



## clinical trials payment policy

### ***description of procedure/service***

This policy applies to the payment for services related to clinical trials. A clinical trial is a research study with human volunteers designed to answer specific questions.

In the United States, the Food and Drug Administration (FDA) must approve drugs, biologics and devices before they can be marketed to the public. The approval process involves several steps including laboratory and animal studies and clinical trials. Clinical trials may be sponsored or funded by individuals, organizations (e.g., biotechnology or pharmaceutical companies) or federal agencies (e.g., one of the National Institutes of Health).

Clinical trials that involve the testing of new drugs or treatments progress in a series of steps or phases. Each phase has a different purpose and helps researchers answer questions about a drug or treatment in a way that protects patients. There are four phases of clinical trials:

- (1) **Phase I trials** are used to evaluate the safety, determine a safe dosage and identify side effects of a drug or treatment in a small group of people.
- (2) **Phase II trials** continue to test safety and begin to evaluate the effectiveness of a drug or treatment in a larger group of people.
- (3) **Phase III trials** are designed to compare the new drug or treatment to the current standard of care (control) and often enroll large numbers of people. Patients are usually randomly assigned to either the control group or the treatment group.
- (4) **Phase IV trials** are post-approval studies designed to gather additional information about a drug or treatment's long-term risks and benefits.

Well-designed clinical trials give participants an opportunity to receive new treatments before they are approved by the FDA and available to the general public, but there are also risks associated with clinical trials. Every clinical trial in the U.S. must be approved and monitored by an Institutional Review Board (IRB). The IRB is a committee of physicians, statisticians, and community members who ensure that the clinical trial is ethical and that the rights of the study participants are protected. All institutions that conduct research must have an IRB that approves and reviews the research.

Before individuals may participate in a clinical trial, they must sign an informed consent. The informed consent is a document that describes the rights of the study participant and includes details about the study, such as its purpose, duration, required procedures, risks and potential benefits. Informed consent is not a contract, and the participant may withdraw at any time. In addition, all clinical trials have a study plan or "protocol." The protocol describes the trial and identifies who may participate, the length of the study, and the schedule of tests, procedures, and/or medications and dosages.

### ***policy***

#### **Commercial plan:**

In accordance with Massachusetts General Law Chapter 176G § 4P and Chapter 175 § 110L, FCHP covers the cost of "patient care services" furnished to commercial plan members enrolled in "qualified clinical trials." Coverage of these patient care services does not imply that FCHP has, in any way, recommended or required the plan member to participate in the clinical trial.

### **Fallon Senior Plan™:**

Effective September 19, 2000, Medicare covers the routine costs of services that Medicare beneficiaries receive related to clinical trials, as well as the cost to diagnose and treat complications arising from participation in clinical trials. (For more information on Medicare coverage of clinical trials, refer to the National Coverage Determination for Routine Costs in Clinical Trials at [www.cms.hhs.gov/mcd/index\\_list.asp?list\\_type=ncd](http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd).)

The Centers for Medicare & Medicaid Services (CMS) requires Medicare Advantage organizations to follow CMS's National Coverage Determinations, however, Medicare regulations provide that if a National Coverage Determination meets a threshold for significant cost, CMS will pay for these services outside of the capitated payments to the Medicare Advantage organization until such time as the costs for these services can be figured into the capitated payments. Coverage for the routine costs of clinical trials meets the significant cost threshold and currently CMS is paying providers directly for these services on a fee-for-service basis. There is no change in FCHP's obligation to provide all other benefits that are covered under Fallon Senior Plan™. In order to ensure that FCHP is aware that a Fallon Senior Plan™ member is enrolled in and receiving services related to a clinical trial, Fallon Senior Plan™ members are asked to notify Customer Service at 1-800-868-5200 before enrolling in a clinical trial.

### ***benefits application***

- FCHP Direct Care / FCHP Select Care
- FCHP Independent Care
- FCHP Flex Care Direct / Select
- Fallon Senior Plan™
- FCHP MassHealth
- Major Medical
- Bill at Home/Direct Enrollment
- Fallon Preferred Care
- Fallon Senior Preferred Care

### ***coverage and reimbursement criteria***

#### **Commercial plan:**

FCHP covers the cost of "patient care services" furnished to commercial plan members enrolled in "qualified clinical trials" for the treatment of cancer only. Coverage is subject to all the terms and conditions of the Evidence of Coverage/Member Handbook, including, but not limited to, provisions requiring the use of network providers, referral and preauthorization procedures, and cost-sharing, , i.e., copayments, deductibles and coinsurance, to the same extent as if the plan member did not receive care in a qualified clinical trial.

**"Patient care services"** are services furnished to a commercial plan member enrolled in a qualified clinical trial which:

- 1.) Are consistent with the usual and customary standard of care for someone with the same diagnosis;
- 2.) Are 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.

Patient care services do not include:

- 1.) Investigational drugs or devices, with the exception of investigational drugs or devices approved for use in the qualified clinical trial, whether or not the FDA has approved the drug or device, to the extent that the drug or device is not paid for by the manufacturer or distributor of the drug or device.

- 2.) Non-health care 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.) Costs of services which are inconsistent with widely accepted and established standards of care.
- 7.) Costs of services which are provided primarily to meet the needs of the trial, including but not limited to:
  - a. Tests, measurements and other services which are typically covered but which are being provided to determine eligibility for participation in the clinical trial.
  - b. Tests, measurements and other services which are typically covered but which are being provided at a greater frequency, intensity or duration in accordance with the trial protocol.
- 8.) Services or costs that are not covered under the plan member's Evidence of Coverage/Member Handbook.
- 9.) Cost of treatment for complications arising from participation in the clinical trial.

A **"qualified clinical trial"** is one that meets the following conditions:

- 1.) The clinical trial is intended to treat cancer in a person who has been diagnosed with cancer.
- 2.) The clinical trial has been peer-reviewed and approved by:
  - a. one of the National Institutes of Health (NIH);
  - b. a cooperative group or center of the NIH;
  - c. a qualified nongovernmental research entity;
  - d. the U.S. FDA pursuant to an investigational new drug exemption;
  - e. the U.S. Department of Defense or Veterans Affairs; or
  - f. with respect to Phase II, III, or IV clinical trials only, a qualified IRB. A qualified IRB is one that meets all the federal requirements for the operation of an IRB as specified in the Code of Federal Regulations, and has not been disqualified to oversee clinical research by the NIH or FDA and has taken corrective action to rectify any noncompliance issue raised by the NIH or FDA within the past three years and has passed all subsequent NIH or FDA inspections.
- 3.) The facility and personnel conducting the clinical trial are capable of doing so by virtue of their experience and training to treat a sufficient volume of patients to maintain their expertise.
- 4.) With respect to Phase I clinical trials only, the facility shall be an academic medical center or an affiliated facility, and the clinicians conducting the trial shall have staff privileges at the academic center.
- 5.) The plan member meets the patient selection criteria in the study protocol.
- 6.) The plan member has signed the informed consent document.
- 7.) The available clinical or pre-clinical data provide a reasonable expectation that the plan member's participation in the clinical trial will provide a medical benefit that is commensurate with the risks of participation in the trial
- 8.) The clinical trial does not unjustifiably duplicate existing studies.
- 9.) The clinical trial must have a therapeutic intent and must, to some extent, assess the effect of the intervention on the plan member; i.e., is not designed exclusively to test toxicity or disease pathophysiology.

**Fallon Senior Plan™:**

CMS pays providers directly on a fee-for-service basis for the costs of services related to clinical trials. There is no change in FCHP's obligation to provide all other benefits that are covered under Fallon Senior Plan™. In order to ensure that FCHP is aware that a Fallon Senior Plan™ member is enrolled in and receiving services related to a clinical trial, Fallon Senior Plan™

members are asked to notify Customer Service at 1-800-868-5200 before enrolling in a clinical trial.

### ***preauthorization guidelines***

#### **Commercial plan:**

Coverage for patient care services provided to plan members enrolled in qualified clinical trials are subject to all the terms and conditions of the Evidence of Coverage/Member Handbook, including, but not limited to, provisions requiring the use of network providers, referral and preauthorization procedures, and cost-sharing, i.e., copayments, deductibles and coinsurance, to the same extent as if the plan member did not receive care in a qualified clinical trial.

#### **Fallon Senior Plan™:**

No referral or preauthorization is required. In order to ensure that FCHP is aware that a Fallon Senior Plan™ member is enrolled in and receiving services related to a clinical trial, Fallon Senior Plan™ members are asked to notify Customer Service at 1-800-868-5200 before enrolling in a clinical trial.

### ***billing/coding guidelines***

#### **Commercial plan:**

Fallon Community Health Plan requires all professional charges to be submitted on a CMS 1500 claims form and hospital charges to be submitted on a UB-92 claims form, or in HIPAA-standard electronic formats, per industry standard guidelines. If a commercial plan member is enrolled in a qualified clinical trial and the study protocol includes a human solid organ, bone marrow or stem cell transplant, at an affiliated transplant facility, FCHP will negotiate a contract with the transplant facility prior to the transplant. See *Transplant Payment Policy*. Plan members are responsible for cost-sharing, i.e., copayments, deductibles and coinsurance specified in the Evidence of Coverage/Member handbook.

#### **Fallon Senior Plan™:**

Providers should not submit claims to FCHP for services furnished to Fallon Senior Plan™ members enrolled in clinical trials. Payment for clinical trial services furnished to beneficiaries enrolled in Medicare Advantage plans will be made by the Medicare contractors that process fee-for-service claims. Providers should submit fee-for-service bills to those entities for covered clinical trial services furnished to Medicare Advantage enrollees. Payment will be based on the current payment methodologies specific to provider type and the service being provided. The Part A deductible is assumed to be met when billed on a fee-for-service basis for Medicare covered clinical trial services furnished to managed care enrollees. The beneficiary is responsible for the coinsurance amounts applicable to services paid under Original Medicare.

Effective for dates of service on or after September 19, 2000 when submitting claims for services or items that meet the requirements as outlined in the National Coverage Determination Routine Costs in Clinical Trials, providers must identify these services with the "QV" procedure code modifier. "QV" - "Item or service provided as routine care in an approved clinical trial" (The full coverage policy regarding clinical trials may be accessed at <http://www.cms.hhs.gov/ClinicalTrialPolicies/>.) The modifier is line item specific and must be used to identify items and services that constitute medically necessary routine patient care or treatment of complications arising from a Medicare beneficiary's participation in a Medicare covered clinical trial. Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the clinical management of the patient are not covered and may not be billed using the QV modifier. Items and services that are not covered by Medicare by virtue of a statutory exclusion or lack of a benefit category also may not be billed using the QV modifier. Finally, items and services customarily provided by the research sponsor free of charge for any enrollee in the trial may not be billed. In addition to the QV modifier,

providers must also report diagnosis code V70.5 (Health Examination of Defined Subpopulations) as a secondary diagnosis for patients participating in Medicare covered clinical trials.

### ***place of service***

This policy applies to all places of service.

### ***policy implementation***

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