

Subject: Investigational Criteria
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Status: Reviewed

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THESE CRITERIA ARE USED IN THE DEVELOPMENT AND UPDATING OF MEDICAL POLICIES. AS THESE CRITERIA MAY NOT BE THE CRITERIA USED IN THE DEFINITION OF INVESTIGATIONAL WITHIN THE COVERED INDIVIDUAL'S PLAN DOCUMENT, THE DEFINITION IN THE COVERED INDIVIDUAL'S PLAN DOCUMENT IS TO BE USED FOR BENEFIT DETERMINATIONS. (SEE COVERED INDIVIDUAL'S BENEFIT PLAN FOR SPECIFIC CONTRACT LANGUAGE).

Definitions

"Investigational" means that the procedure, treatment, supply, device, equipment, facility or drug (all services) does not meet the Company Technology Evaluation Criteria because it does not meet **one or more** of the following criteria:

- have final approval from the appropriate government regulatory body;**or**
- have the credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community which permits reasonable conclusions concerning the effect of the procedure, treatment, supply, device, equipment, facility or drug (all services) on health outcomes; **or**
- be proven materially to improve the net health outcome;**or**
- be as beneficial as any established alternative;**or**
- show improvement outside the investigational settings.

In addition to the above criteria, the Medical Policy & Technology Assessment Committee (MPTAC) will consider recommendations of national physician specialty societies, nationally recognized professional healthcare organizations and public health agencies, and in its sole discretion, may consider other relevant factors, including information from the practicing community.

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Investigational

Document History

Status	Date	Action
Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review.
Reviewed	05/12/2022	MPTAC review.
Reviewed	05/13/2021	MPTAC review.
Reviewed	05/14/2020	MPTAC review.
Reviewed	06/06/2019	MPTAC review.
Reviewed	07/26/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date."
Reviewed	08/03/2017	MPTAC review.
Reviewed	08/04/2016	MPTAC review.
Reviewed	08/06/2015	MPTAC review.
Revised	08/14/2014	MPTAC review. Clarification to header.
Reviewed	08/08/2013	MPTAC review.
Reviewed	08/09/2012	MPTAC review.
Revised	08/18/2011	MPTAC review. Clarification to header.
Reviewed	11/18/2010	MPTAC review.
Revised	11/19/2009	MPTAC review. Title changed; clarifications made.
Reviewed	11/20/2008	MPTAC review.
Reviewed	11/29/2007	MPTAC review.
Reviewed	12/07/2006	MPTAC review. No change to position.
Revised	12/01/2005	MPTAC review.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	N/A	N/A	Definition: Experimental/Investigational
WellPoint Health Networks, Inc.	09/22/2005	Definitions: i	Definition: Investigational

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

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