

CLINICAL TRIALS

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Overview

Clinical trials are research studies using human subjects. There are many different types of clinical trials, including treatment trials, prevention trials and observation trials.

Clinical trials that are designed to answer specific questions about or evaluate the effectiveness or safety of a drug or device are known as treatment trials.

Research using human subjects must be conducted according to strict scientific and ethical principles. Every clinical trial must have a study protocol. The protocol describes why the clinical trial is being conducted and how the trial will be conducted. The clinical trial protocol also includes eligibility criteria. Eligibility criteria are the characteristics that must be shared by all participants in the trial. Eligibility criteria may include age, gender, medical history, and health status. Eligibility criteria for cancer treatment studies require that participants have a particular type and/or stage of cancer.

People who participate in clinical trials are required to sign an informed consent. The informed consent includes details about what is involved in the clinical trial, such as the purpose of the clinical, the tests and other procedures used in the clinical trial, and the possible risks and benefits. Signing the informed consent does not obligate a person to stay in the study. A person can withdraw from a study at any time before the study starts or at any time during the study or the follow-up period.

Policy

Commercial plan

Massachusetts General Law requires coverage for patient care services (defined herein) furnished pursuant to qualified clinical trials (defined herein) to the same extent as they would be covered if the patient did not receive care in a qualified clinical trial. FCHP provides coverage for patient care services provided to commercial plan (defined herein) members enrolled in qualified clinical trials, subject to the terms and conditions of the plan, including, but not limited to, the use of plan providers, referral and authorization requirements, benefit limits, and cost-sharing (e.g., copayments), as specified in the plan member's Evidence of Coverage.

The term 'patient care service' is defined as a health care item or service that is furnished to a plan member enrolled in a qualified clinical trial which:

1. is consistent with the usual and customary standard of care for someone with the plan member's diagnosis,
2. is consistent with the study protocol for the clinical trial, and
3. would be covered if the plan member did not participate in the clinical trial.

The term patient care service does not include the following:

1. The investigational item itself (however an investigational item that has been approved for use in a qualified clinical trial, whether or not the FDA has approved the item for use in treating the plan member's condition, will be considered a patient care service when the investigational item is not paid for by the manufacturer, distributor or provider of the investigational item),
2. Non-healthcare services that a plan member may be required to receive as a result of being enrolled in the clinical trial,
3. Costs associated with managing the research associated with the clinical trial,
4. Costs that would not be covered for non-investigational treatments,
5. Any item, service or cost that is reimbursed or otherwise furnished by the sponsor of the clinical trial,
6. The costs of services which are inconsistent with widely accepted and established national or regional standards of care,
7. The costs of services which are provided primarily to meet the needs of the trial, including, but not limited to, tests, measurements, and other services which are typically covered but which are being provided at a greater frequency, intensity or duration, or
8. Services or costs that are not covered under the plan member's contact with the health plan.

A clinical trial is a 'qualified clinical trial' is when all of the following conditions are met:

1. The clinical trial is intended to treat cancer in a plan member who has been so diagnosed;
2. The clinical trial has been peer-reviewed and is approved by one of the following:
 - a. United States National Institutes of Health;
 - b. a Cooperative Group or Center of the National Institutes of Health;
 - c. a qualified nongovernmental research entity identified in guidelines issued by the National Institutes of Health for center support grants;
 - d. the United States Food and Drug Administration in the form of an investigational new drug exemption;
 - e. the United States Departments of Defense or Veterans Affairs; or
 - f. with respect to Phase II, III and IV clinical trials only, a qualified institutional review board. An institutional review board shall qualify if it:
 - i. meets all federal requirements for the operation of institutional review boards as identified in the Code of Federal Regulations;
 - ii. is not disqualified to oversee clinical research by the National Institutes of Health or the Food and Drug Administration for noncompliance with federal law; and
 - iii. has taken corrective action to rectify any noncompliance issue raised by the National Institutes of Health or the Food and Drug Administration within the past three years and has passed all subsequent National Institutes of Health or Food and Drug Administration inspections, audits or examinations.
3. The facility and personnel conducting the clinical trial are capable of doing so by virtue of their experience and training and treat a sufficient volume of patients to maintain that experience;
4. With respect to Phase I clinical trials, the facility is an academic medical center or an affiliated facility, and the clinicians conducting the trial shall have staff privileges at said academic medical center;
5. The plan member meets the selection criteria enunciated in the study protocol for participation in the clinical trial;

6. The plan member has provided his or her informed consent for participation in the clinical trial, in a manner that is consistent with current legal and ethical standards;
7. The available clinical or pre-clinical data provide a reasonable expectation that the patient's participation in the clinical trial will provide a medical benefit that is commensurate with the risks of participation in the clinical trial;
8. The clinical trial does not unjustifiably duplicate existing studies; and
9. The clinical trial must have a therapeutic intent and must, to some extent, assess the effect of the intervention on plan member.

Fallon Senior Plan™

Routine Costs Associated with Qualifying Clinical Trials

Effective September 19, 2000, Medicare began covering routine costs associated with qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in clinical trials. For additional details on Medicare coverage for qualifying clinical trials, refer to: Medicare National Coverage Determinations Manual 100-3, Chapter 1, Part 4, Section 310.1:

<http://www.cms.hhs.gov/Manuals/IOM/list.asp>.

Medicare requires Medicare Advantage plans, such as Fallon Senior Plan™, to cover all Medicare-covered services, however, Medicare regulations provide that when a Medicare National Coverage Determination meets a certain threshold for significant cost, a Medicare Advantage plan may direct providers to submit claims for such services to Medicare until such time as the Medicare capitation rate to the Medicare Advantage plan is adjusted to include payment for these services. Routine costs associated with qualifying clinical trials meets the significant cost threshold and FCHP has directed providers to submit claims directly to Medicare for these services. There is no change in FCHP's obligation to provide benefits for all other services covered under Fallon Senior Plan™.

Fallon Senior Plan™ members do not need to meet Original Medicare Part A/B fee-for-service deductibles, however, Fallon Senior Plan™ members are responsible for other Original Medicare cost sharing for Medicare-covered services associated with qualifying clinical trials. Effective January 1, 2011, FCHP will reimburse members for cost sharing incurred for Medicare-covered services associated with qualifying clinical trials that exceeds the plan members' in-network cost sharing for the same category of services. Fallon Senior Plan™ members do not need a referral or authorization from FCHP to participate in a clinical trial. Fallon Senior Plan™ members are asked to notify FCHP by calling Customer Service at 1-800-868-5200 before enrolling in a clinical trial.

Category B Investigational Devices

On November 1, 1995, Congress enacted legislation that permits Medicare coverage of FDA-granted Category B investigational devices. Category B investigational devices are newer generation devices of already proven technologies. Initial questions of safety and effectiveness have been resolved. Devices in this category represent evolutionary changes in proven technologies and are viewed as potentially reasonable and necessary by Medicare. This legislation does not guarantee that all Category B devices will be covered under Medicare. It is the Medicare Administrative Contractor (or Medicare Advantage plan as costs for Category B investigational devices are included in the Medicare Advantage payment rates) who makes the final coverage decision based on

the submission of the required documentation. Category B investigational devices must be used in the context of an FDA-approved clinical trial.

FCHP provides coverage for Category B investigational devices and for the routine costs (defined herein) associated with Category B investigational device exemption (IDE) trials, subject to the terms and conditions of the plan, including, but not limited to, the use of plan providers, referral and authorization requirements, benefit limits, and cost-sharing (e.g., copayments), as specified in the plan member's Evidence of Coverage, when all of the following criteria are met:

1. The device must be used within the context of an FDA-approved clinical trial. The device must have an assigned IDE number.
2. The device must be used according to the clinical trial's approved study protocol. The study protocol limits the use of the device to a predetermined limited number of sites and a predetermined limited number of patients.
3. The device must be medically necessary for the particular patient and the amount, duration, and frequency of use or application of the service must be medically appropriate.
4. The device must be furnished in a setting appropriate to the patient's medical needs and condition.
5. The device is not statutorily excluded (e.g., hearing aid) or otherwise non-covered through regulation or a current Medicare National Coverage Determination or Local Coverage Determination.

'Routine costs' include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national or local non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial. Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service--in particular, for the diagnosis or treatment of complications.

Navicare

Navicare is a health care program for people 65 years of age or older who have Medicare and MassHealth Standard, or MassHealth Standard alone. Navicare members receive all the Medicare benefits plus all the MassHealth Standard benefits. Navicare members have coverage for the routine costs associated with Medicare-qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in clinical trials.

Medicare reimburses the routine costs associated with Medicare-qualifying clinical trials provided to Navicare members who have Medicare and MassHealth Standard (as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in clinical trials). FCHP will reimburse Navicare members for

cost-sharing incurred for Medicare-covered services associated with qualifying clinical trials.

FCHP covers routine costs associated with Medicare-qualifying clinical trials provided to Navicare members who have MassHealth Standard alone (as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in clinical trials) subject to the terms and conditions of the plan, including, but not limited to, the use of plan providers, referral and authorization requirements, benefit limits, and cost-sharing (e.g., copayments), as specified in the plan member's Evidence of Coverage.

Navicare members will work with their primary care team to arrange participation in a Medicare-qualifying clinical trial.

Products to which this policy applies

Commercial plan:

- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care (PPO)
- ⊕ Major Medical
- ⊕ Companion Care

Other:

- ⊘ MassHealth (no coverage for clinical trials)
- ⊘ Commonwealth Care (no coverage for clinical trials)
- ⊕ Fallon Senior Plan™
- ⊕ Navicare

References

1. Commonwealth of Massachusetts, Chapter 257 of the Acts 2002, An Act Providing for Insurance Coverage of Certain Clinical Trials.
2. Medicare National Coverage Determination Manual 100-4, Routine Costs in Clinical Trials (310.1).
3. Medicare Benefit Policy Manual 100-2, Chapter 14 – Medical Devices.

Committee review dates

Benefit Committee: 10/01, 08/02

Benefit Oversight Committee: 11/16/05, 07/14/10

IMPORTANT NOTE

Not all services are covered for all products or employer groups. This medical policy expresses FCHP's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this medical policy.