

# Consider Genetic Testing for Hereditary Cancers

BY MARY ELLEN SCHNEIDER  
Senior Writer

WASHINGTON — Clinical genetic testing for the *BRCA1* and *BRCA2* genes allows physicians to more precisely identify who is at high risk for certain cancers, Dr. Karen H. Lu said at the annual meeting of the American College of Obstetricians and Gynecologists.

Armed with this knowledge, physicians can recommend risk-reducing strategies

including prophylactic surgery, said Dr. Lu, associate professor of gynecologic oncology and co-clinical medical director of the Clinical Cancer Genetics program at the MD Anderson Cancer Center in Houston.

For example, performing a bilateral salpingo-oophorectomy in someone who is a *BRCA* mutation carrier decreases their risk for ovarian cancer by 85%-95%, she said.

“In someone who is at such high risk for

developing a disease for which we have no current effective screening, performing this surgery effectively saves their lives,” Dr. Lu said.

In terms of breast cancer management, a 35-year-old woman with breast cancer and a strong family history might otherwise be advised to undergo a lumpectomy, radiation, and chemotherapy.

However, if she knew she carried either a *BRCA1* or *BRCA2* mutation, she might choose to undergo a bilateral mastectomy

with reconstruction upfront to decrease her risk of developing a second cancer, Dr. Lu said.

Physicians can identify women who may be good candidates for genetic testing by asking a few targeted questions during the annual visit, Dr. Lu said.

The hallmarks of hereditary cancers are generally a younger age of onset, more than one cancer in a single family member, and multiple individuals in a family who have developed cancer, she said.

Consider asking these three questions:

► Do you have multiple members of your family who have had breast, ovarian, colon, or uterine cancer?

► Is there anyone in your family who has had both breast and ovarian cancer?

► Is there anyone in your family who has had these cancers under the age of 50?

Keep in mind that these cancers can be inherited through both maternal and paternal relatives, so ask about cancer on the father's side as well, Dr. Lu said.

Also consider ethnicity, she said. The prevalence of *BRCA* genes in the general population is about 1 per 500, or 0.2%.

**The Ashkenazi Jewish population has three founder mutations that put them at about a 10-fold increased risk; instead of a 0.2% risk, there is a 2%-3% frequency.**

However, some populations have “founder” mutations in the *BRCA1* and *BRCA2* genes that increase their risk. For example, the Ashkenazi Jewish population has three founder mutations that put them at about a 10-fold increased risk for having a *BRCA1* or *BRCA2* gene mutation. So instead of a 0.2% risk of having the mutation, there is a 2%-3% frequency of the mutation among this population.

Overall, about 5%-10% of all cancers are hereditary. For breast cancer, that translates into about 10,000 to 20,000 cases a year in the United States and about 2,000 cases each year of ovarian cancer.

The frequency of *BRCA1* or *BRCA2* carriers in the United States is about 1 in 500 in the general U.S. population. “Individuals who carry these mutations have staggering risks of cancer,” Dr. Lu said.

The *BRCA1* mutation carries a lifetime risk of 50% to 85% for breast cancer and a 40% to 60% risk of developing a second breast cancer. And there is a 20%-50% lifetime risk for ovarian cancer with the *BRCA1* gene. This is significantly higher than the lifetime risk in the general population of about 11% for breast cancer and 1.7% for ovarian cancer.

In addition, the *BRCA2* gene carries a lifetime risk of 50%-85% for breast cancer and a 10%-25% risk for ovarian cancer.

Genetic testing can be useful both for cancer patients who want to find out if they face an increased risk of a second cancer and for women unaffected by cancer but with a strong family history.

Continued on following page

**Aldara**<sup>®</sup>  
(5-FLUOROURACIL)

**ALDARA**<sup>®</sup>

[al dar' a]

(imiquimod)

Cream, 5%

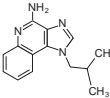
For Dermatologic Use Only

Not for Ophthalmic Use

#### DESCRIPTION

Aldara<sup>®</sup> is the brand name for imiquimod which is an immune response modifier. Each gram of the 5% cream contains 50 mg of imiquimod in an off-white oil-in-water vanishing cream base consisting of isotretinoin acid, cetyl alcohol, stearyl alcohol, white petrolatum, polysorbate 60, sorbitan monoesterate, glycerin, xanthan gum, purified water, benzyl alcohol, methylparaben, and propylparaben.

Chemically, imiquimod is 1-(2-methylpropyl)-1H-imidazo[4,5-c]quinolin-4-amine. Imiquimod has a molecular formula of C<sub>14</sub>H<sub>16</sub>N<sub>4</sub> and a molecular weight of 240.3. Its structural formula is:



#### CLINICAL PHARMACOLOGY

##### Pharmacodynamics

##### External Genital Warts

Imiquimod has no direct antiviral activity in cell culture. A study in 22 patients with genital/perianal warts comparing Aldara Cream and vehicle shows that Aldara Cream induces mRNA encoding cytokines including interferon- $\alpha$  at the treatment site. In addition HPV18 mRNA and HPV DNA are significantly decreased following treatment. However, the clinical relevance of these findings is unknown.

##### INDICATIONS AND USAGE

Aldara Cream is indicated for the treatment of external genital and perianal warts (*condyloma acuminata*) in individuals 12 years old and above.

##### CONTRAINDICATIONS

This drug is contraindicated in individuals with a history of sensitivity reactions to any of its components. It should be discontinued if hypersensitivity to any of its ingredients is noted.

##### WARNINGS

Aldara Cream has not been evaluated for the treatment of urethral, intra-vaginal, cervical, rectal, or intra-anal human papilloma virus disease and is not recommended for these conditions.

##### PRECAUTIONS

##### General

The safety and efficacy of Aldara Cream in immunosuppressed patients have not been established.

Aldara Cream administration is not recommended until the skin is completely healed from any previous drug or surgical treatment.

Aldara Cream has the potential to exacerbate inflammatory conditions of the skin, including chronic graft versus host disease.

Aldara Cream should be used with caution in patients with pre-existing autoimmune conditions.

Intense local inflammatory reactions including skin weeping or erosion can occur after only a few applications of Aldara Cream. Local inflammatory reactions may be accompanied, or even preceded, by flu-like systemic signs and symptoms including malaise, fever, nausea, myalgias, and rigors. An interruption of dosing should be considered.

Exposure to sunlight (including sunlamps) should be avoided or minimized during use of Aldara Cream because of concern for heightened sunburn susceptibility. Patients should be warned to use protective clothing that when using Aldara Cream. Patients with sunburn should be advised not to use Aldara Cream until fully recovered. Patients who may have considerable sun exposure, e.g., due to their occupation, and those patients with inherent sensitivity to sunlight should exercise caution when using Aldara Cream. Phototoxicity has not been adequately assessed for Aldara Cream. The enhancement of ultraviolet carcinogenicity is not necessarily dependent on phototoxic mechanisms. Despite the absence of localized hypopigmentation and hyperpigmentation following Aldara Cream use. Follow-up information suggests that these skin color changes may be permanent in some patients.

##### General Information

Patients using Aldara Cream should receive the following information and instructions:

1. This medication is to be used as directed by a physician. It is for external use only. Eye contact should be avoided.

2. The treatment area should not be bandaged or otherwise covered or wrapped as to be occlusive.

3. Some reports have been received of localized hypopigmentation and hyperpigmentation following Aldara Cream use. Follow-up information suggests that these skin color changes may be permanent in some patients.

##### Patients Being Treated for External Genital Warts

- It is recommended that the treatment area be washed with mild soap and water 6-10 hours following Aldara Cream application.
- It is common for patients to experience local skin reactions such as erythema, erosion, excoriation/flaking, and edema at the site of application or surrounding areas. Most skin reactions are mild to moderate. Severe skin reactions can occur and should be promptly reported to the prescribing physician. Should severe local skin reaction occur, the cream should be removed by washing the treatment area with mild soap and water. Treatment with Aldara Cream can be resumed after the skin reaction has subsided.
- Sexual (genital, anal, oral) contact should be avoided while the cream is on the skin.
- Application of Aldara Cream in the vagina is considered internal and should be avoided. Female patients should take special care if applying the cream at the opening of the vagina because local skin reactions on the delicate moist surfaces can result in pain or swelling, and may cause difficulty in passing urine.
- Uncircumcised males treating warts under the foreskin should retract the foreskin and clean the area daily.
- Patients should be aware that new warts may develop during therapy, as Aldara Cream is not a cure.
- The effect of Aldara Cream on the transmission of genital/perianal warts is unknown.
- Aldara Cream may weaken condoms and vaginal diaphragms, therefore concurrent use is not recommended.

##### Carcinogenesis, Mutagenesis, and Impairment of Fertility

Note: The Maximum Recommended Human Dose (MRHD) was set at 2 packets per treatment of Aldara Cream (25 mg imiquimod) for the animal multiple of human exposure ratios presented in this label. If higher doses than 2 packets of Aldara Cream are used clinically, then the animal multiple of human exposure would be reduced for that dose. A non-proportional increase in systemic exposure with increased dose of Aldara Cream was noted in the clinical pharmacokinetics study conducted in actinic keratosis subjects (see *Pharmacokinetics*). The AUC after topical application of 6 packets of Aldara Cream was 8 fold greater than the AUC after topical application of 2 packets of Aldara Cream in actinic keratosis subjects. Therefore, if a dose of 6 packets per treatment of Aldara Cream was topically administered to an individual, then the animal multiple of human exposure would be either 1/3 of the value provided in the label (based on body surface area comparisons) or 1/8 of the value provided in the label (based on AUC comparisons). The animal multiples of human exposure calculations were based on weekly dose comparisons for the carcinogenicity studies described in this label. The animal multiples of human exposure calculations were based on daily dose comparisons for the reproductive toxicology studies described in this label.

In an oral (gavage) rat carcinogenicity study, imiquimod was administered to Wistar rats on a 2X/week (up to 6 mg/kg/day) or daily (3 mg/kg/day) dosing schedule for 24 months. No treatment related tumors were noted in the oral rat carcinogenicity study up to the highest doses tested in this study of 6 mg/kg administered 2X/week in female rats (87X MRHD based on weekly AUC comparisons), 4 mg/kg administered 2X/week in male rats (75X MRHD based on weekly AUC comparisons) or 3 mg/kg administered 2X/week to male and female rats (153X MRHD based on weekly AUC comparisons).

In a dermal mouse carcinogenicity study, imiquimod cream (up to 5 mg/kg/application imiquimod or 0.3% imiquimod cream) was applied to the backs of mice 3X/week for 24 months. A statistically significant increase in the incidence of liver adenomas and carcinomas was noted in high dose male mice compared to control male mice (251X MRHD based on weekly AUC comparisons). An increased number of skin papillomas was observed in vehicle cream control group animals at the treated site only. The quantitative composition of the vehicle cream used in the dermal mouse carcinogenicity study is the same as the vehicle cream used for Aldara Cream, minus the active moiety (imiquimod).

In a 52-week dermal phototoxicity study, the median time to onset of skin tumor formation was decreased in hairless mice following chronic topical dosing (3X/week; 40 weeks of treatment followed by 12 weeks of observation) with concurrent exposure to UV radiation (5 days per week) with the Aldara Cream vehicle alone. No additional effect on tumor development beyond the vehicle effect was noted with the addition of the active ingredient, imiquimod, to the vehicle cream.

Imiquimod revealed no evidence of mutagenic or clastogenic potential based on the results of five *in vitro* genotoxicity tests (Ames assay, mouse lymphoma L5178Y assay, Chinese hamster ovary cell chromosome aberration assay, human lymphocyte chromosome aberration assay and SHE cell transformation assay) and three *in vivo* genotoxicity tests (rat and hamster bone marrow cytogenetics assay and a mouse dominant lethal test).

Daily oral administration of imiquimod to rats, throughout mating, gestation, parturition and lactation, demonstrated no effects on growth, fertility or reproduction, at doses up to 87X MRHD based on AUC comparisons.

##### Pregnancy

##### Pregnancy Category C:

Systemic embryofetal development studies were conducted in rats and rabbits. Oral doses of 1, 5 and 20 mg/kg/day imiquimod were administered during the period of organogenesis (gestational days 6 - 15) to pregnant female rats. In the presence of maternal toxicity, fetal effects noted at 20 mg/kg/day (577X MRHD based on AUC comparisons) included increased resorptions, decreased fetal body weights, delays in skeletal ossification, bent limb bones, and two fetuses in one litter (2 of 1567 fetuses) demonstrated exencephaly protruding tongues and low-set ears. No treatment related effects on embryofetal toxicity or teratogenicity were noted at 5 mg/kg/day (98X MRHD based on AUC comparisons).

Intravenous doses of 0.5, 1 and 2 mg/kg/day imiquimod were administered during the period of organogenesis (gestational days 6 - 18) to pregnant female rabbits. No treatment related effects on embryofetal toxicity or teratogenicity were noted at 2 mg/kg/day (1.5X MRHD based on BSA comparisons), the highest dose evaluated in this study, or 1 mg/kg/day (407X MRHD based on AUC comparisons).

A combined fertility and peri- and post-natal development study was conducted in rats. Oral doses of 1, 1.5, 3 and 6 mg/kg/day imiquimod were administered to male rats from 70 days prior to mating through the mating period and to female rats from 14 days prior to mating through parturition and lactation. No effects on growth, fertility, reproduction or post-natal development were noted at doses up to 6 mg/kg/day (87X MRHD based on AUC comparisons), the highest dose evaluated in this study. In the absence of maternal toxicity, bent limb bones were noted in the F1 fetuses at a dose of 6 mg/kg/day (87X MRHD based on AUC comparisons). This fetal effect was also noted in the oral rat embryofetal development study conducted with imiquimod. No treatment related effects on teratogenicity were noted at 3 mg/kg/day (41X MRHD based on AUC comparisons).

There are no adequate and well-controlled studies in pregnant women. Aldara Cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

##### Nursing Mothers

It is not known whether topically applied imiquimod is excreted in breast milk.

##### Pediatric Use

Safety and efficacy in patients with external genital/perianal warts below the age of 12 years have not been established.

##### ADVERSE REACTIONS

Healthcare providers and patients may contact 3M or FDA's Medwatch to report adverse reactions by calling 1-800-814-1795 or 1-800-FDA-1088, or on the internet at <http://www.fda.gov/medwatch>.

Dermal safety studies involving induction and challenge phases produced no evidence that Aldara Cream causes photoallergic or contact sensitization in healthy skin; however, cumulative irritancy testing revealed the potential for Aldara Cream to cause irritation, and in the clinical studies application site reactions were reported in a significant percentage of study patients. Phototoxicity testing was incomplete as wavelengths in the UVB range were not included and Aldara Cream has peak absorption in the UVB range (320 nm) of the light spectrum.

##### External Genital Warts

In controlled clinical trials for genital warts, the most frequently reported adverse reactions were local skin and application site reactions.

These reactions were usually mild to moderate in intensity; however, severe reactions were reported with 3X/week application. These reactions were more frequent and more intense with daily application than with 3X/week application. Some patients also reported systemic reactions. Overall, in the 3X/week application clinical studies, 1.2% (4/327) of the patients discontinued due to local skin/application site reactions. The incidence and severity of local skin reactions during controlled clinical trials are shown in the following table.

Wart Site Reaction as Assessed by Investigator (Percentage of Patients)

	3X/Week Application							
	Mild/Moderate/Severe				Severe			
	Females		Males		Females		Males	
	Aldara Cream	Vehicle	Aldara Cream	Vehicle	Aldara Cream	Vehicle	Aldara Cream	Vehicle
	n=114	n=99	n=156	n=157	n=114	n=99	n=156	n=157
Erythema	74 (65%)	21 (21%)	90 (58%)	34 (22%)	4 (4%)	0 (0%)	6 (4%)	0 (0%)
Erosion	35 (31%)	8 (8%)	47 (30%)	10 (6%)	1 (1%)	0 (0%)	2 (1%)	0 (0%)
Excoriation/Flaking	21 (18%)	8 (8%)	40 (26%)	12 (8%)	0 (0%)	0 (0%)	1 (1%)	0 (0%)
Edema	20 (18%)	5 (5%)	19 (12%)	1 (1%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)
Induration	6 (5%)	2 (2%)	11 (7%)	3 (2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Ulceration	9 (8%)	1 (1%)	7 (4%)	1 (1%)	3 (3%)	0 (0%)	0 (0%)	0 (0%)
Scabbing	4 (4%)	0 (0%)	20 (13%)	4 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Vesicles	3 (3%)	0 (0%)	3 (2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Remote site skin reactions were also reported in female and male patients treated 3X/week with Aldara Cream. The severe remote site skin reactions reported for females were erythema (3%), ulceration (2%), and edema (1%), and for males, erosion (2%), and erythema, edema, induration, and excoriation/flaking (each 1%).

Adverse events judged to be probably or possibly related to Aldara Cream reported by more than 5% of patients are listed below; also included are soreness, influenza-like symptoms and myalgia.

	3X/Week Application			
	Females		Males	
	Aldara Cream	Vehicle	Aldara Cream	Vehicle
	n=117	n=103	n=156	n=158
<b>Application Site Disorders:</b>				
<b>Application Site Reactions:</b>				
Wart Site:				
Itching	33%	29%	22%	10%
Burning	26%	12%	9%	5%
Pain	8%	2%	2%	1%
Soreness	3%	0%	0%	1%
Foreign Inclusions*	11%	3%	2%	1%
<b>Systemic Reactions:</b>				
Headache	4%	3%	5%	2%
Influenza-like symptoms	3%	2%	1%	0%
Myalgia	1%	0%	1%	1%
*Incidence reported without regard to causality with Aldara Cream.				

Adverse events judged to be possibly or probably related to Aldara Cream and reported by more than 1% of patients included: **Application Site Disorders:** Wart Site Reactions (burning, hypopigmentation, irritation, itching, pain, rash, sensitivity, soreness, stinging, tenderness); **Remote Site Reactions** (bleeding, burning, itching, pain, tenderness, tinea cruris); **Body as a Whole:** fatigue, fever, influenza-like symptoms; **Central and Peripheral Nervous System Disorders:** headache; **Gastro-Intestinal System Disorders:** diarrhea; **Musculo-Skeletal System Disorders:** myalgia.

##### POSTMARKETING ADVERSE EVENTS

The following adverse reactions have been identified during post-approval use of Aldara Cream. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

**Body as a Whole:** angioedema. **Cardiovascular:** capillary leak syndrome, cardiac failure, cardiomyopathy, pulmonary edema, arrhythmias (tachycardia, atrial fibrillation, palpitations), chest pain, ischemia, myocardial infarction, syncope. **Endocrine:** thyroiditis. **Hematological:** decreases in red cell, white cell and platelet counts. **Hepatic:** abnormal liver function. **Neuropsychiatric:** agitation, cerebrovascular accident, convulsions, depression, insomnia, multiple sclerosis aggravation, paresis, suicide. **Respiratory:** dyspnea. **Urinary System Disorders:** proteinuria. **Skin and Appendages:** colitiform dermatitis.

##### OVERDOSAGE

Persistent topical overdosing of Aldara Cream could result in an increased incidence of severe local skin reactions and may increase the risk for systemic reactions. The most clinically serious adverse event reported following multiple oral imiquimod doses of >200 mg (equivalent to imiquimod content of >16 packets) was hypotension, which resolved following oral or intravenous fluid administration.

##### DOSE AND ADMINISTRATION

##### External Genital Warts

Aldara Cream is to be applied 3 times per week, prior to normal sleeping hours, and left on the skin for 6-10 hours. Patients should be instructed to apply Aldara Cream to external genital/perianal warts. A thin layer is applied to the wart area and rubbed in until the cream is no longer visible. The application site is not to be occluded. Following the treatment period cream should be removed by washing the treated area with mild soap and water. Examples of 3 times per week application schedules are: Monday, Wednesday, Friday; or Tuesday, Thursday, Saturday application prior to sleeping hours. Aldara Cream treatment should continue until there is total clearance of the genital/perianal warts or for a maximum of 16 weeks. Local skin reactions (erythema) at the treatment site are common. A rest period of several days may be taken if required by the patient's discomfort or severity of the local skin reaction. Treatment may resume once the reaction subsides. Non-occlusive dressings such as cotton gauze or cotton underwear may be used in the management of skin reactions. The technique for proper dose administration should be demonstrated by the prescriber to maximize the benefit of Aldara Cream therapy. Handwashing before and after cream application is recommended. Aldara Cream is packaged in single-use packets which contain sufficient cream to cover a wart area of up to 20 cm<sup>2</sup>; use of excessive amounts of cream should be avoided.

##### Keep out of reach of children.

##### Rx only

##### Distributed by:

3M Pharmaceuticals  
Northridge, CA 91324  
July 2004 66280

##### © 3M Pharmaceuticals 2005.

Printed in U.S.A.

AL-9605K

4/05

**3M**

3M Pharmaceuticals  
275-3W-01 3M Center  
St. Paul, MN 55144-1000



# Adding MRI Sensible in BRCA Carriers Age 35-54

BY MARY ANN MOON  
Contributing Writer

For women who carry the *BRCA1* or *BRCA2* genetic mutations, adding MRI screening to mammography screening for breast cancer can be cost effective even though MRI is so expensive, according to Sylvia K. Plevritis, Ph.D., of Stanford (Calif.) University and her associates.

Breast MRI screening is "at least 10 times more expensive than mammographic screening."

It also produces more false-positive results, which generate further costs for unneeded diagnostic workups.

"Because cost may be the greatest barrier to broader evaluation and dissemination of breast MRI screening, its cost-effectiveness is a critical consideration," the investigators noted.

Currently there are no randomized clinical trials examining the cost-effectiveness of MRI screening for women at high risk of breast cancer.

And even if such a trial were initiated today, "mortality outcomes would not be available for at least 15 years," Dr. Plevritis and her associates noted (*J. Am. Med. Assoc.* 2006;295:2374-84).

They estimated the cost-effectiveness of adding breast MRI screening to mammographic screening in women carrying *BRCA1* and *BRCA2* mutations using a computer simulation model that incorporated health benefits as well as expenses.

The model projected the long-term effects on clinical and economic outcomes of no breast cancer screening, annual mammography alone for women aged

25-69 years, and annual mammography plus MRI for specific age groups.

The model used a simulated cohort of women carrying the *BRCA* mutations who were aged 25 in 2005.

MRI screening was found to reduce breast cancer mortality by 23% over that obtained by mammography alone in women carrying either the *BRCA1* or *BRCA2* mutations.

For women with the *BRCA1* mutation, "adding MRI increases the sensitivity of

annual screening from 35% to 85%, the proportion of axillary lymph-node-negative cancers from 57% to 81%, the mean lead time from approximately 1.5 to 3 years, and the false-positive rate from approximately 5% to 25%." Outcomes for women with the *BRCA2* mutation were similar.

"With MRI, life expectancy increases from 71.2 to 73.3 years for *BRCA1* mutation carriers and from 78.2 to 79.6 years for *BRCA2* mutation carriers," Dr. Plevritis

and her associates wrote in their article.

Adding MRI to mammography was found to be cost effective for women aged 35-54 years.

It was not cost effective for the younger women in the simulation model (those aged 25-34 years) because of their lower incidence of the disease, and added MRI was not cost effective for the older women (those aged 55 and older) because of the competing risk of death from other causes. ■



## Make Her Beauty Your Business Too.

### Your Patients Are Asking for More.

Good health is not the only thing your patients are asking for these days. They also want to look as beautiful as they feel. As the physician your patients trust, let them look to you for the beauty of laser and light-based elective aesthetic procedures.

### Follow the Light to Patient Satisfaction.

For most of your patients, looking good means getting rid of wrinkles, redness, age spots, leg veins, unwanted hair or acne. You can safely and effectively treat all of these conditions with the clinically proven laser and light-based technologies from LASERSCOPE®-Aesthetics.



### Gemini® Dual Wavelength Laser

Perform 93% of all aesthetic laser procedures.

What's more, we'll shine the light on your opportunity with our innovative **Success Modules™**, an integrated series of customized, practice-building solutions, available exclusively from LASERSCOPE-Aesthetics.

### We Make Your Success a Beautiful Thing.

Your patients are looking, so make it your business to aim the spotlight on their satisfaction. Combine your trusted care with the latest in aesthetic laser and light-based technologies and value-added services from LASERSCOPE-Aesthetics. Contact us today for your **FREE Personalized Preliminary Market Assessment** or to find out about a complimentary LASERSCOPE-Aesthetics Workshop in your area.

Call or click for more information:

• 800.356.7600

• [www.laserscope.com/aesthetic](http://www.laserscope.com/aesthetic)

**LASERSCOPE®**  
Aesthetics  
Solutions Brought to Light™

Continued from previous page

The ideal person to test in a family is someone who has had ovarian or breast cancer, Dr. Lu said. In the case of a patient unaffected by cancer with a strong family history, advise them to be tested with someone in their family who has had cancer. The person who has had cancer must be tested first.

Pretest counseling is critical, Dr. Lu commented. Patients need to be aware of the range of possible results and the limitations of the test. They may also have questions about genetic discrimination, she said.

The test itself is a simple blood test and does not require fasting. It generally costs about \$3,000 to do a full analysis with complete sequencing of both the *BRCA1* and *BRCA2* genes. The cost of predictive tests on a previously identified familial mutation is about \$200-\$400.

Insurance companies have generally been covering these tests. An analysis of MD Anderson data in 2004 showed that 87% of insurance preauthorization requests for genetic testing were covered. Of those covered, about 90% were covered at 80% or more.

"The bottom line is that insurance companies are paying for this test," Dr. Lu said. "The access to this genetic testing is much wider now than it was in the past." ■