



5068 West Plano Parkway Suite 122
Plano, Texas 75093
Phone: (972) 931-5100
Fax: (888) UMD-82TX (888-863-8289)

DATE OF REVIEW: 09/08/2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

IRO-Gene Expression Profile

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

This case was reviewed by a licensed MD, specializing in Toxicology, Internal Medicine, Emergency Medicine. The physician advisor has the following additional qualifications, if

applicable: ABMS Internal Medicine, Emergency Medicine: Medical Toxicology,

Emergency Medicine

REVIEW OUTCOME:

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

Overturned

| Health Care Service(s) in Dispute | CPT Codes | Date of Service(s) | Outcome of Independent Review |
|-----------------------------------|-----------|--------------------|-------------------------------|
| IRO-Gene Expression Profile | | - | Overturned |

PATIENT CLINICAL HISTORY [SUMMARY]:

Re:

Case #: Requested

by Insurance

Company

September 8, 2009

Materials Reviewed:

Authorization Denial: 08/05/09

Insurance Policy: 06/15/09

Medical records: 07/06/09 through 07/17/09

Tumor marker review

Benefit Plan: 2008

Request for IRO: 09/03/09

Notice of assignment of Independent review: 09/03/09

Clinical case summary:

Summary:

The use of testing for Oncotype-DX also known as 21gene RT-PCR to assess the medical necessity for adjuvant chemotherapy in women with recently diagnosed breast tumors is denied as the patient is a man.

The patient presented with a right breast tumor on xx/xx/xx. The patient is a xx year old with a 2 by 1 cm mass without axillary nodes. His laboratory studies showed slightly low hemoglobin. His EKG is normal. The patient was admitted for a right mastectomy. He had to have his drain replaced as it was removed accidentally following the procedure. He had developed an abscess.

The surgical note indicates that the patient had a Patey modified radical mastectomy for a right breast cancer. His drain fell out accidentally.

On the request for approval it is noted that his breast cancer is non-metastatic, is estrogen receptor positive and is HER2 receptor negative, adjuvant chemotherapy is not precluded due to any other factor, and the member and physician have discussed potential results and agree to use the results to guide therapy.

The clinical case summary states that the mastectomy was performed xx/xx/xx. The patient was found to have a node negative, breast tumor that is estrogen receptor positive, and HER2 receptor negative and is 1 cm in diameter.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION:

Questions:

1. Is the use of this test appropriate and reasonable in this patient?

This test is of value in patients fulfilling the criteria described regardless of whether the patient is male or female. The ability to rule out the need for adjuvant therapy has been well documented to decrease cost and improve quality of life in patients with breast cancer by determining the necessity of adjuvant therapy. The cost of the therapy that would otherwise needs to be considered far outweighs the cost of the test itself.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

The biomarker requested would help to determine the need for adjuvant chemotherapy. If it is negative the patient could avoid therapy that is potentially life threatening, expensive and potentially associated with side effects that could require hospitalization. It is more cost effective and in the best interest of the patient to permit and pay for this type of screening test. The fact that the patient is a man versus a woman with breast cancer should not make a difference in the decision process.

Men with breast cancer have the same risks and profile risk as women. However, due to the fact that only 1% of all breast cancer occurs in men, no large studies have incorporated this subpopulation of patients or evaluated them separately. Treatment is the same for male breast cancer as for women and based on the type of cell and presence of metastasis or node involvement. The use of gene markers would be recommended in breast cancer with mentioned characteristics in women and in men. Most studies do not distinguish between men and women in their populations although due to the rarity of breast cancer in men, it is unlikely that a significant difference in study results would be noted with the inclusion of males with breast cancer. Although in general the recommendations refer to women, the costs savings and benefits of gene testing in the male patient. Note that breast cancer risk is increased in men with a history of increased estrogen, previous radiation exposure and a family history of breast cancer.

References:

Cancer, 2007, vol 109; 1011 – 1018

Impact of a 21-gene RT-PCR assay on treatment decisions in early-stage breast cancer

An economic analysis based on prognostic and predictive validation studies

Gary H. Lyman, MD, MPH , Leon E. Cosler, MD, RPh, PhD , Nicole M. Kuderer, MD , John Hornberger, MD

<http://www.ajmc.com/media/pdf/AJMC05MayHornbergr313to.pdf>

The American Journal of Managed Care 2005, vol 11:313-324

Economic Analysis of Targeting Chemotherapy Using a 21-Gene RT-PCR Assay in Lymph-Node–Negative, Estrogen-Receptor–Positive, Early-Stage Breast Cancer

John Hornberger, MD; Leon E. Cosler, PhD, RPh; and Gary H. Lyman, MD, MPH, FRCP (Edin)

[Breast Cancer Res.](#) 2006; 8(3):R25.

A population-based study of tumor gene expression and risk of breast cancer death among lymph node-negative patients.

[Habel LA](#), [Shak S](#), [Jacobs MK](#), [Capra A](#), [Alexander C](#), [Pho M](#), [Baker J](#), [Walker M](#), [Watson D](#), [Hackett J](#), [Blick NT](#), [Greenberg D](#), [Fehrenbacher L](#), [Langholz B](#), [Quesenberry CP](#).

http://www.medicinenet.com/male_breast_cancer/article.htm

<http://www.imaginis.com/breasthealth/bcmn2.asp>