

# **Heartsbreath Test**

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Effective Date 10/2007

Next Review Date 2/15/2024

**Coverage Policy** Medical 257

Version 4

Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details \*.

### Purpose:

This policy addresses the medical necessity of Heartsbreath Test.

# Description & Definitions:

Heartsbreath Test is a noninvasive test that measures a marker found in the breath of an individual to detect heart transplant rejection.

### Criteria:

Heartsbreath Test is considered **not medically necessary** for any indication.

# Coding:

Medically necessary with criteria.

Wicarcarry freeco	stary with criteria:
Coding	Description
	None

## Considered Not Medically Necessary:

Coding	Description
84999	Unlisted chemistry procedure

U.S. Food and Drug Administration (FDA) - approved only products only.

# **Document History:**

#### **Revised Dates:**

- 2020: January
- 2016: March, April
- 2015: April

#### **Reviewed Dates:**

2023: February

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- 2022: February
- 2021: January
- 2018: October
- 2017: December
- 2015: March, November
- 2014: April
- 2013: April
- 2012: January
- 2011: July
- 2010: July
- 2009: July
- 2008: July

### Effective Date:

October 2007

### References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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The Heartsbreath Test: Product Labeling for Physicians. (2022). Retrieved Nov 23, 2022, from FDA: https://www.accessdata.fda.gov/cdrh\_docs/pdf3/h030004c.pdf

# Special Notes: \*

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or

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medical care. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving, and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

# **Keywords:**

SHP Heartsbreath Test for Detection of Heart Transplant Rejection, SHP Medical 257, heart transplant, rejection, cardiac transplant, organ rejection, organ transplant

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