

Clinical Trials Payment Policy

Applicability

This Policy applies to the following Fallon Health products:

- Fallon Medicare Plus and Fallon Medicare Plus Central (Medicare Advantage)
- MassHealth ACO
- NaviCare HMO SNP
- NaviCare SCO (Medicaid-only)
- Summit Eldercare PACE
- Fallon Health Weinberg PACE
- Fallon Health Weinberg Managed Long-Term Care
- Community Care (Commercial/Exchange)

Policy

Community Care

The Plan covers *routine patient costs* incurred by *qualified individuals* participating in *approved clinical trials* for the treatment of cancer or another *life-threatening disease or condition* in accordance with Section 2709 of the Patient Protection and Affordable Care Act.

Routine patient costs include items and services consistent with coverage provided by the Plan that would be typically covered for a member who is not enrolled in a clinical trial.

Routine patient costs do not include:

- The investigational drug, device or service, itself (except as noted below);
- Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the member; or
- A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis. For example, laboratory tests or imaging studies that a clinical trial protocol requires be done at specific intervals that would not be covered for a member not participating in the trial.

Note: A drug or device that has been approved for use in the clinical trial, whether or not the Food and Drug Administration has approved the drug or device for use in treating the member's particular condition, will be considered a routine patient cost to the extent that it is not paid for by the manufacturer, distributor or provider of the drug or device, as required under Massachusetts General Law (MGL) Chapter 175, Section 110L

A *qualified individual* is a plan member who is eligible to participate in an approved clinical trial, according to the clinical trial protocol, for the treatment of cancer or another life-threatening disease or condition; and either:

1. The referring health care professional is a plan provider who has concluded that the member's participation would be appropriate because the member is eligible for the trial according to its protocol; or
2. The member provides medical and scientific information establishing that participation would be appropriate because the member is eligible for the trial according to its protocol.

An *approved clinical trial* is Phase I, Phase II, Phase III or Phase IV clinical trial that is conducted in relation to the prevention, detection or treatment of cancer or other life-threatening disease or condition and is described by one or more of the following:

- The trial is approved or funded by one of the following:
 - One of the National Institutes of Health;
 - The Centers for Disease Control and Prevention;
 - The Agency for Health Care Research and Quality;
 - The Centers for Medicare & Medicaid Services;

- A cooperative group or center of any of the entities described above or the Department of Defense or the Department of Veterans Affairs;
- A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants; or
- The Department of Veterans Affairs, Defense or Energy, provided that the trial has been reviewed and approved through a system of peer review that the Secretary of the United States Department of Health and Human Services determines is comparable to the system of peer review used by the National Institutes of Health and ensures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.
- The trial is conducted under an investigational new drug application reviewed by the Food and Drug Administration.
- The trial is a drug trial that is exempt from having such an investigational new drug application.
- With respect to Phase II, III and IV clinical trials only, the trial is approved by a qualified institutional review board, as required under MGL Chapter 175, Section 110L. (Note: A qualified institutional review board is defined in MGL Chapter 175, Section 110L (d).)

The term *life-threatening disease or condition* means any disease or condition from which the likelihood of death is probably unless the course of the disease or condition is interrupted.

Reimbursement of *routine patient costs* is subject to the terms and conditions of the plan member's Member Handbook/Evidence of Coverage, including, but not limited to, provisions requiring the use of plan providers, referral and prior authorization requirements, and member cost-sharing.

MassHealth ACO and NaviCare SCO

The Plan covers *patient care services* furnished to MassHealth ACO and NaviCare SCO members participating in *qualified clinical trials*, as defined in MGL Chapter 175, Section 110L.

A *patient care service* is a health care item or service that is furnished to a member enrolled in a qualified clinical trial, which is consistent with the usual and customary standard of care for someone with the patient's diagnosis, is consistent with the study protocol for the clinical trial, and would be covered if the patient did not participate in the clinical trial.

A *patient care service* does not include:

1. An investigational drug or device but a drug or device that has been approved for use in the qualified clinical trial, whether or not the Food and Drug Administration has approved the drug or device for use in treating the patient's particular condition, shall be a patient care service to the extent that the drug or device is not paid for by the manufacturer, distributor or provider of the drug or device.
2. No health care services that a patient 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.
8. Services or costs that are not covered under the patient's contract with the health plan.

A *qualified clinical trial* is a clinical trial that meets all of the following conditions:

1. The clinical trial is intended to treat cancer in a member who has been so diagnosed.
2. The clinical trial has been peer reviewed and is approved by one of the United States National Institutes of Health, a cooperative group or center of the National Institutes of

- Health, a qualified nongovernmental research entity identified in guidelines issued by the National Institutes of Health for center support grants, the United States Food and Drug Administration pursuant to an investigational new drug exemption, the United States Departments of Defense or Veterans Affairs, or, with respect to Phase II, III and IV clinical trials only, a qualified institutional review board. A qualified institutional review board is defined in MGL Chapter 175, Section 110L (d).
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 expertise.
 4. With respect to Phase I clinical trials, the facility shall be 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 member meets the patient selection criteria enunciated in the study protocol for participation in the clinical trial.
 6. The member has provided 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 member'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.
 9. The clinical trial must have a therapeutic intent and must, to some extent, assess the effect of the intervention on the member.

Reimbursement of *patient care services* furnished to MassHealth ACO and NaviCare SCO members participating in *qualified clinical trials* is subject to the terms and conditions of the Member Handbook, including, but not limited to, provisions requiring the use of plan providers, referral and prior authorization requirements, and member cost-sharing.

Fallon Medicare Plus, Fallon Medicare Plus Central and NaviCare HMO SNP

For clinical trials covered under National Coverage Determination (NCD) 310.1 – Routine Costs in Clinical Trials, Original Medicare pays for the *routine costs* of qualifying clinical trials, as well as services for the diagnosis and treatment of complications arising from participation in qualifying clinical trials, for all Medicare beneficiaries, including those enrolled in Medicare Advantage, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in qualifying clinical trials (§ 422.109(e) Clinical trials specified in NCD 310.1; Medicare Managed Care Manual (MMCM), Chapter 4, Section 10.7.1 - Payment for Services).

Providers should not submit claims for *routine costs* of qualifying clinical trials or claims for the diagnosis and treatment of complications arising from participation in qualifying clinical trials to the Plan. The Medicare Administrative Contractors will reimburse providers on a fee-for-service basis for these services.

The Plan will reimburse the difference between Original Medicare cost-sharing incurred for qualified clinical trial items and services and the Plan's in-network cost-sharing for the same category of items and services.

Fallon Medicare Plus, Fallon Medicare Plus Central and NaviCare HMO SNP

The Plan covers *CMS-Approved Category A and B Investigational Device Exemption (IDE) studies* in accordance with § 422.109(f) A and B IDE trials, and Medicare Managed Care Manual (MMCM), Chapter 4, Section 10.7.2 – Payment for Investigational Device Exemption (IDE) Studies. CMS approval for a Category A IDE study allows coverage of *routine costs* furnished in the study, but not of the Category A device, which is statutorily excluded from coverage. CMS approval for a Category B IDE study allows coverage of the Category B device and the *routine costs* in the trial.

The Plan covers *routine costs* incurred by members participating in *CMS-approved Coverage with Evidence Development (CED) studies* in accordance with § 422.101(b)(1), §422.109 and

MMCM, Chapter 4, Section 10.7.3 – Payment for Clinical Studies Approved under Coverage with Evidence Development (CED).

Routine costs include all items and services that are otherwise available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) and that would be otherwise furnished even if the member were not enrolled in 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.

Routine costs do not include:

- The investigational item or service, itself unless otherwise covered outside of the clinical trial;
- 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 (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

CMS-Approved Category A and B Investigational Device Exemption (IDE) studies – Regulations at 42 CFR § 405 Subpart B established Medicare coverage criteria for IDE studies effective January 1, 2015. Prior to January 1, 2015, IDE studies were reviewed and approved by the Medicare Administrative Contractors. CMS approval for a Category A IDE study allows Medicare coverage of *routine costs* furnished in the study, but not of the Category A device itself, which is statutorily excluded from coverage. CMS approval for a Category B IDE study allows Medicare coverage of the *routine costs* furnished in the study and the Category B device, unless the device is provided at no cost by the study sponsor. CMS-approved IDE studies are listed on the CMS website at: <https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html>. Each IDE study is assigned a 7-digit IDE Number by CMS.

CMS-approved Coverage with Evidence Development (CED) studies - CMS, as part of a National Coverage Determination (NCD), may determine coverage of an item or service in the context of a CMS-approved clinical trial or registry. Medicare Advantage plans are responsible for payment of items and services in CMS-approved CED studies, unless CMS determines that the significant cost threshold is exceeded for that item or service. NCDs requiring CED are listed on the CMS website at: <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>; clicking on an NCD link will lead to a listing of CMS-approved clinical trials and/or registries for that specific NCD.

Reimbursement of *routine costs* of qualifying clinical trials is subject to the terms and conditions of the Member Handbook, including, but not limited to, provisions requiring the use of plan providers, referral and prior authorization requirements, and member cost-sharing.

The following services are not covered for all plans

The Plan does not cover transportation costs to and from the trial location (e.g., airfare), local transportation costs (e.g., taxi), lodging costs (e.g., hotel charges) or meals for clinical trial participants. The following codes are not covered:

- S9992 Transportation costs to and from trial location and local transportation costs (examples: fares for taxicab or bus) for clinical trial participant and one caregiver/companion.
- S9994 Lodging costs (example: hotel charges) for clinical trial participant and one caregiver/companion.
- S9996 Meals for clinical trial participant and one caregiver/companion

The Plan does not cover services to determine eligibility for participation in a clinical trial.

Definitions

Clinical trials are regulated by several federal and state laws and regulations. As such, terminology related to clinical trials varies. Definitions for terms used in this Payment Policy are provided with the description of coverage in the Policy section above.

Reimbursement

In all cases, reimbursement of clinical trial-related services is subject to the terms and conditions of the plan member's Member Handbook/Evidence of Coverage, including, but not limited to, provisions requiring the use of plan providers, referral and prior authorization requirements and member cost-sharing.

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, the Plan will negotiate a contract with the transplant facility prior to the transplant. See Transplant Payment Policy.

The Plan will reimburse Medicare Advantage (including NaviCare HMO SNP) members for the difference between Original Medicare cost-sharing incurred for qualified clinical trial items and services and the Plan's in-network cost-sharing for the same category of items and services. In order to be reimbursed, the member must submit a request for reimbursement along with a copy of the Medicare Summary Notice (MSN) or other documentation that shows the services covered by Medicare under the clinical trial. Reimbursement requests should be mailed to:

Fallon Health
Attention: COB
P.O. Box 211308
Eagan, MN 55121-2908

In order to ensure that the Plan is aware that a member is receiving services related to a clinical trial, members are asked to notify Customer Service at 1-800-868-5200 before enrolling in a clinical trial.

Referral/notification/prior authorization requirements

Participation in a clinical trial does not require referral or prior authorization, however in order to ensure that the Plan is aware that a member is receiving services related to a clinical trial, members are asked to notify Customer Service at 1-800-868-5200 before enrolling in a clinical trial.

Coverage for services related to clinical trials is subject to the terms and conditions of the plan member's Member Handbook/Evidence of Coverage, including, but not limited to, provisions requiring the use of plan providers, referral and prior authorization requirements and member cost-sharing.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as approved by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be approved by the interdisciplinary team.

Billing/coding guidelines

The Plan 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.

The Plan follows Medicare billing and coding guidelines for clinical trials.

Coding for Clinical Trial Claims

Providers are required to submit clinical trial claims in accordance with the coding requirements listed below. Clinical trial claims received on or after September 1, 2023 will be denied if any of the following clinical trial identifiers are missing on the claim:

- All clinical trial claims must include ICD-10 diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program) in either the primary or secondary position.
- Professional claims and outpatient facility claims for services provided in a clinical trial must include the modifier Q0 or Q1, as appropriate
 - Q0 - Investigational clinical service provided in a clinical research study that is in an approved clinical research study.
 - Q1 - Routine clinical service provided in a clinical research study that is in an approved clinical research study.
- Facility claims for services provided in a clinical trial must include Condition Code 30.
- All clinical trial claims *must* include the 8-digit National Clinical Trial (NCT) Identifier assigned to the clinical trial in the ClinicalTrials.gov database.
 - For CMS-1500 paper claims, enter the 8-digit NCT Identifier, preceded by “CT”, in Item 19.
 - For electronic claims (837p and 837i), enter the 8-digit NCT Identifier in Loop 2300 REF02 (REF01=P4). Do not use “CT” on electronic claims.
- The 7-digit alpha-numeric IDE Number assigned by CMS must be included on all claims for CMS-Approved Category A and B device studies (in addition to the NCT Identifier).
 - For CMS 1500 paper claims, enter the IDE Number in Item 23.
 - For electronic claims (837p and 837i), enter the IDE Number in Loop 2300, REF02 (REF01=LX).

Reminder: Providers should not submit claims for routine costs of qualifying clinical trials or claims for the diagnosis and treatment of complications arising from participation in qualifying clinical trials to the Plan for Fallon Medicare Plus, Fallon Medicare Plus Central and NaviCare HMO SNP members. The Medicare Administrative Contractors will reimburse providers on a fee-for-service basis for these services. Providers may refer to the Medicare Claims Processing Manual, Chapter 32, Section 69.9 for additional information.

Where to Submit Claims for Fallon Medicare Plus, Fallon Medicare Plus Central and NaviCare HMO SNP members

Type of Clinical Trial	Where to Submit the Claim
Category A or B IDE trial	Fallon Health
Coverage with Evidence Development NCD	Fallon Health (unless CMS determines that the significant cost threshold is exceeded)
NCD 310.1 Routine Costs in Clinical Trials	Medicare Administrative Contractor

Place of service

This policy applies to services rendered in all settings.

Policy history

Origination date: 2/15/2006
 Previous revision date(s): 10/25/2006
 7/1/2009 – 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.
 1/1/2011 – Updated to reflect that FCHP reimburses Senior Plan members enrolled in Medicare qualifying clinical trials for the

cost sharing amounts applicable to services paid under original Medicare.

1/1/2014 - Updated the discussion of documentation needed to reimburse Fallon Senior Plan members.

3/1/2014 - Updated the description of reimbursed services for Commercial members and added ICD-10-CM code Z00.6 (Encounter for examination for normal comparison and control in clinical research program) to the billing/coding guidelines.

03/01/2015 - Moved to Fallon Health template; updated discussion on Category B investigational devices.

11/01/2015 - Moved to new Plan template.

05/01/2016 - Updated qualified clinical trials definition to include life-threatening conditions or diseases.

Connection date & details:

January 2017 – Added CED and IDE A study information.

November 2017 – Clarified Masshealth follows CMS rules

October 2018 – Annual review, no updates.

January 2019 – Clarified Masshealth reimbursement and billing sections.

October 2019 – Added requirement to include National Clinical Trial (NCT) indicator to the claim. Clarified policy, definitions, reimbursement, and billing sections.

April 2021 – Corrected definition of an approved clinical trial.

July 2023 – Updated Billing/coding guidelines to include mandatory reporting of clinical trial identifiers effective for claims received on or after September 1, 2023.

October 2023 – Updated Policy section to include applicable Code of Federal Regulations citations related to clinical trials for Fallon Medicare Plus, Fallon Medicare Plus Central and NaviCare HMO SNP members.

The criteria listed above apply to Fallon Health plan and its subsidiaries. This payment policy has been developed to provide information regarding general billing, coding and documentation guidelines for the Plan. 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. The Plan reserves the right to apply this payment policy to all of the Plan companies and subsidiaries. The Plan routinely verifies that charges billed are in accordance with the guidelines stated in this payment policy and are appropriately documented in the medical records. Payments are subject to post-payment audits and retraction of overpayments.