

## MEDICAL POLICY

POLICY TITLE	COVERAGE WITH EVIDENCE DEVELOPMENT
POLICY NUMBER	MP 4.048

CLINICAL BENEFIT	<input checked="" type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input checked="" type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	6/1/2024

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### I. POLICY

In order to accelerate the development and emergence of high-quality, affordable health care, Capital Blue Cross may implement coverage with evidence development (CED) medical policies. Development of CED policies is at the sole discretion of Capital Blue Cross.

Coverage with Evidence Development Policy may include, but not be limited to:

- Members participating in a CED study approved by Capital Blue Cross
- Coverage of technology through an agreement with the provider for CED.

CED medical policies may provide coverage for promising new technologies that meet **ALL** the following criteria:

- Potential to improve health outcomes or reduces cost, waste and/or inefficiency
- Proven safety, including any required governmental regulatory approval
- Medically necessary
  - Services or supplies that a physician exercising prudent clinical judgment would provide to an individual for the diagnosis and/or the direct care and treatment of the individual's medical condition, disease, illness, or injury; **and**
  - In accordance with accepted standards of good medical practice; **and**
  - Clinically appropriate for the individual's medical condition, disease, illness, or injury; **and**
  - Not primarily for the convenience of the individual and/or individual's family, physician, or other health care provider; **and**
  - Not costlier than alternative services or supplies at least as likely to produce equivalent results for the individual's condition, disease, illness, or injury.

**Cross-reference:**

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**MP 2.010** Clinical Trials

**MP 4.003** Medical Necessity

**MPC-AP-12** How We Evaluate New and Existing Technology

### 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 Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

### IV. DISCLAIMER

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*Capital Blue Cross' 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 Blue Cross' Provider Services or Member Services. Capital Blue Cross 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	<b>07/19/2018 New policy</b> used to establish coverage with evidence development policies.
	<b>04/22/2019 Consensus review.</b> No changes to policy statements.
	<b>07/17/2020 Consensus review.</b> No changes to policy statement.

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	<b>01/29/2021 Consensus review.</b> No change to policy statement. “Certificate of Coverage” changed to “Benefit Booklet” to match language change.
	<b>01/04/2022 Consensus review.</b> No change to policy statement.
	<b>12/28/2023 Major review.</b> Removed sentence regarding purpose of document. Removed references to Benefit Booklet. Added criteria regarding medical necessity. Removed CED process, requirements for CED status, Study Characteristics and External Contracted Entity sections. Added Cross referenced policies.

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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.*