

**Policy** # 00322

Original Effective Date: 05/22/2013 Current Effective Date: 11/09/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

# When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider brands other than CONTOUR<sup>®‡</sup>, BREEZE 2<sup>®‡</sup>, or TRUE<sup>®‡</sup> blood glucose test strips to be **eligible for coverage\*\*** when one of the below patient selection criteria is met:

#### Patient Selection Criteria

Coverage eligibility will be considered for brands other than CONTOUR, BREEZE 2, or TRUE blood glucose test strips when one of the following criteria is met:

- The patient has visual impairment that would require a specific brand (other than CONTOUR, BREEZE 2, or TRUE) of blood glucose test strips; or
- The patient has an insulin pump that would require a specific brand (other than CONTOUR, BREEZE 2, or TRUE) of blood glucose test strips; or
- There is clinical evidence or patient history that suggests the use of CONTOUR, BREEZE
  2, or TRUE brand blood glucose test strips will be/was ineffective or will/did cause an
  adverse reaction to the patient.

## When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brands other than CONTOUR, BREEZE 2, or TRUE blood glucose test strips when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary**.\*\*

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### **Background/Overview**

Blood glucose test strips are used in conjunction with a blood glucose meter to measure a patient's blood glucose.

## Rationale/Source

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the use of CONTOUR, BREEZE 2, or TRUE brand blood glucose test strips will be/was ineffective or will/did cause an adverse reaction to the patient. It also takes into account whether or not the patient has visual impairment or uses an insulin pump that would require a different brand of blood glucose test strips (other than CONTOUR, BREEZE 2, or TRUE). Based on a review of the data, in the absence of the above mentioned caveats, there is no advantage of using a brand other than CONTOUR, BREEZE 2, or TRUE brand blood glucose test strips.

### References

- 1. Freckmann G, Baumstark A, Jendrike N, Zschornack E, Kocher S, Tshiananga J, Heister F, and Haug C. System Accuracy Evaluation of 27 Blood Glucose Monitoring Systems According to DIN EN ISO 15197. Diabetes Technology & Therapeutics. March 2010, 12(3): 221-231. doi:10.1089/dia.2009.0128.
- 2. Harrison B, Leazenby C, Halldorsdottir S. Accuracy of the Countour Blood Glucose Monitoring System. J Diabetes Sci Technol. 2011. July; 5(4):1009-1013.
- 3. Frank J, Block T, Carter J, Mullen L, Tideman A, Parkes J. Performance and Ease of Use of the Breeze 2 Blood Glucose Monitoring System. Bayer Health Care Diabetes Care. 2007.
- 4. Nipro Diagnostics.

### **Policy History**

Original Effective Date: 05/22/2013 Current Effective Date: 11/09/2020

05/02/2013 Medical Policy Committee review

05/22/2013 Medical Policy Implementation Committee approval. New policy.

05/01/2014 Medical Policy Committee review

05/21/2014 Medical Policy Implementation Committee approval. No change to coverage.

10/02/2014 Medical Policy Committee review

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10/15/2014	Medical Policy Implementation Committee approval. Removed Roche as
	preferred test strip (AccuCheck). Added Nipro as a preferred strip (TRUE).
10/08/2015	Medical Policy Committee review
10/21/2015	Medical Policy Implementation Committee approval. No change to coverage.
10/06/2016	Medical Policy Committee review
10/19/2016	Medical Policy Implementation Committee approval. No change to coverage.
10/05/2017	Medical Policy Committee review
10/18/2017	Medical Policy Implementation Committee approval. No change to coverage.
10/04/2018	Medical Policy Committee review
10/17/2018	Medical Policy Implementation Committee approval. No change to coverage.
10/03/2019	Medical Policy Committee review
10/09/2019	Medical Policy Implementation Committee approval. No change to coverage.
10/01/2020	Medical Policy Committee review
10/07/2020	Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled	Review Date: 10/2021

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\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. Reference to federal regulations.

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\*\*Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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