 Draft New Policy: Do Not Implement

Protein Profiling Assays for Breast Cancer Prognosis

DESCRIPTION

There are new genomic tests being proposed to predict the likelihood of breast cancer development (e.g., BBDRiskDX®) or reoccurrence and expected benefit from radiation therapy (e.g., DCISionRT®). These tests are gene expression assays that assess genes active in tumor tissue. BBDRisk Dx® assay is being utilized to predict the risk of developing breast cancer in individuals with a diagnosis of Atypical Ductal Hyperplasia (ADH), Atypical Lobular Hyperplasia (ALH), Usual Ductal Hyperplasia (UDH), Papilloma or Sclerosing adenosis. DCISionRT® is being used to predict reoccurrence risk after breast conservative surgery and expected benefit from radiation therapy within 10 years in individuals who already have a diagnosis of breast cancer (Ductal Cell Carcinoma In situ).

POLICY

- Protein Profiling Assays for breast cancer prognosis (e.g., BBDRisk DX®, DCISionRT®) to predict the likelihood of breast cancer are considered ***investigational.***

IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g., statement.
- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

ADDITIONAL INFORMATION

The peer-reviewed medical literature does not support the test or are industry sponsored studies. There is a lack of studies to define their clinical role and if they are beneficial for the diagnosis and treatment of an individual's illness. National Comprehensive Cancer Network's (NCCN) Breast Cancer guideline does not mention BBBDRisk (MMP-1, CEACAM6, HYAL1, or HEC1) or DCISionRT®.

SOURCES

Dabbs, D., Mittal, K., Heineman, S., Whitworth, P., Shah, C., Savala, J., et al. (2023). Analytical validation of the 7-gene biosignature for prediction of recurrence risk and radiation therapy benefit for breast ductal carcinoma in situ. *Frontiers in Oncology,* 13, 1069059. Doi 10.3389/fonc.2023. 1069059. (Level 5 evidence)

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Kim, H., Vargo, J.A., Smith, K.J., & Beriwal, S. (2021). Cost – effectiveness analysis of biological signature DCISionRT use for DCIS treatment. *Clinical Breast Cancer,* 21 (3), e271-e278. Abstract retrieved October 24, 2024 from PubMed Database.

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EFFECTIVE DATE

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