Washington State Health Care Authority

Gene expression profile testing of cancer tissue

Clinical Expert

Nancy E. Davidson, MD

Senior Vice President and Director, Clinical Research Division
Fred Hutchinson Cancer Research Center

President and Executive Director, Seattle Cancer Care Alliance

Head, Department of Medicine, Division of Medical Oncology
University of Washington School of Medicine

Applicant Name Nancy E. Davidson, MD

Address 1100 Fairview Avenue N.
M/S D5-310
Seattle, WA 98109

1. Business Activities

(a) If you or a member of your household was ***an officer or director of a business*** during the immediately preceding calendar year and the current year to date, provide the following:

Title	Business Name & Address	Business Type
None		

(b) If you or a member of your household ***did business under an assumed business name*** during the immediately preceding calendar year or the current year to date, provide the following information:

Business Name	Business Address	Business Type
None		

2. Honorarium

If you ***received an honorarium of more than $100*** during the immediately preceding calendar year and the current year to date, list all such honoraria:

Received From	Organization Address	Service Performed
Damon Runyon	New York, NY	exec. reviewer/advisor
Sidney Kimmel	Philadelphia, PA	exec. reviewer/advisor
Harvard University	Cambridge, MA	exec. reviewer/advisor

(see add'l sheet - 2A of 4)

3. Sources of Income

(a) Identify ***income source(s) that contributed 10% or more of the combined total gross household income*** received by you or a member of your household during the immediately preceding calendar year and the current year to date.

Source Name & Address	Received By	Source Type
Fred Hutchinson	Nancy E. Davidson	Salary
University of Pittsburgh	Thomas Kensler (spouse)	Salary
Johns Hopkins University	" " "	Salary

WA – Health Technology Assessment

Continuation - #2: Honorarium

Received From	Organization Address	Services Performed
Memorial Sloan Kettering	New York, NY	Reviewer/Advisor
George Washington University	Washington, DC	Reviewer/Advisor
University of Michigan	Ann Arbor, MI	Reviewer/Advisor
MD Anderson Cancer Center	Houston, TX	Reviewer/Advisor
University of Chicago	Chicago, IL	Reviewer/Advisor
University of Chapel Hill	Chapel Hill, NC	Reviewer/Advisor
University of WA	Seattle, WA	Reviewer/Advisor
University of Pennsylvania	Philadelphia, PA	Reviewer/Advisor
UBM, LLC	San Francisco, CA	Journal Co-editor

(b) Does any income source listed above relate to, or could it reasonably be expected to relate to, business that has, or may, come before the Committee?

☐ Yes ☒ No

If "yes", describe: Click here to enter text.

(c) Does an income source listed above have a legislative or administrative interest in the business of the Committee?

☐ Yes ☒ No

If "yes", describe: Click here to enter text.

4. Business Shared With a Lobbyist

If you or a member of your household ***shared a partnership, joint venture, or similar substantial economic relationship with a paid lobbyist***, were employed by, or employed, a paid lobbyist during please list the following:

(Owning stock in a publicly traded company in which the lobbyist also owns stock is not a relationship which requires disclosure.)

Lobbyist Name	Business Name	Type Business Shared
None		

Provide the information requested in items 5, 6, and 7 below only if:
(a) Your response involves an individual or business if you or a member of your household did business with, or reasonably could be expected to relate to business that has or may come before the Health Technology Clinical Committee.
(b) The information requested involves an individual or business with a legislative or administrative interest in the Committee.

5. Income of More Than $1,000

List each source (***not amounts***) of income over $1,000, other than a source listed under question 3 above, which you or a member of your household received during the immediately preceding calendar year and the current year to date:

Income Source	Address	Description of Income Source
See #2		

6. Business Investments of More Than $1,000

(Do not list the amount of the investment or include individual items held in a mutual fund or blind trust, a time or demand deposit in a financial institution, shares in a credit union, or the cash surrender value of life insurance.)

If you or a member of your household had a personal, beneficial interest or investment in a business during the immediate preceding calendar year of more than $1,000, list the following:

Business Name	Business Address	Description of Business
None		

7. Service Fee of More Than $1,000

(Do not list fees if you are prohibited from doing so by law or professional ethics.)

List each ***person for whom you performed a service for a fee of more than $1,000*** in the immediate preceding calendar year or the current year to date.

Name	Description of Service
None	

I certify that I have read and understand this Conflict of Interest Form and the information I have provided is true and correct as of this date.

Print Name ~~Click here to enter text.~~ Nancy E. Davidson

Check One: ☒ Committee Member ☐ Subgroup Member ☐ Contractor

[redacted] 3/6/18

Signature Date

UNIVERSITY OF WASHINGTON SCHOOL OF MEDICINE CV
FOR NANCY ELLEN DAVIDSON, MD

1. Personal Data:

Birth Place: Denver, Colorado

Business Address: Fred Hutchinson Cancer Research Center
1100 Fairview Avenue North
Thomas Bldg., M/S D5-310
Seattle, Washington 98109

Business Phone: 206-667-6363

Business Fax: 206-667-6936

Email Address: ndavidson@fredhutch.org

2. Education:

9/1971 – 6/1975 Wellesley College; Wellesley, Massachusetts; BA, Molecular Biology

9/1975 – 6/1979 Harvard Medical School; Boston, Massachusetts; MD, Medicine

3. Postgraduate Training: Internship, residencies, fellowships (dates and places, oldest to newest).

7/1979 – 6/1980 Hospital of the University of Pennsylvania; Philadelphia, Pennsylvania; Intern, Internal Medicine

7/1980 – 6/1982 The Johns Hopkins Hospital; Baltimore, Maryland; Resident, Internal Medicine

7/1982 – 7/1985 National Cancer Institute, National Institutes of Health; Bethesda, Maryland Medical Staff Fellow

4. Faculty Positions Held:

1985-1987	Medical Breast Cancer Section, Medicine Branch, National Cancer Institute Bethesda, Maryland	Guest Worker
1985-1986	Uniformed Services University of Health Sciences Bethesda, Maryland	Research Assistant Professor of Pharmacology
1986-1992	The Johns Hopkins University Baltimore, Maryland	Assistant Professor of Oncology Associate Professor of Oncology
1995-2009	The Johns Hopkins University Baltimore, Maryland	Breast Cancer Research Chair of Oncology
1999-2009	The Johns Hopkins University Baltimore, Maryland	Professor of Oncology
1986-2009	Johns Hopkins Hospital	Active Staff

	Baltimore, Maryland	
1994-2009	The Johns Hopkins Oncology Center Baltimore, Maryland	Director, Breast Cancer Program
1997-2009	The Johns Hopkins Bloomberg School of Public Health Baltimore, Maryland	Joint Appointment in Department of Biochemistry and Molecular Biology
2009-Present	The Johns Hopkins University Baltimore, Maryland	Adjunct Professor of Oncology
2009-2010	University of Pittsburgh Pittsburgh, PA	Chief, Division of Hematology/Oncology
2009-2016	University of Pittsburgh Pittsburgh, PA	Director, University of Pittsburgh Cancer Institute Professor of Medicine and Pharmacology and Chemical Biology Associate Vice Chancellor for Cancer Research Hillman Professor of Oncology
2010-2016	University of Pittsburgh Pittsburgh, PA	Professor, Clinical and Translational Science Institute
2013-2016	University of Pittsburgh Pittsburgh, PA	Distinguished Professor of Medicine
2016 – Present	Seattle Cancer Care Alliance Seattle, WA	President & Executive Director
2016 – Present	Fred Hutchinson Cancer Research Center, Clinical Research Division Seattle, WA	Senior Vice President & Full Member
2016 - Present	University of Washington Department of Medicine Seattle, WA	Division Head, Medical Oncology
2016- Present	University of Pittsburgh School of Medicine Pittsburgh, PA	Adjunct Professor of Medicine

5. Hospital Positions Held:

12/2016 – Present	University of Washington Medical Center 1959 NE Pacific Street Seattle, WA 98195
7/2009 - 11/2016	Magee Women's Hospital of UPMC 300 Halket Street Pittsburgh, PA 15213
7/2009 -	UPMC Shadyside Hospital

11/2016	5230 Centre Avenue Pittsburgh, PA 15232
7/2009 - 10/2011	UPMC Presbyterian Hospital 200 Lothrop Street Pittsburgh, PA 15213
7/1986 - 1/2009	The Johns Hopkins Hospital 1800 Orleans Street Baltimore, Maryland 21287

6. **Honors**:

Phi Beta Kappa	1974
Sigma X	1975
American Society of Clinical Oncology Young Investigator Award	1986-1987
Susan Komen Foundation Award	1987-1988
American Cancer Society Clinical Oncology Career Development Award	1988-1991
Merck Clinician Scientist Award	1989-1990
Breast Cancer Research Chair in Oncology, Johns Hopkins	1995-2009
ACS Research Award, American Cancer Society - Maryland Division	1998
Brinker International Award for Breast Cancer Research	1999
Wellesley College Alumnae Achievement Award	2000
William L. McGuire Memorial Lectureship, 24th Annual San Antonio Breast Cancer Symposium	2001
Avon Foundation Medical Advancement Award	2003
President, American Society of Clinical Oncology	2007-2008
7th Rosalind E. Franklin Award for Women in Science, National Cancer Institute	2008
11th American Association for Cancer Research-Women in Cancer Research Charlotte Friend Award	2008
Johns Hopkins University Alumni Association Distinguished Alumna Award	2009
American Society of Clinical Oncology Gianni Bonadonna Breast Cancer Award	2010
Association of American Physicians	2010
National Academy of Medicine (formerly the Institute of Medicine)	2011
Pennsylvania Breast Cancer Coalition Potamkin Award	2012
Distinguished Professor of Medicine, University of Pittsburgh	2013
Thomson Reuters Highly Cited Researchers	2014, 2015
The Johns Hopkins Women's Medical Alumnae Assoc. Hall of Fame	2015
Johns Hopkins University Society of Scholars	2016
Fellow, American College of Physicians	2016
Distinguished Daughters of Pennsylvania	2016
Fellow of the AACR Academy	2017
Jill Rose Award, Breast Cancer Research Foundation	2017

7. Board Certification:

National Board of Medical Examiners	1980
American Board of Internal Medicine	1982
Medical Oncology	1985

8. Current License(s) to Practice:

State of Maryland	1982
Commonwealth of Pennsylvania	2009
State of Washington Dept. of Health #MD.60721914	2017

9. Professional Organizations:

American Society of Clinical Oncology	**1985-present**
Member, Program Committee	1992, 1998, 2002, 2003
Session Chairman	1992, 1993, 1998
Member, Public Issues Committee	1992-1996
Member, Award Selection Committee	1992-1996
Chair, Award Selection Committee	1994-1995
Member, Ad hoc Technology Assessment Committee for Development of Growth Factor Clinical Practice Guidelines	1993-1994
Co-Chair, Breast Cancer Follow-up Testing Guidelines Expert Panel	1996- present
Member, Membership Committee	1997-1999
Member, Board of Directors	1996-1999
Member, Grants Selection Committee	1999-2002
Member, Task Force on Quality of Cancer Care	1999-2004
Member, Publications Committee	2004-2007
Chair, Publications Committee	2005-2006
Member, Translational Research Task Force	2005-2006
President-Elect, President, and Immediate Past President	2006-2009
Member, Value in Cancer Care Task Force	2007-present
Chair, Special Awards Selection Committee	2008-2009
Member, Translational Research Professorship Selection Committee	2008-2009
Government Relations Committee	2013-2016
By-laws Committee Chair, 2012-2014	2010-2014

American Association for Cancer Research	**1988- present**
Session Chair 1991, 1995, 1998	2004, 2006, 2013
Member, Maryland Legislative Committee	1993-1997
Member, Program Committee	2000-2001, 2002-2003
Co-Chair, Program Committee	2003-2004
Member, Clinical Cancer Research Committee	2001

Member, AACR-Richard and Hinda Rosenthal Foundation Award	1998-1999,
Selection Committee	2001-2003
Member, Board of Directors	2002-2005
Chair, Education Committee	2003-2004
Member, Grants Selection Committee	2004-2005
Member, Lifetime Achievement Award Selection Committee	2004-2005
Member, Landon Award Selection Committee	2005-2006
Chair, AACR-Breast Cancer Research Foundation Grants Selection Committee	2008-2009
Member, Landon Translational Award Selection Committee	2008-2009
Co-Chair, Program Committee, 7th Annual Frontiers in Cancer Prevention Research Conference	2008
Member and Chair (2010-11), AACR Nominating Committee	2010-2012
Member, Continuing Medical Education Committee, Chair 2015-2016	2010-2016
Member, AACR-San Antonio Breast Cancer Symposium,	
Education Committee	2012-2013
Program Committee	2011-2014
President-Elect, President, and Immediate Past President	2015-2018

Eastern Cooperative Oncology Group ECOG ACRIN	**1987-present**
Member, Breast Cancer Core Committee	1987-present
Chair, Breast Cancer Biology Committee	1992-1996
Co-Chair, Breast Cancer Committee	1992-1996
Chair - Breast Cancer Committee	1997-2002

American College of Physicians	**2009-present**
Member, National Surgical Adjuvant Bowel and Breast Project	**2010-present**
Board of Directors, Association of American Cancer Institutes	**2010-2013**
Member, Association of American Physicians Council	**2015-present**

10. Teaching Responsibilities at Johns Hopkins and University of Pittsburgh

1988-2005	Lecturer, Pathophysiology Course for 2nd Year Medical Students
1991	Medical Student Advisor
1996-2009	Lecturer, Fundamentals of Clinical Oncology for Public Health Practitioners
1997-2009	Lecturer, Topics in Molecular Endocrinology, School of Public Health
2004-2009	Lecturer, Pathophysiology of Disease, Cellular and Molecular Medicine
2010-2016	Lecturer, Cancer Biology and Therapy
2013-2016	ILS Neoplasia & Neoplastic Diseases

Mentoring:

Postdoctoral Fellows – Laboratory		Current Position
1988-1990	M. John Kennedy, MD	Consultant, St. James Hospital, Dublin, Ireland
1989-1992	Deborah K. Armstrong, MD	Professor of Oncology, Johns Hopkins

1991-1993	Yvonne L. Ottaviano, MD	Private Practice, Baltimore, MD
1993-1996	Diane McCloskey, PhD	Associate Professor of Cellular & Molecular Physiology, Penn State, Hershey, PA
1993-1997	Rena Lapidus, PhD	Director, Translational Core Laboratory Associate Professor, University of Maryland
1993-1998	Anne Ferguson, PhD	Non-profits, San Francisco, CA
1994-1995	Christian Jackisch, MD	Chief, Clinic for Gynecology and Obstetrics, Klinikum Offenbach, Offenbach, Germany
1996-1999	Hillary Hahm, MD, PhD	Private Practice, Atlanta, GA
1997-1999	Sharyl Nass, PhD	Director of the National Cancer Policy Forum Institute of Medicine, National Academy of Medicine, Washington, DC
1998-2001	Xiaowei Yang, MD, PhD	Staff Scientist, National Cancer Institute
1999-2001	Valerie Dunn, MD	Private Practice, Rochester, NY
2000-2001	Lan Yan, MD, PhD	Staff Scientist, Amgen, Thousand Oaks, CA
2001-2006	Yi Huang, MD, PhD	Assistant Professor, University of Pittsburgh, Pittsburgh, PA
2001-2004	Judith C. Keen, PhD	Director of Scientific Affairs at the American Society for Radiation Oncology (ASTRO)
2002-2003	Dipali Sharma, PhD	Associate Professor of Oncology, Johns Hopkins University School of Medicine, Baltimore, MD
2004-2008	Qun Zhou, MD, PhD	Associate Professor of Biochemistry and Molecular Biology, University of Maryland Medical School
2005-2006	Allison Tracy, PhD	Lecturer of Chemistry and Biochemistry, UMBC
2006-2009	Qingsong Zhu, PhD	Chief Operating Officer, InSilico Medicine, Inc., Baltimore, MD
2006-2009	Madhavi Billam, PhD	Senior Toxicologist, L'Oreal USA & RI
2011-2013	Tiffany Katz, PhD	Instructor, Baylor College of Medicine, Center for Precision Environmental Health Department of Molecular and Cellular Biology
2014-2016	Nilgun Tasdemir, PhD	Postdoctoral Fellow, University of Pittsburgh
2015-2017	Lin Chen	Pre-doctoral Student, Tsinghua University, Beijing, PRC

Doctoral Students		Current Position
2000-2005	Julie Blum, PhD	Clinical Content Manager, MED-IQ
2001-2005	Allison Pledgie, PhD	Senior Lecturer in Chemistry and Biochemistry at University of Maryland Baltimore County (UMBC)
2004-2010	Abigail Witt, PhD	Postdoctoral Fellow, University of Miami School of Medicine
2005-2010	Talmesha Richards, PhD	Chief Academic and Diversity Officer at STEMconnector
2006-2010	Patrick Shaw, PhD	Chief, Pathogen Detection Lab. USA Public Health Command Region-Pacific Camp Zama, Japan

Graduate Training Programs

1997-2011	Biochemistry and Molecular Biology, Hopkins Bloomberg School of Public Health (adjunct 2009-2011)
1999-2013	Cellular and Molecular Medicine, Hopkins School of Medicine (adjunct 2009-2013)

11. Editorial Board Responsibilities:

1993-1995, 2006-9	Journal of Clinical Oncology
1995-2005	Cancer Research
1995-2009	The Breast Journal
1996-2011	The Breast
1997-2005	American Journal of Medicine
1999-2005	Clinical Cancer Research
2007-2014	Hem/Onc Today
2008-present	Oncology
2008-present	Cancer Prevention Research
2012-present	Journal of the National Cancer Institute
2012-present	Breast Cancer Research and Treatment

12. Special National Responsibilities:

Study Section Memberships:

1988	Member, Ad Hoc Technical Review Section, National Cancer Institute, Bethesda, MD
1990, 1991, 1992	Ad Hoc Member, Reproductive Endocrinology Study Section, National Institutes of Health, Bethesda, MD
1992-1993	Member, Awards Committee, Susan G. Komen Foundation, Dallas, TX
1993-1997	Member, Reproductive Endocrinology Study Section, National Institutes of Health, Bethesda, MD
1994	Member, Walt Disney – American Cancer Society Breast Cancer Professorship Selection Committee, Atlanta, GA
1997-1998	Co-Chair, Progress Review Group for Breast Cancer Research, National Cancer Institute, Bethesda, MD
1996-1998	Chair, Pre-clinical and Clinical Studies Study Section, California Breast Cancer Research Program, San Francisco, CA
1999-Present	Medical Advisory Board, Breast Cancer Research Foundation, New York City, NY
2001	Member, Breast and Prostate SPORE Review Group, National Cancer Institute
2002	Co-chair, Breast Cancer SPORE Review Group, National Cancer Institute
2003-2008	Vice-Chair, National Cancer Institute Breast Cancer Intergroup Correlative Science Committee
2002-2005	Member, Charles Kettering Prize Selection Committee, General Motors Cancer Research Foundation, Chair, 2005
2003	Chair, Innovator Award Review Committee, Department of Defense Breast Cancer Program
2005	Member, Lung and Bladder Cancer SPORE Review Group, National Cancer Institute
2005-2006	Ad hoc member, Kimmel Scholars Award Committee
2006-2017	Member, Kimmel Scholars Award Committee
2006-2010	Member, Subcommittee A – Cancer Centers, National Cancer Institute
2008	Co-chair, Lung Cancer and Lymphoma SPORE Review Group, National Cancer Institute

2008-Present	Member, Scientific Advisory Board, V Foundation for Cancer Research
2008	Chair, Therapeutic Targets I Review Committee, Susan G Komen for the Cure
2012-Present	Member, Damon Runyon Cancer Research Foundation Clinical Investigator Award Committee
2012-2013	Chair of the Cancer Program Review, Helmholtz Senate Commission, Helmholtz Association of German Research Centers, Berlin, Germany
2014	Member, Scientific Advisory Committee, Breakthrough Breast Cancer, London, UK
2014	Chair, CTAC SPORE Program Evaluation Working Group, NCI
2015	Chair, Stand Up To Cancer Canada-Canadian Breast Cancer Foundation Breast Cancer Dream Review Team Committee

Extra-mural Grant Reviewing:

Ad hoc grant reviewer for: National Institutes of Health, American Cancer Society, Veterans Administration, Manitoba (Canada) Health Council, Health Research Council of New Zealand, National Cancer Institute - Canada, Medical Research Council - Canada, Department of Defense Breast Cancer Program, many others

Advisory Board Memberships:

2000-present	Member, External Advisory Board, Vanderbilt-Ingram Cancer Center, Nashville, TN
2001-2006	Member, External Advisory Board, Fox Chase Cancer Center, Philadelphia, PA
2001-2011	Member, External Advisory Board, Bay Area UCSF Breast Cancer SPORE, San Francisco, SF
2003-2016	Member, External Advisory Board, Karmanos Cancer Center, Detroit, MI
2003-2008	Member, External Advisory Board, Indiana University Cancer Center, Indianapolis, IN
2005-2016	Member, External Advisory Board, University of Maryland Cancer Center, Baltimore, MD
2008-Present	Member, Board of Scientific Consultants, Memorial Sloan Kettering Cancer Center, NY, NY
2008-Present	Member, External Advisory Board, Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill, Chapel Hill, NC, Chair 2014-
2009-Present	Member, External Advisory Board, MD Anderson Cancer Center, Houston, TX Chair 2014-
2010-Present	Member, External Advisory Board, University of Michigan Comprehensive Cancer Center
2010-Present	Member, External Advisory Board, Washington University Siteman Cancer Center, St. Louis, MO
2010-Present	Member, External Advisory Board Breast Cancer SPORE, Mayo Clinic, Rochester, MN
2010-Present	Member, External Advisory Board, Institut National du Cancer, Paris, France
2011-2016	Member, External Advisory Board, Fred Hutchinson Cancer Research Center University of Washington Cancer Consortium, Seattle, Washington
2011-2016	Member, Scientific Advisory Board, CTSA, Case Western Reserve University School of Medicine, Cleveland, Ohio
2012-Present	Member, Scientific Advisory Board, Cologne Center for Integrated Oncology, Cologne, Germany
2013-Present	Member, External Advisory Board, Baylor College of Medicine Breast Cancer SPORE
2014-Present	Member, External Advisory Board, University of Chicago Comprehensive Cancer Center, Chicago, IL
2014-2015	Member, Scientific Advisory Board, A. Alfred Taubman Medical Research Institute, University of Michigan, Ann Arbor, MI

External Organizations:

1993-1995	Member, Medical Advisory Committee, Maryland Cancer Consortium
1994-1996	Executive Committee, American Cancer Society – Maryland Division Chair, Research Committee
1995-1998	Member, Medical Knowledge Self-Assessment Program 11-Oncology, American College of Physicians
1999-2000	Planning Committee, National Institutes of Health Consensus Development Conference on Adjuvant Therapy for Breast Cancer, Bethesda, MD
1998-2001	Data Monitoring Committee, Southwest Oncology Group
1999-2006	Data Monitoring Committee, RUTH Trial, Lilly
2000-2006	Data Monitoring Committee, Breast Cancer International Research Group (BCIRG)
2003, 2005, 2007, 2009, 2011, 2013, 2015	Member, St. Gallen Consensus Panel, St. Gallen, Switzerland
2006-2011	Member, Data and Safety Monitoring Committee, TEACH Trial, Glaxo Smith Kline
2009-2012	NMR Center Advisory Committee, Carnegie Mellon University
2010-2016	Co-Chair, Breast Cancer Steering Committee, National Cancer Institute
2011-Present	Member, Clinical Trials and Translational Research Advisory Committee (CTAC), National Cancer Institute, Chair 2015-present
2013-2016	Board of Trustees, Phipps Conservatory, Pittsburgh, PA
2015	Member, Search Committee for the Scientific Director (SD), Center for Cancer Research (CCR), National Cancer Institute
2015-2017	Member, Breast Cancer Now's Science Strategy Committee, United Kingdom
2017-Present	Member, Board of Scientific Counselors-Clinical Sciences and Epidemiology, NCI

13. **Special Local Responsibilities**:

Committees - Johns Hopkins

1987	Co-Director, Oncology Multidisciplinary Conference
1987-1997	Member, Oncology Fellowship Selection Committee
1993-1995	Department Representative, Medical School Council
1999-2003	Departmental Appointments and Promotions Committee
2000-2005	Member, School of Medicine Professorial Promotion Committee
2001-2009	Member, MD-PhD Admissions Committee
2003-2005	Member, Search Committee for Director of Biophysics and Biophysical Chemistry

Committees – University of Pittsburgh, University of Pittsburgh Physicians (UPP), UPMC

2009-2016	Member, Chair Management Committee
2009-2016	Member, UPP Clinical Chairs Committee
2009-2016	Member, Breast Cancer Steering Committee
2009-2016	Member, Clinical Research Oversight Committee
2009-2012	Member, ReSet Steering Committee
2009-2016	Member, Adolescent and Young Adult Cancer Committee
2010-2011	Member, Search Committee for Department of Medicine Chairman
2011-2012	Member, Search Committee for the Institute of Personalized Medicine
2012-2016	Member, UPMC Presbyterian Shadyside Hillman Cancer Committee

2012-2016 Member, School of Medicine Financial Oversight Committee

2012-2016 Member, Internal Advisory Board Skin SPORE

2014-2016 Member, Internal Advisory Board Gynecologic SPORE

2015-2016 Member, Internal Advisory Board for the Center for Causal Discovery

2015-2016 Member, Internal Advisory Board of the Center for Medical Counter Measures Against Radiation (CMCR)

14. Research Funding:

Current Research Funding

NIH P30CA015704 Gilliland, PI	Cancer Center Support Grant Davidson co-deputy director	15%	2017-2019	$5,408,473
NIH T32 CA009515	Training in Cancer Biology and Transplantation	5%	2017-2020	$593,274
BCRF Davidson, PI	Identifying kinase vulnerabilities of dormant disseminated breast tumor cells and micrometastases using cutting edge models	1%	1998-2018	$208,334
BCRF Davidson, PI	NABCG-BIG North American Breast Cancer Group/Breast International Group Collaboration	5%	2010-2018	$208,333

Past Research Funding

Grants Awarded as Principal Investigator

1986-1987 American Society of Clinical Oncology Young Investigator Award, "Isolation of estrogen- induced genes from human breast cancer."

1987-1988 American Cancer Society Institutional Grant, "The relationship between epidermal growth factor receptor and estrogen receptor in breast cancer."

1987-1989 American Cancer Society Maryland Division. "The role of epidermal growth factor and its receptor in breast cancer."

1987-1988 Susan G. Komen Foundation. "The role of epidermal growth factor and its receptor in human breast cancer."

1988-1991 American Cancer Society Clinical Oncology Career Development Award.

1989-1995 NIH Grant R29 CA 49634. "Epidermal growth factor receptor in human breast cancer."

1989-1990 Phil N. Allen Charitable Trust Grant. "Novel approaches to hormone-unresponsive breast cancers."

1989-1990 Merck Clinician Scientist Award, Johns Hopkins University School of Medicine.

1990-1991 Johns Hopkins University School of Medicine Institutional Research Grant, "Elimination of breast cancer cells from human bone marrow by counter flow centrifugal elutriation".

1991-1993 Susan G. Komen Breast Cancer Foundation Fellowship.

1991-1992 Mildred Mindell Cancer Foundation, Inc. "Incidence of p53 mutations in the germ-line of young women with breast cancer".

1992-1994 NIH Grant R01 CA57545. "Programmed cell death in human breast cancer cells"

1992-1994 NIH Grant P30 CA06973 pilot. "DNA methylation and estrogen receptor expression in human breast cancer cells"

1995-1997 Susan G. Komen Breast Cancer Foundation Fellowship.

1994-1998 NIH Grant R21 CA/ES 66204 "Development of a breast cancer program at Johns Hopkins".

1994-1995	NIH Grant 5P50 CA-58236 pilot. "Effects of polyamine analogues on growth of human prostatic cancer cells"
1995-1999	NIH Grant 1 U01 CA66084. "New therapeutic approaches for breast cancer".
1995-1998	American Cancer Society BE-237 "Methylation of steroid receptors in human breast cancer".
1996-1997	Susan G. Komen Foundation, "Functional significance of DNA methylation of estrogen receptor in breast cancer."
1998-2004	NIH Grant R01 CA78352 "DNA methylation as a determinant of hormone resistant breast cancer."
1999-2003	DOD-USAMRDC DAMD 17-99-1-9242. "Therapeutic and chemopreventive actions of a novel polyamine analog against breast cancer"
1998-1999	NIH Grant P50 pilot. "Activity of a novel polyamine analog against breast cancer"
2001-2009	Avon Foundation
2001-2005	Susan G. Komen Foundation Postdoctoral Fellowship
2003-2005	Susan G. Komen Foundation Predoctoral Fellowship
2000-2009	American Breast Cancer Foundation
2006-2008	Susan G. Komen Foundation, BCTR 65706, "Polyamine analogues as novel anti-estrogen receptor alpha agents
2007-2009	Lee Jeans Translational Breast Cancer Research Program (with Entertainment Industry Foundation)
2008-2011	Susan G. Komen for the Cure, KG080923, Inhibition of lysine specific demethylase 1 (LSD1) as a strategy for re-expression of epigenetically silenced genes in breast cancer; Robert Casero, Jr. and Nancy E. Davidson , Co-PIs
2000-2013	NIH P50 CA88843. SPORE in Breast Cancer Nancy E. Davidson co-PI of University of Pittsburgh site 2009-2012
2011-2013	Gynecologic Center of Excellence. Henry M. Jackson Foundation
2009-2013	Stand up to Cancer (AACR). Bringing epigenetic therapy to the forefront of cancer. Dream Team Principal, with Stephen Baylin and Peter Jones
2009-2016	P30CA047904 Cancer Center Support Grant-- National Cancer Institute. To support senior leadership, shared resources, and developmental funds for the University of Pittsburgh Cancer Institute
2009-2016	Translational Breast Cancer Research Consortium and the Komen Foundation
2009-2016	Translational Breast Cancer Research Consortium and the Avon Foundation
2014-2017	DOD Grant W81WH-14-1-0237 Breast Cancer Research Program (BCRP) Breakthrough Award. "Targeting histone abnormality in triple negative breast cancer"
2014-2016	U10 CA180844, NCI NCTN-Network, Lead Academic Site at University of Pittsburgh

15. Bibliography

a) Publications in Refereed Journals

1. Kensler TW, Busby WF, Jr., **Davidson NE**, and Wogan GN. Aflatoxin inhibition of glucocorticoid binding capacity of rat liver nuclei. Biochim. Biophys. Acta. 473:200-10, 1976. PMID 181075
2. Kensler TW, Busby WF, **Davidson NE**, and Wogan GN. Effect of hepatocarcinogens on the binding of glucocorticoid-receptor complex in rat liver nuclei. Cancer Res. 36:4647-51, 1976. PMID 1000507
3. Michejda CJ, **Davidson NE**, and Keefer LK. Photochemical perturbation of Z=E equilibria in nitrosamines. J. Chemistry Soc. Chem. Comm. 633-634, 1976
4. Hochberg MC, **Davidson NE**, and Kim WS. Lupus nephritis. Johns Hopkins Med. J. 150:101-106, 1982. PMID 7062572
5. **Davidson NE**, Bronzert DA, Chambon P, Gelmann EP and Lippman ME. Use of two MCF-7 cell variants to evaluate the growth regulatory potential of estrogen-induced products. Cancer Res. 46:1904-08, 1986. PMID 3948173
6. Kasid A, **Davidson NE**, Gelmann EP and Lippman ME. Transcriptional control of thymidine kinase gene expression by estrogens and antiestrogens in MCF-7 human breast cancer cells. J. Biol. Chem. 261:5562-7, 1986. PMID 2420802
7. Lippman ME, Dickson R, Kasid A, Gelmann EP, **Davidson NE**, McManaway M, Huff K, Bronzert D, Bates S, Swain S and Knabbe C. Autocrine and paracrine growth regulation of human breast cancer. J. Steroid Biochem. 24:147-54, 1986. PMID 3486321

8. Bronzert DA, **Davidson N**, and Lippman M. Estrogen and antiestrogen resistance in human breast cancer cell lines. Adv. Exp. Med. Biol. 196:329-45, 1986. PMID 3521223
9. Kensler TW, Egner PA, **Davidson NE**, Roebuck BD, Pikul A, and Groopman JD. Modulation of aflatoxin metabolism, aflatoxin- N7-quanine formation, and hepatic tumorigenesis in rats fed ethoxyquin: role of induction of glutathione S-transferases. Cancer Res. 46:3924-31, 1986. PMID 2873884
10. **Davidson NE**, Gelmann EP, Lippman ME and Dickson RB. EGF receptor gene expression in estrogen receptor positive and negative human breast cancer cell lines. Molecular Endocrinology, 1:216-23, 1987. PMID 3502607
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24. Oesterreich, S, Lee AV, **Davidson NE**. Is it time to reSET the standard for estrogen receptor testing in breast cancer? J Clin Oncol 28:4101-3, 2010. PMID: 2069707.
25. Davidson, NE, Kensler TW. "MAPping" the course of chemoprevention in breast cancer. N Engl J Med 364(25):2463-4, 2011. PMID: 21639807.
26. Puhalla S, Jankowitz RC, **Davidson NE**. Adjuvant endocrine therapy for breast cancer: don't ditch the switch! J Natl Cancer Inst 103:1280-2, 2011. PMID: 21859987
27. Bhargava R, Brufsky AM, **Davidson NE**. Prognostic/predictive immunohistochemistry asays for estrogen receptor-positive breast cancer: back to the future? J Clin Onc 30(36):4451-3, 2012. PMID: 23045595
28. McAuliffe PF, Danoff S, Shapiro SD, **Davidson NE**. Treatment for breast cancer: is time really of the essence? J Natl Cancer Inst 105(2):8-2, 2012. PMID 23264682
29. Sharma D, **Davidson NE**. Obesity and breast cancer: a multipartite connection. J Mammary Gland Biol Neoplasia. 18(3-4):253-5, 2013. PMID:24190309
30. Oesterreich S, Brufsky AM, **Davidson NE**. Using mice to treat (wo)men: mining genetic changes in patient xenografts to attack breast cancer. Cell Rep. 4(6):1061-2, 2013 PMID24075202[PubMed - in process]
31. Oesterreich S, **Davidson NE**. The search for ESR1 mutations in breast cancer. Nat Genet. 45(12):1415-6, 2013. PMID 24270445
32. Jankowitz RC, Puhalla S, **Davidson NE**. Should we embrace or ablate our urge to (ovarian) suppress? J Clin Oncol. 32(35): 3920-2, 2014. PMID 25366692.
33. Mathew A, Brufsky AM, **Davidson NE**. Can circulating tumor cells predict resistance in metastatic breast cancer? Clin Cancer Res 2:2967, 2014. PMID 25645864
34. **Davidson NE**, Rimm DL. Expertise vs evidence in assessment of breast biopsies: an atypical science. JAMA 17:313(11):1109-10, 2015. PMID 25781438
35. Brufsky AM, **Davidson NE**. Multiparametric genomic assays for breast cancer: time for the next generation? Clin Cancer Res. 22(20)4963-4965, 2016. PMID 27521446
36. Bhargava R, **Davidson NE**. "Take two"? the role of second opinions for breast biopsy specimens. BMJ 353:i3256. Doi:10.1136/bmj.i3256. PMID 27339037
37. Puhalla SL, **Davidson NE**. Breast cancer: the 21-gene recurrence score-biology remains at the forefront. Nat Rev Clin Oncol 13(8)470-2, 2016. PMID: 27296295
38. **Davidson NE**. Serendipity and purpose. Endocrine-related cancer. 23(5):P1-3, 2016. PMID: 27059549
39. **Davidson NE**. Conquering metastatic breast cancer. J Oncol Pract.12(1):11-2, 2016.Pub Med Central PMCID: 4960463.
40. Specht JM, **Davidson NE**. Optimal duration of trastuzumab for early HER2-positive breast cancer. Lancet 389 (10075):1167-1168, 2017. PMID 28215659
41. Stanton SE, **Davidson NE**. Breast cancer: What lies beyond APHINITY for HER2-positive breast cancer? Nat Rev Clin Oncol. 2017 Aug 8. doi: 10.1038/nrclinonc.2017.125. [Epub ahead of print] PubMed PMID: 28786414.
42. Yung RL, **Davidson NE**. Searching for the IDEAL duration of adjuvant endocrine therapy. J Natl Cancer Inst in press
43. **Davidson NE**. Incident cancer in cancer survivors --When cancer lurks in the background. JAMA Oncology, in press

Articles in the Lay Press:

1. **Davidson NE**. Is hormone replacement a risk? Scientific American. 275:101, 1996.
2. **Davidson NE**. Hormone replacement therapy in perspective; Medical and Health Annual, Encyclopedia Britannica, Inc., Chicago, IL pp. 361-6, 1997.

e) Manuscripts Submitted.

None

f) Abstracts.

Not recorded

16. Other:

Invited Seminars

1985 Grand Rounds, Washington Veterans Administration Hospital, Washington, DC

1986 Medical Grand Rounds, Johns Hopkins Medical Institutions, Baltimore, MD
Symposium on Breast Cancer, Millville Hospital, Vineland, NJ
Department of Hematology-Oncology, University of Missouri, Kansas City, MO
Kansas City Round Table of Hematology/Oncology, Kansas City, MO
American Association of Osteopathic Internists, Washington, DC
Cincinnati Cancer Conference V, Cincinnati, OH
Advances in Oncology, Cherry Hill, NJ

1987 13th Annual Symposium on Diagnosis and Treatment of Neoplastic Disorders Course, Johns Hopkins Medical Institutions, MD
Breast Cancer Session, Eastern Cooperative Oncology Group, Clearwater, FL

1988 Early Breast Cancer Conference, Memorial Hospital, Colorado Springs, CO
Grand Rounds, Liberty Medical Center, Baltimore, MD
Medical Grand Rounds, Johns Hopkins Medical Institutions, Baltimore, MD
Annual Hematology/Oncology Conference, The Medical Center of Delaware, Wilmington, DE
Department of Medicine Professors Rounds, Johns Hopkins Medical Institutions, Baltimore, MD
Medical Residents Journal Club, Johns Hopkins Medical Institutions, Baltimore, MD
Plastic Surgery Grand Rounds, Johns Hopkins Medical Institutions, Baltimore, MD

1989 Department of Medicine Bench to Bedside, Johns Hopkins Medical Institutions, Baltimore, MD
Twelfth Annual Symposium on Current Concepts in Medicine and Surgery, Peninsula General Hospital, Salisbury, MD
Topics in Internal Medicine Course, Johns Hopkins Medical Institutions, Baltimore, MD
15th Annual Symposium on Diagnosis and Treatment of Neoplastic Disorders, Johns Hopkins Medical Institutions, Baltimore, MD
Eleventh Annual Cancer Symposium Selected Topics in Oncology, Raleigh, NC
Plastic Surgery Grand Rounds, Johns Hopkins Medical Institutions, Baltimore, MD
St. George's Society, Johns Hopkins Medical Institutions, Baltimore, MD
Hematology-Oncology Division Seminar, Indiana University School of Medicine, Indianapolis, IN

1990 Grand Rounds, St. Agnes Hospital, Baltimore, MD

Department of Medicine Bench to Bedside, Johns Hopkins Medical Institutions, Baltimore, MD
American Cancer Society, Maryland Division, Baltimore, MD
Medical Grand Rounds, Johns Hopkins Medical Institutions, Baltimore, MD
16th Annual Symposium on Diagnosis and Treatment of Neoplastic Disorders, Johns Hopkins Medical Institutions, Baltimore, MD
NCI Strategy Meeting on High Dose Chemotherapy in Breast Cancer, National Cancer Institute, Bethesda, MD
Hematology-Oncology Division Seminar, University of Maryland School of Medicine, Baltimore, MD

1991 Hematology-Oncology Conference, Chester Hospital, West Chester, PA
Department of Medicine Professors Rounds, Johns Hopkins Medical Institutions, Baltimore, MD
Symposium on Early Breast Cancer, Montgomery General Hospital, Olney, MD
Hematology-Oncology Division Seminar, Northwestern University School of Medicine, Chicago, IL
Pennsylvania Oncology Society, Gettysburg, PA
Susan G. Komen Foundation Scientific Symposium, University of Texas - Southwestern Medical School. Dallas, TX

1992 Breast Cancer Symposium, Crozer-Chester Hospital, Upland, PA
Hematology-Oncology Grand Rounds, University of Maryland School of Medicine, Baltimore, MD
Department of Medicine Ambulatory Care Rounds, Johns Hopkins Medical Institutes, Baltimore, MD
Staff Conference, Roswell Park Cancer Institute, Buffalo, NY
Tumor Board, Anne Arundel Hospital, Annapolis, MD
18th Annual Symposium on the Diagnosis and Treatment of Neoplastic Disorders, Johns Hopkins Medical Institutions, Baltimore, MD
American Cancer Society, Teaneck, NJ
Australia - New Zealand Breast Cancer Trials Group, Surfers Paradise, Australia
Laboratory of Biologic Chemistry, National Cancer Institute, Bethesda, MD
Lederle Advisory Board, New York City, NY
Gordon Conference on Cancer, Newport, RI
American Society of Clinical Pathologists, Las Vegas, NV
The Cancer Center at Fairfax Hospital, Fairfax, VA
American Fertility Society, New Orleans, LA
Visiting Professor, Department of Medicine, Hahnemann University School of Medicine, Philadelphia, PA

1993 NCI Strategy Meeting on Breast Cancer in Young Women, National Institutes of Health, Bethesda, MD
St. Georges Society, University of Maryland School of Medicine, Baltimore, MD
US-Japanese Joint Scientific Meeting on New Breast Cancer Therapies, Oakland, CA
Isaac Lewin Symposium, Baystate Medical Center, Springfield MA
Discussant, Adjuvant Breast Cancer Session, American Society of Clinical Oncology, Orlando, FL
Educational Session, National Cancer Institute Phase I Meeting, Bethesda, MD
Working Group on the Pulmonary Complications Associated with Breast Cancer Therapy, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD
Shanghai Cancer Institute, Shanghai, Peoples Republic of China
Ethics and Politics in Clinical Trials, Johns Hopkins Medical Institutions, Baltimore, MD
NCI Workshop on Prognostic and Predictive Factors in Breast Cancer, Bethesda, MD

1994 Hematology/Oncology Grand Rounds, Wayne State University School of Medicine, Detroit, MI
Clinical Oncology Program Grand Rounds, National Cancer Institute, Bethesda, MD
NCI Strategy Meeting on High Dose Chemotherapy for Breast Cancer, Bethesda, MD

11th Annual Advances in Cancer Treatment Research, Albert Einstein College of Medicine, New York City, NY
Recent Advances in the Biology of Breast, Colon, and Lung Cancer, American Society of Clinical Oncology, Dallas, TX
Discussant, Plenary Session, American Society of Clinical Oncology, Dallas, TX
Women's Health Seminar Series, Breast Cancer, National Institutes of Health, Bethesda, MD
Chemotherapy Symposium, Berlex Oncology Foundation, Leesburg, VA
The State of Breast Cancer 1994: An Interactive Symposium, University of California at San Francisco, San Francisco, CA
Grand Rounds, Washington County Hospital, Hagerstown, MD
Y-ME of the Cumberland Valley, Hagerstown, MD

1995 Department of Pharmacology and Toxicology, Robert C. Byrd Health Sciences Center of West Virginia University, Morgantown, WV
12th Annual International Breast Cancer Conference, Miami, FL
Controversy Session, American Association for Cancer Research, Toronto, Canada
Department of Pharmacology, Mayo Clinic, Rochester, MN
Susan G. Komen Foundation Congressional Breakfast, Washington, DC
Commonwealth of Massachusetts Course on Breast Cancer, Boston, MA
Law and Health Care Program, University of Maryland and Baltimore School of Law, Baltimore, MD
Discussant, Breast Cancer Session, American Society of Clinical Oncology, Los Angeles, CA
Topics in Clinical Medicine, Johns Hopkins University School of Medicine, Baltimore, MD
Gordon Research Conference on Mammary Gland Biology, New London, NH
The Endocrine Society's 51st Conference on Recent Progress in Hormone Research, Stevenson, WA
Eighteenth Thomas W. Green Memorial Lecture, East Tennessee State University James H. Quillen College of Medicine, Bristol, TN
Fifth International Congress on Hormones and Cancer, Quebec City, Canada
Cancer Medicine, Harvard Medical School, Boston, MA
Medical Oncology Board Review, George Washington University School of Medicine, Washington, DC
The First Annual Kimmel-Slavin Memorial Lecture, George Washington University School of Medicine, Washington, DC
Chemotherapy Symposium, Berlex Oncology Foundation, Leesburg, VA
Meet the Professor, American Society of Clinical Oncology Fall Educational Conference, Washington, DC
Grand Rounds, Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD
Division of Hematology/Oncology, Washington Hospital Center, Washington, DC
18th Annual San Antonio Breast Cancer Symposium, San Antonio, TX
Department of Medicine, St. Joseph Hospital, Baltimore, MD
Dana-Farber Cancer Institute, Boston, MA
22nd Annual Symposium on the Diagnosis and Treatment of Neoplastic Disorders, Johns Hopkins

1996 Department of Embryology, Carnegie Institute of Washington, Baltimore, MD
Mayo Clinic Cancer Center, Rochester, MN
New Approaches to Cancer Therapy, The Johns Hopkins Oncology Center, Baltimore, MD
Topics in Clinical Medicine, Johns Hopkins University School of Medicine, Baltimore, MD
University of Maryland Cancer Center, Baltimore, MD
Discussant, Breast Cancer Session, American Society of Clinical Oncology, Philadelphia, PA
Bowman Gray Comprehensive Cancer Center, Wake Forest University, Winston-Salem, NC
American College of Surgeons, San Francisco, CA
Session Chair, Gordon Conference on Cancer Chemotherapy, Oxford, UK
Chemotherapy Symposium, Berlex Oncology Foundation, Leesburg, VA

City of Hope National Medical Center, Duarte, CA
Upstate New York Cancer Research and Education Foundation, Syracuse, NY
Wendy and Emery Reeves International Breast Cancer Symposium, University of Texas Southwestern Medical Center, Dallas, TX 30th Anniversary Symposium, National Institute of Environmental Health Sciences, Research Triangle, NC
Meet the Professor, American Society of Clinical Oncology Fall Educational Conference, Phoenix, AZ
Maryland Cancer Control Symposium, Baltimore, MD
Lombardi Cancer Center, Georgetown University Medical Center, Washington, DC
Department of Biochemistry, Johns Hopkins School of Hygiene and Public Health, Baltimore, MD

1997 Breast Cancer Think Tank 7, St. Lucia
4th Annual Breast Cancer Symposium of the New York Metropolitan Breast Cancer Group, New York City, NY
2nd Annual Multidisciplinary Symposium on Breast Disease, Amelia Island, FL
University of Colorado Cancer Center, Denver, CO
Cambridge Symposium, Genetic Approaches to Breast and Prostate Cancer, Lake Tahoe, CA
St. George's Society, University of Maryland Medical School, Baltimore, MD
Issues in the Treatment of Breast Cancer, Greater Baltimore Medical Center, Baltimore, MD
University of Chicago Cancer Center, Chicago, IL
Conjoint Clinic, Johns Hopkins University School of Medicine, Baltimore, MD
Breast Cancer Tumor Panel, American Society of Clinical Oncology, Denver, CO
Pittsburgh Cancer Institute, University of Pittsburgh Medical School, Pittsburgh, PA
International Cancer Alliance, Washington, DC
Perspectives in Breast Cancer, Emory University, Atlanta, GA
US Public Health Services Office on Women's Health Healthy Women 2000, Washington, DC
Chemotherapy Symposium, Berlex Oncology Foundation, Leesburg, VA
American College of Surgeons, Chicago, IL
Susan G. Komen Foundation Breast Cancer Symposium, Dallas, TX
Medical Oncology Board Review, George Washington University School of Medicine, Washington, DC
Case Western Reserve University/Ireland Cancer Center, Cleveland, OH
Holy Cross Hospital, Silver Spring, MD
Department of Medicine and Cancer Center, University of California at San Francisco, San Francisco, CA
American Society of Clinical Oncology Fall Education Conference, Orlando, FL
14th Annual American College of Physicians/Army Regional Meeting, Reston, VA Fallston Hospital, Fallston, MD

1998 Breast Cancer Think Tank 8, Tobago
Session Co-Chair, 6th International Conference on Adjuvant Therapy of Primary Breast Cancer, St. Gallen, Switzerland
Controversy Session Chair, American Association for Cancer Research, New Orleans, LA
24th Annual Symposium on Diagnosis and Treatment of Neoplastic Diseases, Johns Hopkins Medical Institutions, Baltimore, MD
Breast Cancer Symposium, Inova Fairfax Hospital, Fairfax, VA
Discussant, Plenary Session, American Society of Clinical Oncology, Los Angeles, CA
Department of Pathology, Vanderbilt School of Medicine, Nashville, TN
Suburban Hospital, Bethesda, MD
Department of Medicine, Columbia-Presbyterian Medical Center, New York City, NY
Gordon Conference on Cancer, Newport, RI
Current Topics in Breast Cancer Research III: Cell Death in Breast Cancer, Cambridge, UK
Chemotherapy Symposium, Berlex Oncology Foundation, Leesburg, VA
2nd Annual Advances in Cancer Therapy, VCU/MCV, Richmond, VA
Kent and Queen Anne's Hospital, Chestertown, MD
Breast Cancer Awareness Month, The White House Washington, DC
Medical Oncology Board Review, George Washington University School of Medicine, Washington, DC
21st Annual San Antonio Breast Cancer Symposium, San Antonio, TX

1999 Breast Cancer Think Tank 9, St. Thomas, Virgin Islands
Joint Cancer Conference of the Florida Universities, Orlando, FL
Grand Rounds, Department of Medicine, Johns Hopkins Medical Institutions, Baltimore, MD
Congressionally Directed Medical Research Programs, Frederick, MD
Topics in Internal Medicine, Department of Medicine, Johns Hopkins, Baltimore, MD
American Society of Clinical Oncology, Atlanta, GA
1st Milan Breast Cancer Conference, Milan, Italy
Johns Hopkins Singapore, Singapore
Grand Rounds, Department of Surgery, Northwest Hospital, Baltimore, MD
6th Nottingham International Breast Cancer Conference, Nottingham, England
Seeking Excellence in Breast Cancer Care: Best Practices in Diagnosis and Treatment, Johns Hopkins University School of Medicine, Baltimore, MD
First Annual Lynn Sage Breast Cancer Symposium, Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Chicago, IL
Chemotherapy Symposium, Berlex Oncology Foundation, Leesburg, VA
Cancer Medicine, Harvard Medical School, Boston, MA
41st Annual Meeting of the American Society of Therapeutic and Radiation Oncology, San Antonio, TX
SERMs - Implication for Prevention and Treatment of Cancer, Philadelphia, PA
American Society of Clinical Oncology Fall Education Conference, San Francisco, CA
Genetics Program, University of Missouri, Columbia, MO
22nd Annual San Antonio Breast Cancer Symposium, San Antonio, TX

2000 Sibley Hospital, Washington, DC
Franklin Square Hospital, Baltimore, MD
Molecular Biology of Breast Cancer, Lillehammer, Norway
Keystone Symposium in Advances in Human Breast and Prostate Cancer, Lake Tahoe, NV
NIH Workshop on Selective Estrogen Receptor Modulators (SERMs), Bethesda, MD
Topics in Internal Medicine, Johns Hopkins University School of Medicine, Baltimore, MD
National Breast Cancer Coalition Eighteenth Annual Advocacy Training Conference
2nd Milan Breast Cancer Conference, Milan, Italy
Australia - New Zealand Breast Cancer Trials Group, Queenstown, New Zealand
Suburban Hospital, Bethesda, MD
15th Annual Excalibur Round Table, American Cancer Society, Baltimore, MD
Susan G. Komen Breast Cancer Foundation National Symposium - Reaching for the Cure..... Making a Difference, Washington, DC
WellStar Kennestone Hospital, Marietta, GA
WellStar Cobb Hospital, Marietta, GA
Hematology-Oncology Board Review, George Washington University School of Medicine, Arlington, VA
Berlex Oncology Foundation Clinical Pharmacology of Anticancer Drugs, Leesburg, VA
42nd Annual Meeting of the American Society of Therapeutic and Radiation Oncology, Boston, MA
National Institutes of Health Consensus Development Conference on Adjuvant Therapy of Breast Cancer, Bethesda, MD
Seeking Excellence in Breast Cancer Care, Johns Hopkins University School of Nursing and School of Medicine, Baltimore, MD

2001 Breast Cancer Think Tank 11, Punta Cana, Dominican Republic Potential Clinical Applications for GnRH Agonists, National Institutes of Health, Bethesda, MD
7th International Conference on Adjuvant Therapy of Primary Breast Cancer, St. Gallen, Switzerland
8th Annual Miami Breast Cancer Conference, Miami, FL
Central Pennsylvania Oncology Group, Harrisburg, PA
Mary E. Humphreys Biology Lecture, Mary Baldwin College, Staunton, VA
Department of Medicine Grand Rounds, Johns Hopkins Bayview, Baltimore, MD
Discussant, American Society of Clinical Oncology, San Francisco, CA
Anne Arundel Medical Center, Annapolis, MD

Lombardi Comprehensive Cancer Center, Georgetown University, Washington, DC
Women's Malignancy Group, MD Anderson Cancer Center, Houston, TX
3rd Milan Breast Conference, Milan, Italy
Gordon Conference on Polyamines, New London, CT
Australian Society for Breast Diseases, Surfers Paradise, Australia (by video conference)
White House/Komen Breast Cancer Summit, Washington, DC
3rd Annual Lynn Sage Breast Cancer Symposium, Northwestern University, Chicago, IL
Hematology-Oncology Board Review, George Washington University School of Medicine, Arlington, VA
Berlex Oncology Foundation Clinical Pharmacology of Anticancer Drugs, Leesburg, VA
Tumor Board, Greater Baltimore Medical Center, Baltimore, MD
Hematology Grand Rounds, Johns Hopkins, Baltimore, MD
William L. McGuire Memorial Lecture, 24th Annual San Antonio Breast Cancer Symposium, San Antonio, TX

2002 Breast Cancer Symposium Think Tank 12, St. Maarten, The Netherlands Antilles
Grand Rounds Department of Medicine, Johns Hopkins University, Baltimore, MD
Current Trends in Breast Cancer, Philadelphia, PA
3rd European Breast Cancer Conference, Barcelona, Spain
The Third North American Symposium on Skeletal Complications of Malignancy, National Institutes of Health, Bethesda, MD
Educational Symposium, American Society for Clinical Oncology, Orlando, FL
4th Milan Breast Cancer Conference, Milan, Italy
Second International Conference on Recent Advances and Future Directions in Endocrine Manipulation of Breast Cancer. Cambridge, MA
Breast Cancer: Current Controversies and New Horizons, Dana Farber Cancer Institute, Boston, MA
Center for Cancer Research Grand Rounds, National Cancer Institute, Bethesda, MD
2nd Annual Karmanos Cancer Institute Breast Cancer Symposium, Detroit, MI
Era of Hope, Department of Defense Breast Cancer Research Program, Orlando, FL
Fox Chase Cancer Center, Philadelphia, PA
IX Congresso Nacional de Oncologia, Lisbon, Portugal

2003 NCI – Hopkins Workshop on Clinical Translation of Gene Re-expression in Cancer, Baltimore, MD
Breast Cancer Think Tank 13, Aruba
20th Annual Miami Breast Cancer Conference, Miami, FL
8th International Conference on Primary Therapy of Early Breast Cancer**,** St. Gallen, Switzerland
American Society for Breast Disease, Dallas, TX
Upper Chesapeake Medical Center, Fallston, MD
American Society of Clinical Oncology, Chicago, IL
Gordon Conference on Cancer Chemotherapy, Oxford, UK
National Cancer Institute Workshop on Ductal Lavage, Bethesda, MD
9th Annual Perspectives in Breast Cancer, Boston, MA
Cancer Education Consortium Clinical Pharmacology of Anticancer Agents, Leesburg, VA
Indiana University Cancer Center, Indianapolis, IN
4th Annual Hampton Roads Fall Cancer Conference, Portsmouth, VA
Friends of Cancer Research, Woodrow Wilson International Center for Scholars, Washington, DC
Astrazeneca Breast Cancer Symposium, Waltham, MA

2004 Breast Cancer Think Tank 14, St Kitts
Translational Conference, Johns Hopkins Oncology Center, Baltimore, MD
Current Trends in Breast Cancer: Updates from the 2003 San Antonio Breast Cancer Symposium, Washington, DC
Breast Cancer—Bench to Bedside, Loyola University, Chicago, IL
Massachusetts General Hospital, Boston, MA

4th European Breast Cancer Conference, Hamburg, Germany
American Association for Cancer Research, Orlando, FL
The Philip A. Tumulty Topics in Clinical Medicine at Johns Hopkins, Baltimore, MD
Medical Grand Rounds, University of Florida—Shands Medical School, Gainesville, FL
Henry Lemon Memorial Lecture, University of Nebraska—Eppley Cancer Center, Omaha, NE
Discussant, Best of Oncology Symposium, American Society of Clinical Oncology, New Orleans, LA
6th Milan Breast Cancer Symposium, Milan, Italy
Gordon Conference on Molecular Therapeutics of Cancer, New London, NH
7th Annual Mission Conference of the Susan G. Komen Breast Cancer Foundation, Washington, DC
George Washington University Hematology-Oncology Board Review Course, Alexandria, VA
Cancer Education Consortium Clinical Pharmacology of Anticancer Agents, Leesburg, VA
6th Lynn Sage Breast Cancer Symposium of Northwestern University, Chicago, IL
Alta Bates Summit Medical Center, Berkeley, CA
Association of Northern California Oncologists, San Francisco, CA
4th American Association for Cancer Research Prevention Meeting, Seattle, WA
Project LEAD, National Breast Cancer Coalition, Washington, DC
Mayo Clinic Oncology Society, Rochester, MN
Department of Molecular Pharmacology and Experimental Therapeutics, Mayo Clinic, Rochester, MN
Career Day, Baltimore Polytechnic Institute, Baltimore, MD
2nd Breast Cancer Inter-SPORE Meeting, Chapel Hill, NC
27th Annual San Antonio Breast Cancer Symposium, San Antonio, TX

2005 Greenebaum Cancer Center, University of Maryland Medical School, Baltimore, MD
Breast Cancer Think Tank 15, Curacao
22nd Miami Breast Cancer Symposium, Miami, FL
Lorne Cancer Conference, Phillip Island, Australia
Delaware Oncology Society, Wilmington, DE
New Strategies in Breast Cancer Conference, Philadelphia, PA
Educational Symposium, American Society of Clinical Oncology, Orlando, FL
Highlights of the Day Symposium, American Society of Clinical Oncology, Orlando, FL
National Breast Cancer Coalition Fund Annual Advocacy Conference, Washington, DC
Third International Symposium on the Molecular Biology of Breast Cancer, Molde, Norway
Breast Cancer: Current Controversies and New Horizons, Harvard Medical School, Boston, MA
New England Journal of Medicine Clinical Pathologic Conference, Harvard Medical School, Boston, MA
Hematology-Oncology Board Review, George Washington University Medical Center, Washington, DC
Frances Bull Lecture, University of Michigan, Ann Arbor, MI
University of Minnesota Cancer Center, Minneapolis, MN
50th Anniversary Avon Foundation Symposium, New York City, NY
Cancer Education Consortium Clinical Pharmacology of Anticancer Agents, Leesburg, VA
100 Women Professors Symposium, Johns Hopkins, Baltimore, MD
Working Group on Translational Epigenetics in Cancer, National Cancer Institute,
Bethesda, MD

2006 Mayo Clinic, Rochester, MD
Helen Padykula Lecture, Wellesley College, Wellesley, MA
Lynne Abraham Symposium, Susan G. Komen Foundation, New York City, NY
Third Current Concepts in the Multidisciplinary Management of Breast Cancer, Johns Hopkins, Baltimore, DC
Forum on Breast Cancer Prevention. American Association of Cancer Research, Washington, DC
Vth Santiago Breast Cancer Symposium, Santiago, Chile
8th Milan Breast Cancer Symposium, Milan, Italy
International Union Against Cancer (UICC) World Cancer Congress, Washington, DC
8th Lynn Sage Breast Cancer Symposium, Chicago, IL
Hematology-Oncology Board Review, George Washington University Medical Center, Washington, DC
Cancer Education Consortium Clinical Pharmacology of Anti-Cancer Agents, Leesburg, VA

44th Meeting of the Japan Society of Clinical Oncology, Tokyo, Japan
National Comprehensive Cancer Network Adjuvant Therapy in Breast Cancer Symposium, Baltimore, MD
Women's Board, Johns Hopkins Hospital, Baltimore, MD
National Cancer Institute-Ft. Detrick Distinguished Scientist Seminar, Frederick, MD
Science Lecture Series 2006-7 Radcliffe Institute for Advanced Study, Cambridge, MA

2007 Johns Hopkins Workshop on Clinical Targeting of Epigenetic Changes in Cancer Treatment, Phoenix, AZ
24th Annual Miami Breast Cancer Conference, Miami, FL
6th Annual Mid-Atlantic Oncology Update, St Agnes Hospital, Baltimore, MD
10th International Conference on Primary Therapy of Early Breast Cancer**,** St. Gallen, Switzerland
Breast Cancer Think Tank 17, Playa del Carmen, Mexico
Annual Advances in Basic Science Symposium, Northwestern University Cancer Center, Chicago, IL
American Society of Clinical Oncology Education Symposium, Chicago, IL
10th Komen Mission Conference, Washington, DC
St Joseph's Hospital, Baltimore, MD
Australia-New Zealand Breast Cancer Clinical Trials Annual Meeting, Alice Springs, Australia
National Cancer Advisory Board, Bethesda, MD
Hematology-Oncology Board Review, George Washington University Medical Center, Washington, DC
CR-UK Cambridge Research Institute Plenary Lecture, 3rd National Cancer Research
Institute Cancer Conference, Birmingham, UK
President's Cancer Panel, San Diego, CA
Scientific Symposium, Breast Cancer Research Foundation, New York City, NY
Florida Oncology Society, Orlando, FL
Collaborative Summit on Breast Cancer Research, Foundation for the NIH, Lansdowne, VA
American Association of Cancer Research Prevention Symposium, Philadelphia, PA

2008 7th Rosalind E. Franklin Award for Women in Science, National Cancer Institute, Bethesda, MD
Breast Cancer Think Tank 18, Waikaloa, HI
Cancer Institute of New Jersey, New Brunswick, NJ
5th Early Detection Research Network Scientific Workshop, National Cancer Institute, Bethesda, MD
Vanderbilt-Ingram Comprehensive Cancer Center, Nashville, TN
11th American Association for Cancer Research-Women in Cancer Research Charlotte Friend Award, San Diego, CA
14th Annual Educational Symposium, Susan G. Komen for the Cure Maryland, Baltimore, MD
4th Current Concepts in the Multidisciplinary Management of Breast Cancer, Johns Hopkins University, Baltimore, MD
Department of Medicine, University of Pennsylvania School of Medicine, Philadelphia, PA
Best of ASCO, Boston, MA
Annual Meeting of the American Association for Clinical Chemistry, Washington, DC
Seventh International Congress on the Future of Breast Cancer, Kauai, HI
Nuclear Hormone Receptors, Cold Spring Harbor Laboratory, Cold Spring Harbor, NY
Hematology-Oncology Board Review, George Washington University, Washington, DC
Fourth Annual Oncology Congress, San Francisco, CA
Oberstar Lecture, George Washington University, Washington, DC

2009 Breast Cancer Think Tank 19, Costa Rica
Bernard Fisher Lecture, University of Pittsburgh, Pittsburgh PA
11th International Congress Oncology Conference on Primary Therapy of Early Breast Cancer, Saint Gallen, Switzerland
Grand Rounds, MD Anderson Cancer Center – Houston TX
Women Leading the Way, MD Anderson Cancer Center, Houston, TX
Jean Sindab Lecture, Emory Winship Cancer Institute, Atlanta, GA
Oncology Grand Rounds, Ohio State University, Columbus, OH
16th Annual Pennsylvania Bar Association Women in the Profession, Pittsburgh, PA
American Society of Clinical Oncology Educational Symposium, Orlando, FL

24th Annual Aspen Cancer Conference, Aspen, CO
Harvard Breast Cancer Conference, Boston, MA
Medical Grand Rounds, UPMC Shadyside Hospital, Pittsburgh, PA
University of Pittsburgh Postdoctoral Association Data and Dine Lecture, Pittsburgh, PA
Women's Studies and the Provost's Advisory Committee on Women's Concerns New Faculty Lecture, University of Pittsburgh, Pittsburgh, PA
Pancreasfest 2009, University of Pittsburgh, Pittsburgh, PA
AACR Advances in Breast Cancer Research, San Diego, CA
Cincinnati Cancer Symposium, Jensen Symposium on Nuclear Receptors, Cincinnati, OH
Translating Scientific Advances into Clinical Care Cancer, Lineberger Comprehensive Cancer Center, Chapel Hill, NC
New Options in Breast Cancer Treatment, UPMC Cancer Centers, Johnstown, PA

2010 University of Pittsburgh Winter Academy, Naples, FL
Achievement Rewards for College Scientists, Pittsburgh, PA
Medical Grand Rounds, UPMC Montefiore University Hospital, Pittsburgh, PA
Katz Lecture, Magee Womens Hospital of Pittsburgh, Pittsburgh, PA
NYU Cancer Institute Seminar Series, New York, NY
The Regional Cancer Center, Erie, PA
Lesses Visiting Professor, Medical Grand Rounds, Beth Israel Deaconess Medical Center, Boston, MA
Hematology-Oncology Grand Rounds, Beth Israel Deaconess Medical Center, Boston, MA
University of Maryland Marlene and Stewart Greenebaum Cancer Center, Hormone Responsive Cancer Program Retreat, Baltimore, MD
Lois O'Grady Breast Cancer Lecture, University of California Davis Cancer Center, Sacramento, CA
11th Annual Advances in Oncology, University of California Davis Cancer Center, Sacramento, CA
American Society of Clinical Oncology Breast Cancer Symposium - Gianni Bonadonna Award, Washington, DC
Advances in Oncology, Keynote speaker, UPMC Beacon Hospital, Ireland
Oncology Grand Rounds, Thomas Jefferson University Kimmel Cancer Center, Philadelphia, PA

2011

Dept of Environmental & Occupational Health, University of Pittsburgh, Pittsburgh, PA
Department of Pharmaceutical Sciences, University of Pittsburgh, Pittsburgh, PA
Breast Cancer Program Retreat, UCSF Cancer Center, San Francisco, CA
Lineberger Cancer Center, UNC Chapel Hill, Chapel Hill, NC
XI Michelangelo Foundation Seminar, Milan Italy
Georgetown University, Undergraduate Research Conference Keynote Speaker, Washington, DC
City of Hope Cancer Center Grand Rounds, Duarte, CA
Cleveland Clinic Grand Rounds, Taussig Cancer Center, Cleveland, Ohio
McArdle Laboratory Seminar, University of Wisconsin, Madison, WI
13th Milan Breast Cancer Conference, Milan, Italy
Annual Meeting, American Society of Clinical Oncology, Chicago, IL
International Cancer Conference, Trinity Medical School, Dublin, Ireland
Fifth Annual Ri.MED Scientific Symposium, Palermo, Italy
Medical Oncology Board Review, George Washington University, Washington, DC
Department of Epidemiology, University of Pittsburgh, Pittsburgh, PA
Department of Pharmacology and Chemical Biology, University of Pittsburgh, Pgh, PA
San Antonio Breast Cancer Symposium, San Antonio, TX

2012 Breast Cancer Think Tank 22, Mexico
Siteman Cancer Center at Washington University, Saint Louis, MO
Miami Breast Cancer Conference, Miami, FL
University of Pittsburgh Department of Pathology, Pittsburgh, PA
American Society of Preventive Oncology, Washington, DC

Tsinghua University, Beijing, China
University of Pittsburgh, Chancellors Inaugural Lecture - Hillman Professor of Oncology, Pittsburgh, PA
University of Chicago Cancer Biology Seminar Series, Chicago, IL
Johns Hopkins University School of Medicine, Baltimore, MD
American Society of Clinical Oncology, Chicago, IL
34th Annual Scientific Meeting, Australia-New Zealand Breast Cancer Trials Group, Hobart, Australia
Medical Oncology Board Review, George Washington University, Washington, DC
University of Texas Southwestern, Pamela Hearn Isom Lecture, Medicine Grand Rounds, Dallas Texas
Potamkin Lecture, PA Breast Cancer Coalition Conference, Harrisburg, PA
Northwestern University Feinberg School of Medicine's 16th Annual Department of Pathology Joseph C. Calandra Lecture, Chicago, IL
The Shanghai Breast Cancer Symposium, Shanghai, China

2013 Bay City Capital Scientific Advisory Board Meeting
13th International Congress Oncology Conference on Primary Therapy of Early Breast Cancer, St. Gallen, Switzerland
Annual Meeting, American Association of Cancer Research, Washington, DC
Case Western Reserve Comprehensive Cancer Center, Cleveland, Ohio
Medical Oncology Board Review, George Washington University, Washington, DC
The Hong Kong University of Science and Technology, Tetralateral Symposium, Hong Kong
PA Cancer Planning Summit, Pittsburgh, PA
Breast Cancer Symposium, San Francisco, CA
Cancer Caucus, House of Representatives, Harrisburg, PA
Science 2013, Pittsburgh, PA
Global Breast Cancer Conference, Seoul, South Korea

2014 Annual Meeting, American Association for Cancer Research, San Diego, CA
American Society of Clinical Oncology, Chicago, IL
German Cancer Research Center (DKFZ), Heidelberg, Germany
Medical Oncology Board Review, George Washington University, Washington, DC
National Cancer Advisory Board, Bethesda, MD
International Oncology Symposium, Astana, Kazakhstan
University of Chicago Simon M. Shubitz Lecture, Chicago, IL
Congressional Briefing, Alliance for Health Reform, Washington, DC
San Antonio Breast Cancer Conference, San Antonio, TX

2015 14th St. Gallen International Breast Cancer Conference, Primary Therapy of Early Breast Cancer, Vienna, Austria
Pediatric Hematology/Oncology Pediatric Hematology/Oncology BMT & CT Conference, Childrens Hospital of Pittsburgh, Pittsburgh, PA
University of Pittsburgh, Winter Academy, Palm Beach, Florida
The Wistar Institute, Distinguished Lecture, Philadelphia, PA
Annual Meeting, American Association for Cancer Research, Philadelphia, PA
Inaugural Lecture as Distinguished Professor of Medicine, University of Pittsburgh, Pittsburgh PA
Stephen D Williams, MD Lectureship, Indiana University Simon Cancer Center, Indianapolis, IN
Medical Oncology Board Review, George Washington University, Washington, DC
ASCO 2015 Breast Cancer Symposium, San Francisco, CA
Taipei Medical University, Taipei, Taiwan
Eighth Annual Robert B. Dickson Memorial Lectureship, Georgetown University Lombardi Cancer Center, Washington DC
First Gabriel Hortobagyi Lecture, MD Anderson Cancer Center, Houston, TX

Lynn Sage Distinguished Lecture, Robert H. Curie Comprehensive Cancer Center of Northwestern University, Chicago, IL

2016 University of Pittsburgh, Winter Academy, Palm Beach, Florida
American Association for Cancer Research (AACR), 2016 Annual Meeting, New Orleans, LA
American Society of Clinical Oncology (ASCO), 2016 Annual Meeting, Chicago, IL
Maryland Breast Cancer Consortium, Baltimore, MD
AACR High Tech Strategic Business Meeting, Sunnyvale, CA
Medical Oncology Board Review, George Washington University, Washington, DC
Great Lakes Breast Cancer Symposium, University of Pittsburgh, Pittsburgh, PA
Seattle Cancer Care Alliance, Dutch Harbor, Alaska
2016 Cooper Lecture, University of Pittsburgh, Pittsburgh, PA

2017 AACR New Frontiers in Cancer Research, Cape Town, South Africa
The David & Lyn Silfen University Forum, A Formidable Foe: Cancer in the 21st Century, Philadelphia, PA
American Association of Cancer Research (AACR), 2017 Annual Meeting, Washington, DC
Fred Hutchinson Cancer Research Center, HICOR Value in Cancer Care Summit, Seattle, WA
American Society of Clinical Oncology (ASCO) 2017 Annual Meeting
Fred Hutchinson Cancer Research Center Breast Cancer Program
Medical Oncology Board Review, George Washington University, Washington, DC
Cambridge Cancer Institute, University of Cambridge, Cambridge, UK
Breast Cancer Research Foundation Symposium, New York City, NY
University of Washington Thoracic and Breast Malignancies Symposium, Seattle, WA

Washington State Health Care Authority

Agency medical director comments

Gene expression profile testing of cancer tissue

Emily Transue, MD, MHA
Associate Medical Director, WA Health Care Authority

March 16, 2017

Washington State Health Care Authority

Background

- 40% of Americans will receive a cancer diagnosis over a lifetime
- 20% of Americans will die from cancer
- Increasing number of patients are being detected at early stages, where risk for progression and need for aggressive treatment is unclear
- Gene expression profile testing (GEP) identifies groups of genes in cancer tissue that predict risk of progression and metastasis
- Clearer prognostic information can strongly influence a patient's choices about chemotherapy and other treatment

2

Gene expression profile testing: use case

- Assesses expression of genes in cancer tissue to clarify risk of progression/metastasis

  NOT:

  - Screening of individual's genome to determine risk of developing cancer
  - Testing for sensitivity to specific chemo agents

- Typical use is to determine whether adjuvant therapy* is needed to reduce recurrence risk

* Therapy beyond the initial cancer treatment; i.e., chemo or hormone therapy after surgical resection.

3

Stages of care

- Diagnosis (biopsy)
- Risk assessment: Staging, etc.
- Treatment decision
- Outcome (short term)
- Outcome (long term)

4

Stages of care

- Diagnosis (biopsy)
- Risk assessment: staging, etc.
  - Size, grade, tumor markers, GEP
- Treatment:
  - Preference-sensitive decisions informed by prognosis, weighing pros and cons of treatment
- Outcome
  - Short term: side effects, work loss, etc.
  - Long-term: recurrence risk, side effects, survival

5

Adjuvant therapy: Risks and side effects

- Chemotherapy (varies by agent):
  - Neuropathy (may be permanent)
  - Cardiotoxicity (may be permanent)
  - Fatigue, nausea, malaise, hair loss
  - Work loss

For the purposes of this presentation:
- "**Chemotherapy**" refers to cytotoxic therapy
- "**Endocrine therapy**" refers to hormonal modulation therapy

- Endocrine therapy (varies by agent):
  - Elevated risk of blood clots/DVT/PE
  - Sexual dysfunction
  - Menopausal symptoms in women
  - Impact on bone density and fracture risk

6

Treatment decisions

Active Surveillance (AS):

- Avoid risks and side effects of treatment
- No decrease in recurrence risk

Adjuvant Therapy:

- Risks vary by aggressiveness of therapy
- Decreased recurrence risk proportional to baseline risk (i.e., benefit depends on prognosis)

7

Treatment decisions: Hypothetical example

Chemotherapy regimen X:

- Reduces relative recurrence risk by 50%
- Nausea, fatigue and work loss for 3 months are typical
- Permanent neuropathy occurs in 15%

Patient A:
30% recurrence risk

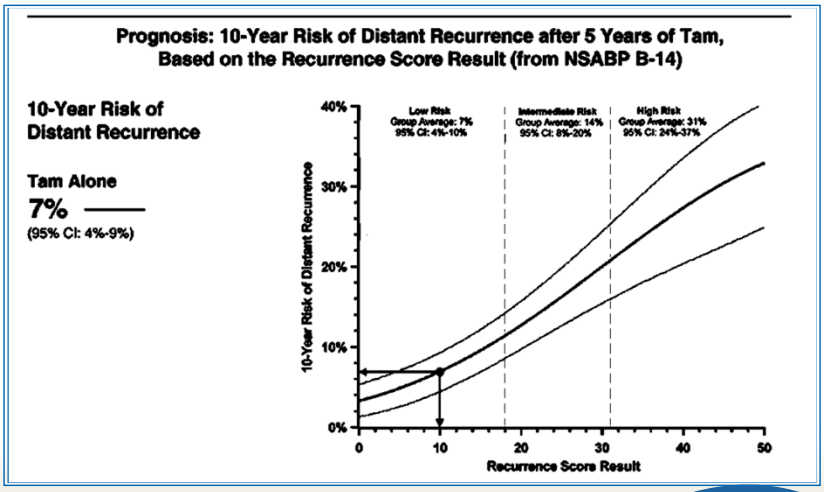
Chemotherapy X reduces absolute recurrence risk by 15%, balanced against above side effects/risks

Patient B:
6% recurrence risk

Chemotherapy X reduces absolute recurrence risk by 3%, balanced against above side effects/risks

8

Sample report (Oncotype Dx)



9

Gene expression profile: theory of impact

- GEP result predicts prognosis/recurrence risk (enhances existing staging data)
- Altered baseline risk impacts treatment recommendations
- Recommendations impact treatment selected
- Treatment selection impacts patient experience/outcomes
  - Short term (side effects, etc.)
  - Long term (recurrence, survival)

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Gene expression profile: testing impact

- Question 1: Does GEP predict prognosis/recurrence risk?
- Question 2: Does GEP impact treatment recommendation?
- Question 3: Does GEP impact treatment selection?
- Question 4: Does GEP impact patient experience/outcomes?
  - 4a – Short term (side effects, etc.)
  - 4b – Long term

11

Clinical validity vs. Clinical utility

- Clinical validity: Does the test do what it says it does?
  - ***Is it correct?***
  - In this case, does the GEP add prognostic information beyond existing data? (Question 1)
- Clinical utility: Does the test impact treatment decisions and/or outcomes?
  - ***Does it matter?***
    1. Does testing impact treatment selection? (Questions 2, 3)
    2. Does it impact risks and outcomes (includes therapy and disease)? (Questions 4a, 4b)

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Tests

Gene expression profile testing of cancer tissue to inform treatment decisions:

Breast Cancer —
Oncotype DX Breast Cancer Assay, EndoPredict, MammaPrint, Prosigna Breast Cancer Prognostic Gene Signature Assay (PAM50), Mammostrat, Breast Cancer Index (BCI)

Prostate Cancer —
Prolaris, Decipher, Oncotype DX Prostate Cancer Assay

Colon Cancer —
Oncotype DX Colon Cancer Assay, ColoPrint

Multiple Myeloma –
Myeloma Prognostic Risk Signature (MyPRS), SKY92-signature (formerly EMC92)

13

Current state agency policy

• PEBB	PreAuth
• HCA/MCO Medicaid:	PreAuth; Expedited Pre-Auth for Oncotype Dx and Mammaprint
• Labor and Industries	No policy

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Agency Medical Director Concerns

Safety = Medium

Efficacy = Medium High

Cost = High

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Washington State Health Care Authority

2015 – 2017 Claims for gene expression profile

PEBB/UMP (No Medicare)

Condition/Test	Services	Allowed Dollars
Breast Cancer	126	$515,650
Prostate	1	$165
Colon Cancer	4	$1,859
Multiple Myeloma	13	$5,558

Medicaid HCA and Medicaid MCO

Condition/Test	Services	Paid Dollars
Breast Cancer	255	$690,137
Prostate	1	$560

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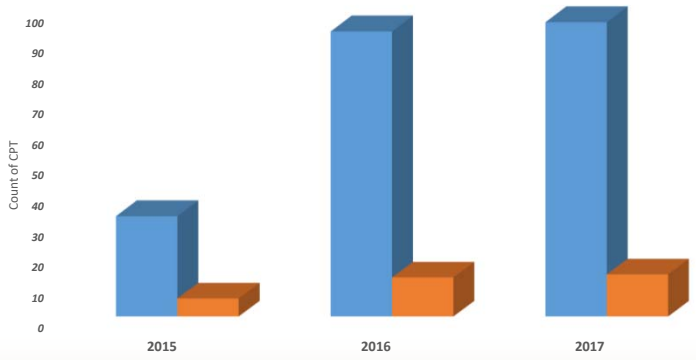
2015 - 2017 Medicaid MCO and Medicaid HCA Utilization CPT Code 81519

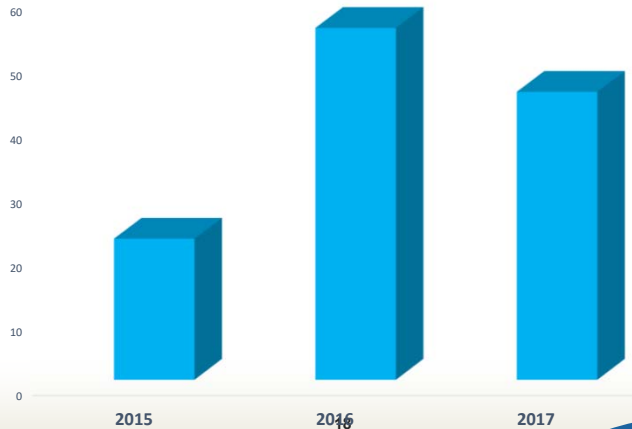
Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score



17

2015-2017 PEBB/UMP Utilization CPT Code 81519

Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score



18

Breast cancer
Gene expression profile tests

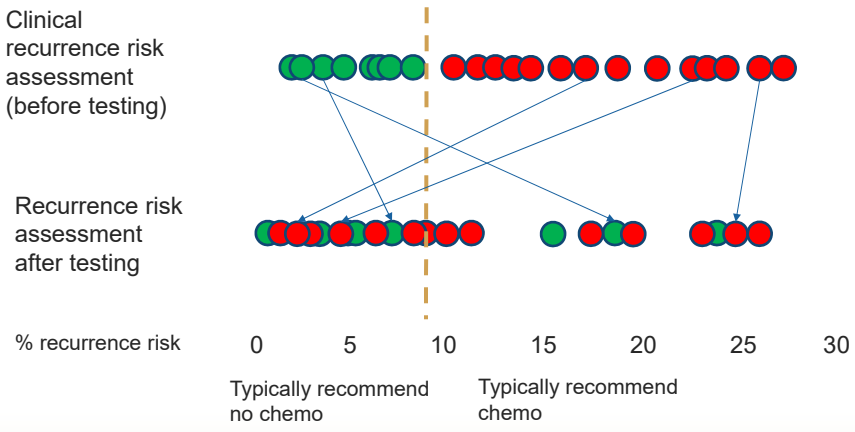
19

Oncotype Dx data (Breast, 21 gene)

- Population: LN- or 1-3 LN+; ER+; HER-
- Clinical validity: High (per Blok et al)
- Impact on treatment recommendation: High
  - 21-74% of patients had change in recommendation
  - Roughly 3:1 ratio of reduced intensity to increased intensity of rx
- Impact on patient choice: High
  - Cohort studies showed pts with test had less chemo than those w no test
- Impact on long term recurrence: No data
- Subsets: Pts w int. score did better with hormone rx than chemo
- Data quality: 64 studies; bias risk ranged from low to high; all directionally similar

20

Treatment intensity recommendation impact



21

Mammaprint (Breast, 70 gene)

- Population: LN- or 1-3 LN+; ER+; HER-
- Clinical validity: High (per Blok et al)
- Impact on treatment recommendation: High
  - 10-51% of patients had change in recommendation
  - ~3:1 ratio of reduced intensity to increased intensity; 10% less chemo
- Impact on patient choice: High
  - 90-91% followed recommendation
- Impact on long term recurrence:
  - For women with low clinical and high genomic risk or vice versa, 5 year met-free survival similar with or without chemo
- Misc: Increased MD confidence in rec 78.6% of the time
- Data quality: 8 studies; bias risk high

Prosigna PAM 50 (Breast, 50 gene)

- Population: Early stage breast cancer
- Clinical validity: High (per Blok et al)
- Impact on treatment recommendation: High
  - 18% of patients had change in recommendation
  - ~3:1 ratio of reduced intensity to increased intensity
- Impact on long term recurrence: No data
- Data quality: 3 studies, 608 pts, mod bias risk

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Endopredict (Breast, 12 gene)

- Population: Early stage breast cancer
- Clinical validity: High (per Blok et al)
- Impact on treatment recommendation: High
  - 37.7% of patients had change in recommendation
  - ~2:1 ratio of reduced intensity to increased intensity
- Impact on long term recurrence: No data
- Data quality: 1 study, 167 pts, mod bias risk

24

Breast Cancer Impact (BCI) (Breast, 7 gene)

- Population: Women who have had 3.5+ years of adjuvant hormone rx, deciding about additional hormone rx
- Impact on treatment recommendation: High
  - 27% of patients had change in recommendation
  - ~3:1 ratio of less aggressive rx to more aggressive rx
- Impact on long term recurrence: No data
- Data quality: 1 study, 26 pts

25

Mammostrat (Breast, 5 protein immunoassay)

- Population: Women with early stage cancer randomized to adjuvant Tamoxifen therapy
- Evaluated benefit of tamoxifen relative to Mammostrat score range (high, medium, or low risk)
  - Low risk patients had a 5% absolute improvement in recurrence free survival with Tamoxifen
  - Mod risks patients had no benefit (unexpected result)
  - High risk patients had a 21% absolute improvement
- 1 study, 711 women

26

Cost impact estimates: Breast GEP (con't)

- Wide variation in estimates including net positive and net negative impact on costs
- Cost/QALY generally within acceptable ranges
- Quality of evidence low to very low

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Guidelines

- 5/5 support Oncotype Dx
- 3/5 support Mammaprint, Endopredict, Prosigna
- 2/5 support BCI in LN-
- None support Mammastrat
- Typically require:
  - Early stage CA (stage 1 or 2)
    - ER positive (sometimes also PR positive)
    - HER2-NEU negative
    - LN negative or 1-3 positive
  - Test results will impact treatment decisions

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Payer Policies: Breast GEP

- No Medicare National Coverage Determinations (NCD)
- Local Coverage Decisions (LCD) for WA
  - Provide coverage for Endopredict, Prosigna, and BCI
  - No LCDs for Oncotype x, Mammaprint, or Mammostrat
- Aetna, Cigna, and Regence:
  - All cover Oncotype Dx
  - Two cover Mammaprint, Endopredict, Prosigna, and BCI
  - None cover Mammastrat

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Prostate cancer
Gene expression profile tests

30

Oncotype Dx (Prostate, 17 gene)

- Population: Men with positive bx or surgery deciding about further therapy
- Clinical validity: High significance (Canfield et al), but not a large impact (Brand et al)
- Impact on treatment recommendation: High
  - Range: 11-59% of patients had change in recommendation
  - ~2:1 ratio of reduced intensity to increased intensity
- Impact on patient choice: AS increased 24% with test
- Impact on long term recurrence: No data
- Data quality: 4 studies, high risk of bias

Canfield, Steven E et al. "A Guide for Clinicians in the Evaluation of Emerging Molecular Diagnostics for Newly Diagnosed Prostate Cancer." *Reviews in Urology* 16.4 (2014): 172–180.

Prolaris (Prostate, 46 gene)

- Population: Men with positive bx deciding about further therapy
- Clinical validity: High (Canfield et al)
- Impact on treatment recommendation: High
  - 37-48% of patients had change in recommendation
  - ~3:1 ratio of reduced intensity to increased intensity
- Impact on long term recurrence: Unknown
- Data quality: 2 studies

32

Decipher (Prostate, 22 gene)

- Population: Men considering adjuvant treatment after radical prostatectomy
- Clinical validity: High (Canfield, Spratt)
- Impact on treatment recommendation: High
  - Range: 18-42% of patients had change in recommendation
  - Roughly equal ratio of less aggressive rx to more aggressive rx
- Impact on long term recurrence: No data
- Misc: Decreased decisional conflict
- Data quality: 2 studies

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Prostate GEP: Cost impact

- Polaris: Ontario HTA estimated test increased costs for province (mod bias risk)
- Decipher (Lubo et al): Increased cost $5,453 per pt, QALY 0.066, cost/QALY $90K (high bias risk)
- Oncotype (Abala et al): Decreased cost $2,286 relative to historical costs (high bias risk)

34

Prostate Guidelines

- American Urological Association, American Society for Radiation Oncology, and Society of Urologic Oncology, 2017
  - "…Have not shown a clear role in active surveillance for localized prostate cancer."
- National Comprehensive Cancer Network, 2017
  - Recommend Decipher after prostatectomy with specific criteria
  - Recommend Prolaris and Oncotype Dx for low risk patients…who are candidates for AS or definitive rx

35

Payer Policies: Prostate GEP

- No Medicare National Coverage Determinations (NCD)
- Local Coverage Decisions (LCD) for WA
  - Coverage with conditions for Decipher, Prolaris, and Oncotype Dx
  - Decipher: Radical prostatectomy w/in 5 yrs, PSA nadir after surgery, no meds or neoadjuvant rx, adverse surgical pathology
  - Prolaris and Oncotype Dx: localized, under 5 mm, low or very low risk stage OR favorable intermediate risk (Prolaris only); used to determine treatment, etc.
- Aetna, Cigna, and Regence:
  - No coverage, or not included on list of medically necessary tests

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Colon cancer
Gene expression profile tests

37

Washington State Health Care Authority

Oncotype Dx (colon, 12 gene)

- Population: Stage 2 disease, considering adjuvant rx
- Clinical validity: Unestablished (per NCCN guideline)
- Impact on treatment recommendation: High
  - Increased intensity for 11.4%
  - Decreased intensity for 32.9%
- Impact on patient choice:
  - Increased intensity for 9.7%
  - Decreased intensity for 28.3%
- Impact on long term recurrence: Unknown
- Data: 2 studies

38

Colon: Cost impact

- Alberts et al (mod bias risk)
- Pts with stage 2 colon CA
- Slightly lower lifetime costs with testing than without ($103,775 with, $104,767 without; $991 savings)

39

Colon policies and guidelines

- No clinical practice guidelines with recommendations
- NCCN guideline (fair quality):
  - "There is no evidence of predictive value…"

40

Guidelines and Policies: Colon GEP

- No Medicare National Coverage Determinations (NCD)
- No Local Coverage Decisions (LCD) for WA
- Aetna, Cigna, and Regence:
  - No coverage

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Multiple Myeloma
Gene expression profile tests

42

Multiple Myeloma GEP

- Clinical validity: Unclear whether test adds prognostic information beyond clinical prediction
- Clinical utility: No studies available
- NCCN guidelines: No recommendations
  - "Could be helpful in selected patients"
- European Society for Medical Oncology:
  - "More research is needed"
- Payer policies: Medicare, Aetna, Cigna, Regence
  - Either not covered or not mentioned

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Gene Expression Profile: Testing Impact

Question 1: • Does GEP predict prognosis/recurrence risk?
Question 2: • Does GEP impact treatment recommendation?
Question 3: • Does GEP impact treatment selection?
Question 4: • Does GEP impact patient experience/outcomes?
- 4a – Short term (side effects, etc.)
- 4b – Long term

44

Question 1: Do GEP results add significant information about prognosis/recurrence risk?

- Varies by test
- Strongest data is for breast GEPs including Oncotype Dx breast, Endopredict, Prosigna, and Mammaprint
- Multiple studies in prostate
- Not well supported for colon or multiple myeloma

45

Question 2: Does GEP impact treatment recommendations?

- Strong evidence for high impact on treatment recommendations for breast and prostate testing
- Only one study in colon cancer, also appears to have high impact on treatment recommendation
- No data for multiple myeloma

46

Question 3: Does GEP impact treatment selection?

- Limited data shows high correlation between treatment recommended and treatment selected

47

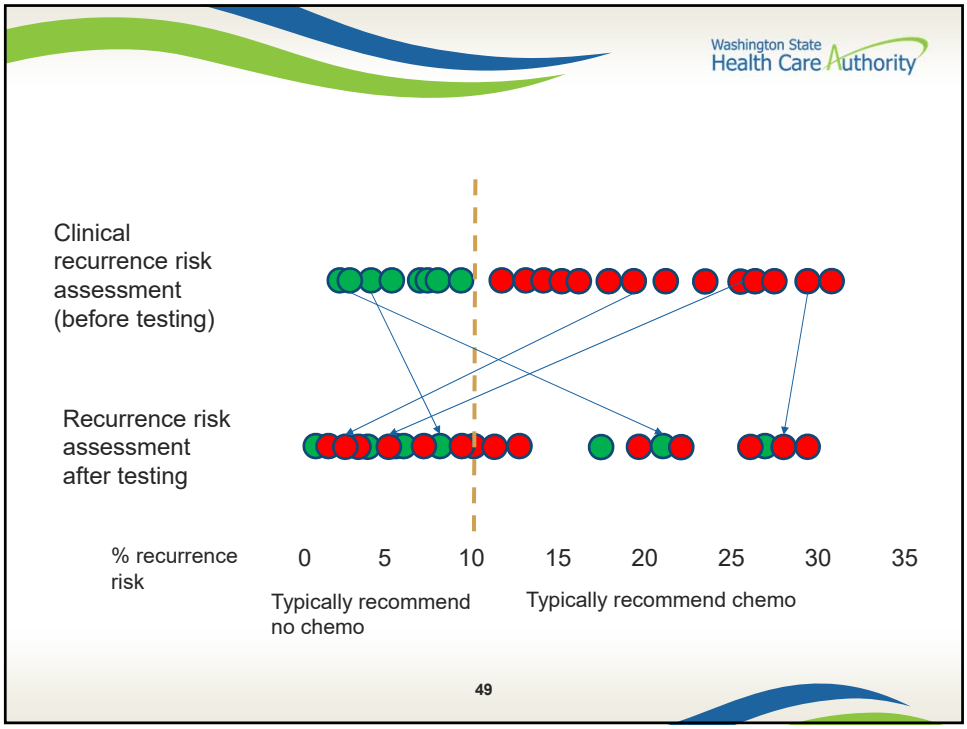
Question 4: Does GEP impact patient experience/ outcomes?

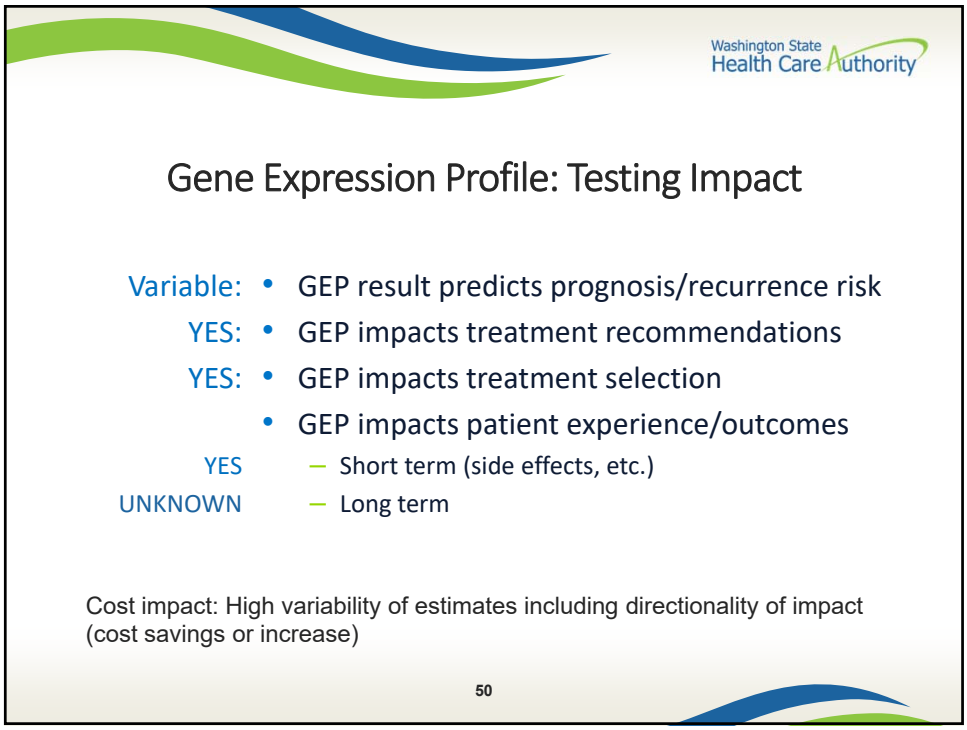
Question 4A: Short term (side effects, etc)

Question 4B: Long term

- 4A: Extensive evidence that many patients choose to forego adjuvant chemo or hormone therapy with associated risks and side effects based on testing. A smaller number choose more aggressive treatment based on testing.
- 4B: Only evidence available is one trial showing patients with high clinical risk and low Mammaprint score can safely forego chemotherapy

48


Washington State Health Care Authority
Clinical recurrence risk assessment (before testing)
Recurrence risk assessment after testing
% recurrence risk
0
5
10
15
20
25
30
35
Typically recommend no chemo
Typically recommend chemo
49


Washington State Health Care Authority
Gene Expression Profile: Testing Impact
Variable: • GEP result predicts prognosis/recurrence risk
YES: • GEP impacts treatment recommendations
YES: • GEP impacts treatment selection
• GEP impacts patient experience/outcomes
YES – Short term (side effects, etc.)
UNKNOWN – Long term
Cost impact: High variability of estimates including directionality of impact (cost savings or increase)
50

Treatment decisions

Active Surveillance (AS):
- Avoid risks and side effects of treatment
- No decrease in recurrence risk

Adjuvant Therapy:
- Risks vary by aggressiveness of therapy
- Decreased recurrence risk proportional to baseline risk (i.e., benefit depends on prognosis)

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Proposed decision rubric

- Value of testing to patients and providers as an aid to informed decision making about the relative benefits of adjuvant therapy is high.
  - Demonstrated by high impact on treatment recommendations and decisions in nearly all studies
  - Adjuvant rx carries significant short-term and long-term impact on symptoms and quality of life
- Definitive impact on long-term outcomes is unlikely to be available given time frames and barriers to study
- Given the high value to patients and providers in the setting of preference-sensitive decisions, deferring coverage until/unless this level of evidence becomes available is unreasonable
- Tests should be covered if there is high evidence of clinical validity and of impact on decision making

52

AMDG Recommendation: Breast GEPs

- **Oncotype DX, Endopredict, Prosigna and Mammaprint**:
  - Cover with conditions
    Early stage CA (stage 1 or 2)
    - ER positive, HER2-NEU negative
    - LN negative or 1-3 LN positive
  - Test results will impact treatment decisions
- **Mammostrat and BCI**: Cover with conditions
  - Only for women with stage 1-2 deciding about hormone rx
- **Other breast cancer tests**/indications:
  - Covered at agency discretion in the future if developers can show prognostic equivalence or superiority to the above tests

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AMDG Recommendation: Prostate GEPs

- Cover with conditions
- **Oncotype DX**, **Prolaris**: Cover with conditions
  - Early stage disease
  - Test results will impact treatment decisions
- **Decipher**: Cover with conditions
  - Men deciding between active surveillance and adjuvant or salvage radiotherapy after radical prostatectomy
  - Test results will impact treatment decisions

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AMDG Recommendation: Other GEPs

- Colon GEPs:
  - Recommend non-coverage
  - Evidence is insufficient to support coverage
- Multiple Myeloma GEPs:
  - Recommend non-coverage
  - Evidence is insufficient to support coverage

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Questions?

More information:

Emily.Transue@hca.wa.gov

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Washington State Health Care Authority

Order of scheduled presentations:

Gene expression profile testing of cancer tissue

	Name	
1	Devki Saraiya MS, CGC,	Myriad Genetic Laboratories
2	Karen Heller, MS, CGC,	Myriad Genetic Laboratories

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.	X	
2.	Equity interests such as stocks, stock options or other ownership interests.	X	
3.	Status or position as an officer, board member, trustee, owner.		X
4.	Loan or intellectual property rights.		X
5.	Research funding.		X
6.	Any other relationship, including travel arrangements.	X	

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

Myriad Genetic Laboratories employee

#6: travel arrangements

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).	X	

If yes to #7, provide name and funding Sources: representing Myriad Genetic Laboratories

*If you believe that you do not have a conflict, but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.*

I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

X [redacted] 2/22/18 DEVKI SARAIYA

Signature *Date* *Print Name*

So we may contact you regarding your presentation, please provide the following:

Email Address: dsaraiya@myriad.com

Phone Number: 206-240-4340

Prostate Cancer
Gene Expression Profile Tests

Devki Saraiya, MS, CGC

Certified Genetic Counselor

Myriad Genetic Laboratories

myriad® WHEN DECISIONS MATTER

Simon et al. Level of Evidence (LOE) descriptions and requirements.

Levels of evidence in the Simon et al. evidentiary framework		
LOE	DESCRIPTION	REQUIREMENTS
I	Practice-changing. The biomarker reliably influences clinical treatment decisions.	**One "Category A" study:** PRCT that tests the biomarker's prognostic or predictive value. -or- **At least two "Category B" studies with consistent results:** • Utilizes archived samples from a prospective clinical trial not specifically designed to test the biomarker. • Both studies must be designed, conducted, and analyzed in a similar manner.
II	Category C studies meeting LOE II could be sufficient to change practice under "particularly compelling circumstances."	**One "Category B" study** -or- **Three* or more independent "Category C" studies that provide consistent results** • Utilizes archived samples from patients enrolled in a prospective observational registry with specimen collection, treatment, and follow-up dictated by standard of care. • Requires careful assessment to rule out confounding or selection bias. • At least two validation studies must be designed, conducted, and analyzed in a similar manner.

*One development study + two validation studies

Simon RM, et al. J Natl Cancer Inst 2009; Nov 4; 101(21): 1446-52.

myriad WHEN DECISIONS MATTER

Simon et al. Applied to Prostate Cancer

- Two “compelling circumstances” qualify PCa as a condition warranting practice change using a validated LOE II prognostic biomarker

1

Overtreatment: In the United States, providers lack trust in current clinicopathologic measures to guide selection between active surveillance (AS) and interventional treatment, i.e., radical prostatectomy or radiation therapy. This often results in interventional treatment for patients who do not need it (Andriole et al., 2009; Chou et al., 2011; Welch et al., 2009)

2

Long natural history of PCa: The indolent, slow-growing nature of most prostate tumors presents challenges to completing prospective, randomized biomarker trials in a time-efficient, cost-efficient, and ethical manner. LOE I is not achievable for PCa prognostics within the current paradigm. Based on an 80% power to detect a statistically significant 25% difference in PCa death, it is estimated that a 5-year study would require between 33,000 and 43,000 subjects with low-risk PCa (Myriad internal analysis).

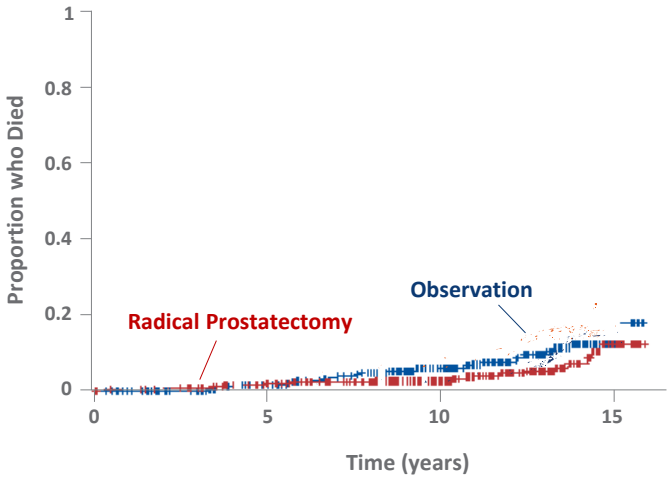
Simon RM, et al. J Natl Cancer Inst 2009; Nov 4; 101(21): 1446-52.
Andriole GL, et al. N Engl J Med 2009; 360:1210-19.
Chou R, et al. Ann Intern Med 2011; 155:762-71.
Welch HG, et al. J Natl Cancer Inst 2009; 101:1325-9.

myriad WHEN DECISIONS MATTER

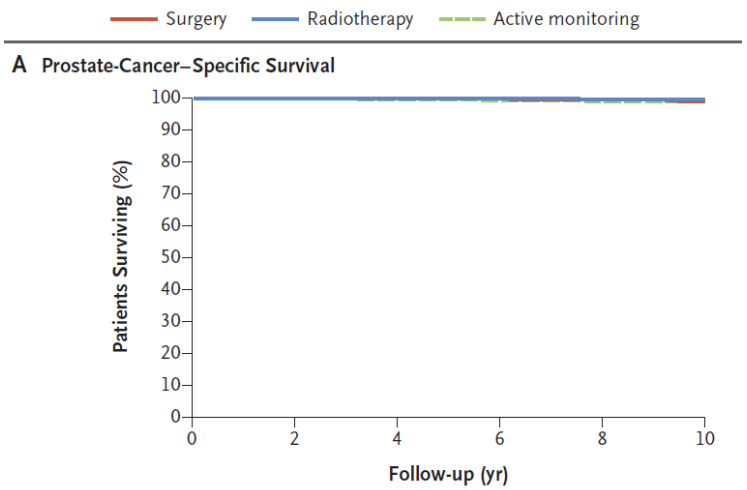
Treatment Outcomes from Two Landmark Trials

Treatment of Localized Prostate Cancer Does NOT Improve Mortality Outcomes[1,3]

Death from Prostate Cancer
n = 731



Prostate-Cancer-Specific Survival
n = 1643



> …studies suggest that all of the major management options produce very similar rates of survival.
>
> *– Institute for Clinical and Economic Review (ICER)[2]*

> …death from prostate cancer […] remained low at a median of 10 years of follow-up, at approximately 1%, irrespective of the treatment assigned…
>
> *– ProtecT trial findings[3]*

[1]*Wilt TJ, et al. N Engl J Med 2012; 367:203-13; Wilt TJ, et al. N Engl J Med 2017; 377:132-42.*
[2]*ICER Prostate Portal RSS. Retrieved July 2015 from: http://prostateoptions.icer-review.org/treatment-options/*
[3]*Hamdy FC, et al. N Engl J Med 2016; 375:1415-24.*

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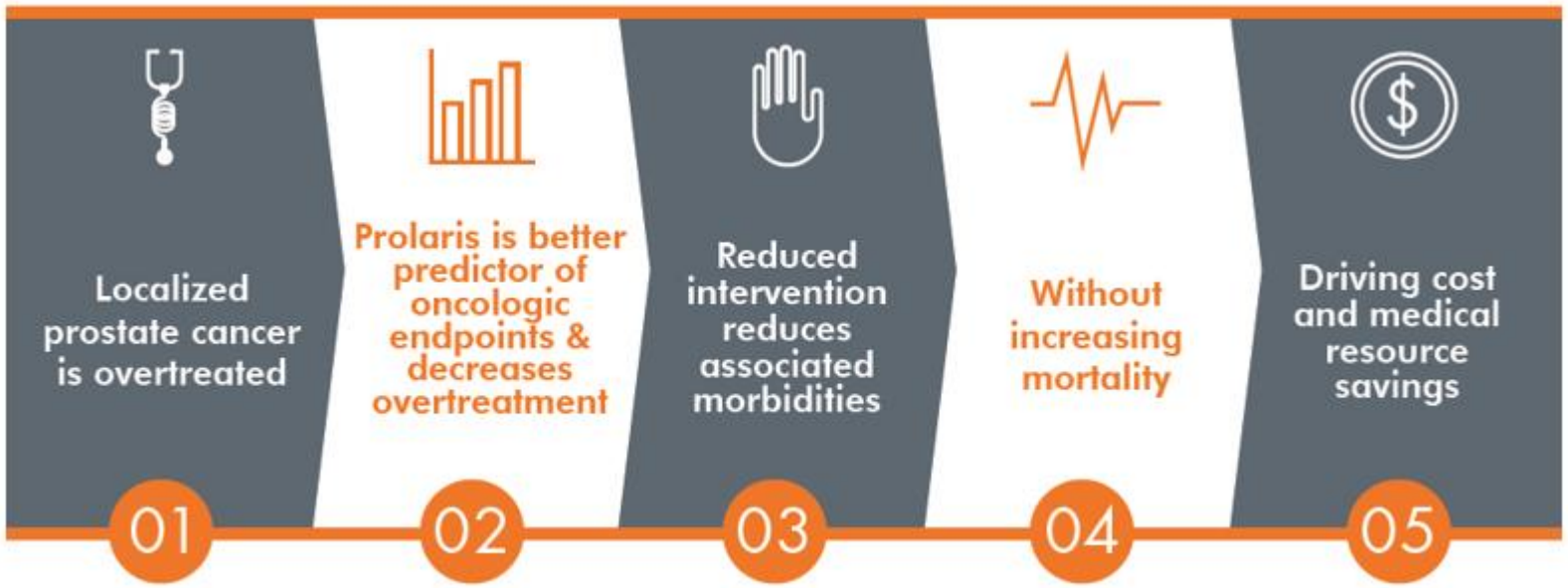
Chain-of-Evidence for Prolaris

Improving Outcomes by Reducing Morbidities



Draisma G, et al. J *Natl Cancer Inst* 2009; 101:374-83.

ICER Prostate Portal RSS. Retrieved July 2015.

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Donovan JL, et al. *N Engl J Med* 2016 Oct 13; 375(15): 1425-37.

Jeldres C, et al. Cancer 2015; 121:2465-73.

Wilt TJ, et al. N Engl J Med 2017; 377:132-42.

Tosoian JT, et al. *J Clin Oncol* 2015; 3(30):3379-86.

Hamdy FC, et al. *N Engl J Med* 2016; 375:1415-24.

Crawford ED, et al. *Poster Presentation SUO 2014 and ASCO-GU 2015*.

Center for Medical Technology Policy (CMTP) guidance document: Evaluation of clinical validity and clinical utility of actionable molecular diagnostic tests in adjult oncology. May 2013. http://www.cmtpnet.org/docs/resources/MDX_EGD.pdf

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Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.	✓	
2.	Equity interests such as stocks, stock options or other ownership interests.	✓	
3.	Status or position as an officer, board member, trustee, owner.		✓
4.	Loan or intellectual property rights.		✓
5.	Research funding.		✓
6.	Any other relationship, including travel arrangements.	✓	

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

Myriad Genetic Laboratories

#6 = travel arrangements

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).	✓	

If yes to #7, provide name and funding Sources:

Myriad Genetics – commercial products

*If you believe that you do not have a conflict, but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.*

I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

X [redacted] 2/13/18 *Date* Karen Heller *Print Name*

So we may contact you regarding this information, please provide the following:

Email Address: ~~karenheller@~~ kheller@myriad.com

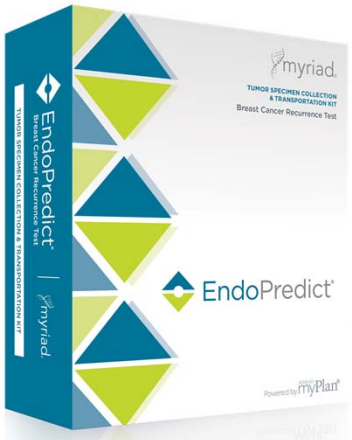
Phone Number: 214-789-5014

EndoPredict: Gene Expression Test for Breast Cancer

Karen Heller, MS, CGC
Certified Genetic Counselor
Medical Policy Manager
Myriad Genetic Laboratories

EndoPredict®

EndoPredict: Gene Expression Test for Breast Cancer



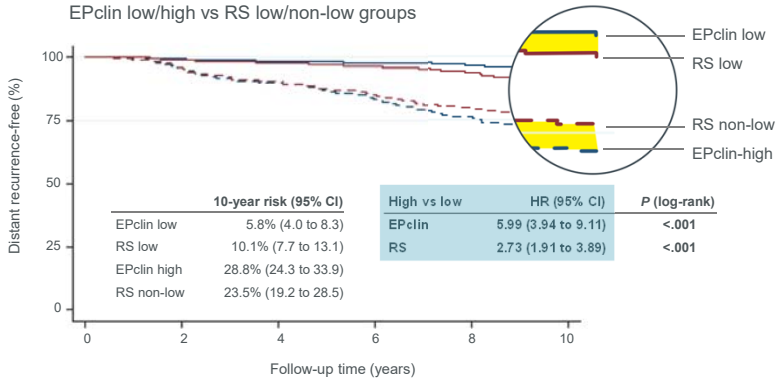
Targeted patients
- ER+, HER2-
- Node -, Node +
- Early-stage disease

Proven outcomes
- 10-year risk of DR
- Low risk, high risk categories

Proven prognostic power
- Combines molecular and clinical information

EndoPredict®

EPclin discriminates breast cancer recurrence risk better than Oncotype DX



	10-year risk (95% CI)
EPclin low	5.8% (4.0 to 8.3)
RS low	10.1% (7.7 to 13.1)
EPclin high	28.8% (24.3 to 33.9)
RS non-low	23.5% (19.2 to 28.5)

High vs low	HR (95% CI)	*P* (log-rank)
EPclin	5.99 (3.94 to 9.11)	<.001
RS	2.73 (1.91 to 3.89)	<.001

Buus R, Sestak I, Kronenwett R, et al *J Natl Cancer Inst*. 2016 Jul 10;108(11). pii: djw149. doi: 10.1093/jnci/djw149.

EndoPredict®

Comparison of the Performance of 6 Prognostic Signatures for Estrogen Receptor–Positive Breast Cancer. A Secondary Analysis of a Randomized Clinical Trial. Sestak et al.
JAMA Oncol 2018

Table 1. Univariate HRs and C Indexes for All Prognostic Signatures According to Nodal Status During Years 0 to 10

Gene Signature	Patient Group: Node-Negative Disease (n = 591)		Node-Positive Disease (n = 227)	
	HR (95% CI)[a]	C Index (95% CI)	HR (95% CI)[a]	C Index (95% CI)
CTS	1.99 (1.58-2.50)	0.721 (0.668-0.774)	1.63 (1.20-2.21)	0.640 (0.554-0.726)
IHC4	1.95 (1.55-2.45)	0.725 (0.665-0.785)	1.33 (0.99-1.78)	0.601 (0.511-0.690)
RS	1.69 (1.40-2.03)	0.667 (0.585-0.750)	1.39 (1.05-1.85)	0.603 (0.513-0.693)
BCI	2.46 (1.88-3.23)	0.762 (0.704-0.820)	1.67 (1.21-2.29)	0.652 (0.566-0.739)
ROR	2.56 (1.96-3.35)	0.764 (0.707-0.821)	1.58 (1.16-2.15)	0.636 (0.552-0.719)
EPclin	2.14 (1.71-2.68)	0.765 (0.716-0.814)	1.69 (1.29-2.22)	0.671 (0.590-0.752)

Table 3. Univariate HRs and C Indexes for All Prognostic Signatures According to Nodal Status During Years 5 to 10

Gene Signature	Patient Group: Node-Negative Disease (n = 535)		Node-Positive Disease (n = 154)	
	HR (95% CI)[a]	C Index (95% CI)	HR (95% CI)[a]	C Index (95% CI)
CTS	1.95 (1.43-2.65)	0.721 (0.654-0.788)	1.61 (1.05-2.47)	0.644 (0.534-0.753)
IHC4	1.59 (1.16-2.16)	0.660 (0.576-0.745)	1.20 (0.79-1.81)	0.579 (0.460-0.697)
RS	1.46 (1.09-1.96)	0.585 (0.467-0.702)	1.24 (0.81-1.90)	0.555 (0.418-0.693)
BCI	2.30 (1.61-3.30)	0.749 (0.668-0.830)	1.60 (1.04-2.47)	0.633 (0.514-0.751)
ROR	2.77 (1.93-3.96)	0.789 (0.724-0.854)	1.65 (1.08-2.51)	0.643 (0.528-0.758)
EPclin	2.19 (1.62-2.97)	0.768 (0.701-0.835)	1.87 (1.27-2.76)	0.697 (0.594-0.799)

Use of Biomarkers to Guide Decisions on Adjuvant Chemotherapy for Women with Early Stage Breast Cancer: American Society of Clinical Oncology Practice Guideline. Harris et al.
J Clin Oncol 2016

Table 1. Requirements for a Marker-Based Test to Reach Level IB Evidence of Clinical Utility on the Basis of Prospective-Retrospective Studies

Requirements
1. Adequate amounts of archived specimen must be available from enough patients from a prospective trial (which for predictive factors should generally be a randomized design) for analyses to have adequate statistical power and for the patients included in the evaluation to be clearly representative of the patients in the trial.
2. The marker-based test should be analytically and preanalytically validated for use with archived specimens.
3. The plan for marker evaluation should be completely specified in writing before the performance of marker assays on archived specimens and should be focused on the evaluation of a completely defined marker-based test.
4. The results from archived specimens should be validated by using specimens from one or more similar, but separate studies.

NOTE. Adapted from Simon et al.[9]

EndoPredict Joins Well-Established Breast Prognostic Assays

Inclusion in 2016 ASCO Guidelines[1]	"…the panel found **sufficient evidence of clinical utility** for the biomarker assays Oncotype DX, **EndoPredict**, PAM50, Breast Cancer Index, and urokinase plasminogen activator…in specific subgroups of breast cancer"ǂ
Equivalent 1B Evidence as proposed by Simon et al.[2,3]	"…the **EndoPredict assay has been assigned the level of evidence 1** according to Simon et al., this level of evidence is identical e.g. to the Oncotype DX recurrence score."
Positive recommendation from Blue Cross Blue Shield Association[4]	"[Regarding EndoPredict] The **evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome**."
Favorable Local Coverage Determination[5] N0 or (1-3 positive nodes)	"This **Medicare contractor** will provide limited **coverage for the EndoPredict** breast cancer gene expression test for the management of post-menopausal women…"

ǂASCO has stated that healthcare providers may consider utilizing the listed tests for node-negative patients

[1]Harris LN, Ismaila N, McShane LM, et al; American Society of Clinical Oncology*J Clin Oncol*. 2016 Apr 1;34(10):1134-50.
[2]Simon RM, Paik S, Hayes DF. *J Natl Cancer Inst*. 2009;101:1446–52.
[3]Müller BM, Keil E, Lehmann A, et al. *PLoS One*. 2013;8(6):e68252.
[4]Blue Cross Blue Shield Association Evidence Street. (2016, December) Retrieved December 2016 from: https://app.evidencestreet.com/
[5]Centers for Medicare & Medicaid Services. (2017, December) Retrieved Dec 2017 from: https://www.cms.gov/medicare-coverage database

EndoPredict®

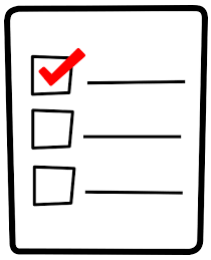
Gene Expression Profile Testing of Cancer Tissue

Washington State Health Care Authority
Health Technology Clinical Committee
March 16, 2018

Valerie J. King, MD, MPH

Outline

- Background
- Methods and search results
- Order of presentation:
  - Evidence review by test
  - GRADE summary
  - Clinical practice guidelines
  - Payer policies
- Conditions under consideration:
  - Breast cancer tests
  - Prostate cancer tests
  - Colon cancer tests
  - Multiple myeloma tests



1

Background

- Lifetime risk of developing cancer is about 40%
- 1 in 5 Americans will die from cancer
- Strategies to reduce the burden of cancer include prevention, early diagnosis, improving treatment
- Common treatments for cancer are surgery, radiation therapy, chemotherapy, hormone therapy, and immunotherapy
  - Most appropriate treatments for a particular cancer depend on the cancer's characteristics (e.g., cancer stage and grade), the patient's age and health status, response to previous treatments, and other factors

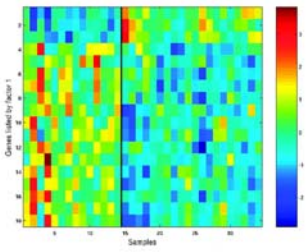
2

Background

- There are a growing number of gene expression profile (GEP) tests for cancers designed to help inform treatment decisions after a cancer diagnosis
- Theoretical benefits of GEP testing:
  - More appropriate treatment decisions
  - Improved patient outcomes, including improved survival and avoidance of treatment-related side effects by forgoing unnecessary treatments
- Purpose of this evidence report is to review the clinical utility and cost-effectiveness of selected GEP tests for breast, prostate, and colon cancers and multiple myeloma

3

Background



- GEP testing identifies genes in cancer tissue making messenger RNA, which carries the genetic information that cancer cells need to make proteins
- GEP tests are designed to provide additional information for patients and clinicians
  - If a test predicts that a cancer is slow growing or unlikely to metastasize, then active surveillance could be the most appropriate course
  - If a test predicts that a cancer is likely to progress and metastasize, then more aggressive or different treatments could be warranted

4

FDA Regulation

- Molecular diagnostic tests are regulated by the U.S. Food and Drug Administration (FDA)
- FDA has exercised discretion in its requirements for approval of in vitro diagnostic assays
  - In vitro tests developed, validated, and performed in-house by a specific reference laboratory are required to abide by Clinical Laboratory Improvement Amendments (CLIA)
  - FDA clearance and approval is currently not required for these laboratory-developed tests (LDTs)
- MammaPrint and Prosigna have received FDA premarket approval
- All the other tests discussed are regulated as LDTs

5

Scope: PICO

- **Population**
  - Adults with breast, prostate, or colon cancers or multiple myeloma
- **Interventions**
  - Gene expression profile testing of cancer tissue to inform treatment decisions (specific tests listed on next slides)
- **Comparators**
  - Usual care without gene expression profile testing of cancer tissue, alternate gene expression profile tests (i.e., 1 test intervention listed above vs. another)

6

Gene Expression Profile Tests

- Breast Cancer
  - Oncotype DX breast (21-gene test)
  - MammaPrint (70 gene test)
  - EndoPredict (12-gene test)
  - Prosigna: PAM50 (50-gene test)
  - Breast Cancer Index (BCI)
  - Mammostrat
- Prostate Cancer
  - Decipher (22-gene test)
  - Prolaris (46-gene test)
  - Oncotype DX prostate (17-gene test)

7

Gene Expression Profile Tests

- Colon Cancer
  - ColoPrint (18-gene test)
  - Oncotype DX colon (12-gene test)
- Multiple Myeloma
  - Myeloma Prognostic Risk Signature, MyPRS (70-gene or GEP70 test)
  - SKY92, EMC92 (92-gene test)

8

Scope: PICO

- **Outcomes**
  - Clinical outcomes (e.g., morbidity, mortality, quality of life)
  - Patient management decisions (including selection of active surveillance rather than active treatment)
  - Harms, such as consequences of false-positive or false-negative test results
  - Cost-effectiveness and other economic outcomes

9

Scope: Key Questions

1. Effectiveness: What is the clinical utility of gene expression profile testing of cancer tissue to inform treatment decisions?
   a. Is there evidence that test results affect treatment decisions?
   b. Do treatment decisions guided by gene expression profile testing result in clinically meaningful improvements in patient outcomes?
2. Harms: What harms are associated with conducting gene expression profile testing?

10

Scope: Key Questions

3. Special populations: Compared with usual care, do treatment decisions, patient outcomes, or harms after gene expression profile testing of cancer tissue vary by:
   a. Patient demographics (e.g., age, sex, race/ethnicity)?
   b. Clinical history (e.g., means of diagnosis, stage or grade of cancer, results of other testing, previous treatments, chronicity)?
   c. Medical comorbidities?
   d. Provider type or care setting?
4. What are the cost-effectiveness and other economic outcomes of gene expression profile testing used to inform treatment management decisions?

11

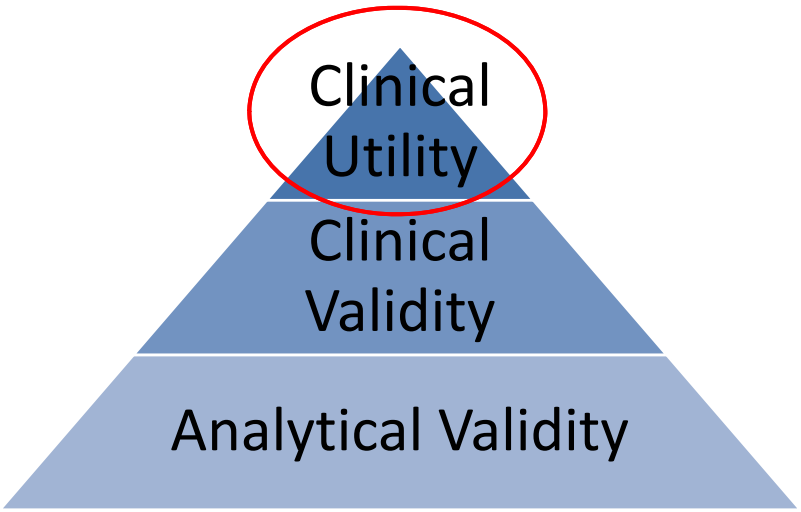
Prognostic vs. Predictive Biomarkers
Clinical Validity vs. Clinical Utility

- A biomarker used to identify <u>likelihood of a clinical event or disease recurrence or progression</u> in patients who have the disease or medical condition of interest
- A biomarker used to identify individuals who are more likely than similar individuals without the biomarker to experience a favorable or unfavorable <u>effect from exposure to a medical product</u> or an environmental agent

12

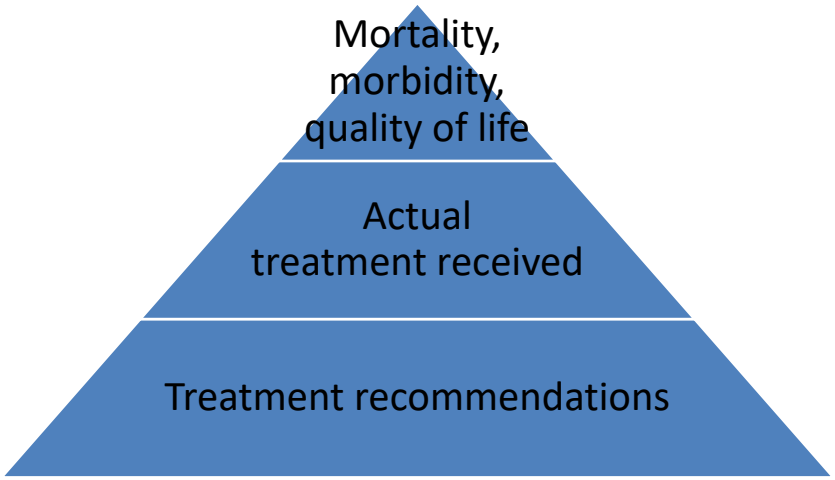
FDA-NIH Biomarker Working Group. BEST (Biomarkers, EndpointS, and other Tools) Resource, 2017

Hierarchy of Genetic Test Evidence Development



13

Clinical Utility Outcomes



14

Eligible Studies

- Key Questions 1, 2, and 3:
  - Randomized controlled trials and nonrandomized comparative studies (prospective or retrospective)
  - Systematic reviews (with and without meta-analysis) of these two types of studies
- Key Question 4:
  - Cost-effectiveness studies and other comparative economic evaluations
  - Systematic reviews (with and without meta-analysis) of these types of studies

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Evidence Sources

- Search of multiple databases:
  - Ovid MEDLINE
  - Cochrane Database of Systematic Reviews
  - Cochrane Central Register of Controlled Trials
- Additional evidence sources included:
  - Agency for Healthcare Research and Quality (AHRQ)
  - U.K. National Institute for Health and Care Excellence (NICE)
  - Veterans Administration Evidence-based Synthesis Program
  - Reference lists of included studies, test manufacturer websites, and a dossier submitted to the Washington State Agency Medical Directors' Group in December 2016

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Evidence Sources

- ClinicalTrials.gov database for ongoing and recently completed registered trials
- For clinical practice guidelines:
  - Evidence sources (e.g., MEDLINE)
  - AHRQ National Guideline Clearinghouse
  - American Society of Clinical Oncology (ASCO)
  - National Comprehensive Cancer Network (NCCN)
- For payer policies:
  - Centers for Medicare & Medicaid Services (CMS) Medicare Coverage Database for National and Local Coverage Determinations applicable to Washington State
  - Private payers: Aetna, Cigna, and Regence websites

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Evidence Search Results

- Separate searching and screening was conducted for each of the four cancers
- Number of citations identified by searches

Cancer	Number of Studies
Breast Cancer	2,005
Prostate Cancer	266
Colon Cancer	431
Multiple Myeloma	247
TOTAL	2,949

18

Risk of Bias for Studies

- Two independent Center researchers evaluated studies for methodological risk of bias, and disagreement among these assessments was settled by a third researcher
- Each study was assessed using Center instruments adapted from international standards and assessments for methodological quality
- A rating of high, moderate, or low risk of bias was assigned to each study or review based on adherence to recommended methods and potential for bias affecting validity
- Risk-of-bias criteria for all study types are in Appendix B of the report

19

Overall Quality of Evidence

- Center researchers assigned a summary judgment for the overall quality of evidence for each outcome
- Based on GRADE: Grading of Recommendations, Assessment, Development, and Evaluation
- The GRADE system defines the confidence that the estimate of the effect of the intervention on the outcome lies close to the true effect (listed on next slide)

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GRADE Definitions of Quality of Evidence

High	Very confident that the estimate of the effect of the intervention on the outcome lies close to the true effect
Moderate	True effect is likely to be close to the estimate of the effect, but there is a possibility that it is different
Low	Little confidence in the estimate of the effect of the intervention on the outcome and the true effect may be substantially different from the estimate of the effect
Very Low	No confidence in the estimate of the effect of the intervention on the outcome and the true effect is likely to be substantially different from the estimate of effect

21

Clinical Utility of Breast Cancer GEP Tests

Number of Breast Cancer GEP Studies by Test

Test	Number of Studies
Oncotype DX	38 primary studies from 3 systematic reviews plus 10 additional studies
MammaPrint	7 primary studies from 2 systematic reviews and 4 additional studies
Prosigna	1 primary study from a systematic review
EndoPredict	1 primary study
BCI	1 primary study
Mammostrat	1 primary study

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Oncotype DX

Oncotype DX: Blok et al. Systematic Review

- Systematic review assessed as having a moderate risk of bias
- Most studies were of patients with LN-negative tumors, although some included patients with LN-negative and LN-positive tumors
- 22 before-after studies (n = 3,743) examined Oncotype DX
- Authors did not provide risk-of-bias assessments for the included studies
- Change, after testing, in proportion of patients with a recommendation for a more invasive treatment: -14.6%
- Change, after testing, in proportion of patients with a recommendation for a less invasive treatment: +51.1%

25

Oncotype DX: Augustovski et al. Systematic Review

- Assessed systematic review as having a low risk of bias
- Included 15 before-after studies of women with LN-negative, early-stage invasive breast cancer
- Analysis of the 7 studies at lower risk of bias because they used universal subject enrollment vs. selective enrollment
  - Proportion of patients whose treatment decision was altered with use of the Oncotype DX test: 28.97% (95% CI, 26.65% to 31.34%); $I^2 = 0.00\%$
  - Patients assigned to receive chemotherapy after the test decreased 9.00% (95% CI, 4.00% to 14.00%); $I^2 = 89.00\%$

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Oncotype DX: Scope et al. Systematic Review

- Assessed systematic review as having a high risk of bias
- 28 before-after studies reported outcomes on changes in recommended treatment after Oncotype DX testing
- Authors did not present pooled estimates because of concern about heterogeneity among studies
- Use of Oncotype DX led to changes in treatment recommendations for 21% to 74% of patients
- Change from a recommendation of chemotherapy to no chemotherapy ranged from 6% to 51% of patients after Oncotype DX use

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Oncotype DX: Bear et al. RCT

- Assessed as having high risk of bias
- 33 women with Oncotype DX scores of 11 to 25 were randomized to neoadjuvant hormone therapy (NHT) or neoadjuvant chemotherapy (NCT)
- Women who received NHT had lower clinical response rate than women who received NCT 22.2% vs. 36.4%; p = .034
  - Clinical response rate is a poor surrogate for survival, and this study provides very little evidence about clinical utility for important patient outcomes

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Oncotype DX: Retrospective Cohort Studies

- 6 retrospective cohort studies using databases (Friese et al., Jasem et al. (2016), Jasem et al. (2017), Parsons et al., O'Neill et al., Ray et al.)
  - Studies assessed as having either a moderate or high risk of bias
  - Overall, patients who had Oncotype DX ordered received chemotherapy less often than patients who did not have test
  - Patients with intermediate- and high-risk Oncotype DX scores were more likely to receive chemotherapy than those with low-risk scores

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MammaPrint

MammaPrint: Blok et al. Systematic Review

- Studies included patients with LN-negative and LN-positive tumors, although most studies were of patients with LN-negative tumors
- Four included studies of 790 patients used the MammaPrint test
- Change, after testing, in proportion of patients with a recommendation for a more invasive treatment: -17%
- Change, after testing, in proportion of patients with a recommendation for a less invasive treatment: +32.2%

31

MammaPrint: Scope et al. Systematic Review

- Use of MammaPrint led to changes in treatment recommendations for 18% to 40% of patients
- Change from a recommendation of chemotherapy to no chemotherapy ranged from 2% to 32% of patients after MammaPrint use

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MammaPrint: Cardosa et al. (MINDACT) RCT

- Cardoso et al. RCT, Microarray in Node-Negative and 1 to 3 Positive Lymph Node Disease May Avoid Chemotherapy (MINDACT)
  - Center researchers assessed this RCT as having a moderate risk of bias
  - 6,693 women with early-stage invasive breast cancer
  - Most women were postmenopausal with ER-positive, HER2-negative, and LN-negative tumors
  - Women underwent clinical risk assessment using a modified version of the Adjuvant! Online tool and genomic risk assessment using MammaPrint

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MammaPrint: Cardosa et al. (MINDACT) RCT

- 2,187 women with discordant clinical and genomic risks were randomized to receive or not receive chemotherapy
- Among women with high clinical risk and low genomic risk, rates of five-year survival without distant metastasis were similar for those treated with chemotherapy and those given no adjuvant chemotherapy:
  95.9% vs. 94.4%; aHR, 0.78; 95% CI, 0.50 to 1.21
- Among women who had low clinical risk and high genomic risk, risks of death and distant metastases were similar in the chemotherapy vs. no chemotherapy groups:
  95.8% vs. 95.0%; aHR, 1.17; 95% CI, 0.59 to 2.28

34

MammaPrint: Kuijer et al. (2016) Retrospective Cohort

- Center researchers assessed this study as having high risk of bias
- 2,043 women with breast cancer, surgically treated in the Netherlands
- Compared women who received MammaPrint test to inform treatment decisions to women whose treatment was determined by standard clinicopathological factors
- Use of MammaPrint was associated with 9.5% absolute reduction (95% CI, -15.7% to -3.3%) in use of chemotherapy

35

MammaPrint: Kuijer et al. (2017) Before-After Study

- Center researchers assessed this study as having a high risk of bias
- 660 women in the Netherlands who had surgically treated early-stage invasive breast cancer and were eligible for adjuvant chemotherapy treatment
- After MammaPrint test, treatment recommendations changed for 51% (95% CI, 46% to 56%)
- Chemotherapy actually administered comported with what was recommended based on the test 90% to 91% of the time

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MammaPrint: Tsai et al. Before-After Study

- Center researchers assessed as having a high risk of bias
- Study examined whether MammaPrint test affected treatment decisions among women (n = 840) with an intermediate Oncotype DX score (score of 18 to 30)
- Overall, 33.6% of treatment recommendations changed after the MammaPrint test was administered
- Among all patients, the odds of chemotherapy treatment withdrawal were 0.64 (95% CI, 0.50 to 0.82)
- Physicians were surveyed about how MammaPrint influenced their decision and reported it increased their confidence in the final treatment plan in 78.6%, reduced it in 5.8%, and had no influence in 15.6% of cases

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Prosigna

Prosigna Studies

- Blok et al. systematic review included 1 before-after study on a single group of patients (n = 200)
  - Change, after testing, in proportion of patients with a recommendation for a more invasive treatment: -12.9%
  - Change, after testing, in proportion of patients with a recommendation for a less invasive treatment: +37.3%

Two additional studies:

- Hequet et al. before-after study on a single group of patients (n = 210) assessed as having a high risk of bias
  - Treatment recommendation changed for 18% of women
    - Recommendation of no adjuvant chemotherapy to adjuvant chemotherapy for 13% of women
    - Recommendation of adjuvant chemotherapy to no chemotherapy for 5% of women

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Prosigna: Wuerstlein et al. Before-After Study

- West German Study Group (WSG) Breast Cancer Intrinsic Subtype before-after study on a single group of patients (n = 198)
- Center researchers assessed as having a high risk of bias
- Treatment recommendation changed for 18%
  - No adjuvant chemotherapy recommendation changed to adjuvant chemotherapy recommendation for 11% of cases
  - Adjuvant chemotherapy recommendation changed to against adjuvant chemotherapy for 2%
  - For 5% of women, there was a change in the particular type of chemotherapy regimen

40

EndoPredict

EndoPredict: Blok et al. Systematic Review

- Blok et al. systematic review included 1 before-after study on a single group of patients (n = 167)
  - Change, after testing, in proportion of patients with a recommendation for a more invasive treatment: -34%
  - Change, after testing, in proportion of patients with a recommendation for a less invasive treatment: +53.2%
- No additional individual clinical utility studies

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Breast Cancer Index

BCI: Sanft et al. Before-After Study

- Center researchers assessed as having a high risk of bias
- Women (n = 96) from a single U.S. institution who had completed at least 3.5 years of adjuvant endocrine therapy and were eligible for extended endocrine treatment
- 26% of women had a change of treatment recommendation after use of the test
- Decline in recommendations for extended adjuvant chemotherapy (74% before the test vs. 54% after the test; OR, 0.14; 95% CI, 0.04 to 0.46)

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Mammostrat

Mammostrat: Scope et al. Systematic Review

- 1 study of Mammostrat included in the Scope et al. systematic review: Ross et al. (2008)
  - Prospective-retrospective study of 711 women
  - Change in distant recurrence-free interval when treated with tamoxifen:
    - Low risk: improved by 5% from 86% to 91% (HR, 0.4; 95% CI, 0.2 to 0.8)
    - High risk: improved by 21% from 64% to 85% (HR, 0.4; 95% CI, 0.2 to 0.9)
    - Low- and high-risk groups benefited from chemotherapy, whereas patients in the intermediate-risk group did not

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Breast Cancer Evidence Summary

- Majority of studies on gene tests to inform treatment of breast cancer have a high risk of bias
- Findings are consistent regarding an association between test use and changes in recommended or actual treatment based on the test result
  - Largest body of evidence for Oncotype DX test
  - Moderate amount of evidence for MammaPrint and Prosigna
  - Very little for BCI, EndoPredict, and Mammostrat
  - Evidence is limited because of lack of information on important patient outcomes such as survival, with the exception of the MINDACT study of MammaPrint

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Breast Cancer Key Question 2: Harms

- No studies reported outcomes related to false reassurance or false alarm from these tests
- In general, studies that reported on decisional conflict, anxiety, function, or patient-perceived usefulness of testing found small differences in favor of testing
- Similarly, studies reporting the outcome found physicians perceived testing to be useful and that it increased their confidence in treatment recommendations

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Breast Cancer Key Question 3: Subpopulations

- Few studies reported results stratified by subpopulations of interest such as by age, race, or disease characteristics
- Jasem et al. (2017) reported that older patients were more likely to receive testing than younger patients, and that African American women and patients without insurance were less likely to be tested
- Studies reporting differences in subpopulation test receipt or treatment recommendations are difficult to interpret because of small effect sizes, high risk of bias, and residual confounding

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Breast Cancer Key Question 4
Economic Outcomes

- Blok et al. systematic review included studies with economic outcomes
- Economic studies published after the Blok et al. systematic review: Hall et al. considered Oncotype DX, MammaPrint, and Prosigna
  - Loncaster et al. reported cost outcomes related to the use of Oncotype DX
- Decision analysis on BCI test by Gustavsen et al.

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Breast Cancer: Blok et al. Systematic Review

- 2 studies comparing testing to not testing using patient groups found increased costs per patient ($400 to $1,367) with the use of Oncotype DX
- 26 cost-utility models reported results in costs per QALY:
  - 14 studies on Oncotype DX for women with LN-negative tumors reported cost/QALY ranges of $3,843 to $43,044, CAD$3,206 to CAD$63,064, or £29,502
  - 5 studies evaluated Oncotype DX for women with LN-positive tumors (or studies with mixed LN-negative and LN-positive populations) reported costs/QALY of $1,914 to $49,059, CAD$464 to CAD$14,844, and £5,529
  - 5 studies on MammaPrint reported cost/QALY ranging from $10,000 to $43,044, and €4,614 to €134,000

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Breast Cancer: Additional Economic Studies

- Hall et al. assessed as having moderate risk of bias
  - Modeling study to accompany UK NHS feasibility study for Oncotype DX testing (using cutoff score of 25) vs. standard risk assessment or alternative tests (MammaPrint and Prosigna)
  - Mean incremental per-person cost and QALY changes:

	Cost (£) (95% CI)	QALY (95% CI)
Oncotype DX	-108 (-4610 to +4292)	0.20 (-1.07 to 1.40)
MammaPrint	+195 (-3206 to +3430)	0.18 (-0.87 to 1.10)
Prosigna	-474 (-4078 to +2955)	0.18 (-0.91 to 1.15)

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Breast Cancer: Additional Economic Studies

- Loncaster et al. assessed as having high risk of bias
  - Modeling study showing that use of Oncotype DX test would result in budget savings of £1,325 per patient
- Gustavsen et al. assessed as having high risk of bias
  - Using BCI test for newly diagnosed women with ER-positive, LN-negative breast cancer would result in mean cost savings per patient of $3,803

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Breast Cancer Economic Evidence Summary

- Estimates of costs and QALY varied widely among the studies
- Quality of economic evidence for Oncotype DX and MammaPrint is low when the Blok et al. systematic review and additional economic analysis by Hall et al. are considered together
- Overall quality of economic evidence about Prosigna, EndoPredict, and Mammostrat is very low

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Breast Cancer GRADE Summary

Outcome	Quality of Evidence
Clinical Utility—mortality or morbidity	Oncotype DX ●○○○ Very low MammaPrint ●●●○ Moderate
Clinical Utility—patient management decisions	Oncotype DX Breast ●●●○ Moderate MammaPrint ●●○○ Low Prosigna, EndoPredict, BCI, and Mammostrat ●○○○ Very low

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Breast Cancer GRADE Summary

Outcome	Quality of Evidence
Clinical Utility—quality of life	Oncotype DX, Prosigna, and BCI ●○○○ Very low Other tests Not applicable (no eligible studies)
Harms	Oncotype DX ●○○○ Very low Other tests Not applicable (no eligible studies)
Cost-effectiveness and other economic outcomes	Oncotype DX and MammaPrint: ●●○○ Low EndoPredict, Mammostrat, Prosigna, BCI: ●○○○ Very low

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Breast Cancer Guidelines

Guideline	Methodological quality assessment
American Society of Clinical Oncology (ASCO, 2016)	Good
European Group on Tumor Markers (EGTM) 2017	Poor
European Society for Medical Oncology (ESMO) 2015	Poor
National Institute for Health and Care Excellence (NICE) 2013	Good
National Comprehensive Cancer Network (NCCN) 2017	Fair

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Breast Cancer Guidelines

- When these guidelines recommend a GEP test, the recommendations generally include these restrictions:
  - Early-stage breast cancer (usually stage 1 and stage 2)
  - ER-positive (sometimes also includes PR-positive)
  - HER2-negative
  - Test results will affect treatment decisions
  - LN-negative patients (sometimes also includes 1-3 positive lymph nodes) – see next slide

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Breast Cancer Guidelines

Test	ASCO	NCCN	NICE	ESMO**	EGTM
Oncotype DX	LN-negative	LN-negative LN-positive	LN-negative	LN-negative LN-positive	LN-negative LN-positive
MammaPrint	LN-negative LN-positive	Not recommended*	Not recommended	LN-negative LN-positive	LN-negative LN-positive
EndoPredict	LN-negative	Not recommended*	No guideline recommended	LN-negative LN-positive	LN-negative LN-positive
Prosigna	LN-negative	Not recommended*	No guideline recommended	LN-negative LN-positive	LN-negative LN-positive
Breast Cancer Index	LN-negative	Not recommended*	No guideline recommended	No guideline recommended	LN-negative
Mammostrat	Not recommended	Not recommended*	Not recommended	No guideline recommended	No guideline recommended

**NCCN guidelines stated that prognostic multigene assays other than Oncotype DX may be considered to help assess risk of recurrence but have not been validated to predict response to chemotherapy.*
***ESMO guidelines did not distinguish between LN-negative and LN-positive cancers.*

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Breast Cancer Payer Policies

- No Medicare National Coverage Determinations (NCDs) were found for any of the GEP tests for breast cancer
- Local Coverage Determinations (LCDs) applying to Washington provide coverage for EndoPredict, Prosigna, and BCI
- No LCDs applying to Washington provide coverage for Oncotype DX, MammaPrint, or Mammostrat

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Breast Cancer Private Payer Policies

	Aetna	Cigna	Regence
Oncotype DX	LN-negative LN-positive	LN-negative LN-positive	LN-negative
MammaPrint	LN-negative LN-positive	LN-negative LN-positive	No coverage
EndoPredict	LN-negative	No coverage	LN-negative
Prosigna	LN-negative	LN-negative	No coverage
BCI	LN-negative	No coverage	LN-negative
Mammostrat	No coverage	No coverage	No coverage

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Clinical Utility of Prostate Cancer GEP Tests

Prostate Cancer Evidence

- Total of 8 individual studies identified for prostate cancer
- All studies were assessed as having a high risk of bias
- All studies used before-after designs that reported treatment recommendations before and after the test result was available
  - Four of these studies used a single group of patients and tracked decision outcomes before and after the test results were provided
  - Four studies employed a historical group from a time period when treatment decisions were made without the assistance of genomic testing

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Prostate Cancer Evidence

- Test used after an initial diagnosis of prostate cancer to predict the cancer's aggressiveness and thus inform treatment decisions
  - Oncotype DX: 4 before-after studies
  - Prolaris: 2 before-after studies
- Test used after radical prostatectomy to predict the probability of metastasis and inform clinical decisions on the use of adjuvant prostate cancer treatments
  - Decipher: 2 before-after studies

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Oncotype DX Prostate Studies

- 3 studies used historical comparison groups
  - Albala et al. reported that more men received recommendations for active surveillance after testing (59% vs. 38%)
  - Dall-Era et al. reported that use of active surveillance increased after testing (67% vs. 43%)
  - Eure et al. reported 51% of patients switched from interventional treatment to active surveillance after testing
- Badani et al. before-after study on a single group of patients
  - After testing, recommended treatment intensity decreased for 15.8% of men and increased for 8.9%

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Prolaris Studies

- Crawford et al. before-after study using a historical comparison
  - For 37% of subjects, recommendation for interventional treatment changed to active surveillance or watchful waiting after testing
- Shore et al. before-after study on a single group of patients
  - After testing, treatment recommendations changed for 47.8% of subjects
    - Nearly 75% of treatment modifications were changing to decreased treatment intensity

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Decipher Studies

- Decipher: 2 before-after studies (each using a single group of patients) of men who have had a radical prostatectomy
- Gore et al.: Decipher test use is associated with changes in treatment recommendations
  - Men considering adjuvant radiotherapy:
    OR, 1.48; 95% CI, 1.19 to 1.85
  - Men considering salvage radiotherapy:
    OR, 1.30; 95% CI, 1.03 to 1.65
- Michalopoulos et al.: Changes in treatment recommendations before-after Decipher test
  - 42% of patients who had a recommendation of any active treatment experienced a change to observation only
  - 18% with an initial recommendation of observation had a posttest recommendation of an active treatment strategy

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Prostate Cancer

- Key Question 2: Harms
  - No studies met inclusion criteria for this key question
- Key Question 3: Subpopulations
  - No studies met inclusion criteria for this key question, (except that Oncotype DX and Prolaris are used in different clinical situations than the Decipher test)

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Prostate Cancer Key Question 4 Economic Outcomes

- Ontario Health Technology Advisory Committee study of Prolaris, assessed as having a moderate risk of bias
  - Budget impact analysis showed that use of test increased costs for province of Ontario
- Lobo et al. cost-effectiveness study of Decipher, assessed as having a high risk of bias
  - Test-based care increased per-person cost of care by $5,453; increased the mean QALY per individual by 0.066; with an incremental cost-effectiveness ratio of $90,883
- Albala et al. study of Oncotype DX, assessed as having a high risk of bias
  - Total cost of care was $2,286 less for men who had received the test compared to historical costs

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Prostate Cancer GRADE Summary

- Study findings are consistent regarding an association between use of Oncotype DX, Prolaris, or Decipher and recommendations for decreased treatment intensity and increased decision confidence for patients and physicians
- Quality of evidence very low for these findings because of high risk of bias and other limitations, including
  - Use of before-after designs
  - Reporting of recommended rather than actual treatments
  - Lack of important patient outcomes such as survival or treatment-related morbidity
- Quality of evidence very low for economic outcomes

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Prostate Cancer Guidelines

Guideline	Methodological Quality	Recommendation
American Urological Association, American Society for Radiation Oncology, and Society of Urologic Oncology (2017)	Good	Tissue-based genomic biomarkers have not shown a clear role in active surveillance for localized prostate cancer
National Comprehensive Cancer Network (NCCN, 2017)	Fair	May consider the use of tumor-based molecular assays; specific recommendations on when to use Decipher, Prolaris, and Oncotype DX

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Prostate Cancer Payer Policies

Payer	Coverage policies for Decipher, Prolaris, and Oncotype DX
Medicare National Coverage Determination	Not found
Medicare Local Coverage Determination applying to WA	Coverage for Decipher, Prolaris, and Oncotype DX under certain conditions
Private Payers	
Aetna	No coverage
Cigna	Not included on the list of medically necessary prostate cancer prognostic tests
Regence	No coverage

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Clinical Utility of Colon Cancer GEP Tests

Colon Cancer Evidence

- ColoPrint: no systematic reviews or individual studies
- Oncotype DX: no systematic reviews; 2 individual studies
- Both individual studies for Oncotype DX were assessed as having a high risk of bias
  - Svrivastava et al.: use of the test resulted in changes in treatment recommendations
    - Increased intensity of recommended therapy for 11.4%
    - Decreased intensity recommendations for 32.9%
  - Brenner et al.: actual treatment received compared to treatment recommended before the test results were known
    - Increased intensity of treatment for 9.7%
    - Decreased intensity for 28.3%

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Colon Cancer

- Key Question 2: Harms
  - No studies met inclusion criteria for this key question
- Key Question 3: Subpopulations
  - No studies met inclusion criteria for this key question

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Colon Cancer Key Question 4
Economic Outcomes

- Alberts et al. study of Oncotype DX colon cancer test
  - Assessed as having a moderate risk of bias
  - Cost-effectiveness of using Oncotype DX to guide therapy for patients with resected stage 2 MMR-P colon cancer
  - Slightly lower total lifetime costs ($991 less) with the test ($103,775) than without it ($104,767)

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Colon Cancer GRADE Summary

- Quality of evidence very low for Oncotype DX clinical and economic outcomes
- No evidence found for ColoPrint

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Colon Cancer Guidelines

- No clinical practice guidelines were found that included recommendations for the use of ColoPrint or Oncotype DX for colon cancer
- NCCN guideline on colon cancer, assessed as having fair methodological quality
  - "There is no evidence of predictive value in terms of the potential benefit of chemotherapy to any of the multigene assays"

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Colon Cancer Payer Policies

Payer	Coverage policies for ColoPrint and Oncotype DX
Medicare National Coverage Determination	Not found
Medicare Local Coverage Determination applying to WA	Not found
Private Payers	
Aetna	No coverage
Cigna	No coverage
Regence	No coverage

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Multiple Myeloma GEP tests

Multiple Myeloma

- No multiple myeloma studies found for clinical utility or economic outcomes

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Multiple Myeloma Guidelines

- NCCN (2017) guidelines on multiple myeloma, assessed as having fair methodological quality
  - No recommendation provided
  - Stated that although GEP tests are not routinely used, they could be helpful in selected patients to estimate the aggressiveness of disease and/or individualize treatment
- European Society for Medical Oncology (ESMO, 2017), assessed as having fair methodological quality
  - Gene-expression profiling is not currently used routinely, and more research is needed to identify molecular markers, which could lead to advances in this area

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Multiple Myeloma Payer Policies

Payer	Coverage policies for MyPRS and SKY92
Medicare National Coverage Determination	Not found
Medicare Local Coverage Determination applying to WA	Not found
Private Payers	
Aetna	No coverage for MyPRS Does not mention SKY92
Cigna	Does not mention MyPRS or SKY92
Regence	Does not cover MyPRS or SKY92

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Overall Summary

Limitations

- Risk of bias of included studies varied, but was often high
- Evidence base limited for assessing the clinical utility, harms, and cost-effectiveness of most of the tests
- Clinical utility limited to influence on clinical decision making for nearly all tests
- Without evidence of clinical endpoint data, cannot be certain that effects on decision making are actually improving care
- Populations included were generally not diverse in terms of race, ethnicity, or socioeconomic factors
- Many studies were conducted in Europe, which could limit generalizability to the U.S. context
- Given limited evidence on effectiveness, economic modeling studies were not able to use solid estimates of effectiveness

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Overall Summary

- There was no high-quality evidence of clinical utility to guide decisions about any GEP tests
- Only condition with quality of evidence ratings above very low was breast cancer and only for the MammaPrint and Oncotype DX
- Based on 1 RCT, there is moderate-quality evidence that women with early-stage invasive breast cancer who are at high clinical risk by the Adjuvant! Online risk assessment tool may safely forego adjuvant systemic chemotherapy if their MammaPrint genomic risk score is low

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Overall Summary

- Moderate-quality evidence supports the use of Oncotype DX because of its impact on clinical treatment recommendations
- Based primarily on modeling studies, there is low-quality evidence that both Oncotype DX and MammaPrint are cost-effective at conventional thresholds of cost/QALY
- For prostate cancer, colon cancer, and multiple myeloma, there is very low-quality evidence or a complete absence of evidence to support use of these tests to improve clinical decision making and important patient outcomes

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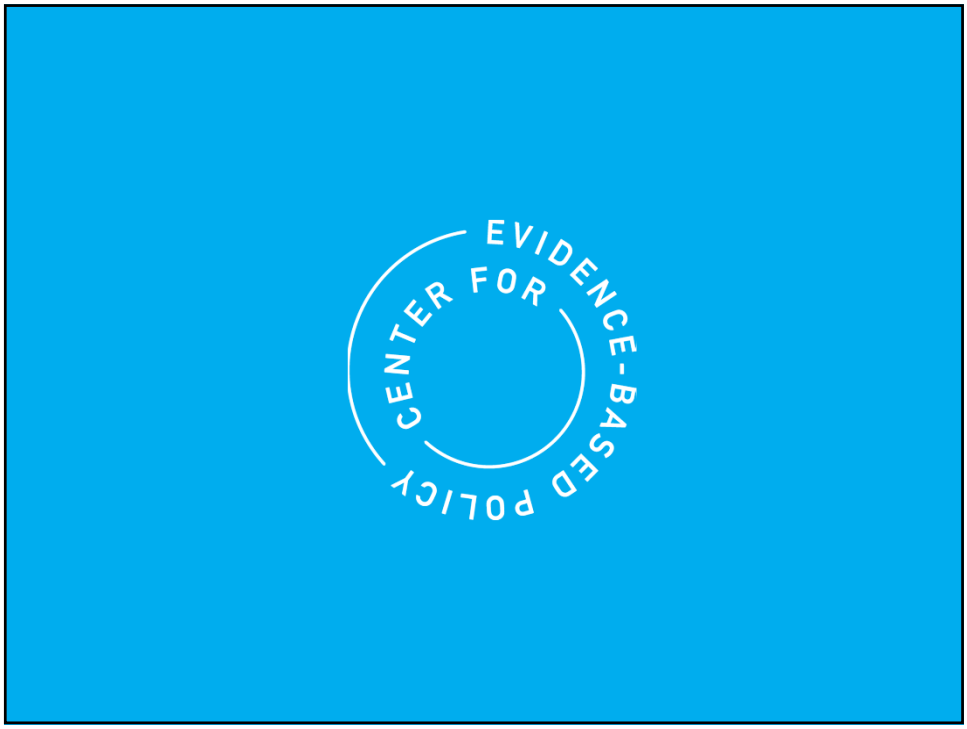

EVIDENCE-BASED POLICY
CENTER FOR

Washington State Health Care Authority

FINAL key questions and background

Gene expression profile testing of cancer tissue

Background

The lifetime risk of developing cancer is about 40%, and one in every five Americans will die from cancer.[1] Strategies for reducing the burden of cancer include preventing the disease, early diagnosis of cancer, and appropriate treatments of diagnosed cancers.[2] Common treatments for cancer include surgery, chemotherapy, radiation therapy, hormone therapy, and immunotherapy.[3] The most appropriate treatments for a particular cancer depend on the cancer's severity (e.g., cancer stage and grade), the patient's age and health status, response to previous treatments, and other factors.

In recent years, gene expression profile testing of cancer tissue has been used to help inform decisions on the most appropriate treatments. Gene expression profile testing identifies the genes in a cancer cell or tissue that are making messenger RNA, which carry the genetic information that cancer cells need to make proteins. Some gene expression profile tests are designed to increase the accuracy of the prognosis for a patient with cancer. If a test predicts that a cancer is slow growing or is unlikely to metastasize, then active surveillance of the cancer could be the most appropriate course. If a test predicts that a cancer is at high risk for progression and metastasis, then more aggressive treatments could be warranted.[4]

Policy context

There are a growing number of gene expression profile tests for cancer tissue designed to inform treatment decisions after diagnosis. Potential benefits of these tests are more appropriate treatment decisions and better patient outcomes, including avoiding treatment-related side effects and the potential cost savings from forgoing unnecessary treatments. This topic was selected for a health technology assessment because of medium concerns for the safety of these tests, medium/high concerns for efficacy, and high concerns for cost.

This evidence review will help to inform Washington's independent Health Technology Clinical Committee as the committee determines coverage regarding selected gene expression profile tests for patients with eligible breast, prostate, or colon cancers or multiple myeloma.

Proposed Scope

Population: Adults with breast, prostate, or colon cancers or multiple myeloma

Interventions: Gene expression profile testing of cancer tissue to inform treatment decisions, including the following tests by cancer type:

- Breast Cancer—Oncotype DX Breast Cancer Assay, EndoPredict, MammaPrint, Prosigna Breast Cancer Prognostic Gene Signature Assay (PAM50), Mammostrat, Breast Cancer Index (BCI)
- Prostate Cancer—Prolaris, Decipher, Oncotype DX Prostate Cancer Assay
- Colon Cancer—Oncotype DX Colon Cancer Assay, ColoPrint
- Multiple Myeloma—Myeloma Prognostic Risk Signature (MyPRS), SKY92-signature (formerly EMC92)

Comparators: Usual care without gene expression profile testing of cancer tissue, alternate gene expression profile tests (i.e., one test intervention listed above versus another)

Outcomes:

- Patient management decisions (including selection of active surveillance rather than active treatment)
- Clinical outcomes (e.g., morbidity, mortality, quality of life)
- Harms, such as consequences of false-positive or false-negative test results
- Cost-effectiveness and other economic outcomes

Time period for literature search: 2007 to 2017

Key Questions

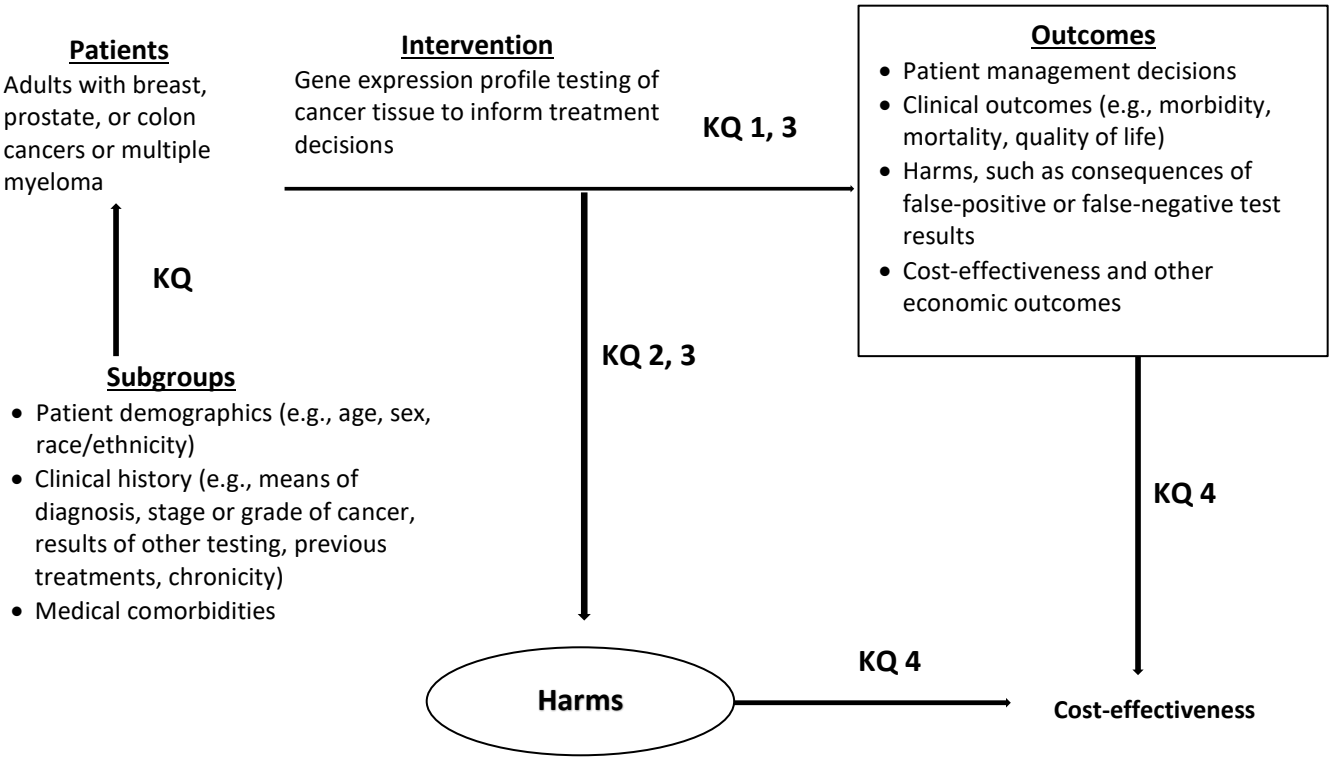
1. Effectiveness: What is the clinical utility of gene expression profile testing of cancer tissue to inform treatment decisions for patients with breast, prostate, and colon cancers and multiple myeloma?
    a. Is there evidence that test results affect treatment decisions?
    b. Do treatment decisions guided by gene expression profile testing of cancer tissue result in clinically meaningful improvements in patient outcomes?
2. Harms: What harms are associated with conducting gene expression profile testing of cancer tissue?
3. Special populations: Compared with usual care, do treatment decisions, patient outcomes, or harms after gene expression profile testing of cancer tissue vary by:
    a. Patient demographics (e.g., age, sex, race/ethnicity)?
    b. Clinical history (e.g., means of diagnosis, stage or grade of cancer, results of other testing, previous treatments, chronicity)?
    c. Medical comorbidities?
    d. Provider type or care setting?
4. What are the cost-effectiveness and other economic outcomes of gene expression profile testing used to inform treatment management decisions?

Eligible Studies

Randomized controlled trials, nonrandomized comparative studies, and systematic reviews of these two types of studies that assess clinical utility will be considered for Key Questions 1, 2, and 3. Cost-effectiveness studies and other comparative economic evaluations, along with systematic reviews of these types of studies, will be considered for Key Question 4.

Analytic framework

The analytic framework below will guide the selection, synthesis, and interpretation of available evidence.



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Public comment and response

See Draft key questions: Comment and response document published separately.

HTCC Coverage and Reimbursement Determination

Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are evidence-based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards[2]:

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms[3]:

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially

[1] Based on Legislative mandate: See RCW 70.14.100(2).

[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

[3] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

within the population, coverage or reimbursement determinations may be more selective based on the variation.

- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

Using evidence as the basis for a coverage decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of Evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the Evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

3. Factors for Consideration - Importance

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage

[4] Based on GRADE recommendation.

decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

Clinical Committee Findings and Decisions

Efficacy Considerations

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy?
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
  - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
  - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?

- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

Next Step: Cover or No Cover

If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions

If covered with conditions, the Committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
    - Refer to evidence identification document and discussion.
    - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
    - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
    - What are the known conditions/criteria and evidence state
    - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Clinical Committee Evidence Votes

First Voting Question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Discussion Document: What are the key factors and health outcomes and what evidence is there? (Applies to the population in the PICO for this review)

Safety Outcomes	Importance of Outcome	Safety Evidence / Confidence in Evidence
Adverse effects		
False positive or negative		
Harms associated with testing		
Anxiety		

Efficacy – Effectiveness Outcomes	Importance of Outcome	Efficacy / Effectiveness Evidence
Clinical Utility –Morbidity/Mortality		
Clinical Utility- Patient management decisions		
Quality of life		

Cost Outcomes	Importance of Outcome	Cost Evidence
Costs of testing		
Cost effectiveness		

Special Population / Considerations Outcomes	Importance of Outcome	Special Populations/ Considerations Evidence
Age		
Gender		
Race/ethnicity		
Clinical history		
Comorbidities		
Care setting		

For Safety: Is there sufficient evidence that the technology is safe for the indications considered?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all

For Efficacy/Effectiveness: Is there sufficient evidence that the technology has a meaningful impact on patients and patient care?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all

For Cost Outcomes/Cost-Effectiveness: Is there sufficient evidence that the technology is cost-effective for the indications considered?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all

Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____Not Covered _____ Covered Unconditionally _____ Covered Under Certain Conditions

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Next Step: Proposed Findings and Decision and Public Comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

1) Based on public comment was evidence overlooked in the process that should be considered?

2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next Step: Final Determination

Following review of the proposed findings and decision document and public comments:

Final Vote

Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or an unclear (i.e., tie) outcome Chair will lead discussion to determine next steps.

Medicare and Coverage Guidelines

[From page 25 of the Final Evidence Report]

No Medicare National Coverage Determinations (NCDs) were found for any of the gene expression profile tests for breast cancer. Center researchers identified Local Coverage Determinations (LCDs) by Noridian Healthcare Solutions, which apply to Washington, that provide coverage for EndoPredict, Prosigna, and BCI.

The EndoPredict LCD provides coverage for women with T1-3, N0-1 breast cancer when the following criteria are met:

- Patient is postmenopausal
- Pathology reveals invasive carcinoma of the breast that is ER-positive, HER2-negative
- Patient is either LN-negative or has 1 to 3 positive lymph nodes
- Patient has no evidence of distant metastasis
- Test result will be used to determine treatment choice between endocrine therapy alone vs. endocrine therapy plus chemotherapy[72]

The Prosigna LCD provides coverage for postmenopausal women with either of the following:

- ER-positive, LN-negative, stage 1 or 2 breast cancer or
- ER-positive, LN-positive (one to three positive nodes), stage 2 breast cancer[73]

The BCI LCD provides coverage for patients who have non-relapsed, ER-positive, LN-negative breast cancer, among other criteria.[74] No Medicare LCDs covering Washington were found for the Oncotype DX breast cancer assay, MammaPrint, or Mammostrat.
Center researchers assessed private payer policies for Aetna, Cigna, and Regence. The Aetna policy on tumor markers provides coverage for the Oncotype DX breast cancer assay, MammaPrint, EndoPredict, Prosigna, and BCI to assess the necessity of adjuvant chemotherapy in females or males with recently diagnosed breast tumors.[75] Oncotype DX and MammaPrint are covered for breast cancers that are LN-negative or with one to three involved ipsilateral axillary lymph nodes.[75] EndoPredict, Prosigna, and BCI are covered for only LN-negative cancers.[75] Coverage for all of these tests requires that adjuvant chemotherapy is not precluded by any other factor (e.g., advanced age or significant comorbidities) and that the patient and physician have discussed the potential results of the test and agree to use the results to guide therapy, among other criteria.[75] Aetna does not cover Mammostrat.[75]

The Cigna policy on gene expression assays covers the Oncotype DX breast cancer assay, MammaPrint, and Prosigna under certain conditions, and does not provide coverage for EndoPredict, BCI, or Mammostrat.[76] Oncotype DX and MammaPrint are covered for LN-negative cancers and for cancers with up to three positive nodes, and Prosigna is covered for only LN-negative cancers.[76] The Regence policy on gene expression testing for breast cancer provides coverage for the Oncotype DX breast cancer assay, EndoPredict, and BCI under certain conditions, and does not cover MammaPrint, Prosigna, or Mammostrat.[77] Regence covers the Oncotype DX breast cancer assay, EndoPredict, and BCI for women with primary breast cancer, stages 1, 2, or 3, that are LN-negative, among other criteria.[77]

Prostate Cancer

No Medicare NCDs were found for Decipher, Prolaris, or Oncotype DX for prostate cancer. There are LCDs for Noridian Healthcare Solutions, applying to the state of Washington, that provide coverage for Decipher, Prolaris, and Oncotype DX for prostate cancer under certain conditions. The LCD for Decipher provides coverage after radical prostatectomy when certain conditions are met.[78] There are two LCDs providing coverage for Prolaris, under certain conditions, one for patients with early stage, needle-biopsy-proven prostate cancer[79] and the other for patients with favorable intermediate-risk, needle-biopsy-proven prostate cancer.[80] The LCD for Oncotype DX for early-stage, needle-biopsy-proven prostate cancer provides coverage with specified condictions.[81]
The coverage policies for Aetna[75] and Regence[82] consider Decipher, Prolaris, and Oncotype DX prostate cancer assay to be experimental or investigational. Cigna does not include Decipher, Prolaris, or Oncotype DX prostate cancer assay in the list of medically necessary prostate cancer prognostic tests.[76]

Colon Cancer

No Medicare National or Local Coverage Determinations were found for ColoPrint or the Oncotype DX colon cancer assay. The policies for Aetna,[75] Cigna,[76] and Regence[83] do not cover ColoPrint or Oncotype DX colon cancer assay.

Multiple Myeloma

No Medicare National or Local Coverage Determinations were found for MyPRS or SKY92. The policy for Aetna does not cover MyPRS and does not mention SKY92.[75] Cigna's coverage policy on tumor markers does not mention MyPRS or SKY92.[76] The Regence coverage policy states that all microarray-based gene expression profile testing for multiple myeloma is considered investigational.[84]

Guidelines

[From page 73 of Final Evidence Report]

Clinical Practice Guidelines

Breast Cancer

The most detailed clinical practice guideline, *Use of Biomarkers to Guide Decisions on Adjuvant Systemic Therapy for Women with Early-Stage Invasive Breast Cancer,* was published by the American Society of Clinical Oncology (ASCO) in 2016.[59] ASCO published a guideline update in 2017 modifying the recommendations regarding MammaPrint, which draws upon recently published studies.[60] Both of these guidelines were rated as having good methodological quality. The detailed ASCO recommendations for the use of biomarkers in early-stage breast cancer are in Appendix G.

The ASCO guidelines outlined recommendations for when Oncotype DX breast cancer assay, MammaPrint, EndoPredict, Prosigna, BCI, and Mammostrat should or should not be used in patients with early-stage breast cancer. All of these tests, except for Mammostrat, are recommended for use in patients who have ER-positive/PR-positive, HER2-negative, LN-negative breast cancer.[59,60] The guidelines recommend against the use of Mammostrat for the following categories of breast cancers: ER-positive/PR-positive, HER2-negative (LN-positive or negative); HER2-positive; or ER-negative/PR-negative, HER2-negative, LN-negative.[59]

According to the ASCO guidelines, MammaPrint should not be used in patients with low clinical risk (as defined by the Adjuvant! Online tool as used in the MINDACT study[19]), because women in the low clinical risk category had very good outcomes and did not appear to benefit from chemotherapy even with a genomic high-risk cancer.[60] MammaPrint can be used in patients with ER-positive/PR-positive, HER2-negative, LN-positive breast cancer who have one to three positive nodes and are at high clinical risk per MINDACT categorization.[60] Still, these patients should be informed that a benefit of chemotherapy cannot be excluded, particularly among patients with more than one involved lymph node.[60] The ASCO guidelines recommended against using the other tests in patients with ER-positive/PR-positive, HER2-negative, LN-positive breast cancer; HER2-positive breast cancer; or ER-negative/PR-negative, HER2-negative, LN-negative breast cancer.[59]
The authors of the 2017 NCCN clinical practice guidelines on breast cancer discussed the evidence for Oncotype DX (21-gene breast cancer assay), MammaPrint (70-gene assay), and Prosigna (50-gene assay).[61] According to the guidelines, Oncotype DX can be considered for ER-positive/PR-positive, HER2-negative cancers with pT1, pT2, or pT3, and pN0 or pN1mi ≤ 2 mm axillary node metastasis and a tumor greater than 0.5 cm.[61] Oncotype DX can also be considered in certain patients with one to three involved ipsilateral axillary lymph nodes to guide the addition of combination chemotherapy to standard hormone therapy.[61] The NCCN guideline authors stated that the other gene expression profile tests can be considered to assess risk of cancer recurrence, but that they have not been validated to predict response to chemotherapy.[61] Center researchers rated the NCCN guidelines as having fair methodological quality.

NICE published guidelines in 2013 that assessed the use of Oncotype DX breast cancer assay, MammaPrint, Mammostrat, and immunohistochemical 4 (IHC4) score in early-stage breast cancer.[62] The guidelines recommend Oncotype DX as an option for guiding adjuvant chemotherapy decisions for people with ER-positive, HER2-negative, LN-negative early-stage breast cancer when the patient is assessed as being at intermediate risk.[62] According to the guidelines, Oncotype DX should only be used when the test results are likely to help in predicting the course of the disease, and therefore in the decision of whether to prescribe chemotherapy.[62] MammaPrint and Mammostrat are only recommended for use in research in patients with ER-positive, HER2-negative, LN-negative early-stage breast cancer.[62] Center researchers rated the NICE guidelines as having good methodological quality.

The European Society for Medical Oncology (ESMO) published breast cancer clinical practice guidelines in 2015.[63] The ESMO guidelines recommend that gene expression profile tests, such as Oncotype DX breast cancer assay, MammaPrint, EndoPredict, and Prosigna, can be used to complement pathology assessments to predict the benefit of adjuvant chemotherapy.[63] In cases when decisions might be challenging, such as in luminal B HER2-negative and LN-negative breast cancer, Oncotype DX, EndoPredict, and Prosigna can be used.[63] For all types of breast cancer (pN0–1), MammaPrint can be used in conjunction with clinicopathological factors to help in decision making about treatment.[63] Center researchers rated the ESMO guidelines as having poor methodological quality.

The European Group on Tumor Markers (EGTM) published a guideline in 2017 on the use of biomarkers in breast cancer.[64] These guidelines recommend that the Oncotype DX breast cancer assay, MammaPrint, EndoPredict, Prosigna, and BCI can be used to aid in adjuvant therapy decision making in ER-positive, HER2-negative, LN-negative patients.[64] In addition, Oncotype DX, MammaPrint, EndoPredict, and Prosigna can be used in patients with one to three metastatic lymph nodes.[64] Center researchers rated the EGTM guidelines as having poor methodological quality. The detailed recommendations from the EGTM are in Appendix G. Table 1 summarizes these five guidelines on breast cancer, indicating whether the gene expression profile tests are recommended for LN-negative and/or LN-positive cancers.

Table 1. Recommendations for Lymph Node Status in Guidelines on the Use of Gene Expression Tests in Early-Stage Breast Cancer

Test	ASCO	NCCN	NICE	ESMO**	EGTM
Oncotype DX	LN-negative	LN-negative LN-positive	LN-negative	LN-negative LN-positive	LN-negative LN-positive
MammaPrint	LN-negative LN-positive	Not recommended*	Not recommended	LN-negative LN-positive	LN-negative LN-positive
EndoPredict	LN-negative	Not recommended*	No guideline recommendation	LN-negative LN-positive	LN-negative LN-positive
Prosigna	LN-negative	Not recommended*	No guideline recommendation	LN-negative LN-positive	LN-negative LN-positive
Breast Cancer Index	LN-negative	Not recommended*	No guideline recommendation	No guideline recommendation	LN-negative
Mammostrat	Not recommended	Not recommended*	Not recommended	No guideline recommendation	No guideline recommendation

*NCCN guidelines state that prognostic multigene assays other than Oncotype DX may be considered to help assess risk of recurrence but have not been validated to predict response to chemotherapy. **The ESMO guideline authors did not distinguish between LN-negative and LN-positive cancers in their recommendations.

Prostate Cancer

Two clinical practice guidelines were identified that included recommendations on the use of Decipher, Prolaris, and Oncotype DX prostate cancer assay. The 2017 NCCN guidelines on prostate cancer stated that men with clinically localized prostate cancer may consider the use of tumor-based molecular assays, and the authors made specific recommendations on the use of Decipher, Prolaris, and Oncotype DX for prostate cancer.[65] The guidelines recommend Decipher after a radical prostatectomy for patients with pT2 (confined to prostate) with positive margins, any pT3 (extraprostatic extension) disease, and a rising PSA level.[65] Prolaris and Oncotype DX are recommended post-biopsy for low- and very low-risk prostate cancer in patients with at least 10 years of life expectancy who have not received other active treatment for prostate cancer and who are candidates for active surveillance or definitive therapy.[65] Center researchers rated the NCCN guidelines as having fair methodological quality.

A guideline on clinically localized prostate cancer has been jointly published by the American Urological Association, American Society for Radiation Oncology, and Society of Urologic Oncology in 2017.[66] These guidelines include the following recommendation based on expert opinion: "Tissue-based genomic biomarkers have not shown a clear role in active surveillance for localized prostate cancer and are not necessary for follow up."[66(p. 4)] Center researchers rated these guidelines as having good methodological quality.

Colon Cancer

No clinical practice guidelines were found that included recommendations for the use of ColoPrint or Oncotype DX for colon cancer. The American Society for Clinical Pathology, College of American Pathologists, Association for Molecular Pathology, and ASCO published a guideline on molecular biomarkers for colorectal cancer in 2017.[67] This guideline stated, "A problem of quantitative assays, such as gene expression, microRNA expression, and methylation levels, tested in solid tumors, results from the intrinsic mixed nature of the tissue with significant variability of tumor and non-tumor tissue content. Another limitation of molecular biomarker discovery approaches that rely on expression levels is that these biomarkers have not been evaluated in the context of complex molecular regulation of individual cancer subtypes."[67(p. 1482)] Center researchers rated these guidelines as having good methodological quality.

The fair-methodological-quality 2017 NCCN guidelines on colon cancer discussed multigene assays, including ColoPrint and Oncotype DX colon cancer assay, and concluded that there is no evidence of predictive value in terms of the potential benefit of chemotherapy for any of the multigene assays.[68] Similarly, the 2016 guidelines on metastatic colon cancer from ESMO concluded that gene expression signatures have failed to accurately predict disease recurrence and prognosis.[69] Center researchers rated the ESMO guidelines as having poor methodological quality.

Multiple Myeloma

The authors of the 2017 NCCN guidelines on multiple myeloma discussed gene expression profiling tests, including MyPRS and SKY92, but did not make any recommendations about the use of these tests.[70] The NCCN panel unanimously agreed that although gene expression profile tests are not routinely used, they could be helpful in selected patients to estimate the aggressiveness of the disease and to individualize treatment.[70] Center researchers rated the NCCN guidelines as having fair methodological quality. The authors of the 2017 guidelines on multiple myeloma from ESMO stated that gene-expression profiling is not currently used routinely, and more research is needed to identify molecular markers, which could lead to advances in this area.[71] Center researchers rated the ESMO guidelines as having fair methodological quality. No other clinical practice guidelines were found that included recommendations for the use of My Prognostic Risk Signature (MyPRS) or SKY92 tests.