#### **WOMEN'S HEALTH**

## From Breast Cancer Screening to Diagnosis

# New Recommendations for Expanded Coverage and Patient Navigation

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Achieving effective population-wide breast cancer screening in the US remains elusive despite decades of research and multiple versions of clinical practice recommendations from well-intended guideline groups. 1,2 Mammography screening is only effective when subsequent steps in the clinical pathway are also completed. An abnormality or area of suspicion detected within the initial mammogram findings usually requires additional mammographic views, ultrasonography, or another imaging modality. A biopsy is required to establish the pathologic diagnosis and guide treatment decisions. Short-interval follow-up imaging may also be needed, regardless of whether a biopsy is performed. When breast cancer is diagnosed, the cancer type, pathologic stage, and tumor characteristics are used to determine prognosis and inform treatment decisions. Timely follow-up and initiation of cancer treatment, which may include various combinations of surgery, radiation, and chemotherapy, improve clinical outcomes, including survival.

For many patients, screening falls short of its potential. Although breast cancer screening is a standard of care in the US and is included in the prevention services no-cost coverage requirements of the Patient Protection and Affordable Care Act (PPACA), rates of breast cancer screening fail to meet benchmarks and follow-up varies significantly across socioeconomic and demographic groups. <sup>1,3</sup> In a systematic review of 17 studies among patients with abnormalities in the initial screening mammogram findings, lack of follow-up ranged from 7.2% to 33% for 3-month follow-up and from 27.3% to 71.6% for 6-month follow-up. <sup>3</sup> No-cost coverage in the US has typically included only the initial mammogram, and it is therefore unsurprising that inadequate follow-up is associated with lack of insurance, having a high-deductible plan, cost-sharing, and other barriers, such as inadequate health system communication and patient support. <sup>1,3</sup>

To improve breast cancer screening in clinical practice, more comprehensive guidelines are needed that include the entire clinical pathway from screening to diagnosis. This approach was taken by the Women's Preventive Services Initiative (WPSI) in its newest recommendations for breast cancer screening and patient navigation. WPSI, a national alliance of more than 20 health professional organizations and patient representatives that develops evidence-based clinical recommendations to fill gaps in women's preventive health care services in the US, is supported by the US Department of Health and Human Services and Health Resources & Services Administration (HRSA) and led by the American College of Obstetricians and Gynecologists. WPSI recommendations inform the coverage rules issued by HRSA in the implementation of the PPACA requirements regarding preventive services. Nonlegacied plans and issuers are required to cover HRSA-supported

Table. Recommendations for Breast Cancer Screening and Patient Navigation for Breast and Cervical Cancer Screening<sup>a</sup>

Recommendation	Eligibility	Prevention services included
Breast cancer screening	Women at average risk of breast cancer who are 40 years and older <sup>b</sup>	Annual or biennial mammography screening beginning no earlier than age 40 years and no later than age 50 years, and continuing through at least age 74 years; age alone should not be the basis for discontinuing screening
		Additional imaging (eg, magnetic resonance imaging, ultrasonography, mammography) and pathology evaluation when needed to complete the screening process or address findings on the initial screening mammography
Patient navigation services for breast and cervical cancer screening and follow-up	Patients eligible for breast or cervical cancer screening and needing assistance accessing screening and follow-up services	Individualized navigation services based on assessment of the patient's needs and involving person-to-person contact with the patient can include person-centered assessment and planning, health care access and health system navigation, referrals to appropriate support services (eg, language translation, transportation, social services), and patient education

<sup>&</sup>lt;sup>a</sup> Approved by the Health Resources & Services Administration, these services will be covered without co-pay or deductible charges for most women under the prevention services no-cost coverage requirements of the Patient Protection and Affordable Care Act beginning in 2026.

Women's Preventive Services guidelines without cost-sharing, and covered benefits apply to most group health plans and issuers of group and individual health insurance coverage and to patients qualifying for Medicaid.<sup>5</sup>

The updated WPSI breast cancer screening recommendation does not change screening eligibility but expands coverage to include follow-up services that may be required to complete the screening process. <sup>1,4,5</sup> The recommendation includes initiating annual or biennial mammography screening for women at average risk of breast cancer between ages 40 and 50 years and, if indicated, providing additional imaging and pathology evaluation to complete the screening process (Table). <sup>4,5</sup> Coverage of these services is intended to reduce financial barriers that limit follow-up care, similar

<sup>&</sup>lt;sup>b</sup>Women at increased risk (eg, previous breast cancer, ductal carcinoma in situ, pathogenic genetic variants) should also undergo periodic mammography screening; however, recommendations for specialized services are beyond the scope of this recommendation.

to coverage rules for colorectal cancer screening introduced in 2023. Although data describing outcomes have not yet been published, modeling studies indicate Medicare coverage of follow-up colonoscopy after positive stool-based screening results may increase overall colorectal cancer screening rates and improve clinical and economic outcomes.<sup>6</sup>

To support patients through the breast cancer screening clinical pathway, the WPSI also recommends patient navigation services for patients needing them. 4.5 This recommendation is supported by a systematic review of 42 randomized clinical trials of the effectiveness of patient navigation services for breast or cervical cancer screening and follow-up.<sup>7</sup> Patient navigation included individualized services, such as education, scheduling assistance, transportation, information about logistics, financial support, communication with a physician, referrals, and reminders. In a meta-analysis of trials comparing patient navigation with usual care or active controls, the predicted 1-year absolute breast cancer screening rate was 13.8% higher with patient navigation (53.1% vs 39.3% [28 trials]) and the follow-up rate was 17.6% higher (96.1% vs 78.5% [3 trials]). In the trials, rates were higher in a wide range of health care settings, including large health systems and localized clinics, for both general and select patient populations, and regardless of the specific services included as long as they addressed individual patient needs.

Implementation of expanded coverage of breast cancer screening and adding patient navigation services present several anticipated challenges. Breast imaging, biopsies, and follow-up are already established practices, but these services will require revisions in billing and payment procedures when they are covered as part

of the complete screening process. Although patient navigation services are often available for cancer treatment, they are generally not provided for cancer screening. Depending on existing services and structures in health systems, patient navigation can be adapted for delivery by different types of health care professionals in person or remotely. However, educational materials, clinical workflows, and billing and payment methods will need to be developed for screening navigation specifically. Once in place, patient navigation resources could be further utilized for other services outside the WPSI recommendation, such as colorectal cancer screening.

Despite a compelling evidence base supporting the new recommendations, many questions remain. These include identifying optimal approaches to patient navigation based on delivery, intensity, and type of navigator and best practices for implementation. Patient outcomes following expanded coverage and availability of patient navigation are unknown. Future research should examine key clinical outcomes, such as improvement in time to treatment and breast cancer morbidity and mortality. Additionally, the impact of shifting health policies and coverage decisions on implementation of the new recommendations in clinical practice is currently unclear.

More research will be needed to determine clinical and economic outcomes of the new breast cancer screening guidelines, and answers will take time. Nevertheless, coverage of services across the entire clinical pathway, from screening to diagnosis, and navigation services to support patients in this process provide an innovative, evidence-based approach to improving the effectiveness of screening.

### ARTICLE INFORMATION

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