

MEDICAL POLICY

POLICY TITLE	COVERAGE WITH EVIDENCE DEVELOPMENT
POLICY NUMBER	MP 4.048

Effective Date:	4/1/2022
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I. POLICY

The purpose of this document is to describe the policy and procedures used by Capital BlueCross to implement Coverage with Evidence Development policies.

In order to accelerate the development and emergence of high-quality, affordable health care in the Capital BlueCross network, it is the policy of Capital BlueCross to implement written “coverage with evidence development” (CED) medical policies.

Requirements for Coverage with Evidence Development Policy include:

- Capital BlueCross members participating in a Capital BlueCross authorized study and whom are compliant with the study protocol
- Development of CED policy is at the sole discretion of Capital BlueCross. Capital BlueCross is not obligated to establish a CED policy. Except as authorized by the Benefit Booklet (previous known as the Certificate of Coverage), Capital BlueCross is not obligated to cover any technology if it has not yet established a CED policy using the CED development process (below).

CED medical policies will provide coverage for promising new technologies which have not yet been established as effective according to generally accepted professional medical standards when the following criteria is met:

- May otherwise be considered Medically Necessary AND
- Safety has been proven AND
- Shows significant potential to improve health outcomes AND
- Reduces waste and inefficiency in the health care system AND
- Part of high quality research and clinical development

CED Process

1. Capital BlueCross may review a technology for CED for the following reasons:

- a. In the process of prior authorization, claims review or appeal, CBC receives a request for coverage for a technology associated with high-quality research or quality-improvement clinical study that meets the criteria for CED

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b. CBC identifies a technology associated with a high-quality research or quality improvement clinical study that meets the criteria for CED

2. Any study involving a new technology for CED shall be evaluated by Capital BlueCross' Innovation Review Committee to make a preliminary determination that the study can be operationalized and that criteria for CED inclusion are met (below)
3. Studies initially approved by the Innovation Review Committee will be referred to a contracted external entity for review and recommendation as to whether the proposed study meets the criteria in section C below
4. The contracted external entity shall be responsible for monitoring the conduct of the study and for reporting back to Capital BlueCross' Innovation Review Committee at least monthly. Monitoring will include making a determination when appropriate to terminate a CED study.
5. Upon termination of a study, Capital BlueCross will consider the results of the study to determine any necessary policy revisions and for ongoing coverage.

Requirements for CED status

1. The technology is safe and considered to be low risk to the member
2. There is sufficient evidence that the technology has potential to cause a clinically meaningful improvement in net health outcomes, OR the quality, value or affordability of healthcare services
3. There is urgency to promote development of evidence that will determine that the technology improves healthcare costs, the patient experience, health outcomes and/or the work life/engagement of the provider (Quadruple Aim)
4. The technology has received any required governmental regulatory approval
5. The available scientific and medical information support further study, the results of which are not expected to duplicate existing data
6. The technology is implemented in a scalable, clinical context designed to impact the Quadruple Aim
7. The technology can be implemented by Capital BlueCross with minimal operational burden or expense AND
8. Except for exclusions for technologies which have not yet been established as effective, the technology is not otherwise excluded from the Certificate of Coverage.

Required CED study characteristics (all must be satisfied):

1. The study is feasible and resources necessary for the completion of the study have been identified
2. The study is likely to be effective in the development of informative evidence
3. The evidence is expected to be of sufficient quality to draw conclusions regarding the benefit of the technology
4. The cost of obtaining the evidence is commensurate with its value
5. The study is conducted by an organization capable of completing it successfully and within a reasonable period of time (<5 years)

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- 6. All aspects of the study are conducted according to appropriate standards of scientific integrity as determined by the International MPC of Medical Journal Editors (<http://www.icmje.org>) and are compliant with all applicable Federal regulations
- 7. The study has a written protocol which demonstrates adherence to the above standards
- 8. The study protocol specifies the method and timing of release of outcomes, both positive and negative. Study results must be made public within 24 months of the conclusion of data collection.
- 9. The study is registered on the ClinicalTrials.gov website and/or the Registry of Patient Registries by the principal investigator prior to the enrollment process
- 10. The study design is appropriate to the key questions of interest

Requirements for the External Contracted Entity (all must be satisfied):

- 1. Expertise and experience with CED issues as well as the design and implementation of CED studies, clinical research methods and the development of methodologic standards for the evaluation of clinical utility
- 2. Experience with project management, coordinating communication through virtual and in-person meetings

Cross-reference:
None

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

III. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

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IV. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

V. CODING INFORMATION

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NA

VI. REFERENCES

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NA

VII. POLICY HISTORY

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MP 4.048	7/19/18 New policy used to establish coverage with evidence development policies.
	04/22/2019 Consensus review. No changes to policy statements.
	07/17/2020-Consensus review. No changes to policy statement.
	1/29/2021 Consensus review. No change to policy statement. "Certificate of Coverage" changed to "Benefit Booklet" to match language change.
	1/4/2022 Consensus review. No change to policy statement.

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Health care benefit programs issued or administered by Capital BlueCross and/or its subsidiaries, Capital Advantage Insurance Company®, Capital Advantage Assurance Company® and Keystone Health Plan® Central. Independent licensees of the BlueCross BlueShield Association. Communications issued by Capital BlueCross in its capacity as administrator of programs and provider relations for all companies.