myriad Choice CDx

The most comprehensive HRD tumor test to guide PARP inhibitor treatment decisions

HRD tests are not equivalent



First-line treatment decisions are **crucial** for women's life expectancy

The introduction of PARP inhibitor maintenance therapy to the first-line treatment strategy provides an opportunity to extend the longest PFS interval.¹⁻³



myChoice® identifies the most appropriate patients for this first-line decision.

myChoice[®] is recommended by clinical guidelines

myChoice[®] is the only HRD test with Level 1A evidence for first-line PARPi maintenance⁴⁻⁶



European Society of Medical Oncology

"In the first-line maintenance setting...use a validated scar based HRD test to establish the magnitude of benefit conferred by PARPi use" 4

ESMO recognizes myChoice® is the only scar based HRD test validated in the first-line maintenance setting



of Clinical Oncology

"The addition of olaparib to bevacizumab maintenance may be offered to patients who have stage III-IV HGS or endometrioid ovarian cancer and germline or somatic pathogenic or likely pathogenic variants in BRCA1 or BRCA2 genes and/or genomic instability, as determined by Myriad myChoice® CDx"⁵ National Comprehensive Cancer Network®

NCCN

"Germline and/or somatic BRCA 1/2 status informs selection of maintenance therapy... In the absence of a BRCA 1/2 mutation, homologous recombination deficiency (HRD) status may provide information on the magnitude of benefit of PARP inhibitor maintenance therapy"⁶

1. Giornelli GH 2016 2. Ray-Coquard et al 2019 3. Gonzalez-Martin et al 2019 4. Miller et al 2020 5. Tews et al 2020 6. NCCN Guidelines for Ovarian Cancer V.1.2021 7. Miller et al 2020 8. Tews et al 2020 9. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Ovarian Cancer V.1.2021. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed May 7, 2021. To view the most recent and complete version of the guidelines, go online to NCCN.org.

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myChoice[®] Genomic Instability Score (GIS) measures three HRD biomarkers (LOH, TAI, LST)





The combination of three biomarkers generates a bimodal distribution

There is a high-scoring (HRD positive) and low-scoring (HRD-negative) group represented by the two peaks.



1. Mills et al SGO 2016

Potential alternative Companion Diagnostics fail to reach FDA requirements for being CDx

Where a new CDx lacks clinical evidence, FDA indicates the assay needs to be highly correlated with the original CDx. The specifications in purple reflect the minimum requirements based on the reproducibility of myChoice[®] CDx PLUS. New tests need to exceed both NPA and PPA minimum standards.



*Comparison of 16 non-BRCA HRR genes vs BRCAwt PAOLA-1 patients

Each alternative HRD assay would lead to substantially less accurate treatment of patients when compared to myChoice[®]. Tests analysing LOH, TAI, LST (OncoScan and CytoSNP) also fail correlation.³

HRD tests are not equivalent

Don't miss treatable patients with uncorrelated assays.

A study of 3,278 ovarian tumors compares Myriad's proprietary Genomic Instability Status (GIS) and %LOH.² In the 2,991 BRCAwt patients in the study, results between the two assays had a correlation = 0.841.

myChoice[®] identified ~32% more tumors with HRD.²

According to the Phase III trials PAOLA-1, PRIMA and VELIA, this patient group had significant PFS improvement compared to the control arm.



myChoice-GIS CDx Commercial Ovarian BRCA (Wildtype) Samples

Non-BRCA HRRm are not interchangeable with GIS and should not be considered substitutes

As previously described by Nordquist et al 2018, non-BRCA HRR mutations are very uncommon. In this PAOLA-1 exploratory analysis, non-BRCA HRR mutations were not predictive of improved PFS.¹



myRIAD Choice CDx

Prospectively Validated^{2,3,4,5}

Trusted assay for multiple clinical trials by pharmaceutical partners

Clinically Actionable Results

Identifies patients eligible for treatment with PARP inhibitors

International Guidelines

Include recommendations for myChoice® testing for ovarian cancer^{6,7}

Fast TAT

myChoice[®] CDx PLUS delivers accurate results in approx. 14 working days after sample receipt

myChoice[®] CDx PLUS can inform treatment decisions

myChoice® CDx PLUS Intended Use

Myriad myChoice[®] CDx PLUS is used to detect Homologous Recombination Deficiency (HRD) by assessing the Genomic Instability Status and the Tumor Mutation *BRCA1/BRCA2* Status in genomic DNA extracted from tumor specimens. Results are used as an aid to determine the eligibility of patients with ovarian cancer for treatment with certain Poly-ADP Ribose Polymerase (PARP) inhibitors in accordance with the approved therapeutic product labeling.



Analytical concordance studies have been performed with the FDA approved myChoice[®] CDx test.



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