Section (Primary Department) **Utilization Management**		**SUBJECT (Document Title)** **Experimental and Investigational Treatment - CA**	
Effective Date 05/16/2001	**Date of Last Review** 02/06/2024	**Date of Last Revision** 05/22/2024	**Dept. Approval Date** 05/22/2024
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 (Anthem) ensures the appropriate and timely resolution of requests for investigational or experimental treatment and informs the member of their right to Independent Medical Review (IMR) within five (5) business days of the decision to deny coverage.

The IMR process examines the plan's coverage decisions regarding investigational or experimental therapies for members meeting all of the following criteria:

1. The member has a life-threatening or seriously debilitating medical condition.

2. The member's physician certifies that the member has a condition as defined in number 1, for which standard therapies have not been effective in improving the condition of the member, for which standard therapies would not be medically appropriate for the member, or for which there is no more beneficial standard therapy covered by the plan than the therapy proposed, and

3. Either (a) the member's physician, who is under contract with or employed by the plan, has recommended a drug, device, procedure or other therapy that the physician certifies in writing is likely to be more beneficial to the member than any available standard therapies, or (b) the member, or the member's physician who is a licensed, board-certified or board-eligible physician qualified to practice in the area of specialty appropriate to treat the member's condition, has requested a therapy that, based on two (2) peer-reviewed scientific studies published by medical journals that meet nationally-recognized requirements for scientific manuscripts, is likely to be more beneficial for the member than any available standard therapy, and

4. The member has been denied coverage by the plan for a drug, device, procedure or other therapy recommended by the member's physician, and

5. The specific drug, device, procedure or other recommended therapy would be a covered service, except for the plan's determination that the service is investigational or experimental.

DEFINITIONS:

Clinical Trial - A qualifying clinical trial is a clinical trial in any clinical phase of development that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition.

Life-threatening - Either or both of the following:
1. Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.
2. Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

Routine patient care costs - costs associated with the provision of health care services, including drugs, items, devices, and services that would otherwise be covered under the Medi-Cal program if those drugs, items, devices, and services were not provided in connection with an approved clinical trial program.

Seriously debilitating - diseases or conditions that cause major irreversible morbidity.

PROCEDURE:

I. Investigational/Experimental Adverse Determinations

A. Treatment/procedures that are denied as experimental and investigational by peer clinical reviewers (PCRs) are reviewed by the Medical Director.

B. When an authorization request for experimental/investigational treatment is denied by Anthem, an initial denial letter, IMR application and IMR instructions are sent to the member and provider within the required timeframes.

C. Requests for an IMR are directed to the Department of Managed Health Care (DMHC) and are processed according to the procedure described in Policy and Procedure #CA_GAXX_051 "Appeals Member".

II. Clinical trials- Routine Patient care Costs

A. The plan will cover routine patient care costs for Members participating in a qualifying clinical trial including items and services furnished in connection with participation by Members in a qualifying clinical trial. A qualifying clinical trial is a clinical trial in any clinical phase of development that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition.

B. The plan will provide coverage regardless of geographic location or if treating Medi-Cal Provider is a Network Provider.

C. Coverage must be based on Provider's and principal investigator's approval regarding the Member's appropriateness for the qualifying clinical trial.

D. The coverage determination must be expedited and completed within 72 hours.

E. Contractor must require the submission of the "Medicaid Attestation Form on the Appropriateness of the Qualifying Clinical Trial" for approval of the clinical trial. The attestation form must include the following information:

i. The Member's name and client identification number.

ii. The national clinical trial number.

iii. A statement signed by the principal investigator attesting to the appropriateness of the qualified clinical trial; and

iv. A statement signed by the Provider attesting to the appropriateness of the qualified clinical trial.

REFERENCES:

- Anthem Blue Cross Providers Manual, Last Updated January 2023
- California Health and Safety Code Section 1370.4
- California Senate Bill 189, Chaptered September 28, 1999
- NCQA UM Standards, 2023
- Policy and Procedure #CA_GAXX_051 "Appeals Member"

Section (Primary Department) **Utilization Management**	**SUBJECT (Document Title)** **Experimental and Investigational Treatment - CA**

RESPONSIBLE DEPARTMENTS:

Primary Department: Utilization Management (UM)

Secondary Department(s): Case Management (CM)
Grievance & Appeals (G&A)

EXCEPTIONS:

None

REVISION HISTORY:

Review Date	Changes
05/22/24	• Off-Cycle Review • Updated language in accordance with contract updates doe clinical trial medications under Procedure section
02/06/24	• Annual Review • Updated Definitions and Procedure sections
07/27/23	• Off Cycle Review • Added G&A as a secondary department
01/25/23	• Annual Review • Updated References section • Updated Primary Department section from "Medical Management: Utilization Management (UM) Case Management (CM)" to "Utilization Management (UM)" to match primary department in header • Added "Case Management (CM)" as a secondary department
02/03/22	• Annual Review, updated references
01/27/21	• Annual Review, no changes
01/29/20	• Annual Review, updated references
01/30/19	• Annual Review, updated references
01/30/18	• Annual Review, updated references
01/30/17	• Annual review. Updated NCQA reference
02/17/16	• Updated references
03/13/15	• Removed Healthy Families
03/13/14	• Corrected company name as per a Compliance directive • Updated references
02/06/13	• Refined this policy to be more specific to Utilization Management processes.

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Review Date	Changes
	• Changed G&A policy reference from CA_GAXX_016 to CA_ GAXX_051 • Updated references
03/20/12	• Minor revisions made. Reviewing new NCQA Standards for any changes. No NCQA changes; review is complete. DW