similar to that offered to individuals receiving care at a transplant COE.
- Coverage for travel (by car, train or economy coach air travel), plus a per diem to assist with lodging costs, meals, etc., are commonly provided by employers.
- Clinical staff who work with transplant or cancer COE programs should make individuals aware of this benefit, as well as low-cost or free assistance programs and housing options.
- Many transplant and cancer centers have low-cost lodging options (Ronald McDonald House, Hope Lodge, etc.), especially for children, but families may still incur significant costs.
- Lodging assistance should include a per diem that will defray a substantial portion of the lodging and living cost if the transplant or cancer center is not in the patient's local community.
- Employers and employees should be aware that this type of assistance may have tax implications for beneficiaries.

RFP Assessment & Vendor Scoring

RFP Q 1.4

Does the medical plan administrator, transplant and/or cancer COE program vendor currently administer, or document their ability to administer, a travel and lodging (T&L) assistance program? [Yes/No]

Suggested Follow-up

If yes, can the T&L assistance program be implemented in a way that is consistent with this recommendation? (Yes/No)

If yes, then how will this program be administered?

RFP Evaluation Criteria

The response should address how a customized program would be implemented.

Medical Benefit 1.5

Recommended Benefit or Practice

1. Benefit plan should cover services that are components of a second opinion for individuals with a diagnosis or suspected diagnosis of cancer.
2. 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.

Benefit Plan Recommendation

- **Applicable Plan:** General Medical
- **Benefit or Practice Definition:** Second opinion services
- **Recommended Cost Sharing:** Consistent with health care plan benefits
- **Recommended Copayment/Coinsurance Level:** Consistent with health care plan benefits
- **Covered Provider:** Network providers

Administrative Guidance

For many cancers—especially those that are difficult to diagnose, complex, aggressive or rare—it may be important to obtain a second opinion from a large, academic cancer center with extensive experience and subspecialty expertise. Misdiagnosis is relatively common for certain types of cancer, such as lymphoma and brain tumors.

A second opinion may consist of sending pathology slides to a lab that specializes in a particular type of cancer, or may involve an in-person visit to a subspecialist for review of medical records and treatment options. Subspecialty expertise is most likely to be found at large, academic cancer centers.

Secondary review of pathology slides and other lab testing by a subspecialist is frequently required to ensure that treatment recommendations are based on an accurate and precise diagnosis. Less often, redoing diagnostic radiology procedures may be needed if the original imaging is of poor quality or insufficient to validate the diagnosis or develop a comprehensive treatment plan. It may be appropriate to use a prior authorization process to evaluate the evidence for redoing radiology procedures.

**Administrative
Guidance (Continued)**

If the employer offers a cancer COE network program, a second opinion can be obtained at a cancer center that is part of this network. Clinical staff supporting the program should be capable of discussing second opinion options with patients. At a minimum, the second opinion should be obtained from a cancer center with extensive experience and expertise and a multidisciplinary team that focuses on the patient's specific type of cancer.

RFP Assessment & Vendor Scoring

RFP Q 1.5

Does the medical plan 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.

Suggested Follow-up

If yes, how is coverage for these services documented and paid?

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

OR

2. Documentation 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, the medical plan pays the claims at standard reimbursement levels for services that are components of a second opinion.

a) What is turnaround time? (*Note: 72 hours used as standard requirement unless an urgent/emergency oncologic condition requires immediate treatment and same day turnaround*)

b) For what services (i.e., diagnostic radiology or lab tests) is prior authorization required?

RFP Evaluation Criteria

The response should address:

1. Specific coverage and policies.
2. Claims adjudication process that ensures coverage at standard reimbursement levels.
3. Actual average turnaround time achieved on prior authorization (PA) requests during the previous year.

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.

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.

Benefit Plan Recommendation

- **Applicable Plan:** General Medical
- **Benefit or Practice Definition:** Clinical trials
- **Recommended Cost Sharing:** Same as for services that are not related to participation in a clinical trial.
- **Recommended Copayment / Coinsurance Levels:** Same as for services that are not related to participation in a clinical trial.
- **Covered Providers:** Network providers

Administrative Guidance

For individuals with cancer, the best option—and sometimes the only option—may be treatment in a clinical trial. Self-funded employers are encouraged to cover routine costs of care when patients are enrolled in an approved 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 approximately \$0.10 per member per month (PMPM).

“Routine” patient care costs for clinical trials include:

1. Covered health services for which benefits are typically provided when not in 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.
3. Covered health services needed for reasonable and necessary care arising from the provision of an investigational item or service.

**Administrative
Guidance (Continued)**

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 are not used in the direct clinical management of the patient.
3. Items and services provided by the research sponsors free of charge for any person enrolled in the 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:

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.

RFP Assessment & Vendor Scoring

RFP Q 1.6-a

Does the medical 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]

Suggested Follow-up

If yes, indicate the method used to support this recommendation:

1. Medical policy or other documentation is provided 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 is provided 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.

**Suggested Follow-up
(Continued)**

If no, the medical plan is able to document its ability to implement the benefit in a way that is consistent with the employer's requirements.

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]

Suggested Follow-up

If yes, what is the turnaround time to provide coverage determination?

RFP Evaluation Criteria

The response should address:

1. Policy regarding coverage of routine costs of care when a beneficiary is enrolled in an approved clinical trial.
2. Any prior notification requirements for clinical trial participation to confirm that the trial meets criteria to be considered an approved clinical trial.
3. Turnaround time of 72 hours if PA is required.

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.

Recommended Benefit or Practice (Continued)

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.

Benefit Plan Recommendation

- **Applicable Plan:** General Medical
- **Benefit or Practice Definition:** Hospice services
- **Recommended Cost Sharing:** No cost sharing for hospice per diem; cost sharing for residential care should be the same as required for inpatient care.
- **Recommended Copayment / Coinsurance Levels:** No copayment or coinsurance for hospice per diem. Copayment or coinsurance for residential care is the same as is the requirement for inpatient care.
- **Covered Providers:** Approved hospice programs and other network providers.

Administrative Guidance

- Hospice is an important option for individuals with limited life expectancy who want to focus on quality of life and supportive care. Hospice programs provide support services for patients, their loved ones and caregivers.
- Hospice benefits should be available when the individual is considered to have less than 12 months to live if their disease runs its usual course, as attested to by the physician treating the terminal illness.
- Aetna conducted a pilot to assess the impact of an enhanced hospice benefit. The enhanced benefit included an expanded definition of hospice eligibility to an estimated life expectancy of 12 months or less instead of the Medicare definition of 6 months or less.

**Administrative
Guidance (Continued)**

- A critical component of Aetna’s enhanced hospice program is the team of specially trained nurse care managers. These nurses receive additional training on how to work with patients and families telephonically to address end-of-life issues. They conduct a comprehensive assessment and develop individual plans of care to address patients’ needs and preferences. They assist patients and families by providing education on the disease process, completing advance directives, determining care preferences, identifying psychosocial support resources, and addressing palliative care and other needs. They also coordinate with treating physician(s) and hospice providers.¹⁻³
- Some patients have good performance status when they enroll in hospice and are able to live alone with support from the hospice team. As the terminal condition progresses and more assistance with activities of daily living is needed, the patient will require in-home care from family, friends, volunteers and/or paid caregivers. At some point, the patient may need to move in with a family member, move to an assisted living or skilled nursing facility (SNF) and receive hospice services there, or enroll in a residential hospice if one is available. Coverage for residential care is recommended since such support can help avoid unnecessary hospital admissions and related costs.
- Hospice programs must have Centers for Medicare & Medicaid Services (CMS) certification, should be accredited by The Joint Commission and/or the Community Health Accreditation Program (CHAP) and should participate in the National Hospice and Palliative Care Organization (NHPCO) Quality Partners program and performance measure reporting.

Supporting Information

[National Board for Certification of Hospice and Palliative Nurses](#)

RFP Assessment & Vendor Scoring

RFP Q 1.7-a

Does the medical plan include a hospice benefit as described in this recommendation for individuals with an estimated life expectancy of 12 months or less? [Yes/No]

Suggested Follow-up

If yes, the medical plan provides the medical policy or other documentation that it covers hospice services based on eligibility consistent with this recommendation.

If no, the medical plan documents its ability to implement the hospice benefit in a way that is consistent with this recommendation.

RFP Evaluation Criteria	<p>The response should address:</p> <ol style="list-style-type: none"> 1. Medical policy or other documentation stating that it covers hospice services. 2. Description of eligibility requirements. 3. Demonstrated ability to implement this recommendation.
RFP Q 1.7-b	<p>Does the medical plan 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]</p>
Suggested Follow-up	<p>If yes, the medical plan provides the medical policy or other documentation that it covers routine costs of care for individuals enrolled in an approved clinical trial while also enrolled in hospice.</p> <p>If no, the medical plan documents its ability to implement this benefit in a way that is consistent with this recommendation.</p>
RFP Evaluation Criteria	<p>The response should address payment for routine costs of care in clinical trials that are paid separately from the hospice per diem.</p>
RFP Q 1.7-c	<p>Does the medical plan 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]</p>
Suggested Follow-up	<p>If yes, the medical plan provides the medical policy or other written documentation stating that it covers residential services consistent with the options and eligibility criteria described in this recommendation.</p> <p>If no, the medical plan documents its ability to implement this benefit in a way that is consistent with this recommendation.</p>
RFP Evaluation Criteria	<p>The response should address:</p> <ol style="list-style-type: none"> 1. Coverage policy for residential services. 2. Eligibility criteria for coverage of residential services. 3. Demonstrated ability to implement this recommendation.
RFP Q 1.7-d	<p>Does the medical plan or other vendor provide care management support for individuals who have a diagnosis of cancer, an advanced illness and/or who are terminally ill? [Yes/No]</p>

Suggested Follow-up

If yes, is the care management program focused on this patient population or does it serve this patient population as part of a general care management program?

1. Care management program focuses on meeting the needs of individuals who have a diagnosis of cancer, an advanced illness and/or who are terminally ill.
2. Services are provided as 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.

Do nurses have specific training and experience with these conditions? [Yes/No] If yes, describe minimum required qualifications and training program.

Are nurses supported by a physician/medical director with expertise in cancer, palliative care and/or hospice care? [Yes/No]
If yes, describe the qualifications of the physician/medical director or provide a biosketch.

RFP Evaluation Criteria

The response should address:

1. Description of care management program model (i.e., focused on these specific populations or the general employee population).
2. Adequacy of training and experience of those staffing the program (nurses and physicians).

RFP Q 1.7-e

Does the medical plan administrator employ a qualification process for hospice programs to ensure that they have appropriate certification and meet quality standards? [Yes/No]

Suggested Follow-up

If yes, the medical plan indicates the method used to support this recommendation:

1. Criteria used to evaluate hospice programs are provided.
2. Written documentation indicating that criteria are used to evaluate hospice programs, but criteria are not provided.

RFP Evaluation Criteria

The response should address criteria used to evaluate hospice programs. (Refer to administrative guidance section for criteria.)

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.

Benefit Plan Recommendation

- **Applicable Plan:** General Medical
- **Benefit or Practice Definition:** Patient and family consultation on care planning
- **Recommended Cost Sharing:** Consistent with health care plan benefits
- **Recommended Copayment/Coinsurance Level:** Consistent with health care plan benefits
- **Covered Providers:** All network physicians. Palliative care and hospice physicians should be part of the contracted physician network.

Administrative Guidance

- In order to make informed decisions, patients should be made aware of all appropriate options, including the range of evidence-based, clinically appropriate treatments and the appropriate time to end active treatment. Options should take into account patient values and preferences, potential for cure, extended survival, relief of symptoms and quality of life.
- Treatment decisions should be made collaboratively among the physician, the patient and those the patient chooses to include in the decision-making process.
- Patients should also be educated about and encouraged to complete an advance directive early in the course of treatment so that their choices can be implemented if they are unable to speak for themselves.

RFP Assessment & Vendor Scoring

RFP Q 1.8 Does the medical plan cover consultation by a network physician with patients and family members about options for care at standard reimbursement rates? [Yes/No]

Suggested Follow-up If yes, medical plan provides medical policy or other documentation indicating it pays claims for evaluation & management (E&M) or consultation services when applicable CPT codes are used. This is true even if equivalent services were previously billed by other providers and claims were paid.

RFP Evaluation Criteria The response should include:

1. Policy for payment of evaluation and management claims.
2. CPT codes to be used.
3. Coverage and reimbursement procedures.

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.

Benefit Plan Recommendation

- **Applicable Plan:** General Medical
- **Benefit or Practice Definition:** Medical nutrition services
- **Recommended Cost Sharing:** Consistent with health care plan benefits
- **Recommended Copayment/Coinsurance Level:** Consistent with health care plan benefits
- **Covered Providers:** Registered dietitians that are Board-certified specialists in oncology (CSO)

Administrative Guidance

- Approximately 50%-60% of patients diagnosed with cancer experience significant weight loss and poor nutrition during the course of their illness.^{4,5}
- Individualized nutrition counseling results in clinically significant changes in quality of life, tolerance to treatment and improvement in performance status in patients with cancer during and after treatment.⁶
- Treatment side effects causing nutritional difficulties include nausea and vomiting, inflammation of the mucous membranes and stomach (mucositis and stomatitis), changes in taste of foods (dysgeusia), dry mouth (xerostomia), diarrhea, constipation, anorexia and immune suppression.
- Medical nutrition therapy (MNT) has been shown to be of benefit through the entire spectrum of cancer care, from prevention through treatment and recovery. MNT should be provided by appropriately trained and credentialed practitioners—registered dietitians that are Board-Certified specialists in oncology (CSO).⁷

RFP Assessment & Vendor Scoring

RFP Q 1.9-a

Does the medical plan cover nutrition counseling and medical nutrition therapy in conjunction with a diagnosis of cancer? [Yes/No]

Suggested Follow-up

If yes, medical plan indicates the method(s) used to support this recommendation:

1. Medical plan covers nutrition counseling and medical nutrition therapy when services are provided by registered dietitians.
2. Medical plan covers nutrition counseling and medical nutrition therapy when provided by registered dietitians for cancer only with prior authorization. [Yes/No]
 - a) If yes, what is the actual average turnaround time for prior authorization for nutrition counseling and medical nutrition therapy provided by registered dietitians for cancer?

If no, how will the medical plan implement this benefit in a way that is consistent with this recommendation?

RFP Evaluation Criteria

The response should address:

1. Evidence of current policy or ability to implement coverage consistent with this recommendation.
2. Acceptable turnaround time (72 hours).

RFP Q 1.9-b

Does the medical plan network include registered dietitians within its provider network, including dietitians that are Board-certified in oncology (CSO)? [Yes/No]

Suggested Follow-up

If yes, medical plan indicates the method(s) used to support this recommendation:

1. Medical plan network includes registered dietitians and uses an accreditation process to ensure that participating dietitians have required qualifications. Through this process, the medical plan confirms that dietitians who are Board-certified specialists in oncology (CSO) are included in the network when available.
2. Medical plan network includes registered dietitians but does not use an accreditation process to ensure that dietitians have the required qualifications.

If no, how will the medical plan implement this benefit in a way that is consistent with this recommendation?

RFP Evaluation Criteria

The response should address:

1. Accreditation process to ensure that participating dietitians have required qualifications.
2. Number of Board-certified specialists in oncology (CSO) in the network.
3. Ability to implement the recommendation consistent with this recommendation.

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.

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.

Benefit Plan Recommendation

- **Applicable Plan:** General Medical
- **Benefit or Practice Definition:** Preventive, restorative and reconstructive dental and oral health services when related to cancer, cancer treatment or stem cell transplantation and when not otherwise covered by the dental benefit, including:
 - oral examination and dental x-rays related to treatment or diagnosis;
 - extraction of teeth necessary before radiation or chemotherapy can take place;
 - non-surgical elimination of oral infection, including non-surgical periodontics;
 - preventive care related to the teeth, jawbones or gums, including fluoride treatment and prophylaxis to reduce bacterial flora of the teeth and gums, which may cause infection to spread beyond the mouth;
 - fillings, crowns or onlays if needed to treat dental disease;
 - custom fluoride trays and radiation trays; and
 - pulp testing (to help determine if a tooth requires root canal treatment).
- **Recommended Cost Sharing:** No specific limit; coverage to be considered part of medical benefit limits.
- **Recommended Copayment/Coinsurance Level:** Same as cost sharing for medical services.
- **Covered Providers:** Dentists in community or academic settings can provide preventive services and basic procedures, such as extractions, cleaning, fillings and crowns. Treatment of infections (root canals or gum disease) can be performed by dentists that specialize in these services in community or academic settings. Dentists, including maxillofacial surgeons and maxillofacial prosthodontists in academic medical centers/cancer centers with specialized expertise in treating cancer and transplant patients, should provide surgical, prosthetic and reconstructive services and should be included in the provider network.

Administrative Guidance

- Including dental and oral surgery services in a medical benefit is appropriate when the need for dental services—including preventive, restorative and reconstructive—is directly related to the cancer and/or cancer treatment. Dental services within a medical plan are primarily needed for individuals with head and neck cancers, those whose treatments affect the oral cavity, those who require dental services prior to treatment or those who need dental services to enable cancer treatment.
- Regular dental benefits are not intended or designed to cover many of these services, and are insufficient to cover most cancer-related needs.
- The target audience for this benefit is quite small, and the financial impact would be minimal. One analysis indicated that the incremental costs would be negligible – less than \$0.01 per member per month (PMPM).⁸
- Many individuals have untreated dental problems, such as gum disease, dental caries or infections, that must be treated prior to receiving immunosuppressive treatment, including chemotherapy, stem cell transplantation or organ transplants. In some cases, dental fillings, crowns, root canals or extractions are required prior to treatment to prevent or treat infections.
- Some cancer patients, including those who have surgery or receive radiation to the head and neck area and those who receive certain drugs that affect the oral cavity, will require both preventive and therapeutic dental services and/or maxillofacial reconstruction. This applies to most if not all head and neck cancer patients. These services are needed to restore the ability to speak, eat and swallow. Treatments include those to help patients open the mouth adequately to eat, brush their teeth and receive dental services.
- Dental appliances, prostheses or jawbone reconstruction may be needed following surgery to the mouth or jaw.
- Osteonecrosis (bone death caused by poor blood supply) or osteoradionecrosis (bone death caused by complications of radiation therapy) of the jaw may occur following treatment with certain chemotherapy drugs or radiation therapy. Therefore, pretreatment and medication may be required to minimize this side effect.
- Dental procedures provided at cancer centers should be covered under the medical benefit. This includes oral hygiene services, orthopedic (bone) and soft tissue implants, restorations, crowns, bridges and dentures for both the upper and lower jaws. These services will enable patients to receive safe, comprehensive and effective treatment and rehabilitation.⁹

RFP Assessment & Vendor Scoring

RFP Q 1.10-a

Does the medical plan cover dental preventive services and treatments when required prior to, during and after cancer treatment or stem cell transplantation? Furthermore, does the medical plan's standard benefit plan cover these services when they are not otherwise covered by dental benefits in a way that is consistent with this recommendation? [Yes/No]

Suggested Follow-up

If yes, the medical plan provides the medical policy or other written documentation that it covers dental services consistent with this recommendation.

If no, the medical plan describes how it will implement this benefit consistent with this recommendation.

RFP Evaluation Criteria

The response should address:

1. Coverage level for dental prevention services and treatments.
2. Coverage in-network or out-of-network.
3. Ability to implement the recommendation consistent with employer's requirements.

RFP Q 1.10-b

Does the 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]

Suggested Follow-up

If yes, the medical plan provides documentation that:

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

OR

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

RFP Evaluation Criteria

The response should address:

1. Accreditation criteria.
2. Geoaccess mapping or comparable evidence to demonstrate adequacy of dentists and oral surgeons in the network.

Medical Benefit 1.11

Recommended Benefit or Practice

Benefit plan should provide coverage for [molecular or 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.

Benefit Plan Recommendation

- **Applicable Plan:** General Medical
- **Benefit or Practice Definition:** Molecular testing
- **Recommended Cost Sharing:** Consistent with health care plan benefits
- **Recommended Copayment/Coinsurance Level:** Consistent with health care plan benefits
- **Covered Providers:** Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories

Administrative Guidance

- Molecular and biomarker tests have a variety of clinical uses: confirmation of diagnosis, identification of cancer subtype, estimation of prognosis, prediction of effectiveness of a therapy, prediction of side effects of a treatment, and monitoring of disease while the patient is undergoing therapy. Molecular and biomarker testing allows pathologists to better diagnose certain cancers and gives the oncologist important information on how an individual's cancer is expected to behave. After reviewing the results of these tests, the pathologist and oncologist can use them to determine if an individual has cancer; how aggressive the cancer is; what drugs, surgery, or radiation could be used to best treat the cancer; and/or whether the tumor has been eradicated after treatment.¹⁰
- New tests are continually being developed that, while of research interest, do not have a proven role in patient management. However, at this time, there is a lack of consistent coding to clearly identify specific tests. Several initiatives are underway, including the development of a methodology to determine when claims submitted are for tests that are recommended in NCCN Guidelines® and, in the future, the NCCN Molecular Testing Compendium.

Administrative Guidance (Continued)

- NCCN is developing a molecular and biomarker testing compendium that, like the NCCN Drugs & Biologics Compendium (NCCN Compendium[®]), will provide recommendations for the appropriate use of molecular tests and biomarkers to help oncologists provide effective care to their patients. It will help differentiate between those tests that comprise standard treatment and those that are not yet ready for routine use. This new compendium is expected to be available in mid-2012.
- Approximately 20% of molecular genetic tests are used inappropriately. Companion tests (used to determine if a drug is likely to be effective in treating an individual) that are considered “standard of care” are available for only a limited number of cancer drugs; other tests may be available but are considered unproven. As more drugs in the pipeline are labeled with a companion test, the potential for increased spending on tests also will grow. Therefore, it will be important to cover only those tests that are considered standard of care.^{11, 12}

Supporting Information

[Molecular and Biomarker Testing](#)

RFP Assessment & Vendor Scoring

RFP Q 1.11

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

Suggested Follow-up

1. Indicate the process used when evaluating new lab vendors that provide molecular tests and when evaluating existing lab vendors that provide molecular and biomarker testing.
2. Describe processes used to determine how these labs submit claims for molecular and biomarker testing.
3. Describe the data analytics utilized 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.

RFP Evaluation Criteria

Evaluation and scoring criteria forthcoming as the field matures.

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.

Benefit Plan Recommendation

- **Applicable Plan:** General Medical
- **Benefit or Practice Definition:** Genetic testing and counseling
- **Recommended Cost Sharing:** Consistent with health care plan benefits and applicable Affordable Care Act requirements
- **Recommended Copayment/Coinsurance Level:** Consistent with health care plan benefits
- **Covered Providers:** CLIA-accredited laboratories; certified genetic counselors

Administrative Guidance

- A number of cancers have a genetic component in their risk profiles. Hereditary cancers are often characterized by mutations associated with a high probability of cancer development. Assessment of an individual's risk of hereditary cancer is based on a thorough evaluation of family history. Advances in molecular genetics have identified a number of genes associated with inherited susceptibility to certain cancers.¹³
- Genetic testing should be available to individuals considered to be at high risk for developing a specific type of cancer based on family or personal cancer history. When used appropriately (consistent with NCCN Guidelines), genetic testing and genetic counseling can help individuals make informed decisions about whether to undergo more aggressive screening for cancer (to help ensure that it is diagnosed at an early, potentially curable stage), or possibly undergo risk reduction therapy. Therapy may include risk reduction drug therapy or surgery to remove the part of the body at highest

Administrative Guidance (Continued)

risk of cancer; for example, having a prophylactic mastectomy if a woman has the gene for breast cancer. Genetic testing can also help identify other family members who might benefit from genetic testing and counseling.

- Genetic counseling is a critical component of the cancer risk assessment process. Counseling places genetic risk in the context of other related risk factors. It should be customized to the experiences of the individual. The purpose of cancer genetic counseling is to educate individuals about the genetic, biological and environmental factors related to his/her cancer diagnosis and/or risk of disease to help them: (1) derive personal meaning from cancer genetic information and (2) empower them to make educated, informed decisions about genetic testing, cancer screening and cancer prevention.
- The information is most effective when tailored to the age and education of the person undergoing counseling and that individual's personal exposure to the disease, level of risk and social environment. Pre-test counseling is an essential element of the process. Post-test counseling must also be performed and includes disclosure of results, a discussion of the significance of the results, assessment of the impact of the results on the individual, discussion of the impact of the results on medical management, and how and where the patient will be followed. Discussion of other relatives' possible inherited cancer risk and the importance of informing family members about test results may also be necessary.¹⁴
- Genetic counseling should be conducted by certified professionals. With an estimated 2,400 genetic counselors in the U.S., there is a shortage of such experts. Some physicians, however, have specific training in medical genetics. Health plans should ensure that reasonable access to these experts is available within the provider network and that genetic counseling can be obtained telephonically if a genetic counselor is not available in the local community.

Supporting Information

[Genetic Testing and Counseling](#)

RFP Assessment & Vendor Scoring

RFP Q 1.12-a

Does the medical plan 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]

Suggested Follow-up	<p>If yes, the medical plan provides coverage policy or description of coverage.</p> <p>If no, the medical plan describes how it will implement this benefit in a way that is consistent with this recommendation.</p>
RFP Evaluation Criteria	Current practice or demonstrated ability to implement this coverage policy in a way that is consistent with this recommendation.
RFP Q 1.12-b	Does the medical plan 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]
Suggested Follow-up	<p>If yes, the medical plan describes the process used to ensure that counseling is covered only when provided by certified genetic counselors and other qualified providers.</p> <p>If no, the medical plan indicates how it will implement this benefit in a way that is consistent with this recommendation.</p>
RFP Evaluation Criteria	<p>The response should address:</p> <ol style="list-style-type: none"> 1. Evidence of certified genetic counselors in the provider network. 2. Evidence of ability to ensure coverage of genetic counseling services when provided by Board-certified or Board-eligible counselors and other qualified professionals.
RFP Q 1.12-c	Does the medical plan network provide access to Board-certified or Board-eligible genetic counselors and medical geneticists? [Yes/No]
Suggested Follow-up	<p>If yes, the medical plan describes the method used to support this recommendation:</p> <ol style="list-style-type: none"> 1. Medical plan network includes Board-certified or Board-eligible genetic counselors and uses an accreditation process to ensure that genetic counselors have the required qualifications. <p>OR</p> <ol style="list-style-type: none"> 2. Medical plan network includes Board-certified or Board-eligible genetic counselors but does not use an accreditation process to ensure that they have the required qualifications.

RFP Evaluation Criteria	The response should address: <ol style="list-style-type: none"> 1. Accreditation criteria. 2. Geoaccess mapping or comparable evidence to demonstrate adequacy of certified genetic counselors in the network.
RFP Q 1.12-d	Does the medical plan network cover genetic counseling services when provided in person and/or telephonically? [Yes/No]
Suggested Follow-up	<p>If yes, the medical plan describes the process used to ensure that genetic counseling services are covered whether provided in person or telephonically.</p> <p>If no, the medical plan indicates how it will implement this benefit in a way that is consistent with this recommendation.</p>
RFP Evaluation Criteria	Demonstrated experience or ability to ensure that genetic counseling services are covered whether provided in person and/or telephonically.

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.
Benefit Plan Recommendation	<ul style="list-style-type: none"> • Applicable Plan: General Medical • Benefit or Practice Definition: Fertility preservation for individuals with iatrogenic infertility. (This recommendation does not address benefits for in vitro fertilization [IVF] for non-iatrogenic infertility, other reproductive services or “other parenting options” such as surrogacy and adoption.)

Benefit Plan Recommendation (Continued)

- **Recommended Cost Sharing:** Same as for other services covered under the policy
- **Recommended Copayment/Coinsurance Level:** Same as for other services covered under the policy
- **Covered Providers:** Physicians with Board certification (by the American Board of Obstetrics and Gynecology) in reproductive endocrinology.

Administrative Guidance

- For benefit plans that already have traditional infertility coverage, the plan can amend the definition of infertility to allow access to the benefit for those at risk for infertility resulting from necessary medical treatments. Any requirement to demonstrate attempts to conceive for six months or longer before infertility benefits become available should be waived for individuals at risk for iatrogenic infertility.
- If the benefit plan does not currently include infertility coverage, then coverage should be added for medically necessary expenses for standard fertility preservation treatments when a necessary medical treatment may directly or indirectly cause iatrogenic infertility (an unintended consequence of cancer treatment).
- A study undertaken by **LIVESTRONG** estimates that covering fertility preservation services would cost approximately \$0.03 PMPM. This cost calculation was confirmed in an independent analysis undertaken by the State of California as part of its review about whether to require such coverage in health plans governed by the state. The calculation assumes that covered services are sperm banking and embryo freezing. The state also estimates that cost savings may exist. Research shows that breast cancer patients take future fertility into account when making cancer treatment decisions; some patients may forgo more effective treatment to avoid infertility, leading to higher costs for treatment of metastatic cancer in the future.¹⁴⁻¹⁶

RFP Assessment & Vendor Scoring

RFP Q 1.13

Does the medical plan's 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]

Suggested Follow-up

If yes, the medical plan should provide documentation of process utilized to confirm that the patient is at risk of infertility related to a planned cancer treatment.

If no, the medical plan describes how it will administer this benefit in a way that is consistent with this recommendation.

RFP Evaluation Criteria

The response should include policy and procedures used to confirm that the patient is at risk of infertility related to a planned cancer treatment.

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.

Benefit Plan Recommendation

- *Applicable Plan:* General Medical
- *Benefit or Practice Definition:* Home health services
- *Recommended Cost Sharing:* None
- *Recommended Copayment/Coinsurance Level:* No cost to the beneficiary
- *Covered Providers:* Certified home health care agencies included in the plan network

Administrative Guidance

Cancer care may be offered in the home setting in lieu of care in a physician's office. Furthermore, home care may be more cost-effective, more convenient and safer for patient and caregivers.

RFP Assessment & Vendor Scoring

RFP Q 1.14

Does the medical plan cover home health visits consistent with this recommendation? [Yes/No]

Suggested Follow-up

If yes, the medical plan provides 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 the medical plan will administer this benefit in a way that is consistent with this recommendation.

RFP Evaluation Criteria

The response should address:

1. Number of home health visits or hours of home health services.
2. Conditions under which services are covered.
3. Process for approval of additional home health services.

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.

Benefit Plan Recommendations

- *Applicable Plan:* Stop-loss insurance
- *Benefit or Practice Definition:* Covered benefits are consistent between the health plan and the stop-loss carriers.
- *Recommended Cost Sharing:* N/A
- *Recommended Copayment/Coinsurance Level:* N/A
- *Covered Providers:* N/A

Administrative Guidance

- In health insurance, stop-loss is a policy that takes effect after a certain amount has been paid in claims. Companies providing health insurance for their employees through a self-insured plan often subscribe to stop-loss policies in order to protect themselves against catastrophic claims.

Administrative Guidance (Continued)

- Some companies that issue stop-loss insurance offer policies that, at times, conflict with the coverage chosen by a self-funded employer and established through language in its Summary Plan Description (SPD) or other plan documents. This misalignment of coverage policies can result in (1) the stop-loss carrier declining to cover catastrophic claims for certain patients; (2) refusal of the stop-loss carrier to write coverage for certain types of claims; or (3) the stop-loss carrier charging a substantially higher premium in exchange for agreeing to cover situations that are in conflict with the carrier's usual policies.
- Typically, conflicting policies are found between an employer and the stop-loss carrier when claims are submitted that include (1) a patient's current or past participation in a clinical trial and (2) drugs or biologics that do not have FDA approval for that specific use ("off-label" use).

RFP Assessment & Vendor Scoring

RFP Q 1.15

Does the stop-loss carrier's contract with the employer clearly state that it covers 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]

Suggested Follow-up

If yes, the stop-loss carrier covers 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, the stop-loss carrier indicates how it will implement this benefit in a way that is consistent with this recommendation.

RFP Evaluation Criteria

The response should address language in the contract with the employer that specifies how the stop-loss carrier will implement this coverage in a way that is consistent with this recommendation and the employer's SPD and plan document 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 timely diagnosis and effective treatment of depression.
- To minimize the cost impact for patients with cancer and comorbid depression through quicker diagnosis.

Benefit Plan Recommendations

- **Applicable Plan:** General Medical
- **Benefit or Practice Definition:** Depression screening using a standardized instrument
- **Recommended Cost Sharing:** Same level whether in a community setting or at large, academic cancer centers
- **Covered Providers:** Network physicians and other network providers.

Administrative Guidance

Surveys have found that 20%-40% of newly diagnosed and recurrent cancer patients show a significant level of distress, a term that includes depression, anxiety and other unpleasant psychological states. However, less than 10% of patients are actually identified and referred for psychosocial help.

Failure to recognize and treat distress leads to several problems: trouble making decisions about treatment and adhering to treatment, extra visits to the physician's office and emergency room and greater time and stress for the oncology team. Early evaluation and screening for distress leads to early and timely management of psychological distress, which in turn improves medical management.^{17, 18}

RFP Assessment & Vendor Scoring

RFP Q 1.16-a

Does the medical plan cover depression screening (performed by oncologists and other covered providers) for all cancer patients and other beneficiaries? [Yes/No]

Suggested Follow-up	<p>If yes, indicate the method(s) used to support this recommendation (select all that apply):</p> <ol style="list-style-type: none"> 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 Evaluation Criteria	<p>The response should address:</p> <ol style="list-style-type: none"> 1. Specific policies as well as administrative and reimbursement procedures that support depression screening of patients in a medical setting. 2. Methods of establishing expectations with providers for depression screening of patients. 3. Methods of monitoring provider compliance with referenced policies and procedures. 4. Peer-reviewed literature that supports use of the referenced depression screening tools.
RFP Q 1.16-b	<p>Does the plan reimburse depression screening procedures as a unique lab test? [Yes/No]</p>
Suggested Follow-up	<p>If yes, list applicable CPT codes supported by the plan and covered providers eligible to perform this screening.</p>
RFP Evaluation Criteria	<p>The response should address:</p> <ol style="list-style-type: none"> 1. Specific policies as well as administrative and reimbursement procedures that support depression screening of patients in the medical setting. 2. Methods of establishing expectations with providers for depression screening of patients. 3. Methods of monitoring provider compliance with referenced policies and procedures.

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.

Benefit Plan Recommendations

- **Applicable Plan:** General Medical
- **Benefit or Practice Definition:** Behavioral health screening
- **Recommended Cost Sharing:** Same level whether in a community setting or at large, academic cancer centers
- **Recommended Copayment/Coinsurance Level:** Same level whether in a community setting or at large, academic cancer centers
- **Covered Providers:** Network physicians and other network providers

Administrative Guidance

- Because a significant number of plan members select approved providers to treat their behavioral health condition, employers would be well served to work with their medical plan to clearly define the covered services and related reimbursement schedules needed to clinically manage these members' conditions.
- These clinical services can be organized into four types of services:
 - **Screening:** The identification of key factors/symptoms that may indicate the prevalence of a condition such as depression in patients with cancer.
 - **Assessment:** A structured, systematic process for observing and understanding the characteristics of an individual. For assessing behavioral health conditions, these characteristics are typically classified as biological, psychological or social/functioning traits.
 - **Diagnosis:** A formal method of determining whether an individual exhibits signs and symptoms that correspond to a particular disorder or disease.
 - **Treatment:** A formal intervention designed to reduce or mask the symptoms associated with a particular disorder or disease and/or increase the individual's functional abilities.

RFP Assessment & Vendor Scoring

RFP Q 1.17

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

Suggested Follow-up

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).

RFP Evaluation Criteria

- The response should address:
1. Specific policies as well as administrative and reimbursement procedures that address provider screening, assessment and diagnosis activities, including the extent to which non-behavioral health specialists are to be reimbursed for treatment services for behavioral health conditions.
 2. Provider communication materials that support the Practice Recommendation.
 3. Methods of monitoring provider compliance with referenced policies and procedures (e.g., chart or claims audit).

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.

Benefit Plan Recommendations

- **Applicable Plan:** General Medical and Behavioral Health
- **Benefit or Practice Definition:** Collaborative care
- **Recommended Cost Sharing:** Same level whether in a community setting or at large, academic cancer centers
- **Recommended Copayment/Coinsurance Level:** Same level whether in a community setting or at large, academic cancer centers
- **Covered Providers:** Network providers

Administrative Guidance

Collaborative care incorporates several key components, all of which should be covered by the employer's general medical benefit:

- Screening for behavioral disorders to identify the symptoms associated with a behavioral health diagnosis.
- Assessment to confirm a behavioral health diagnosis.
- Patient education to help the patient select treatment options.
- Treatment (e.g., pharmacotherapy and/or psychotherapy).
- In-person and telephonic care management by a qualified professional who works with and is supervised by the oncologist or primary care provider (PCP). This professional should:
 - coordinate patient education related to the behavioral health diagnosis and help the patient select treatment options;
 - coordinate an initial treatment plan with the PCP and the patient;
 - work with the patient to implement and support the treatment plan, including monitoring patient progress;
 - track clinical outcomes according to the treatment plan outlined by the PCP and work with the oncologist or the PCP to adjust treatment (including making a referral for specialty care, as needed) in cases of lack of progress or adverse effects; and
 - document all activities relating to each case in a file to be stored with the patient's medical record.

Clinical consultation should be provided to the PCP and/or care manager by a qualified behavioral health specialist.

RFP Assessment & Vendor Scoring

RFP Q 1.18

Does the medical plan 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]

Suggested Follow-up

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 patient 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 PCP.
6. Clinical consultation provided by a qualified specialty behavioral health provider to the PCP and/or care manager.

RFP Evaluation Criteria

The response should address:

1. Specific policies as well as administrative and reimbursement procedures that support collaborative care services.
2. Methods of coordinating collaborative care efforts with behavioral health vendors/plan administrators.
3. Methods of establishing expectations for collaborative care with providers.
4. Methods of monitoring provider compliance with referenced policies and procedures.
5. Peer-reviewed literature that supports using the referenced patient management protocols.

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.

Benefit Plan Recommendation

- **Applicable Plan:** General Medical and Behavioral Health
- **Benefit or Practice Definition:** Evidence-based behavioral health care
- **Recommended Cost Sharing:** Same level whether in a community setting or at academic cancer centers
- **Recommended Copayment/Coinsurance Level:** Same level whether in a community setting or at large, academic cancer centers.
- **Covered Providers:** Behavioral Health providers

Administrative Guidance

Individuals with cancer may benefit from or require behavioral health care services from providers with experience and expertise in working with cancer patients.

RFP Assessment & Vendor Scoring

RFP Q 1.19

Does the medical plan credential and contract with behavioral health providers at network cancer centers and children’s hospitals?

Suggested Follow-up

- If yes:
1. What is the medical plan’s 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?

RFP Evaluation Criteria

- The response should address:
1. Credentialing criteria indicating that the behavioral health providers have the necessary skills and knowledge to treat cancer patients, including pediatric cancer patients.

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 medications needed to treat their condition, including maintenance and supportive care drugs.

- The benefit plan should include one individual and one family out-of-pocket maximum that applies to combined medical and pharmacy expenditures.
- Per-prescription copayment and/or coinsurance requirements should be established at a reasonable level.

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.

Objective(s)

- 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.

Benefit Plan Recommendation

- **Applicable Plan:** Pharmacy and Medical Benefits
- **Benefit or Practice Definition:** Pharmacy benefit plan cost sharing
- **Recommended Cost Sharing:** 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. One out-of-pocket maximum should apply to combined medical and pharmacy expenditures.
- **Covered Providers:** Pharmacy benefit manager and Specialty Pharmacy

Administrative Guidance

- Some employers have implemented increased cost sharing and/or instituted coinsurance instead of a fixed copayment for high-cost drugs to make employees more cost sensitive. This approach can have unintended consequences for cancer patients who are unable to both manage the cost of their medications and take their medications as directed.
- Recent studies identified the relationship between higher out-of-pocket costs to beneficiaries and a higher prescription abandonment rate for oral oncology drugs. In the first study, the overall rate was 8.5%, but the rate rose to 16.1% for those with out-of-pocket expenses between \$201 and \$500. For those with out-of-pocket expenses greater than \$500, the abandonment rate was 28.8%. The rate was 4.9% for those with out-of-pocket costs of \$100 or less. Results of the second study were comparable.^{20, 21}
- High deductible health plans (HDHP) with an accompanying health savings account that conforms to IRS standards may not be able to adopt this structure; employees enrolled in this type of plan must pay the full deductible before any type of cost sharing for non-preventive treatments is offered. After the deductible has been met, Pharmacy Benefit Recommendation 2.1 may be put into place. Employers offering HDHPs should consult their legal counsel prior to adjusting their plan design to ensure that it reflects Recommendation 2.1.

RFP Assessment & Vendor Scoring

RFP Q 2.1-a

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

Suggested Follow-up

If the threshold exceeds the limits of the recommendation, how will the pharmacy vendor customize the plan to be consistent with this recommendation?

RFP Evaluation Criteria

Evidence of current practice or ability to implement copayments that are consistent with this recommendation.

RFP Q 2.1-b

Do the pharmacy and medical benefit plan administrators currently work together to implement a single out-of-pocket maximum for medical and pharmacy expenditures? [Yes/No]

Suggested Follow-up	<p>If yes, provide examples of how the collaboration has been successfully implemented.</p> <p>If no, how will the pharmacy and medical benefit plan administrators work together to implement a single out-of-pocket maximum?</p>
RFP Q 2.1-c	Does the SP program provide counseling services to individuals obtaining oncology medications? [Yes/No]
Suggested Follow-up	If yes, describe the objectives of the counseling services. Describe the qualifications of staff that counsel individuals obtaining oncology medications.
RFP Evaluation Criteria	<p>The response should address:</p> <ol style="list-style-type: none"> 1. Ability to minimize nonadherence and promote safe use of medications. 2. All relevant certifications of counseling staff or summary of qualifications. Preferred qualifications, in this order, are: <ol style="list-style-type: none"> a. Board-certified oncology pharmacists (BCOP) b. Clinical pharmacists c. Generalist pharmacists
RFP Q 2.1-d	Does the SP program provide access to information about programs to assist patients with the costs of prescription drugs? [Yes/No]

Pharmacy Benefit 2.2

Recommended Benefit or Practice

Administrators of medical plans, pharmacy benefit management (PBM) programs, specialty pharmacy 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 Drugs & Biologics Compendium](#) (NCCN Compendium®) with Category 1, 2A or 2B level of evidence.

In regard to cancer treatment, employers should adopt the NCCN Drugs & Biologics Compendium® in its entirety.

Objective(s)	<ul style="list-style-type: none"> To ensure that patients receive evidence-based treatment when diagnosed with cancer.
Benefit Plan Recommendation	<ul style="list-style-type: none"> Applicable Plan: Pharmacy Benefit Benefit or Practice Definition: Evidence-based coverage of drugs and biologics. Recommended Cost Sharing: Consistent with the company's benefit plans; no difference in cost sharing for off-label drugs and biologics when consistent with the recommendations in the NCCN Compendium[®] and compared to drugs and biologics that are not off-label. Recommended Copayment/Coinsurance Level: N/A Covered Providers: N/A
Administrative Guidance	<ul style="list-style-type: none"> Off-label use of drugs is much more common in cancer treatment than in the treatment of other conditions. An estimated 50% or more of cancer care is off label; that is, the drug has FDA approval but not for its use in that specific manner.²² NCCN Drugs & Biologics Compendium (NCCN Compendium[®]) is widely viewed as the most comprehensive, up-to-date, evidence-based set of recommendations for cancer care and is widely used as the basis for determining coverage policy by Medicare, Aetna, UnitedHealthcare and others. Using the Compendium as the basis for coverage policy ensures that employers pay only for appropriate treatments—options supported by evidence. The NCCN Compendium[®] also ensures that a consistent standard is used to determine coverage of therapeutic and supportive care agents, rather than having coverage decisions made on an ad hoc basis. The NCCN Compendium, which is derived directly from NCCN Guidelines, provides disease-specific recommendations based on the available evidence from clinical trials and the clinical experience of experts, extrapolating from trials data to clinically similar situations. This is particularly important in oncology because the agents used to treat cancer have side effects that would be unacceptable for a non life-threatening condition. Each treatment decision requires a risk/benefit analysis, balancing the probability of cancer control with the possibility of unacceptable toxicity. Such complications can require treatment and occasionally hospitalization, decreasing quality of life and increasing costs. Therefore, it is important that these agents be used appropriately and only for patients who are likely to benefit. Understanding that the final decision-making authority must rest with the treating physician based on the specific clinical circumstances, NCCN Guideline panels make recommendations that are appropriate for the majority of patients. These recommendations provide appropriate treatment choices while limiting access to treatments that are more likely to cause harm than to benefit the patient.

RFP Assessment & Vendor Scoring

RFP Q 2.2 Do administrators of medical plans, pharmacy benefit management (PBM) programs, specialty pharmacy benefit plans and any other relevant organizations ensure that plans cover evidence-based cancer treatment, whether paid under the medical or pharmacy benefit based on [NCCN Guidelines and Drugs & Biologics Compendium](#) (NCCN Compendium®) recommendations for products with Category 1, 2A or 2B level of evidence? [Yes/No]

Suggested Follow-up

If yes, plan administrators describe the criteria for evidence-based cancer pharmacy treatment and/or medical benefit plans used to determine coverage for drugs and biologics in cancer care based on NCCN Drugs & Biologics Compendium® recommendations with Category 1, 2A or 2B level of evidence.

If no, describe current criteria for coverage determination and indicate how pharmacy and/or medical benefit plans will customize their practices to determine coverage for drugs and biologics in cancer care based on NCCN Drugs & Biologics Compendium recommendations with Category 1, 2A or 2B level of evidence.

RFP Evaluation Basis of evidence for coverage of evidence-based treatment consistent with this recommendation.

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.

Benefit Plan Recommendation

- Applicable Plan:** Medical and Pharmacy Benefits
- Benefit or Practice Definition:** Cost-sharing parity between medical and pharmacy benefits
- Recommended Cost Sharing:** Equivalent out-of-pocket costs to patients in medical and pharmacy benefit

Administrative Guidance

- According to draft language in the proposed law [Cancer Drug Parity Act of 2009](#) of the 111th Congress, parity in coverage of oral cancer drugs means that a group health plan that “provides benefits with respect to intravenously administered or injected cancer medications shall provide for no less favorable coverage for prescribed, orally administered anticancer medication used to kill or slow the growth of cancerous cells. The coverage for such medication may be subject to annual deductibles, and coinsurance provisions as may be applicable to intravenously administered or injected cancer medications under the plan or coverage.”
- Increasingly, oral chemotherapy is being used as an effective treatment option for certain types of cancer. However, high coinsurance or a high copayment may make the oral medications unaffordable to the patient and could result in a decision to receive chemotherapy as an infusion in the physician’s office or outpatient hospital setting.²³

RFP Assessment & Vendor Scoring

RFP Q 2.3

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

Suggested Follow-up

If yes, describe current process.

If no, how should the medical and pharmacy benefit plans work together to establish parity?

RFP Evaluation Criteria

The effectiveness of the existing process in place or a description of the process to be implemented and followed to achieve this objective.

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.

Benefit Plan Recommendation

- *Applicable Plan:* General Medical plan or through direct contracting with vendor.
- *Benefit or Practice Definition:* Nurseline services
- *Recommended Cost Sharing:* N/A
- *Recommended Copayment/Coinsurance Level:* N/A
- *Covered Providers:* N/A

Administrative Guidance

- Credible information on prevention and screening, cancer diagnoses, cancer treatment options and other topics should be provided by clinical staff with access to resources that have been evaluated and approved as evidence-based and credible.
- Nurses and others staffing these resources should be trained and prepared to provide general information about cancer-related topics (diagnoses and treatments), community resources and topics relevant to those with a diagnosis of cancer, such as advance directives, hospice, palliative care and clinical trials.

RFP Assessment & Vendor Scoring

RFP Q 3.1-a

Does the medical plan or separate vendor provide assistance related to a cancer diagnosis via a nurseline service that offers information on cancer-related clinical issues and community resources? [Yes/No]

Suggested Follow-up

If yes, medical plan or nurseline vendor:

1. Provides 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. Describes 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, medical plan or nurseline vendor describes how it will provide this type of service.

RFP Evaluation Criteria

1. Scope of information provided by medical plan or nurseline program.
2. Credibility of sources for information provided.

RFP Q 3.1-b

Does the medical plan or other vendor employ appropriately trained nurses and/or others to staff the nurseline program? [Yes/No]

Suggested Follow-up

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.

RFP Evaluation Criteria

1. Required qualifications of nurses and others.
2. Scope or initial and ongoing training.

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.

Benefit Plan Recommendation

- **Applicable Plan:** General Medical plan or through direct contracting with vendor.
- **Benefit or Practice Definition:** Cancer care management
- **Recommended Cost Sharing:** N/A
- **Recommended Copayment/Coinsurance Level:** N/A
- **Covered Providers:** N/A

Administrative Guidance

- Because cancer consists of dozens of different diagnoses, with many different treatment approaches, it is unrealistic to expect nurses without an oncology background to provide the kind of information and support that individuals with cancer and their loved ones often need.
- Nurses should have several years of oncology nursing experience and/or case management experience, with OCN (oncology-certified nurse) accreditation; CCM (certified case manager) accreditation is desirable. Nurses should be supported by a physician or physicians with oncology expertise, either as program medical directors or as consultants. Oncology social workers are an additional valuable component of such a program. They can provide information on resources and offer psychosocial support to patients and caregivers.
- Nurses and others staffing a cancer management program should be trained and prepared to provide treatment decision support and in-depth information about a wide range of cancer-related topics, including community resources, advance directives, hospice, palliative care and clinical trials. They should be able to discuss issues that need to be considered in deciding where to go for treatment or to get a second opinion. They should be trained on cultural issues in order to effectively serve diverse populations in terms of age, ethnicity and education level.

**Administrative
Guidance (Continued)**

- Cancer case management program staff should be able to coordinate and collaborate with wellness, prevention and screening programs as part of a comprehensive cancer solution.

RFP Assessment & Vendor Scoring

RFP Q 3.2-a

Does the medical plan or external vendor offer a cancer case management/disease management program? [Yes/No]

Suggested Follow-up

If yes, medical plan or case management vendor describes 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 Evaluation Criteria

1. Program's focus on cancer.
2. Qualification of nurses who staff the program (Minimum qualifications: RN or BSN, with 3-5 years of clinical experience in oncology. Previous case management experience, OCN (oncology-certified nurse) and/or CCM (cancer case manager) credentials are also valuable).
3. Physician/medical director with oncology experience and expertise.
4. Robust training program.
5. Primary nurse model: Patients are assigned one nurse for the duration of their participation.

RFP Q 3.2-b

Does the medical plan or external vendor's case management program include social workers with oncology experience to support patients and their families? [Yes/No]

Suggested Follow-up

If yes:

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

RFP Evaluation Criteria

1. Social workers have oncology experience.
2. Robust training program.

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Tool 3, Part II: Request for Proposal (RFP) and Response Evaluation for Employers



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

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PlusOne Studios LLC, Graphic Design

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

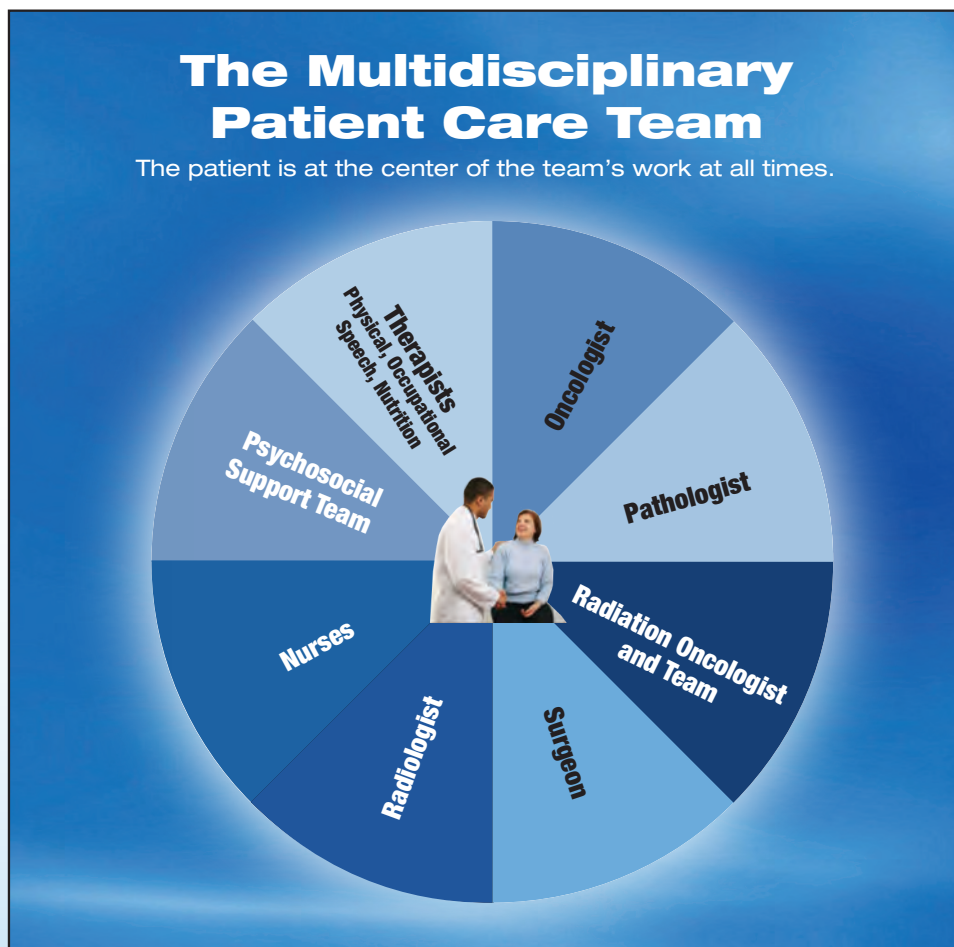
1. Higher volume was linked with lower mortality for pancreatectomy, esophagectomy, liver resection and pelvic exenteration, but most strikingly for esophagectomy and pancreatectomy. Low volume was strongly associated with excess mortality. For esophagectomies, there was a fourfold decrease, and for 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.

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.

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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](#).

Routine Costs of Care for Cancer Clinical Trials

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 SPD 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, effective and 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, the average clinical trial participation rate for adults is very low (about 3%). Pediatric cancer care is provided more often as part of a clinical trial. As a result, 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:

- Covered health services for which benefits are typically provided when not part of a clinical trial;
- 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
- Covered health services needed for reasonable and necessary care arising from the provision of an investigational item or service.

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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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