Policy Number: CP-IFP20-001A Effective Date: January 1, 2024

Coverage for Routine Costs For Members Participating in Clinical Trials

UCare does not discriminate against or deny UCare members from participating in approved clinical trials.

DISCLAIMER

Coverage Policies are developed to assist in identifying coverage for UCare benefits under UCare's health plans. They are intended to serve only as a general reference regarding UCare's administration of health benefits and are not intended to address all issues related to coverage for health services provided to UCare members.

These services may or may not be covered by all UCare products (refer to product section of individual coverage policy for product-specific detail). Providers are encouraged to have their UCare patient refer to their UCare plan documents (Evidence of Coverage/Member Handbook/Member Contract) for specific coverage information. If there is a conflict between a coverage policy and the UCare plan documents, the Member plan documents prevail.

Coverage Policies do not constitute medical advice. Providers are responsible for submission of accurate and compliant claims.

Product Summary

This coverage policy applies to the following UCare products:

UCare Product	Applies To
UCare Individual & Family Plans (IFP), UCare IFP with M Health Fairview	✓
UCare Medicare Plans, UCare Medicare with M Health Fairview & North Memorial Health, UCare Advocate Plus (HMO I-SNP), EssentiaCare	
UCare's Minnesota Senior Health Options (MSHO) (HMO D-SNP)	
UCare Connect + Medicare (HMO D-SNP)	
UCare Connect (SNBC)	
Prepaid Medical Assistance Program (PMAP), MinnesotaCare	
Minnesota Senior Care Plus (MSC+)	

Benefit category:

Eligible services will be covered under the applicable benefit categories as outlined in the benefits chart of the member plan document.

Coverage policy

Covered

The following conditions apply to UCare members who qualify to participate in an approved clinical trial.

Routine patient costs are covered for **qualified individuals** when provided in **approved clinical trials** for the treatment of **cancer or other life-threatening conditions**

- A **qualified individual** is a UCare member who has **cancer OR a life-threatening condition**
    - **Life Threatening Condition**
        - Any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted

Qualified Individual (member eligibility) UCare member is eligible if

- the individual's participation in the trial would be appropriate based upon the trial conditions

Eligible Routine Patient Costs

- All items and services consistent with coverage provided for a qualified individual who is not enrolled in a clinical trial

Approved Clinical Trial

Phase I, Phase II, Phase III, or Phase IV clinical trial or drug trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition

AND

Federally Funded

Study or investigation is approved or funded by one or more of the following:

1. The study or investigation is conducted under an investigational new drug application reviewed by the U.S. Food and Drug Administration; **OR** A drug trial that is exempt from having an investigational new drug application.
2. National Institutes of Health
3. Centers for Disease Control and Prevention
4. Agency for Health Care Research and Quality
5. Centers for Medicare & Medicaid Service
6. Cooperative group or center of any of the entities described above
7. Department of Defense
8. Department of Veterans Affairs
9. A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants
    a. The Department of Veterans Affairs, the Department of Defense or the Department of Energy as long as the study or investigation has been reviewed and approved through a system of peer review that is determined by the Secretary of Health and Human Services to meet both of the following criteria:
        i. Comparable to the system of peer review of studies and investigations used by the National Institutes of Health, AND
        ii. Ensures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review

Routine Patient Costs do not include:

- Investigational item, device, or service that is part of the trial

OR

- Items and services provided solely to satisfy data collection and analysis needs, and are not used in direct clinical management of the patient;

OR

- A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

CPT/ HCPCS/ICD-10 Codes

**Note: If available, codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. This list may not be all-inclusive.*

CPT®, HCPCS or ICD-10 CODES	Modifier	Narrative Description
	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.
	Z00.6	Encounter for examination for normal comparison and control in clinical research program

*CPT is a registered trademark of the American Medical Association.

Prior authorization

Not required.

Related policies and documentation

References to other policies or documentation that may be relevant to this policy

Policy Number	Policy Description
NCD 310.1	National Coverage Determination (NCD) for Routine Costs in Clinical Trials

References and source documents

Links to the UCare contracts, Center for Medicare, and Medicaid Services (CMS), MHCP, Minnesota statute and other relevant documents used to create this policy

Individual & Family Plan Member Contract
Minnesota Statute 62Q.526
Affordable Care Act Reference number
https://www.clinicaltrials.gov/ct2/about-studies/glossary

Coverage policy development and revision history

Version	Date	Note (s)
V1	Jan 1, 2021	New policy
	Dec. 14, 2021	Annual review; no changes
	Nov.30, 2022	Annual review; no changes
	Oct 20, 2023	Annual review: added investigational items, devices, services included as part of trial not included in routine costs.