

**STATE OF MICHIGAN**  
**DEPARTMENT OF ENERGY, LABOR & ECONOMIC GROWTH**  
**OFFICE OF FINANCIAL AND INSURANCE REGULATION**  
**Before the Commissioner of Financial and Insurance Regulation**

In the matter of

XXXXX

Petitioner

File No. 119479-SF

v

City of XXXXX

and

Automated Benefit Services, Inc.  
Respondents

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Issued and entered  
this \_\_\_\_\_ day of April 2011  
by Ken Ross  
Commissioner

**ORDER**

**I**  
**PROCEDURAL BACKGROUND**

On February 8, 2010, XXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 et seq. The Petitioner has health care benefits through the city of XXXXX. She is a retired employee of the city. The benefit plan is administered by Automated Benefit Services, Inc. (ABS), a third party administrator licensed by the Office of Financial and Insurance Regulation (OFIR).

The health care plan is self-funded. Public Act No. 495 of 2006, MCL 550.1951 et seq., authorizes the Commissioner to conduct external reviews for these plans in the same manner as reviews conducted under the Patient's Right to Independent Review Act (PRIRA), MCL 550.1901 et seq.

OFIR notified ABS of the external review and requested the information used in making its adverse determination. The information was received February 9, 2011. The case was accepted for external review on February 15, 2011.

The case presented a medical question which, pursuant to MCL 550.1911(6), was assigned to an independent medical review organization for analysis. The analysis was submitted to the Commissioner on March 1, 2011.

## **II FACTUAL BACKGROUND**

Petitioner has been diagnosed with breast cancer. Her physician prescribed a chemotherapy regimen of Docetaxel, Cytoxan, and Herceptin with Neulasta for the treatment of her condition.

The physician requested coverage from ABS for the regimen. ABS denied the request. The Petitioner appealed the denial through ABS's internal grievance process. ABS maintained its original position and issued a final adverse determination dated January 4, 2011.

## **III ISSUE**

Did Respondent properly deny Petitioner's request for a regimen of Docetaxel, Cytoxan and Herceptin with Neulasta under the terms of the certificate?

## **IV ANALYSIS**

### Petitioner's Argument

In a letter to OFIR dated January 31, 2011, Petitioner wrote:

The coverage was denied because ABS feels that the Chemotherapy regimen of Herceptin, Taxotere and Cytoxan is not a generally accepted adjuvant therapy. However, the only documentation that ABS provided us with when we requested a copy of the guidelines they relied upon in making their determination, was the National Comprehensive Cancer Network (NCCN) Guidelines, which although they do not specifically address this exact adjuvant regimen therapy, they do stipulate that: The selection, dosing, and administration of anti-cancer agents and the management of associated toxicities are complex. Modification of drug

dose and schedule and [initiation] of supportive care are often necessary because of expected toxicities and because of individual patient variability, prior treatment, and comorbidity. In addition, all the drugs that were used have been FDA approved.

Petitioner argues the City of XXXXX should provide coverage for the requested regimen because the therapy is not only FDA approved but also necessary due to individual patient comorbidity.

### Respondent's Argument

In its January 4, 2011, final adverse determination, ABS denied authorization for the requested regimen, stating:

This appeal was sent for an independent review, that determined the chemotherapy regimen of Herceptin, Taxotere and Cytoxan is not a generally accepted adjuvant therapy for Her2 positive breast carcinoma, is not an FDA-approved combination therapy for this indication and not supported by current medical literature and that Herceptin used with Taxotere and Cytoxan is off-label.

As indicated in the Plan Document and Summary Plan Description under Plan Exclusions #11 Experimental or not Medically Necessary. Care and treatment that is either Experimental/Investigational or not Medically Necessary.

#27 Not specified as covered. Non-traditional medical services, treatment and supplies which are not specified as covered under this Plan.

Under Prescription Drug Benefits – Expenses Not Covered #6 Experimental. Experimental drugs and medicines, even though a charge is made to the covered Person.

#17 Non-legend drugs. A charge for FDA approved drugs that are prescribed for non FDA-approved uses.

ABS maintains that its denial was appropriate under the terms of the certificate.

### Commissioner's Review

The City of XXXXX's certificate excludes coverage for drugs that are experimental. The issue of whether the regimen is experimental was presented to an independent review organization (IRO) for review. The IRO reviewer is a physician who is board certified in internal medicine and medical oncology. The reviewer has been in practice for more than 15 years and is familiar with the medical management of patients with the Petitioner's condition. The IRO

reviewer's report includes the following analysis:

[T]he [Petitioner] was started on adjuvant chemotherapy with Herceptin, Taxotere and Cytoxan. . . . Cytoxan was substituted for Carboplatin due to concerns of toxicity. . . . [T]he utility of the combination of Taxotere and Cyclophosphamide (Cytoxan) as compared to Adriamycin and Cyclophosphamide has been proven in a randomized controlled phase III trial and is included in the National Comprehensive Cancer Networks guidelines as a recommended treatment option for HER2 negative early stage breast cancer. However . . . the combination of Taxotere and Cyclophosphamide with Herceptin is not FDA approved or recommended in expert guidelines for adjuvant chemotherapy for HER2 overexpressing breast cancer, which is [Petitioner's] diagnosis. . . . [T]he combination of Herceptin, Taxotere and Cytoxan is currently being tested in a phase II clinical trial. . . . [T]he use of Taxotere and Herceptin would not be considered investigational for treatment of the [Petitioner's] condition, but that the addition of Cytoxan makes the requested combination of adjuvant chemotherapy investigational at this time.

The IRO report concluded that "adjuvant chemotherapy with Herceptin, Taxotere and Cytoxan is investigational for treatment of the [Petitioner's] condition."

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner; in a decision to uphold or reverse an adverse determination the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO's analysis is based on extensive expertise and professional judgment. The Commissioner can discern no reason why that judgment should be rejected in the present case.

The Commissioner accepts the conclusion of the IRO and finds that the City of Melvindale's denial is consistent with the terms of its certificate.

## **V ORDER**

The Commissioner upholds ABS's January 4, 2011, final adverse determination. ABS is not required to provide coverage for the Petitioner's requested treatment regimen.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

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Ken Ross  
Commissioner