 KMTSJ, Inc.	DEPARTMENT:	Utilization Management
	SUBJECT:	Clinical Trials
	PRODUCT LINE:	All
	POLICY NUMBER:	011
	ORIGINAL POLICY EFFECTIVE DATE:	06/20/2006
	LAST REVISED DATE:	02/22/2019
	LAST REVIEWED DATE:	04/30/2023

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 that all product lines require prior authorization for clinical trial participation.

PROCEDURE: Prior Authorization: Yes

Coverage criteria:


Medicaid: Not covered.

Commercial: 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. Purpose of the trial must be the evaluation of an item or service that is not otherwise excluded under the policy, AND
6. The 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.
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 not consistent with signs and symptoms and other standards of care for that diagnosis or treatment.

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Michele Bauer MD.

APPROVED: _____

DATE: 04/30/2023

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.