Review Criteria
Georgia Region

KAISER PERMANENTE®

Title:	**Clinical Trials- Review Criteria**		
Department:	QUALITY RESOURCE MANAGEMENT	**Page:**	1 of 6
Section:	UTILIZATION MANAGEMENT	**Policy Number:**	01-08
Type:	( ) New	**Effective Date:**	06-2003
	(X) Reviewed / Revised	**Date:**	1/29/2018 1/29/19 2/21/2020 1/27/2021 1/10/2022 2/22/2023

Purpose
This policy provides the indications and contraindications necessary for the Quality Resource Management staff to make the most appropriate decision related to the medical necessity of the procedure listed.

DIAGNOSIS ICD-9 CODE AND DESCRIPTION:

DIAGNOSIS/CONDITION: Clinical Trial Process -The target review nurse (TRN) will confirm that the patient does have the benefit for participation in a clinical trial. If so, the TRN working with Martha Trout TSPMG Oncology Manager, will obtain the description of the clinical trial, complete the Clinical trial form and forward to the QRMMD to review and get input from the Chief of Oncology. If the patient does not have clinical trial benefit coverage, then the TRN will send case to QRMMD for determination and a benefit exception may be requested.
CPT-4/ HCPCS CODE AND DESCRIPTION:

INDICATIONS

- Member with cancer diagnosis may be referred to Emory Winship for consideration of a clinical trial as directed by their oncologist.

Clinical Trial Review Process

1) Target Review nurse confirms with Benefits that member has coverage for participation in clinical trials. (all members have coverage)

2) Target Review Nurse completes the Clinical trial (CT) form. -May check with Martha Trout Johnson-Oncology Manager for tracking purposes and potential coordination of care.

3) Target Review Nurse sends completed CT form in referral to the QRMMD for review and discussion with Chief of Oncology or designee.

4) QRMMD sends email to Senior Leadership; AMD of External Medical Cost (Chris Jones) and VP of continuum , Senior Director QRM (Tracy Mussenden) including member name, MR#, diagnosis and the CT location as notification. (This information will also be tracked by Martha Trout Johnson- Oncology Manager.

1.0

1.1 Patients may be eligible for clinical trial at Emory Winship if it is an NCI approved trial

Experimental Therapies:

(Since experimental studies are not typically covered by HP,experimental studies require benefit and Senior leadership approval)

Standard Checklists

1.2 Patient with a disease that has failed therapy, exhausted benefits, or there is no conventional therapy.

1.3 Proposed therapy or treatment should be supported by the patient's specialist with expertise in this area and the primary care physician if appropriate.

1.4 Protocol should be provided to assists in review and discussion with Oncology Chief or designee

1.5 There should be support from the peer review literature and if possible, outcome data that supports the proposed therapy or treatment.

1.6 A contracted provider should normally perform the treatment or procedure. A non-contracted provider may be authorized to perform the Procedure or conduct the Trial of Therapy, if it is not otherwise available.

1.7 All required preliminary work up, including procedures, that can be performed locally, should be done by Kaiser Permanente Georgia, or one of its contracted providers before referring the patient to a research center.

1.8 There should be favorable support from the NTS and its consultants if a transplant is involved.

1.9 When appropriate, there should be approval by the Physician Program Director of QRM (or designee), Director of Benefits implementation (or designee), and Senior Leadership if deemed appropriate.

1.10 QRM Physician Reviewer may contact Martha (Trout) Johnson- TSPMG Oncology Case Manager for assistance with obtaining Clinical Trial Information

Expert Opinion: **TSPMG Chief of Oncology- Dr. Pierson Gladney** 1/26/2021 "I think pts should have options for up front trials with new drugs at Winship. This would not fit that criteria."

[redacted]

COMPLETE FOR CLINICAL TRIAL (CT)

NAME OF CT:
NCI NUMBER: LOCATION OF CT:
NAME OF CONTACT PERSON AT LOCATION:
TELEPHONE NO: EMAIL ADDRESS:
PHASE OF CT:
INTENT OF CT:
ITEM/SERVICES COVERED CT:
ITEM/SERVICES COVERED BY KP:
WHAT SERVICES CAN BE PROVIDED LOCALLY:
SPECIALIST RECOMMENDATION:

POTENTIAL START DATE:

2.0 VIEW OF THE SOUTHEAST PERMANENTE MEDICAL GROUP

The criteria of CMS and the Cancer Coalition of Georgia is followed for experimental treatment

3.0 CLINICAL SUMMARY:

There are many considerations to evaluate before advocating for Experimental Drug Treatment or Experimental Procedures. Most of these will deal with Cancer patients or Transplant patients. Emphasis should be on whether there is any patient benefit to the treatment or is the treatment futile or a plan that does not have any significant chance for benefit. Some experimental treatments can have significant morbidity for a patient who is already very ill. The patient and family should have to have a good understanding of all factors before a decision is rendered. They need to consider and be counseled about quality of life issues at the end of life and not be directed to harmful therapy with minimal chance for success. Involvement of an ethics committee and spiritual/religious counselors may be indicated

4.0 REFERENCES:

1. **Georgia Clinical Trials Agreement**
   Agreement to Reduce Cancer Morbidity and Mortality in Georgia 2004
2. **The Centers for Medicare & Medicaid Services (CMS) issued two national coverage decisions for improving care for cancer patients by expanding coverage for diagnostic tests and chemotherapy treatments for Medicare beneficiaries. 2005**
3. **CMS NCD 2007 for Clinical Trials**

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 noncovered 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.

Note: Email discussion 2/19/2020 with TSPMG Oncologists Dr. Michael Doherty, Dr. Helen Ward AMD of the Continuum, and Michael Nanko- VP of the Continuum- group consensus was that Senior leadership would be notified of clinical trial approvals via email, with tracking and annual review of activity. Martha Trout Johnson – Oncology Manager and Dr. Ryan Shin – will collect data.

Approval

1/17/2023

Luke Beno, MD
Physician Program Director, Quality Resource Management

Date

Date