

WellCare Health Plans, Inc.
The WellCare Group of Companies

Clinical Coverage Guideline



WellCare Prescription Insurance, 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.

Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

WellCare of Texas, Inc.

WellCare Health Plans of New Jersey, Inc.

WellCare of Florida, Inc.

HealthEase of Florida, Inc.

WellCare of Louisiana, Inc.

WellCare of New York, Inc.

WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

Harmony Health Plan of Illinois, Inc.

WellCare of Ohio, Inc.

deCODE ProstateCancer™ Test

Guideline Number: HS-147

Original Effective Date: 12/3/2009

Revision Date: 12/28/2010

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.

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DISCLAIMER

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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.

CLINICAL COVERAGE GUIDELINE

The use of the decode ProstateCancer™ test for the assessment of prostate cancer risk and/or aggressiveness is considered experimental and investigational and NOT a covered benefit.

BACKGROUND

The deCODE ProstateCancer test tests for 8 single nucleotide polymorphisms (SNPs) (rs1447295, rs1859962, rs2710646, rs4430796, rs5945572, rs6983267, rs7947353, and rs16901979) using the Centaurus™ endonuclease IV SNP genotyping platform (Nanogen Inc.). The result of the test is an indicator of an individual's lifetime risk of developing prostate cancer, and ranges from 5.3% for an individual with none of the variant alleles of the 8 SNPs, to 80% for those at highest risk with several of the variant SNPs. The patient groups that might benefit from testing with the deCODE ProstateCancer test are men without prostate cancer to assess their risk of developing prostate cancer, and those diagnosed with prostate cancer to assess the risk of having an aggressive form of the disease.

Data were available from multiple studies indicating that 6 of the 8 SNPs included in the deCODE ProstateCancer test (rs1447295, rs1859962, rs4430796, rs5945572, rs6983267, and rs16901979) were associated with prostate cancer risk. For the SNP rs2710646, the data were more limited as only a single study found an association with prostate cancer risk. For the final SNP rs7947353, data could not be identified that described the association of this SNP with prostate cancer risk. Although several studies found evidence that the SNPs were independent in their contribution to the risk of prostate cancer, no study examined all 8 of the SNPs together; therefore, the assumption that the 8 SNPs are independent predictors of prostate cancer risk that can be combined into a single risk estimate has not been confirmed. Estimates for the prostate cancer risk associations for the 7 SNPs with data varied from odds ratios (OR) of 1.15 to 1.52. Accordingly, 6 of the 8 SNPs have known prostate cancer risk OR that exceed a suggested minimum clinical threshold of 1.15 for OR in genome-wide association studies. Although the associations of the 8 SNPs with aggressive or advanced prostate cancer were not completely clear, SNP rs1447295 had the most evidence in this regard. No studies were identified that specifically addressed the clinical utility or analytical validity of the deCODE ProstateCancer test.

With the lack of clear benefit of current screening techniques, including PSA and DGE, and the significant harms of

overdiagnosis and overtreatment of prostate cancer, the bar for acceptance of new screening technologies for prostate cancer should be high. There are data suggesting that 7 of the SNPs included in the deCODE ProstateCancer test are associated with prostate cancer. However, without data on the clinical utility of this test, any clinical benefits of the deCODE ProstateCancer test are currently not quantifiable (from Hayes, 2009).

CODING

The deCODE ProstateCancer Test is considered experimental and investigational and NOT a covered benefit.

Non-Covered CPT®* Codes

88299 Unlisted cytogenetic study, when billed for deCODE Prostate Cancer Test.

ICD-9-CM Procedure Codes

No applicable procedure codes

HCPCS Codes

No applicable Codes

Non-Covered ICD-9-CM Codes

185 Malignant neoplasm of prostate
790.93 Elevated prostate specific antigen

***Current Procedural Terminology (CPT) 2011 American Medical Association: Chicago, IL.®©**

REFERENCES

1. Hayes GTE Report. deCODE ProstateCancer™ (decode diagnostics). October 2, 2009.