



Clinical Trials Payment Policy

Policy

Commercial plan:

Fallon Community Health Plan (FCHP) reimburses "patient care services" furnished to commercial plan members enrolled in "qualified clinical trials" for the treatment of cancer. Reimbursement is subject to all the terms and conditions of the plan member's *Member Handbook/Evidence of Coverage*, 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:

Medicare qualifying clinical trials:

Medicare reimburses providers directly on a fee-for-service basis for the costs of services related to Medicare qualifying clinical trials. There is no change in FCHP's obligation to provide all other benefits that are covered under Senior Plan. In order to ensure that FCHP is aware that a Senior Plan member is enrolled in and receiving services related to a clinical trial, Senior Plan members are asked to notify Customer Service at 1-800-868-5200 before enrolling in a clinical trial.

Category B investigation device exemption (IDE) trials:

Category B IDE trial costs are included in Medicare Advantage (MA) capitation rates, therefore Fallon Senior Plan rather than Medicare reimburses Category B devices and services related to Category B IDE trials. Reimbursement for the Category B device will be based on comparable FDA-approved devices. Reimbursement for related services is subject to all the terms and conditions of the plan member's *Member Handbook/Evidence of Coverage*, 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 Category B IDE trial.

Definitions

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.

"*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 *Member Handbook/Evidence of Coverage*.
- 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.

Benefits application

Commercial

- FCHP Direct Care/FCHP Select Care
- Commonwealth Care
- Companion Care
- FCHP MassHealth
- Major Medical
- Fallon Preferred Care

Senior Plan

- Fallon Senior Plan™
- Fallon Senior Plan Preferred
- Summit ElderCare®

Reimbursement

Commercial plan:

FCHP reimburses "patient care services" furnished to commercial plan members enrolled in "qualified clinical trials" for the treatment of cancer. Coverage is subject to all the terms and conditions of the *Member Handbook/Evidence of Coverage*, 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. Reimbursement for these services does not imply that FCHP has, in any way, recommended or required the plan member to participate in the clinical trial.

If a commercial plan member enrolls in a 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.

Fallon Senior Plan:

Medicare qualifying clinical trials:

Effective September 19, 2000, Medicare reimburses 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.)

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.

Category B investigation device exemption (IDE) trials:

Category B IDE trial costs are included in Medicare Advantage (MA) capitation rates, therefore Fallon Senior Plan rather than Medicare reimburses Category B devices and services related to Category B IDE trials. Reimbursement for the Category B device will be based on comparable FDA-approved devices. Reimbursement for related services is subject to all the terms and conditions of the plan member's *Member Handbook/Evidence of Coverage*, 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 Category B IDE trial.

Referral/notification/preauthorization requirements

Commercial plan:

Patient care services provided to plan members enrolled in qualified clinical trials are subject to all the terms and conditions of the plan member's *Member Handbook/Evidence of Coverage*, 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:

Medicare qualifying clinical trials:

No referral or preauthorization is required for participation in a Medicare qualifying clinical trial. In order to ensure that FCHP is aware that a Fallon Senior Plan member is enrolled in and

receiving services related to a Medicare qualifying clinical trial, Fallon Senior Plan members are asked to notify Customer Service at 1-800-868-5200 before enrolling in a clinical trial.

Category B investigation device exemption (IDE) trials:

Participation in Category B IDE trials is subject to all the terms and conditions of the plan member's *Member Handbook/Evidence of Coverage*, 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 Category B IDE trial.

Billing/coding guidelines

Commercial plan:

FCHP requires all professional charges to be submitted on a CMS 1500 claims form and hospital charges to be submitted on a UB-04 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 *Member Handbook/Evidence of Coverage*.

When submitting claims to FCHP for services or items that meet the requirements outlined in this payment policy, providers must identify services with either the Q0 or Q1 procedure code modifier:

- Q0 - Investigational clinical service provided in a clinical trial that is in an approved clinical trial. (Q0 replaces QA and QR.)
Investigational clinical services are defined as those items and services that are being investigated as an objective within the study. Investigational clinical services may include items or services that are approved, unapproved, or otherwise covered (or not covered).
- Q1 - Routine clinical service provided in a clinical trial that is in an approved clinical trial. (Q1 replaces QV.)
Routine clinical services are defined as those items and services that are covered for plan members outside of the clinical research study; are used for the direct patient care within the study; and, do not meet the definition of investigational clinical services. Routine clinical services may include items or services required solely for the provision of the investigational clinical services (e.g., administration of a chemotherapeutic agent), clinically appropriate monitoring, whether or not required by the investigational clinical service (e.g., blood tests to measure tumor markers), and items or services required for the prevention, diagnosis, or treatment of research related adverse events (e.g., blood levels of various parameters to measure kidney function).

In addition, for services related to clinical trials that meet the requirements outlined in this payment policy, the primary ICD-9-CM diagnosis code must be consistent with the trial indication and providers should report diagnosis code V70.7 (Examination of participant in clinical trial) as a secondary diagnosis code.

Fallon Senior Plan:

Medicare qualifying clinical trials:

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 Fallon Senior Plan members. 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 Medicare Advantage enrollees. The beneficiary is responsible for the coinsurance amounts applicable to services paid under Original Medicare.

Providers must report ICD-9-CM diagnosis code V70.7 (Examination of participant in clinical trial) as the primary diagnosis for healthy, control-group volunteers participating in Medicare covered clinical trials. V70.7 may be reported as the secondary diagnosis (rather than the primary diagnosis) to identify patients participating in Medicare covered clinical trials for therapeutic purposes. The primary diagnosis code on the claim must be consistent with the trial indication(s).

Category B investigation device exemption (IDE) trials:

Report the IDE number in Item 23 (or the electronic equivalent) on the CMS 1500 claims form. The primary ICD-9-CM diagnosis code on the claim must be consistent with the trial indication(s) and V70.7 must be reported as the secondary diagnosis code. Modifier Q0 must be used to identify the investigational item and modifier Q1 must be used to identify related services.

Place of service

This policy applies to services rendered in all settings.

Policy history

Origination date:	02/15/2006
Previous revision date(s):	10/25/2006
Connection date & details:	07/01/2009 – Moved to new policy template; clarified coverage for Category B Investigational Device Exemption (IDE) trials for Fallon Senior Plan members; updated procedure code modifiers and ICD-9-CM codes.

This payment policy has been developed to provide information regarding general billing, coding and documentation guidelines for FCHP. Even though this payment policy may indicate that a particular service or supply is considered covered, specific provider contract terms and/or member individual benefit plans may apply and this policy is not a guarantee of payment. FCHP reserves the right to apply this payment policy to all FCHP companies and subsidiaries.