STATE OF CONNECTICUT DEPARTMENT OF SOCIAL SERVICES OFFICE OF LEGAL COUNSEL, REGULATIONS, AND ADMINISTRATIVE HEARINGS 55 FARMINGTON AVENUE HARTFORD, CT 06105

Signature confirmation

Client: Request: 776835

NOTICE OF DECISION

PARTY

PROCEDURAL BACKGROUND

On 2016, Community Health Network of Connecticut ("CHNCT") issued 2016 (the "Appellant") a notice stating that it had denied her ordering provider's request for prior authorization of Medicaid payment for BRACAnalysis genetic testing.

On 2016, the Appellant filed a request for an administrative hearing with the Office of Legal Counsel, Regulations, and Administrative Hearings ("OLCRAH") to contest the CHNCT's action.

On 2016, the OLCRAH issued a notice to the Appellant scheduling an administrative hearing for 2016. The OLCRAH granted the Appellant's request for a postponement of the administrative hearing.

On 2016, in accordance with sections 17b-60, 17b-61 and 4-176e to 4-189, inclusive, of the Connecticut General Statutes, the OLCRAH held an administrative hearing. These individuals participated in the proceeding by telephone:

Fabiola Goin, RN, CHNCT's representative Eva Tar, Hearing Officer

The administrative hearing record closed 2016.

STATEMENT OF ISSUE

The issue to be decided is whether CHNCT correctly denied the Appellant's ordering provider's request for prior authorization of Medicaid payment for BRACAnalysis genetic testing.

FINDINGS OF FACT

- 1. The Appellant has medical coverage through the HUSKY program. (CHNCT's Exhibit 3: *Notice of Action*, 16)
- 2. CHNCT is a subcontractor for the HUSKY program. (CHNCT's representative's testimony)
- 3. The Appellant is 46 years old. (Appellant's testimony)
- 4. The Appellant has a 24-year-old daughter. (Appellant's testimony)
- 5. The Appellant had not been diagnosed with breast cancer. (Appellant's testimony)
- 6. The Appellant's mother has not been diagnosed with breast cancer. (Appellant's testimony)
- 7. The Appellant's daughter has not been diagnosed with breast cancer. (Appellant's testimony)
- 8. The Appellant's mother had 12 siblings, four sisters and eight brothers. (Appellant's testimony)
- 9. One of the Appellant's maternal uncles died of skin cancer that had spread to other organs. (Appellant's testimony)
- 10. One of the Appellant's maternal aunts had throat cancer. (Appellant's testimony)
- 11. The Appellant has two first cousins (one on her mother's side and one on her father's side) who are breast cancer survivors; one of these first cousins had a mastectomy. (Appellant's testimony)
- 12. The Appellant's relatives have not been diagnosed with ovarian or pancreatic cancer. (Appellant's testimony)
- 13. The Appellant has the following medical conditions: fibrocystic breast tissue, diabetes, hernia, and cysts and masses. (Appellant's testimony)
- 14. The Appellant has dense breast tissue. (Appellant's testimony)
- 15. The Appellant has had non-cancerous masses and cysts removed from her breasts. (Appellant's testimony)

- 16. The Appellant has had periodic fluid discharge from her breasts for years. (Appellant's testimony)
- 17. On 2016, the Appellant received a breast ultrasound. (CHNCT's Exhibit 7: Medical Review Request, 2016)
- 18. On 2016, the Appellant received a diagnostic mammography, producing direct 2-D digital image, bilateral, all views. (CHNCT's Exhibit 7)
- 19. On 2016, CHNCT received a request for prior authorization from Myriad Genetic Laboratories, Inc. for an Integrated BRACAnalysis genetic testing for the purpose of determining the Appellant's susceptibility to hereditary breast and ovarian cancer syndrome. (CHNCT's Exhibit 1: Prior Authorization Request, 2016)
- 20. The 2016 prior authorization request provides the Appellant's family history of cancer as follows: mother (pre-cancer skin); maternal aunt (skin cancer); maternal aunt (throat cancer), and uncle (skin cancer). (CHNCT's Exhibit 1)
- 21. Heather Kovac, APRN, (the "ordering provider") filed the 2016 prior authorization request. (CHNCT's Exhibit 1)
- 22. On 2016, Richard M. Cowett, MD, FAAP reviewed the 2016 prior authorization request, concluding that the Appellant did not meet the criteria for approval, as she did not have a personal history of breast cancer nor did she have a family history that was within the acceptable degree of relation and diagnosis. (CHNCT's Exhibit 2: Medical Review, 2016)
- 23. An acceptable degree of relation and diagnosis with respect to clinical authorization of BRACAnalysis genetic testing is as follows: 1) a first- or second-degree relative with breast cancer who also has one relative diagnosed prior to age 45; 2) a first- or second-degree relative who had breast cancer diagnosed prior to age 50; 3) a first- or second-degree relative who had multiple primary breast cancers or bilateral breast cancer; or 4) a first- or second-degree relative with a history of ovarian, fallopian tube or primary peritoneal cancer; or 5) a first-or second-degree relative who had triple negative breast cancer diagnosed prior to age 60; or 7) a first- or second-degree relative with a history of breast cancer; or 8) a first-or second-degree relative who has a history of ovarian cancer and two or more first-, second-, and third-degree relatives with pancreatic cancer; or 9) a first- or second-degree relative with a history of ovarian cancer and two or more first-, second-, and third-degree relatives with pancreatic cancer; or 9) a first- or second-degree relative with a history of pancreatic cancer; or 9) a first- or second-degree relatives with pancreatic cancer; or 9) a first- or second-degree relatives with pancreatic cancer; or 9) a first- or second-degree relatives with breast and/or ovarian and/or pancreatic cancer. (CHNCT's Exhibit 2)
- 24. A first-degree relative is a parent, child, or sibling of the individual. (CHNCT's representative's testimony)
- 25. A second-degree relative is an aunt/uncle, niece/nephew, or the grandparents of the individual. (CHNCT's representative's testimony)

- 26. A third-degree relative includes the first cousins of the individual. (CHNCT's representative's testimony)
- 27. On 2016, CHNCT denied the Appellant's ordering provider's request for prior authorization of Medicaid payment for BRACAnalysis genetic testing for the reason that it was not medically necessary, as the test was for people who had a personal or family medical history that put them at risk for breast cancer. (CHNCT's Exhibit 3)
- 28. On 2016, the ordering provider verbally informed the CHNCT's representative that she would not be submitting additional medical information regarding the Appellant's appeal. (CHNCT's representative's testimony)(CHNCT's Exhibit 7)
- 29. On 2016, Attillio Granata, MD, reviewed the 2016 prior authorization request and was unable to confirm medical necessity for BRACAnalysis genetic testing, as there was no history in the patient or family of specific high risk factors, including breast cancer, pancreatic cancer, ovarian cancer and other cancers related to familial breast cancer syndromes. (CHNCT's Exhibit 8: Medical Review Results, 2016)
- 30. BRACAnalysis genetic testing is a genetic test that identifies whether a marker is present that indicates a genetic predisposition to cancer. If the marker is present, it does not necessarily mean that breast cancer will occur in the patient. (CHNCT's representative's testimony)
- 31. The Appellant is worried that she will get breast cancer. (Appellant's testimony)(Hearing request)
- 32. The Appellant is scheduled for an upcoming MRI [magnetic resonance imaging] to scan her breasts. (Appellant's testimony)

CONCLUSIONS OF LAW

- 1. The Commissioner of Social Services may make such regulations as are necessary to administer the medical assistance program. Conn. Gen. Stat. § 17b-262.
- 2. The Commissioner of Social Services, to the extent permitted by federal law, shall amend the Medicaid state plan to provide coverage for mammographic examinations for any woman eligible for Medicaid that is at least equal to the following minimum requirements: (1) A baseline mammogram for any such woman who is thirty-five to thirty-nine years of age, inclusive; and (2) a mammogram every year for any such woman who is forty years of age or older. Conn. Gen. Stat. § 17b-278c.
- Section 38a-503 of the Connecticut General Statutes identifies mandatory coverage for mammography, breast ultrasound and magnetic resonance imaging. Breast density information included in mammography report. (a)(1) Each individual health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (10), (11) and (12) of section 38a-469 delivered, issued for delivery, renewed, amended or continued in this state shall provide benefits for mammographic examinations to any woman covered under the policy that are at least equal to the

following minimum requirements: (A) A baseline mammogram for any woman who is thirty-five to thirty-nine years of age, inclusive; and (B) a mammogram every year for any woman who is forty years of age or older. (2) Such policy shall provide additional benefits for: (A) Comprehensive ultrasound screening of an entire breast or breasts if a mammogram demonstrates heterogeneous or dense breast tissue based on the Breast Imaging Reporting and Data System established by the American College of Radiology or if a woman is believed to be at increased risk for breast cancer due to family history or prior personal history of breast cancer, positive genetic testing or other indications as determined by a woman's physician or advanced practice registered nurse; and (B) Magnetic resonance imaging of an entire breast or breasts in accordance with guidelines established by the American Cancer Society.

Each mammography report provided to a patient shall include information about breast density, based on the Breast Imaging Reporting and Data System established by the American College of Radiology. Where applicable, such report shall include the following notice: "If your mammogram demonstrates that you have dense breast tissue, which could hide small abnormalities, you might benefit from supplementary screening tests, which can include a breast ultrasound screening or a breast MRI examination, or both, depending on your individual risk factors. A report of your mammography results, which contains information about your breast density, has been sent to your physician's office and you should contact your physician if you have any questions or concerns about this report." Conn. Gen. Stat. §38a-503 (c).

- 4. Conn. Gen. Stat. § 38a-503 does not identify BRACAnalysis testing as subject to mandatory coverage for medical insurance.
- 5. The Appellant has received, or is scheduled to receive in the near future, diagnostic testing—mammograms, ultrasounds, and an MRI—that is in accordance with the provisions of Conn. Gen. Stat. § 38a-503.
- 6. For purposes of the administration of the medical assistance programs by the Department of Social Services, "medically necessary" and "medical necessity" mean those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B) recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition. Conn. Gen. Stat. § 17b-259b (a).

- 7. Clinical policies, medical policies, clinical criteria or any other generally accepted clinical practice guidelines used to assist in evaluating the medical necessity of a requested health service shall be used solely as guidelines and shall not be the basis for a final determination of medical necessity. Conn. Gen. Stat. § 17b-259b (b).
- 8. The BRACAnalysis genetic testing will not prevent, identify, diagnose, treat, rehabilitate or ameliorate the Appellant's medical conditions of non-cancerous fibrocystic breast tissue, diabetes, hernia, and non-cancerous cysts and masses.
- 9. The Appellant's circumstances do <u>not</u> support a finding that the BRACAnalysis genetic testing is clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the treatment of the Appellant's medical conditions.
- 10. BRACAnalysis genetic testing is not medically necessary for the Appellant.
- 11. CHNCT correctly denied the Appellant's ordering provider's request for prior authorization of Medicaid payment for BRACAnalysis genetic testing.

DECISION

The Appellant's appeal is DENIED.

Va Tax-electronic signature Eva Tar

Hearing Officer

Cc: Fabiola Goin, CHNCT Fatmata Williams, DSS-Central Office

RIGHT TO REQUEST RECONSIDERATION

The Appellant has the right to file a written reconsideration request within 15 days of the mailing date of the decision on the grounds there was an error of fact or law, new evidence has been discovered or other good cause exists. If the request for reconsideration is granted, the Appellant will be notified within 25 days of the request date. No response within 25 days means that the request for reconsideration has been denied. The right to request a reconsideration is based on § 4-181a (a) of the Connecticut General Statutes.

Reconsideration requests should include <u>specific</u> grounds for the request: for example, indicate <u>what</u> error of fact or law, <u>what</u> new evidence, or <u>what</u> other good cause exists.

Reconsideration requests should be sent to: Department of Social Services, Director, Office of Legal Counsel, Regulations, and Administrative Hearings, 55 Farmington Avenue, Hartford, CT 06105.

RIGHT TO APPEAL

The Appellant has the right to appeal this decision to Superior Court within 45 days of the mailing of this decision, or 45 days after the agency denies a petition for reconsideration of this decision, provided that the petition for reconsideration was filed timely with the Department. The right to appeal is based on § 4-183 of the Connecticut General Statutes. To appeal, a petition must be filed at Superior Court. A copy of the petition must be served upon the Office of the Attorney General, 55 Elm Street, Hartford, CT 06106 or the Commissioner of the Department of Social Services, 55 Farmington Avenue, Hartford, CT 06105. A copy of the petition must also be served on all parties to the hearing.

The 45-day appeal period may be extended in certain instances if there is good cause. The extension request must be filed with the Commissioner of the Department of Social Services in writing no later than 90 days from the mailing of the decision. Good cause circumstances are evaluated by the Commissioner or his designee in accordance with § 17b-61 of the Connecticut General Statutes. The Agency's decision to grant an extension is final and is not subject to review or appeal.

The appeal should be filed with the clerk of the Superior Court in the Judicial District of New Britain or the Judicial District in which the Appellant resides.