Government Business Division
Policies and Procedures

Section (Primary Department) **Utilization Management**		**SUBJECT (Document Title)** **Cancer Clinical Trials - CA**	
Effective Date 12/19/2003	**Date of Last Review** 04/18/2024	**Date of Last Revision** 04/18/2024	**Dept. Approval Date** 04/18/2024
Department Approval/Signature:			

Policy applies to health plans operating in the following State(s). Applicable products noted below.

Products				
☒ **Medicaid/CHIP**	☐ Arkansas	☐ Iowa	☐ Nevada	☐ Tennessee
☐ **Medicare/SNP**	☒ California	☐ Kentucky	☐ New Jersey	☐ Texas
☐ **MMP/Duals**	☐ Colorado	☐ Louisiana	☐ New York	☐ Virginia
	☐ District of Columbia	☐ Maryland	☐ New York (WNY)	☐ Washington
	☐ Florida	☐ Minnesota	☐ North Carolina	☐ Wisconsin
	☐ Georgia	☐ Missouri	☐ Ohio	☐ West Virginia
	☐ Indiana	☐ Nebraska	☐ South Carolina	

POLICY:

Anthem Medicaid ensures that members have access to and receive:

- All phases of federally approved cancer clinical trials.
- Routine patient care through plan providers while participating in the cancer clinical trial inside the plan service area.
- Medically necessary, non-emergent care not related to the cancer clinical trial when the member is outside the plan's service area while participating in a cancer clinical trial.

DEFINITIONS:

Cancer Clinical Trial – A research study with cancer patients, to determine if a new cancer treatment or drug is safe and therapeutic. Cancer Clinical Trial Phases I – IV describe the order of increased efficacy of the treatment or drug. A Cancer Clinical Trial must:

A. Be approved by one of the following federal agencies:
   - National Institutes of Health (NIH),
   - Federal Food and Drug Administration (FDA),
   - U. S. Department of Defense, or
   - U.S. Veterans' Administration.
B. Involve a drug that is exempt under federal regulations from a new drug application.
C. Not have endpoints defined exclusively to test toxicity, but must have a therapeutic intent.

Primary Care Physician (PCP) – A physician whose area of medical practice is one of the five specialties designated by the State Department of Health Services (SDHS) as a primary care specialty, and who is contracted with Anthem Medicaid as a PCP. The five specialties are General Practice, Internal Medicine, Pediatrics, Obstetrics/Gynecology and Family Medicine.

Routine Patient Care – Care associated with the provision of health care services, including drugs, items, devices, and services that would otherwise be covered under the health plan coverage or contract if those drugs, items, devices and services are not provided by the approved clinical trial program.

A. Routine patient care includes, but is not limited to:
   - Health care services that would be provided absent a clinical trial.
   - Health care services required solely for the provision of the investigations drug, item, device or services.
   - Health care services required for the clinically appropriate monitoring of the investigational drug, device, item or service.
   - Health care services provided for the prevention of complications arising from the provision of the investigational drug, device, item or service.
   - Health care services needed for the reasonable and necessary care arising from the provision of the investigational drug, device, item or service, including the diagnosis and/ or treatment of complications.
   - Medically Necessary Cancer Biomarker Testing- No prior authorization required for member diagnosed with or recurrence of Advanced or metastatic stage 3 or 4 cancer associated with federal FDA approved therapy.

B. Routine patient care does not include the care associated with the provision of:
   - Drugs and devices that have not been approved by the Federal Food and Drug Administration and that are associated with the clinical trial.
   - Services other than health care services, such as travel, housing, companion expenses and other non-clinical expenses that an enrollee may require as a result of treatment being provided for the purposes of the clinical trial.
   - Any item or service that is provided solely to satisfy data collection and analysis needs and that is not used in the clinical management of the patient.
   - Health care services that, except for the fact that they are being provided in a clinical trial, are otherwise specifically excluded from coverage by Medi-Cal or under the enrollee's health plan.
   - Health care services customarily provided by the research sponsors free of charge for any enrollee in the trial.
   - Experimental treatment outside of an eligible clinical trial.

PROCEDURE:

Authorization determinations for participation in cancer clinical trials shall be processed in accordance with Anthem Medicaid policies and procedures for referral management and within the time frames established by State and Federal regulations.

If the member's physician recommends participation in the cancer clinical trial, after determining that participation in the clinical trial has a meaningful potential benefit for the member, then *routine patient care* should be authorized as medically necessary for proposed treatment utilizing MCG, Anthem Medical Policies and Clinical Guidelines, and be consistent with benefit coverage.

Medically necessary, non-emergent care when the member is outside the service area, not related to the cancer clinical trial, should be coordinated with the member's primary care provider or primary medical group. This will ensure that non-emergent, medically necessary care is covered out of area while the member is participating in a cancer trial. Non-emergent care that is not medically appropriate should wait until the member returns to the service area.

A. Member Eligibility for Federally Approved Cancer Clinical Trials –
   The member must be:
   - Eligible as an Anthem Medicaid member at the time treatment in a clinical trial is approved.
   - Diagnosed with cancer.
   - Accepted into an approved Phase I, Phase II, Phase III, or Phase IV, clinical trial for cancer.

Relevant documents will be made available to members, which, explain the difference between member participation in an eligible clinical trial, and the member receiving experimental treatment from a provider outside of an eligible trial. All explanations must clearly indicate that experimental treatment outside of an eligible cancer clinical trial may be excluded and that denials will be reviewed pursuant to the independent medical review process.

Basic case management shall be made available throughout the member's participation in the cancer clinical trial, as needed.

If reassessment results in a determination that the member is no longer eligible to continue in the clinical trial, or is no longer receiving benefits from the cancer clinical all needed care will be coordinated through the PCP and UM/CM processes.

REFERENCES:

- DHCS All Plan Letter APL 22-010, issued June 22, 2022 "Cancer Biomarker Testing"
- Federal Listings of Cancer Clinical Trials approved by one of the following federal agencies; National Institutes of Health (NIH), Federal Food and Drug Administration (FDA), U.S. Department of Defense, and U.S. Veterans' Administration.

- Health and Safety Code, Section 1370.6
- Insurance Code, Section 10145.4
- Medi-Cal Member Handbook- Evidence of Coverage (EOC) Effective 2024
- Welfare and Institutions Code Section 14132.98

RESPONSIBLE DEPARTMENTS:

Primary Department:
Utilization Management (UM)

Secondary Department(s):
Case Management (CM)

EXCEPTIONS:

None

REVISION HISTORY:

Review Date	Changes
04/18/24	• Annual Review • Updated References section of EOC to 2024 version
07/26/23	• Annual Review • Updated References section
11/10/22	• Off-cycle Review • Updated clinical trial information to be in line with APL 22-010 “Cancer Biomarker Testing” under Definitions section • Updated Responsible Departments section
07/27/22	• Annual Review • Added Biomarker testing to routine patient care definition • Alphabetized and updated References
07/13/21	• Annual Review • Updated EOC Reference
06/26/20	• Annual Review • Updated References
06/28/19	• Annual Review • Updated References

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Review Date	Changes
06/30/18	• Annual Review, no changes
06/30/17	• Changed Milliman to MCG • Changed WellPoint to Anthem • Reworded non-emergent care paragraph • Updated references
06/30/16	• Annual Review. Updated References.
07/31/15	• Annual Review/ No Changes
09/04/14	• Changed header to Government Business Division • Deleted Healthy Families • Updated EOC reference to 2013 from 2011
09/17/12	• Changed reference from Anthem Blue Cross State Sponsored Business to Anthem Medicaid. • Corrected formatting to correctly place the information from POLICY and DEFINITIONS to the PROCEDURE section. • Changed reference from Care Management to Medical Management • Added revision history to policy