



**PATHWORK® TISSUE
OF ORIGIN TEST
HS-180**



Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*

WellCare Health Insurance of Illinois, Inc.

WellCare Health Insurance of New York, Inc.

WellCare Health Plans of New Jersey, Inc.

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WellCare of Connecticut, Inc.

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WellCare of New York, Inc.

WellCare of Ohio, Inc.

WellCare of Texas, Inc.

WellCare Prescription Insurance, Inc.

**Pathwork® Tissue
Of Origin Test**

Policy Number: HS-180

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DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

The Pathwork® Tissue of Origin test (Pathwork Diagnostics, Inc., Sunnyvale, CA) is a gene expression, microarray-based test, which the company suggests may be useful in identifying the origin of cancers of unknown primary. The test measures the expression of more than 1,500 genes, and compares the similarity of the gene expression profile of a cancer of unknown primary to a database of known profiles from 15 tissues with more than 60 histologic morphologies. The test uses a proprietary Pathchip® microarray and runs on the Affymetrix GeneChip® system. The report generated for each tumor consists of a "similarity score," which is a measure of similarity of the gene expression profile of the specimen to the profile of the 15 known tumors in the database. Scores range from 0 (very low similarity) to 100 (very high similarity), and sum to 100 across all 15 tissues on the panel. If a single similarity score is greater than or equal to 30, it indicates that this is likely the tissue of origin. If every similarity score is between 5 and 30, the test result is considered indeterminate, and a similarity score of less than 5 rules out that tissue type as the likely origin.

The Pathwork® Tissue of Origin test is suggested to be used when traditional tools used to identify tumors of uncertain origin are unable to identify a primary site. The test received clearance for marketing through the U.S. Food and Drug Administration's (FDA) 510(k) process in July 2008 with the limitations that it not be intended to establish the origin of tumors that cannot be diagnosed according to current clinical and pathological practice, and that it not be used to distinguish primary from metastatic tumor.

The molecular classification of cancers is based on the premise that, despite different degrees of dedifferentiation, tumors retain sufficient gene expression "signatures" as to their cell of origin, even after metastasis. Theoretically, it is possible to build a gene expression database spanning many different tumor types to compare to the expression profile of very poorly differentiated tumors or a cancer of unknown primary, to aid in the identification of the tumor type and organ of origin. The feasibility of using molecular classification schemes with gene expression profiling to classify these tumors of uncertain origin needs to be further studied and clarified.

POSITION STATEMENT

Gene expression profiling using the Pathwork® Tissue of Origin test **is considered experimental and investigational** in the following circumstances:

- To evaluate the site of origin of a tumor of unknown primary; **OR**,
- To distinguish a primary from a metastatic tumor; **OR**,
- Any other circumstance not listed above.

CODING

Non-Covered CPT®* Codes - This list is not all inclusive

84999 Unlisted Chemistry Procedure

88299 Unlisted cytogenetic study

88399 Unlisted surgical pathology procedure

ICD-9-CM Procedure Codes - No applicable codes

HCPCS Codes - No applicable codes

Non-Covered ICD-9-CM Diagnosis Codes - All diagnoses are non-covered.

*Current Procedural Terminology CPT® ©2010 American Medical Association: Chicago, IL.

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Government Agencies, Professional and Medical Organizations

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2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Occult Primary. Version 1.2009.

HISTORY AND REVISIONS

Date	Action
12/1/2011	<ul style="list-style-type: none">• New template design approved by MPC.
8/2/2011	<ul style="list-style-type: none">• Approved by MPC. No changes.