Breast Cancer Screening for Women below the Age of 40 and Use of Magnetic Resonance Imaging in the NYS Cancer Services Program

March 2009

This document provides the criteria by which women under age 40 will be eligible for breast cancer screening and/or diagnostic evaluation in the Cancer Services Program (CSP). It also provides the CSP policy regarding use of Magnetic Resonance Imaging (MRI) for breast cancer screening.

As per previous communications, beginning April 1, 2009, women under age 40 will no longer be eligible for breast cancer screening through the CSP, with the exception of women in that age group who are at high risk for breast cancer or with clinically significant findings for breast cancer. The CSP criteria and implementation of evaluation of high risk is consistent with the National Cancer Institute that recommends that women who are at higher than average risk for breast cancer talk with a health care provider about whether to have breast cancer screening before the age of 40. The decision to screen for breast cancer should be based on an informed decision-making process between a woman and her clinician.

Evaluation

There are multiple factors that determine a woman's risk for breast cancer, including, but not limited to, a personal and/or family history of breast, ovarian and other cancers, the age at which the person(s) was diagnosed with the particular cancer, or a history of chest irradiation for treatment of lymphoma during adolescence or young adulthood. These individuals are considered to have an "undetermined" risk for breast cancer and should be referred to an appropriate health care provider for a full risk assessment which can include an evaluation of the lifetime risk of breast cancer using one of several clinically recognized risk assessment tools. Where appropriate (e.g. for women with strong family histories of breast, ovarian or other cancers), individuals can be referred for zero-based sliding fee scale genetic counseling for risk assessment (http://www.nyhealth.gov/diseases/cancer/genetics/genetic_counselors.htm). It is not the role of CSP partnership staff to provide clinical risk assessments.

Women younger than the age of 40 who meet CSP financial eligibility and present to a CSP partnership with a concern of being at high risk for breast cancer should undergo risk assessment by a NYS-licensed health care provider before being referred for breast cancer screening services. The CSP will reimburse for the appropriate breast cancer screening services (screening mammography and/or CBE) and any necessary CSP-reimbursable diagnostic services for individuals under the age of 40 when one or more of the following criteria are met and screening has been recommended and documented by a NYS-licensed health care provider on a *Provider Attestation of Client Eligibility for Women less than 40 years of Age* form:

High Risk for Breast Cancer Criteria

- A woman of any age is determined to have a 5-year risk of invasive breast cancer greater than or equal to 1.7%, or a woman age 35 or older with a lifetime risk greater than or equal to 20% (as determined by a clinically recognized risk assessment tool).^{2,3}
- A woman is determined to have a known genetic predisposition for breast cancer by genetic testing (e.g. *BRCA* 1 or 2 mutation)
- A woman has a personal history of breast cancer (and is not in active treatment)
- A woman has a personal history of receiving thoracic (chest) irradiation in her teens or 20s.

Please note that mammography may not always be indicated for women younger than age 35 who meet one or more of the high risk criteria on a risk assessment. Clinically accepted guidelines through the National Comprehensive Cancer Network (NCCN)⁴ should be utilized when determining whether breast cancer screening is necessary in younger women. These high risk criteria have been adapted from those identified by the NCCN.⁴ Providers are strongly encouraged to review these guidelines when determining risk for breast cancer.

Clinically Significant Findings Criteria

Women younger than the age of 40 presenting with a self-reported symptom concerning breast cancer should undergo an evaluation with a NYS-licensed health care provider. The CSP will not reimburse for CBE in 18-39 year old individuals with self-reported symptoms. The CSP will reimburse for diagnostic evaluation of one or more of the following clinically significant findings after such a finding has been evaluated by a NYS-licensed health care provider who determines whether diagnostic evaluation is necessary and that provider documents the request on a *Provider Attestation of Client Eligibility for Women less than 40 Years of Age* form (see below). The following clinically significant findings have been identified by the CDC's National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and the NCCN⁴:

- Discrete, dominant mass in breast
- Spontaneous nipple discharge without a discrete, dominant mass in breast
- Asymmetric thickening or nodularity
- Skin or nipple changes

The following diagnostic services, where appropriate, are reimbursable through the CSP: diagnostic ultrasound, breast fluid cytology, diagnostic mammography and/or referral for surgical consultation and biopsy if necessary.

Reimbursement of Magnetic Resonance Imaging (MRI) as an Adjunct Screening Tool in Women at High Risk for Breast Cancer (women of all ages)

The CSP acknowledges recent literature regarding the use of MRI as an adjunct screening tool in women at high risk for breast cancer. The level of evidence for these recommendations, however, is based on nonrandomized screening trials, observational studies and expert opinion. In 2005, the NBCCEDP released a white paper on technologies for the early detection of breast cancer. At that time it was recommended that MRI not be reimbursed as a screening examination for women of any age at either high or average risk for breast cancer. The rationale for this decision was based on concerns about program operations, accuracy, reproducibility and access. The NBCCEDP has not changed its position on this topic since that time.

Additionally, in 2007 a Hayes technology review looked at MRI for breast cancer screening in women at high risk. Although moderate evidence was found to suggest that MRI was more sensitive than mammography for the detection of breast cancers, there was a lack of randomized trials found comparing mammography screening programs with programs that combine mammography with MRI. Based on this evidence, or lack thereof, the relative impact of MRI on the breast cancer mortality of high risk women is currently unknown. Therefore, the CSP does not reimburse for the use of MRI as an adjunct screening tool in women at high risk for breast cancer.

References:

- National Cancer Institute (2006) Estimating Breast Cancer Risk: Questions and Answers. Accessed 12/23/08 at http://www.cancer.gov/cancertopics/factsheet/estimating-breast-cancer-risk
- 2. National Cancer Institute(NCI). Breast Cancer Risk Assessment Tool. http://www.cancer.gov/bcrisktool/

NCI CARE Model: BCRA Tool for African American Women (2007) http://dceg.cancer.gov/tools/riskassessment/care Wolfson Institute of Preventive Medicine. IBIS Breast Cancer Risk Evaluation Tool http://www.ems-trials.org/riskevaluator/

University of Texas Southwestern Medical Center (2009) http://www8.utsouthwestern.edu/utsw/cda/dept47829/files/65844.html

BayesMendel Laboratory. BRCAPro (2009) http://astor.som.jhmi.edu/BayesMendel/brcapro.html

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- Saslow D. et al (2007). Online Supplemental Material to American Cancer Society Guidelines for Breast Screening with MRI as an Adjunct to Mammography. CA: A Cancer Journal for Clinicians: 57(2). Accessed 1/27/09 at http://caonline.amcancersoc.org/cgi/data/57/2/75/DC1/1
- National Comprehensive Cancer Network, Inc. (2008) Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis. Accessed 12/14/08 at http://www.nccn.org/professionals/physician_gls/PDF/breast-screening.pdf
- 5. Saslow D. et al (2007). American Cancer Society Guidelines for Breast Screening with MRI as an Adjunct to Mammography. *CA: A Cancer Journal for Clinicians*: 57(2). Accessed 1/29/09 at http://caonline.amcancersoc.org/cgi/reprint/57/2/75
- Management Solutions for Health, Inc. (2005). NBCCEDP Breast Cancer Expert Panel: White Paper on Technologies for the Early Detection of Breast Cancer. Accessed 1/29/09 at http://www.hhs.state.ne.us/womenshealth/docs/BCEPWhitePaper.pdf
- Hayes (2007). Magnetic Resonance Imaging for Breast Cancer Screening in Women at High Risk. Hayes Directory. Available with access at www.hayesinc.com

Cancer Services Program Partnership **Provider Attestation of Client Eligibility for Women less than 40 Years of Age**

(Print name of provider and CSP designated site code) And
(Print name of CSP Partnership)
Print Client Name: CSP client #: Client Date of Birth:
High Risk for Breast Cancer
I have performed a clinically recognized risk assessment for the above named client and it is my clinical judgment that this client meets the criteria outlined in the New York State Department of Health Cancer Services Program (CSP) Operations Manual for breast cancer screening for high risk women less than 40 years of age.
OR
Clinically Significant Finding(s) for Breast Cancer
I have performed a clinical breast exam on the above named client and have determined that she meets the criteria outlined in the New York State Department of Health Cancer Services Program (CSP) Operations Manual for clinically significant finding(s) of breast cancer in women less than 40 years of age.
Provider Signature and Date