Department:	Medical Management	**Original Approval:**	08/03/2000
Policy #:	MM164	**Last Approval:**	03/01/2019
Title:	Clinical Trials for Treatments and Devices		
Approved By:	UM Committee		

BACKGROUND

The purpose of this policy is to document Community Health Plan of Washington's (CHPW) policy regarding experimental and investigational services or devices. This policy applies to both Apple Health and Medicare members. Medicare has additional requirements detailed below.

DEFINITIONS

A clinical trial is a research study that uses human volunteers to study the effects of a treatment on a disease. The treatment can involve medications or other therapies or devices.

INDICATIONS/CRITERIA

Medicaid Members	***Continue to criteria for approval below.***
Medicare Members	

Clinical Trials for Treatments and Devices

CHPW does not cover services that are determined to be experimental or investigational, unless they meet the criteria for exemption for humanitarian use. Because the purpose of a clinical trial is to investigate a treatment that is not yet proven to be beneficial, a clinical trial cannot be considered to be evidence-based.

Therefore, CHPW does not pay for the following:

- the clinical trial, or
- for the study drugs or device, or
- for purely investigational activities, including specific labs or diagnostic studies that do not have general utility for the care of the patient

CHPW does cover the usual Medically Necessary care related to participation in a clinical trial that is designed to evaluate a potential treatment in patients with a medical condition that is not excluded from coverage (such as cosmetic treatments). The usual Medically Necessary care includes:

- medical visits or hospitalizations
- non-study medications
- laboratory tests and imaging studies that would usually be considered to be appropriate for clinical management of a patient with the condition and are not being done only to monitor the clinical trial
- treatment of complications that could possibly result from the clinical trial

Exemption for Humanitarian Use (WAC 182-501-0165)

CHPW applies Medical Necessity Criteria to determine if coverage should be provided in the special circumstance where:

- The requested service or equipment has a humanitarian device exemption from the Food and Drug Administration (FDA); or
- There is a local institutional review board (IRB) protocol addressing issues of efficacy and safety of the requested service that satisfies both CHPW and the requesting provider.

ADDITIONAL REQUIREMENTS FOR MEDICARE

For Medicare Clinical Trials Policy, see National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)

Indications and Limitations of Coverage

Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.

Routine costs of a clinical trial 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 non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

- 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.

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.

This policy does not withdraw Medicare coverage for items and services that may be covered according to Local Coverage Determinations (LCDs) or the regulations on category B investigational device exemptions found in 42 CFR 405.201-405.215, 411.15, and 411.406. For information about LMRPs, refer to www.lmrp.net, a searchable database of Medicare Administrative Contractor local policies.

For non-covered items and services, including items and services for which Medicare payment is statutorily prohibited; Medicare only covers the treatment of complications arising from the delivery of the non-covered item or service and unrelated reasonable and necessary care. However, if the item or service is not covered by virtue of a national non-coverage policy in Pub. 100-03, National Coverage Determination (NCD) Manual, and is the focus of a qualifying clinical trial, the routine costs of the clinical trial (as defined above) will be covered by Medicare but the non-covered item or service, itself, will not.

A. Requirements for Medicare Coverage of Routine Costs

Any clinical trial receiving Medicare coverage of routine costs must meet the following three requirements:

1. The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
2. The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.
3. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

The three requirements above are insufficient by themselves to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials also should have the following desirable characteristics; however, some trials, as described below, are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
3. The trial does not unjustifiably duplicate existing studies;
4. The trial design is appropriate to answer the research question being asked in the trial;
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

B. Qualification Process for Clinical Trials

Using the authority found in §1142 of the Social Security Act (the Act) (cross-referenced in §1862(a)(1)(E) of the Act), the Agency for Healthcare Research and Quality (AHRQ) will convene a multi-agency Federal panel (the "panel") composed of representatives of the Department of Health and Human Services research agencies (National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), AHRQ, and the Office of Human Research

Protection), and the research arms of the Department of Defense (DOD) and the Department of Veterans Affairs (VA) to develop qualifying criteria that will indicate a strong probability that a trial exhibits the desirable characteristics listed above. These criteria will be easily verifiable, and where possible, dichotomous. Trials that meet these qualifying criteria will receive Medicare coverage of their associated routine costs. This panel is not reviewing or approving individual trials. The multi-agency panel will meet periodically to review and evaluate the program and recommend any necessary refinements to the Centers for Medicare & Medicaid Services (CMS).

Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator certifies that the trial meets the criteria. This process will require the principal investigator to enroll the trial in a Medicare clinical trials registry, currently under development.

Some clinical trials are automatically qualified to receive Medicare coverage of their routine costs because they have been deemed by AHRQ, in consultation with the other agencies represented on the multi-agency panel to be highly likely to have the above-listed seven desirable characteristics of clinical trials. The principal investigators of these automatically qualified trials do not need to certify that the trials meet the qualifying criteria, but must enroll the trials in the Medicare clinical trials registry for administrative purposes, once the registry is established.
Effective September 19, 2000, clinical trials that are deemed to be automatically qualified are:

1. Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and VA;
3. Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and
4. Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time the principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain Medicare coverage of routine costs. This certification process will only affect the future status of the trial and will not be used to retroactively change the earlier deemed status.

The CMS, through the NCD process, through an individualized assessment of benefits, risks, and research potential, may determine that certain items and services for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a “reasonable and necessary” determination, are only reasonable and necessary when provided in a clinical trial that meets the requirements defined in that NCD.

Medicare will cover the routine costs of qualifying trials that either have been deemed to be automatically qualified, have certified that they meet the qualifying criteria, or are required through the NCD process, unless CMS's Chief Clinical Officer subsequently finds that a clinical trial does not meet the qualifying criteria or jeopardizes the safety or welfare of Medicare beneficiaries.

Should CMS find that a trial's principal investigator misrepresented that the trial met the necessary qualifying criteria in order to gain Medicare coverage of routine costs, Medicare coverage of the routine

costs would be denied under §1862(a)(1)(E) of the Act. In the case of such a denial, the Medicare beneficiaries enrolled in the trial would not be held liable (i.e., would be held harmless from collection) for the costs consistent with the provisions of §§1879, 1842(l), or 1834(j)(4) of the Act, as applicable. Where appropriate, the billing providers would be held liable for the costs and fraud investigations of the billing providers and the trial's principal investigator may be pursued.

Medicare regulations require Medicare+Choice (M+C) organizations to follow CMS NCDs. This NCD raises special issues that require some modification of most M+C organizations' rules governing provision of items and services in and out of network. The items and services covered under this NCD are inextricably linked to the clinical trials with which they are associated and cannot be covered outside of the context of those clinical trials. M+C organizations therefore must cover these services regardless of whether they are available through in-network providers. M+C organizations may have reporting requirements when enrollees participate in clinical trials, in order to track and coordinate their members' care, but cannot require prior authorization or approval.

For Medicare Investigational Device Policy, see Medicare Coverage Related to Investigational Device Exemption (IDE) Studies

Instructions: Medicare Coverage Related to Investigational Device Exemption (IDE) Studies

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) allowed Medicare payment of the routine costs of care furnished to Medicare beneficiaries in certain categories of Investigational Device Exemption (IDE) studies. Covering the costs in these IDE studies removes a financial barrier that could otherwise discourage beneficiaries from participating.

CMS finalized changes to the IDE regulations (42 CFR § 405 Subpart B), effective January 1, 2015. CMS added criteria for coverage of IDE studies and changed from local Medicare Administrative Contractor (MAC) review and approval of IDE studies to a centralized review and approval of IDE studies. An approval for a Category A (Experimental) IDE study will allow coverage of routine care items and services furnished in the study, but not of the Category A device, which is statutorily excluded from coverage. An approval for a Category B (Nonexperimental/investigational) IDE study will allow coverage of the Category B device and the routine care items and services in the trial.

IDE studies approved by MACs prior to January 1, 2015 will continue to be administered by the MAC. Study sponsors do not have to submit the protocol to CMS if the participating study investigator sites have already received approval from their MAC. Study sponsors should continue to follow the process established by the MAC for any site additions or protocol changes. Click on this link to find a list of MACs: https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/MACJurisdictions.html

Requesting Coverage

Sponsors with Food and Drug Administration (FDA) approval letters dated January 1, 2015 or later for IDE Category A or Category B studies that are seeking Medicare coverage for Category A or B IDE studies must submit a request packet to CMS that includes the following information:

A. A request letter that describes the scope and nature of the IDE study. For your convenience we created a checklist and sample crosswalk to assist submitters in submitting a complete package. We encourage you to submit this crosswalk along with the request packet to facilitate CMS' review. The letter should focus on how the IDE study meets each of the regulatory Medicare coverage IDE study criteria, which are:

   1. The principal purpose of the study is to test whether the device improves health outcomes of appropriately selected patients.
   2. The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
   3. The study results are not anticipated to unjustifiably duplicate existing knowledge.
   4. The study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate to confidently answer the research question(s) being asked in the study.
   5. The study is sponsored by an organization or individual capable of successfully completing the study.
   6. The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 21 CFR parts 50, 56, and 812, and 45 CFR part 46.
   7. Where appropriate, the study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Studies of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this criterion only if the disease or condition being studied is life threatening and the patient has no other viable treatment options.
   8. The study is registered with the National Institutes of Health (NIH) National Library of Medicine's (NLM) ClinicalTrials.gov.
   9. The study protocol describes the method and timing of release of results on all pre-specified outcomes, including release of negative outcomes and that the release should be hastened if the study is terminated early.
   10. The study protocol must describe how Medicare beneficiaries may be affected by the device under investigation, and how the study results are or are not expected to be generalizable to the Medicare beneficiary population. Generalizability to populations eligible for Medicare due to age, disability, or other eligibility status must be explicitly described.

B. The complete FDA approval letter of the Category A or Category B IDE (including any enclosures). (CMS will review a submission with a conditional FDA approval letter; however, please submit the final FDA approval letter to CMS at clinicalstudynotification@cms.hhs.gov.)

C. IDE study protocol.

D. Institutional Review Board (IRB) approval letter (only submit one IRB approval letter per request).

E. National Clinical Trial (NCT) number (e.g., NCT00000123)

F. Supporting materials, as appropriate.

SPECIAL CONSIDERATIONS

None.

LIMITATIONS/EXCLUSIONS

Please refer to a product line's certificate of coverage for benefit limitations and exclusions for these services:

PRODUCT LINE	LINK TO CERTIFICATE OF COVERAGE
MEDICARE ADVANTAGE	http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides
WASHINGTON APPLE HEALTH	http://chpw.org/our-plans/apple-health/
INTEGRATED MANAGED CARE	http://chpw.org/our-plans/apple-health/

Citations & References

CFR		
WAC		
RCW		
Contract Citation	☒ WAH	11.8 Experimental and Investigational Services for Managed Care Enrollees
	☐ IMC	
	☒ MA	
Other Requirements	Medicare Coverage Related to Investigational Device Exemption (IDE) Studies National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)	
NCQA Elements	UM 10	

Revision History

Revision Date	Revision Description	Revision Made By
08/03/2000	Original	UM/CM Manager

08/03/2006	No changes	Georgette Cortel
08/08/2007	Formatting, updated Regulatory References	Georgette Cortel
03/19/2008	Updated Regulatory References	Georgette Cortel
04/20/2009	Reviewed	Sandra Hewett
08/14/2009	Revised for NCQA Compliance	Marcia Bush Mike Hays
10/14/2009	No changes	Verni Jogaratnam
11/06/2009	Edited for style; moved to new template; removed hyperlinks to related P&Ps (links broken)	Jennifer Carlisle
10/27/2010	Approval	MMLT
10/26/2011	Approval	MMLT
11/03/2011	Applied formatting: font and citation block	Jason Horne
07/26/2012	Reviewed; Added CMS and delegated entities criteria	Lucy Sutphen, MD, FACP Jane
08/08/2012	Approval	MMLT
03/06/2013	Added statement under Medical Necessity Criteria heading	Kelly Force/Jane Daughenbaugh
03/13/2013	Approval	MMLT
03/10/2014	Reference to policy MM102 deleted and added statement related to covered person's right to obtain a second opinion. Added clarity to section on Medical Necessity Criteria.	Kelly Force/Tim Reitz
04/08/2014	Approval	MMLT
10/13/2014	Updated WAC references and Contract Citation	Andrew Boe
11/26/2014	Approval	MMLT
01/16/2016	Changed client to enrollee throughout document to align with Apple Health contract; additional criteria added to include LOCUS, CALOCUS, and ASAM.	Kelly Force
03/17/2016	Reviewed with minor edits.	Jane Daughenbaugh
03/21/2016	Approval	MMLT
4/10/2017	Changed WAC 284-43-615(2(h)) to WAC 182-538-120. WAC language added. Minor formatting changes	Cyndi Stilson, RN
4/10/2017	Approval	MMLT
04/02/2018	Conversion of UM200 into MM164. Separating out policy on experimental therapy. Clarification of exemption for humanitarian use. Clarification Medicare requirements for coverage of routine costs related to clinical trials and investigational	LuAnn Chen, MD

	device policies.	
04/03/2018	Transferred to new template	Cindy Bush
04/10/2018	Approved	UM Subcommittee
02/27/2019	Reviewed, no changes	LuAnn Chen
03/01/2019	Approved	UM Medical Subcommittee