 KMTSJ, Inc.	DEPARTMENT:	Utilization Management
	SUBJECT:	Clinical Trials
	PRODUCT LINE:	All
	POLICY NUMBER:	011
	ORIGINAL POLICY EFFECTIVE DATE:	06/20/2006
	LAST REVISED DATE:	06/20/2024
	LAST REVIEWED DATE:	06/20/2024

SCOPE:

To ensure Group Health Cooperative of Eau Claire (the Cooperative) appropriately and consistently authorizes clinical trials. Effective for plan years starting on or after January 1, 2014, the Patient Protection and Affordable Care Act requires non-grandfathered health plans to cover routine patient costs for members participating in an approved clinical trial.

POLICY:

It is the policy of the Cooperative to cover clinical trials according to the Affordable Care Act clinical trials coverage provision which states, "Routine patient costs, as defined in PHS Act section 2709(a)(2), include "all items and services consistent with the coverage provided in the plan (or coverage) that are typically covered for a qualified individual who is not enrolled in a clinical trial." Routine patient costs do not include (i) the investigational item, device, or service being studied in the approved clinical trial; (ii) items and services that are provided solely to satisfy the clinical trial's data collection and analysis needs and that are not used in the direct clinical management of the patient; and (iii) a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis. PHS Act section 2709(c) provides that this section shall not be construed to require a group health plan, or a health insurance issuer offering group or individual health insurance coverage, to provide benefits for routine patient care services provided outside of the plan's (or coverage's) health care provider network unless out-of-network benefits are otherwise provided under the plan (or coverage)."

PROCEDURE: Prior Authorization: No.

The clinical trial does not require prior authorization but any services that would normally require prior authorization would still need to be reviewed prior to the service being rendered.


Coverage criteria for all product lines:

Routine health care services related to a clinical trial will be covered under the following circumstances:

1. The member must be eligible for the clinical trial, AND
2. The clinical trial must have a written scientifically sound protocol that has been approved by an institutional review board, AND
3. Must be a Phase I, Phase II, Phase III, or Phase IV clinical trial, AND
4. The study must be funded by a reputable organization such as the NIH, NCI, CMS, etc., AND
5. The routine health care service must be a service that would be covered if the member was not participating in the trial.

Exclusions:

1. The Experimental or Investigational Service or item that is used in the clinical trial is not covered.
2. Phase 0 clinical trials.

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3. Any health care service, item or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient.
4. Investigational drugs or devices that have not been approved by the FDA.
5. Transportation, food or other patient and family expenses associated with travel to and from a facility providing the clinical trial.
6. Any health care services, items or drugs provided to the patient free of charge.
7. Any health care services, items or drugs that are eligible for reimbursement by a person other than the insurer, including the sponsor of the clinical trial.
8. Laboratory tests and imaging studies done at a frequency dictated by the study protocol and that are not consistent with signs and symptoms and other standards of care for that diagnosis or treatment.

References:

PHS Act section 2709(a)(2)

Michele Bauer MD.

APPROVED: _____

DATE: 06/20/2024

REVISION HISTORY:

Rev. Date	Revised By/Title	Summary of Revision
02/18/2013	Carol E. Ebel, RN HM Mgr.	This is a continuation of the archived P & P.
02/15/2014	Lynne Komanec, RN HM Manager	Reviewed with no changes
01/23/2015	Betsy Kelly, RN	Reviewed without changes.
04/25/2017	Michele Bauer, MD, CMO	Reviewed without changes aside from reformatting.
02/22/2019	Michele Bauer, MD, CMO	Updated criteria
04/28/2020	Michele Bauer, MD, CMO	Reviewed. No changes.
04/28/2021	Michele Bauer, MD, CMO	Reviewed. No changes.
04/28/2022	Michele Bauer, MD, CMO	Reviewed. No changes.
04/30/2023	Michele Bauer, MD, CMO	Reviewed. No changes.
04/01/2024	Michele Bauer, MD, CMO	Reviewed. No changes.
06/20/2024	Michele Bauer, MD, CMO	Updated criteria. Added Reference.