

# CONTEMPORARY SURGERY

## ONCOTYPE DX® ASSAY FOR BREAST CANCER

Personalized, validated, superior to conventional criteria in predicting risk of recurrence

### A ROUNDTABLE DISCUSSION AMONG EXPERTS

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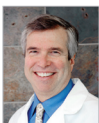
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#### IS THIS PATIENT A CANDIDATE FOR CHEMOTHERAPY?

A 55-year-old, postmenopausal patient presents with a 2.5-cm moderately differentiated tumor that is node-negative, estrogen receptor-positive, and progesterone receptor-positive. She is active, healthy, and exercises frequently. Her surgeon elects to submit a tumor tissue sample for the *Oncotype DX* assay, which returns a Recurrence Score® of 7, corresponding to a risk of distant recurrence of 6% (95% confidence interval, 3%-8%).<sup>1</sup> Assessing this patient using traditional clinical and pathological markers would suggest that her treatment plan should involve chemotherapy; however, the patient's individualized assay indicates she is unlikely to derive significant benefit from the addition of chemotherapy to hormone therapy alone.<sup>2</sup>

#### PREDICTING RISK OF CANCER RECURRENCE

**DR BEAR:** The *Oncotype DX* assay has closed a gap in our understanding of which breast cancer patients will benefit from chemotherapy—particularly those with node-negative, estrogen receptor-positive tumors. The test's Recurrence Score is a prognostic and predictive indicator based on a gene-expression profile that was validated in a population of node-negative, estrogen receptor-positive breast cancer patients. Under the old clinical guidelines, three-quarters of these patients would have received chemotherapy in addition to hormonal therapy (see "The *Oncotype DX* assay: Development and validation" on page S4). A woman with a

#### Disclosures

Dr Bear reports that he serves on the speakers bureaus for Genomic Health® and Genentech. Dr Hyams reports that he receives grant/research support from AstraZeneca and Ortho Biotech; he also serves as a consultant to Genomic Health and on the speakers bureaus of Genomic Health, Ortho Biotech, and AstraZeneca. Dr Laronga serves on the speakers bureau of Genomic Health. Dr Whitworth serves as a consultant to Genomic Health, Veridex, and Myriad; he also serves on the speakers bureaus of Genomic Health, Veridex, and Myriad.

This article summarizes a roundtable discussion that received financial support from Genomic Health. Both the participants and Genomic Health have modified the original transcript in order to ensure that the information provided is concise and factually correct.

However, the opinions put forth in this article are those of the participants and do not necessarily reflect the views of Genomic Health.

Recurrence Score® of less than 18 can usually be spared chemotherapy.<sup>2</sup>

**DR WHITWORTH:** The assay can identify between 30% and 50% of the patients who will derive no net benefit from chemotherapy. The Recurrence Score has greater power to predict outcomes than the criteria we've traditionally relied on.

**DR LARONGA:** The test personalizes treatment. Until now, out of every 100 women we've treated with chemotherapy, only 4 have benefited from it—and we haven't known beforehand which 4 it would be. The Oncotype DX Recurrence Score gives us the ability to address an individual patient and say, this is your tumor, this is your score.

**DR HYAMS:** I think perhaps even more importantly, the Oncotype DX assay is useful because it changes the paradigm that everyone gets a similar benefit from chemotherapy. Patients with a high Recurrence Score get an enormous benefit from cytotoxic agents, but patients with a low Recurrence Score are unlikely to see any further reduction in risk from the addition of chemotherapy to hormonal therapy despite the level of concern they may have.<sup>2</sup>

**DR BEAR:** The assay's result trumps the criteria we have normally referred to: tumor size, tumor grade, patient age, etc. We will find that

some small tumors are high risk and that some larger tumors in young patients may be low risk<sup>2</sup>—contrary to what we would have predicted. Frankly, before the Oncotype DX assay, conversations with patients about prognosis and our decisions about chemotherapy were not much better than educated guesses. The assay yields a 10-year risk of distant recurrence and, more importantly, a prediction of the likelihood of benefit from adding chemotherapy to hormonal therapy.<sup>2</sup>

**INTEGRATING THE ONCOTYPE DX ASSAY INTO CLINICAL PRACTICE**

**DR BEAR:** Optimal care of patients with cancer requires close collaboration among the multidisciplinary team members. Our Breast Health Center tumor board decides patient-by-patient who needs oncotyping. We discuss nearly every patient in a weekly conference, but that approach may not be practical for most readers.

Surgeons in community practices need to be involved in establishing guidelines for deciding which patients should have the assay, which should not, and which are borderline (see "Eligibility criteria," below left). In borderline cases, surgeons can discuss the case with the medical oncologist in advance of the patient visit. Logistically, there's no reason ground rules can't be established by the multidisciplinary team to determine who should have the assay following biopsy or definitive resection, or who might benefit from waiting until after consulting the medical oncologist. The surgeon should be able to make a determination as to when to order the assay. However, one of the advantages of this assay of gene expression is that, because the test can be performed on fixed paraffin-embedded tissue, it can be ordered at any time.

**Eligibility criteria**

Oncotype DX: Considerations for patient selection			
ER+, tamoxifen or AI	STAGE I	pT1, NO	Recommended by ASCO and NCCN Guidelines
		pT2-3, NO	
	STAGE II	pT1-3, N1 mi <sup>a</sup>	Recommended by NCCN Guidelines
		pT0-2, N1	
	STAGE III <sup>b</sup>	pT3, N1	Certain node-positive patients

Patient selection considerations are based on data from the suite of Oncotype DX studies, including: NSABP B-14, NSABP B-20, TransATAC, and SWOG 8814.  
 AI, aromatase inhibitor.  
<sup>a</sup> T1b moderate/poorly differentiated or unfavorable features/1c/2/3, N1 mi, MO; HER2-negative.  
<sup>b</sup> Consider patients from a subset of stage IIIa as indicated, not all stage III patients.

**DR LARONGA:** Yes, prior agreement with the oncology team is key. The test is not meant to decide if you'll refer a patient to the medical oncologist for a decision on chemotherapy. The surgeon can use this test to expedite the first visit with the medical oncologist, and to make that visit as efficient as possible. We adhere to the National Comprehensive Cancer Network (NCCN) guidelines,<sup>3,4</sup> which make it easier for us to decide for whom we should order the assay (see "What do clinical guidelines say about the *Oncotype DX*® assay?" on page S6).

**DR HYAMS:** Making decisions with the multidisciplinary team is optimal, but it's not always possible. When I first meet a new patient with breast cancer, I discuss treatment broadly, from surgery to systemic therapy to radiation therapy. I also discuss emerging tools we have to help make decisions. The first encounter with a patient is the perfect time to raise the question of a molecular diagnostic assay. That's when I do it.

**DR LARONGA:** One of the issues we're addressing is making sure the patient knows about the test and accepts it. If you're going to have a standing order in place, the surgeon needs to know that the patient understands not only that the test will be ordered, but what the assay is. The patient needs to know what the results will tell us about her personal risk of recurrence and the potential benefit of adding chemotherapy to hormonal therapy.

**DR WHITWORTH:** Why is that true for the *Oncotype DX* assay but not for tests of receptor status?

**DR LARONGA:** After we have ordered the test, patients have received calls from Genomic Health®. The patients don't understand what's happening, get nervous, and call us. If they know beforehand, it prevents confusion. Also, while there is extensive reimbursement for *Oncotype DX*, the relative expense of the assay justifies obtaining patient consent.

**DR WHITWORTH:** There's a lot of variation from practice to practice in how this works. We check a box on the benefits investigation section of the requisition form that says "no investigation required." Admittedly, that's

aggressive on our part, but justified by over 90% of US privately insured lives and Medicare patients meeting coverage criteria. In cases of doubt, the Genomic Access Program (GAP) will help patients maximize their reimbursement position, depending on their financial eligibility.

**DR LARONGA:** Another possibility to keep in mind is that the occasional patient will say that you don't need to order that test because she refuses to have chemotherapy, or just the opposite: She wants chemotherapy and is concerned that, if the test results show a low Recurrence Score®, she will not be offered chemotherapy (or that her insurance won't pay for the chemotherapy if her score is low).

**DR WHITWORTH:** That is a tricky situation. I've had patients who clearly state they don't want chemo. But then they change their minds when faced with a Recurrence Score of, say, 56. I've never had a reluctant patient who did not change her mind in this situation. The individual nature of the result seems to make the difference. The patient feels she is receiving a recommendation based on her unique condition, not on a general guideline.

As for recommended processes, the *Oncotype DX* assay can be ordered by agreement in a multidisciplinary conference after the pathologist presents the histology report, or in the community by the surgeon when the case meets guidelines agreed to beforehand by the medical oncologist on the team. Any other scenarios?

**DR BEAR:** Those are likely the 2 most useful procedures in the community. Unfortunately, what's happening now is that the patient sees the medical oncologist, who calls the surgeon, who asks the pathologist to submit the sample—and this is the least efficient process.

**DR WHITWORTH:** The multidisciplinary team should have a standing order for the assay and a prearranged way of opting out of it. It's helpful to have a box on the form that says, "Do not execute" the standing order.

**DR BEAR:** We might opt out of the standing order if a patient is clearly high risk—for example, she has a large HER2-positive tumor.

**DR HYAMS:** Yes, clearly patients with high-risk

## HIGH RISK FOR RELAPSE?

The patient is a 37-year-old woman with an intermediate-grade invasive ductal carcinoma measuring 7 mm. She is node-negative, ER-positive, PR-positive, and HER2-negative. Classical guidelines suggest she should not receive systemic adjuvant chemotherapy. However, patients with this profile sometimes do poorly with that recommendation. The assay ordered for this patient returned a high Recurrence Score, indicating significant risk for relapse and therefore implying a strong potential benefit from chemotherapy.

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# The Oncotype DX assay: Development and validation

The Oncotype DX assay was developed to quantify the risk of distant recurrence for tamoxifen-treated patients with node-negative (N-), estrogen receptor–positive (ER+) breast cancer, and to identify who would and would not benefit from adjuvant chemotherapy.

## DEVELOPMENT OF THE ONCOTYPE DX ASSAY INCLUDED:

- Optimization of methods for quantifying gene expression in fixed, paraffin-embedded tissue, and development of a high-throughput real-time reverse-transcription polymerase chain reaction assay.
- Incorporation of extensive controls and calibrations to ensure precision and reproducibility.
- Thorough review of the genomic databases, cancer literature, and molecular and cell biology experiments to identify 250 initial candidate genes.<sup>1-4</sup>

The resulting assay uses a 21-gene panel based on 3 independent breast cancer studies of the candidate genes. Two factors give the assay its ability to predict cancer recurrence and potential benefit from chemotherapy: the expression of each gene is highly quantifiable and variable among patients; and multiple genes selected are involved in pathways that are biologically important.

## CLINICAL VALIDATION OF THE ONCOTYPE DX ASSAY IN 13 STUDIES WITH OVER 4000 PATIENTS

The Oncotype DX assay has shown consistent results across multiple landmark clinical trials including:

- A large, independent, multicenter clinical trial, NSABP B-14<sup>5</sup>
- A large population-based case-control study in breast cancer patients at Northern California Kaiser Permanente<sup>6</sup>
- A large, independent, multicenter clinical trial, NSABP B-20<sup>7</sup>
- A large, independent, multicenter clinical trial, SWOG 8814<sup>8</sup>
- A large, independent, multicenter clinical trial, TransATAC<sup>9</sup>

The approach to assay development and independent validation for Oncotype DX was consistent with that outlined in a review article published in 2005 in the *Journal of Clinical Oncology* by Richard Simon, DSc, of the National Cancer Institute.<sup>10</sup>

## Trial results

In the NSABP B-14 trial, the rate of distant recurrence for the low-, intermediate-, and high-risk groups was 6.8%, 14.3%, and 30.5% respectively ( $P < .001$ , low risk vs high risk). In a multivariate analysis,

the 21-gene assay outperformed both age and tumor size as an independent prognostic factor.

In the Kaiser Permanente trial of 790 patients, 10-year risk for breast cancer death among the low-risk group was 2.8%.

A subsequent study of N-, ER+ patients randomized to receive tamoxifen alone or tamoxifen plus chemotherapy, NSABP B-20, showed no difference in outcomes in the low-risk group, suggesting that chemotherapy adds no benefit for this group.<sup>7</sup>

Lastly, consistent with previous studies in both pre- and postmenopausal patients with N- disease, the SWOG 8814 and TransATAC trials have demonstrated the predictive and prognostic value of the Oncotype DX test in postmenopausal node-positive (N+), hormone receptor–positive breast cancer patients.<sup>8,9</sup>

## SUMMARY

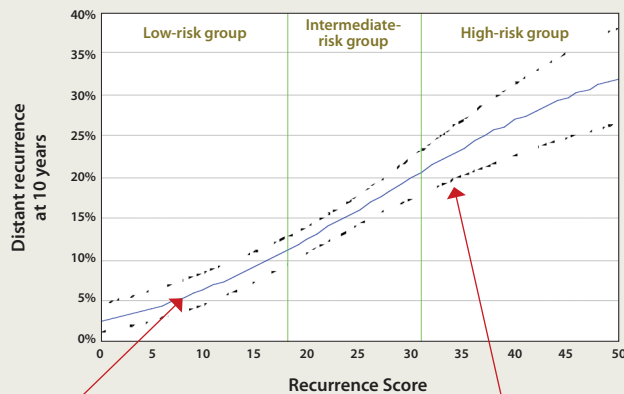
The Oncotype DX Recurrence Score® correlates with the following<sup>5-7,11</sup>:

- Distant recurrence rate at 10 years, assuming 5 years of tamoxifen treatment (the higher the Recurrence Score, the higher the distant recurrence rate)
- Hormone therapy benefit (patients with low or intermediate Recurrence Scores have greater impact from tamoxifen on 10-year distant recurrence-free survival, when given for 5 years)
- Chemotherapy benefit (in the high-risk group, the absolute benefit of chemotherapy is 28% vs no significant benefit in low- or intermediate-risk groups)

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## Standardized quantitative Oncotype DX assay: Recurrence Score in N-, ER+ patients



### Lower Recurrence Scores

- Lower likelihood of recurrence
- Greater magnitude of tamoxifen benefit
- Minimal, if any, chemotherapy benefit

### Higher Recurrence Scores

- Greater likelihood of recurrence
- Lower magnitude of tamoxifen benefit
- Clear chemotherapy benefit

For in-depth details on the trials and methods summarized here, visit [www.oncotypedx.com](http://www.oncotypedx.com).

disease—most commonly the HER2-positive group—will almost certainly receive cytotoxic therapy, and the test will be of little use for them. Other improbable candidates are those with tumor subtypes unlikely to metastasize, the infirm, and those who have made it absolutely clear that they will not accept cytotoxics. Given our responsibility to use resources judiciously, an individual's unique tumor status and general health must determine usage. Even accounting for this group of exceptions, most patients with node-negative, estrogen receptor-positive disease will be good candidates for this assay.

**DR LARONGA:** In private practice, the decision will also reflect the surgeon's relationship with the medical oncologist. If the patient is 45 years old and has a 1.5-cm tumor, I would order the test. My medical oncologist will add other tumor characteristics such as high grade into the mix and state that, even if the score returns as low risk, he would still recommend chemotherapy. Thus, why order the test?

**DR BEAR:** Yes, even despite the data showing that 20% of high-grade tumors get low scores on the assay.

**DR LARONGA:** With guidelines established collaboratively for the standing order, the surgeon can candidly ask the medical oncologist, "If the assay score is low, are you comfortable with my ordering endocrine therapy? Or do you want to see the patient?" I know surgeons who order endocrine therapy all the time because the nearest medical oncologist is 2 hours away. But collaboration, when possible, is the better course.

**DR BEAR:** Keep in mind that The American College of Surgeons Commission on Cancer has said that one quality indicator is ensuring that a patient with a hormone responsive tumor receives, or is at least offered, endocrine therapy within a certain time frame. Providing multidisciplinary care and making sure a patient receives all appropriate treatments after definitive surgery is a quality indicator, and this will increasingly come into play as more people are looking at what we do with every patient. I'm not sure if *Oncotype DX* testing will become a quality measure, but

collaborative interaction and appropriate adjuvant therapy will be an indicator.

**DR HYAMS:** Guidelines to date have been helpful in clearing a path toward use of this assay. However, there are additional applications for which the *Oncotype DX* may also be quite useful. None of us, for instance, has discussed node-positive disease. Although we lack clear guidelines on this matter, and reimbursement may not be as available as it is in the node-negative setting, several studies have confirmed the consistent ability of the Recurrence Score<sup>®</sup> to predict benefit from chemotherapy in both node-negative and node-positive patients. Regardless of our concerns about a node-positive patient's risk, tumors with low Recurrence Score results do not appear to respond to current cytotoxic drugs. Therefore, it is not unreasonable to look closely at node-positive patients in unique circumstances where the treatment decision is a great challenge. An example from my own practice might be a patient with a positive intramammary node, or a patient who is a suboptimal physiologic candidate for chemotherapy but has 1 or 2 positive nodes in the axilla. Use of the genomic assay in this setting can make the difference in deciding to support cytotoxic treatment—or to avoid it. Our concerns about disease risk shouldn't mandate the use of ineffective but toxic therapies. As a result, we need to work harder at finding better biologically effective therapies for high-risk patients with low Recurrence Scores.

### THE ASSAY EXPEDITES DISCUSSION AND SIMPLIFIES DECISIONS

**DR BEAR:** How surgeons decide to incorporate the assay into their practice will vary. Clearly, however, it allows us to send patients to a medical oncologist with information critical to deciding whether to prescribe chemotherapy. If a patient's Recurrence Score has not been determined, it's often less effective for the oncologist to meet with the patient, and it's a huge letdown for the patient, who still has no answers about therapy.

**DR WHITWORTH:** It's comparable to sending the

## ARE PATIENT FEARS JUSTIFIED?

A 60-year-old woman with a 3-cm tumor was advised to start chemotherapy and refused. She had lymphoma as a teenager, and the regimen of doxorubicin she received led to significant cardiomyopathy. Although she recovered, she was now extremely reluctant to consider chemotherapy. Her physician ordered the *Oncotype DX* assay, which, fortunately, yielded a single-digit Recurrence Score, thereby sparing her the trauma of undergoing chemotherapy again.

## What do clinical guidelines say about the Oncotype DX assay?

Both the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN) have included the Oncotype DX assay in their guidelines as an option to predict whether certain patients will benefit from chemotherapy.

### ASCO

The Oncotype DX assay is recommended for use in newly diagnosed ER+, N- breast cancer patients to predict risk of recurrence. The assay can also be used to identify patients who may be successfully treated with tamoxifen and may not require adjuvant chemotherapy. "It has been suggested that tamoxifen-treated patients with an excellent estimated prognosis may be spared adjuvant chemotherapy."

Harris L, Fritsche H, Mennel R, et al. American Society of Clinical Oncology 2007 update of recommendations for the use of tumor markers in breast cancer. *J Clin Oncol.* 2007;25:5287-5312.

### NCCN

Use of the multigene-based assay of tumor tissue (Oncotype DX, Genomic Health®) to help guide chemotherapy treatment decisions is limited to women with hormone receptor-positive, node-negative, HER2-negative tumors that are 0.6 to 1.0 cm and moderately/poorly differentiated or with unfavorable features or >1 cm.

NCCN guidelines recommend adjuvant endocrine therapy alone for women with a low Recurrence Score® (<18); adjuvant endocrine therapy with or without chemotherapy for women with an intermediate Recurrence Score (18-30); and adjuvant endocrine therapy plus adjuvant chemotherapy for women with a high Recurrence Score (>31).

NCCN guidelines for breast cancer are updated. *Oncology Report.* 2008. <http://www.nccn.org/professionals/meetings/13thannual/highlights/1324.html>. Accessed July 20, 2009.

patient to the oncologist without knowing the tumor's estrogen receptor status.

In my practice, knowing the assay result has dramatically focused and simplified my response to the patient's question, "Doctor, will I need chemo?" Before the Oncotype DX assay, we might have included several contingencies in our answer. Now we can tell a patient straightforwardly that we'll conduct a genomic analysis of her tumor, and with this information the medical oncologist will know whether she would benefit from chemotherapy. Conversations with patients are more comfortable and efficient.

**DR LARONGA:** Patients generally view the surgeon as the captain of the ship and will even call after having visited the medical oncologist to confirm the oncologist's opinion, perhaps asking, "Should I really be doing this?" It helps the surgeon to have results of the

assay; it makes that discussion with the patient more meaningful.

**DR HYAMS:** The surgeon who is serious about breast cancer care has to get involved in this process. The complexity of decision-making and the increasing complexity of surgical procedures performed by the primary breast surgeon means that more breast specialty care will be delivered by experts. How can a breast surgeon be considered an expert if she or he defers conversations about systemic therapy to other practitioners weeks down the line? As we move to more targeted oral therapies with better toxicity profiles, the surgical specialist will play a more important role in selecting straightforward oral therapies guided by appropriate diagnostic assays. While

this may sound radical, it is really no more radical than the way we use antibiotics in uncomplicated infectious disease settings today.

**DR BEAR:** Patients have sometimes asked me if they'll need chemotherapy after their biopsy, before they've even had definitive surgery. That's an even more circumspect conversation. I tell them, if nodes are negative we may need to perform a gene-expression analysis and other sophisticated investigations.<sup>2</sup> We need to be able to tell patients there is another factor in the decision-making process following definitive surgery. Lacking familiarity with the Oncotype DX assay, a surgeon will not be prepared to answer such questions.

**DR WHITWORTH:** For surgeons on the fence about ordering the assay, there is one thing they should know: The results will not lead to a longer discussion with the patient but, rather, will simplify that discussion as well as your final

decision with the oncologist. In our practice, once we got used to ordering the test, we started ordering it earlier, from the core biopsy, for selected estrogen receptor-positive patients who were clinically node negative, especially with a negative fine-needle aspiration of an ultrasound-visible axillary lymph node.

I order the test as soon as I learn intraoperatively that the frozen section report on the sentinel node is negative. I don't necessarily have results by the time I see the patient postoperatively, but we have them when the patient sees the medical oncologist.

**DR BEAR:** I usually wait until the permanent section results are back, which takes about 1 week. I'm trying to get patients enrolled in the TAILORx trial,<sup>5</sup> so I have to know their node status.

### TIME-SAVING ASPECTS OF THE ONCOTYPE DX® ASSAY

**DR LARONGA:** Ordering the test is easy. You can do it online.<sup>6</sup> Your staff can easily fill out the single-page form.

**DR BEAR:** The speed at which the report returns is just as impressive. You can then forward it to the medical oncologist and nurse navigator.

**DR WHITWORTH:** The staff is critically important in private practices. Initial ordering by the clerical staff can take 10 to 15 minutes. But my assistant tells me that after a few submissions, 5 minutes is the norm.

**DR BEAR:** Pathologists also have to understand their role as part of the team and be willing to send specimens.

**DR HYAMS:** From insurance approval to shipping to return of results by e-mail, Genomic Health® has created an easy ordering process for the Oncotype DX assay.

### WHAT THE ASSAY IS NOT MEANT TO DETERMINE

**DR LARONGA:** Some surgeons in the community have ordered the assay on a core sample and, on seeing a low Recurrence Score<sup>®</sup>, have told the patient she won't need to undergo a sentinel node biopsy. This test is not meant to help decide on

surgical choices at this point. It's meant to help decide what happens with adjuvant therapy.<sup>7</sup> You can use the core biopsy as the sample you send for the test, but the result has no bearing on what surgical procedure to perform.

**DR BEAR:** Correct, the assay does not alter surgical staging or surgical management of patients at this time.

Moreover, a low Recurrence Score does not mean a patient should forego endocrine therapy. In fact, it is the patient with a low Recurrence Score who will benefit most from endocrine therapy.<sup>1</sup>

**DR HYAMS:** It's important to stress that the assay was validated and the score calculated with patients receiving tamoxifen. The risk percentage is thus based on patients receiving endocrine therapy. The TransATAC data further validate the prognostic role of Oncotype DX, even when using more modern treatments, such as aromatase inhibitors.<sup>8</sup>

**DR WHITWORTH:** A promising development is the use of Oncotype DX to determine whether adjuvant endocrine therapy would be sufficient for some women with a node-positive tumor. But this has yet to be validated. Of note is that the TransATAC data presented at San Antonio in 2008 showed that the assay reliably predicted distant recurrence in postmenopausal women who had received treatment with an aromatase inhibitor or tamoxifen for either node-negative or node-positive cancer.<sup>8</sup>

### REIMBURSEMENT

**DR WHITWORTH:** Only rarely have we seen an insurance company refuse to cover the assay, usually because it was ordered in a node-positive patient where reimbursement might be restricted. Carriers are starting to respect the individual physician's recommendation more in this situation. Medicare patients with 1 to 3 positive nodes are now covered, but it is probably best to check the Medicare coverage criteria.<sup>9</sup>

**DR HYAMS:** While the issue of reimbursement for node-positive patients is evolving, it's important to do what's best for patients first. We faced a similar issue when Oncotype DX was initially released to the market. So I still make

ONCOTYPE DX® ASSAY FOR BREAST CANCER

every effort to work for reimbursement from insurers, and to appeal any denial decisions when it is appropriate and when it can make a critical difference.<sup>10</sup>

**DR LARONGA:** The Genomic Access Program (GAP) sponsored by the company is very effective in helping patients and providers secure coverage, obtain prior authorization if needed, and assist in the appeal of denials. It also has a Financial Assistance Program (FAP) for patients who are uninsured or underinsured, with income thresholds determining eligibility.

**SUMMARY: CONSIDERATIONS IN ORDERING THE ONCOTYPE DX ASSAY**

- The surgeon is often the first provider to

discuss a breast cancer diagnosis and treatment plan with a patient.

- Although the surgeon may not determine the type of adjuvant therapy for a given case, patients often regard the surgeon as the “go to” person for information.
- Agreeing with your multidisciplinary team on guidelines for ordering the assay can simplify and expedite use of *Oncotype DX*.
- Informing patients about the assay enables best outcomes and reduces patient anxiety.
- Ordering the *Oncotype DX* assay early on means that results (which are usually received within 2 weeks) could be available at the patient’s first consultation with the medical oncologist.

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