STATE OF CONNECTICUT DEPARTMENT OF SOCIAL SERVICES OFFICE OF LEGAL COUNSEL, REGULATIONS, AND ADMINISTRATIVE HEARINGS 55 FARMINGTON AVE. HARTFORD, CT 06105-3725

, 2018 Signature Confirmation

Client ID # Request #

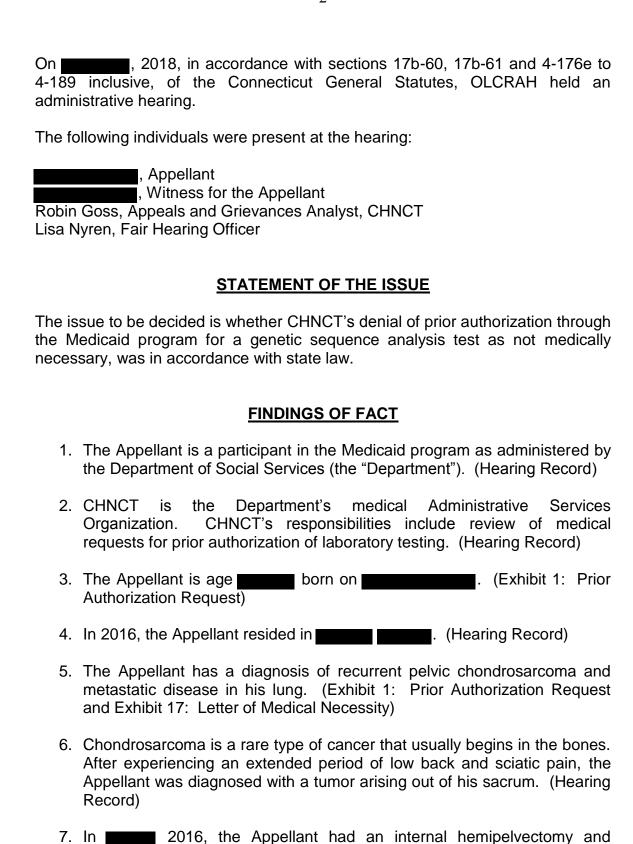
NOTICE OF DECISION

PARTY



PROCEDURAL BACKGROUND

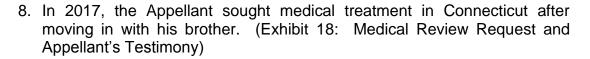
On 2018, Community Health Network of Connecticut ("CHNCT") sent (the "Appellant") a Notice of Action ("NOA) denying the prior authorization request for ("genetic sequence analysis test").
On, 2018, the Appellant requested an administrative hearing to contest CHNCT's decision to deny the prior authorization request.
On 2018, the Office of Legal Counsel, Regulations, and Administrative Hearings ("OLCRAH") issued a notice scheduling the administrative hearing for 2018.
On 2018, the Appellant requested a continuance which OLCRAH granted.
On, 2018, the OLCRAH issued a notice scheduling the administrative hearing for 2018.
On, 2018, the OLCRAH requested a continuance due to inclement weather.
On 2018, the OLCRAH issued a notice scheduling the administrative

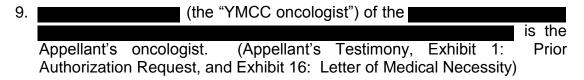


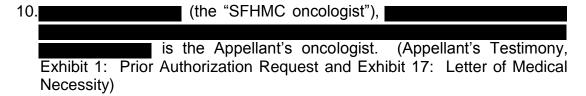
sacrectomy for high-grade chondrosarcoma at I

. The Appellant remained inpatient

for nine months after surgery due to complications. (Exhibit 18: Medical Review Request and Appellant's Testimony)







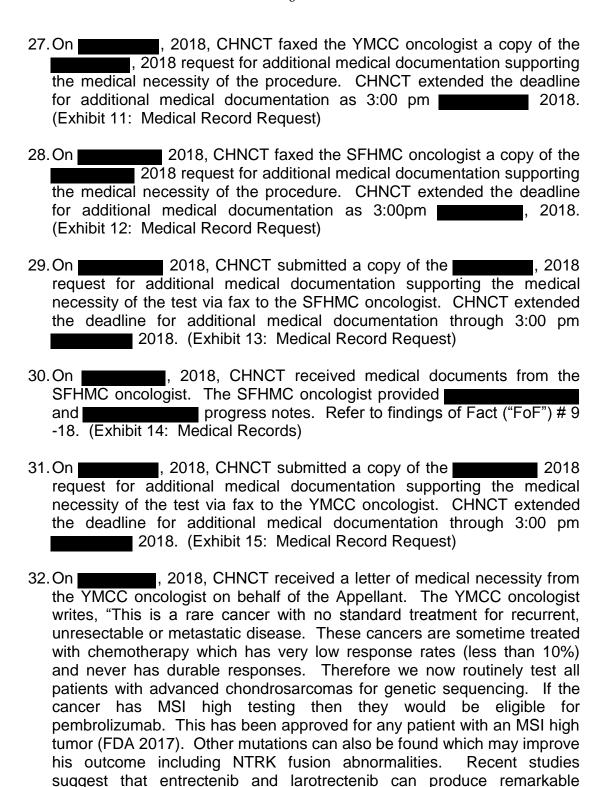
- 11.On 2017, the Appellant had a colostomy due to incontinence of stool. (Exhibit 1: Prior Authorization Request, Exhibit 14: Medical Records and Exhibit 18: Medical Review Request)
- 12. The Appellant self-catheterizes for urine. (Exhibit 1: Prior Authorization Request, Exhibit 14: Medical Records and Exhibit 18: Medical Review Request)
- 13. On _______, 2017, the Appellant began first cycle of chemotherapy: Doxorubicin, Ifosfamide, and Mesna administered over a three day period with three weeks between chemotherapy cycles. (Exhibit 1: Prior Authorization Request, Exhibit 14: Medical Records, and Exhibit 18: Medical Review Request)
- 14. On _______ 2018, the Appellant met with the SFHMC oncologist. The SFHMC oncologist comments, "Tolerating therapy reasonably well. His day 11 counts are not bad, so hopefully we will be able to stay on an every 3 week schedule. Will plan to repeat scans after 2 cycles. His pelvic mass is clearly seen. The lung mass is questionable, and may represent residual or prior pulmonary infection." (Exhibit 14: Medical Records)
- 15. On 2017, after two cycles of chemotherapy, Doxorubicin, Ifosfamide, and Mesna, new CT scans of chest, abdomen, and pelvis were taken. Scans exhibited tumor growth in pelvis and right lung. Chemotherapy, Doxorubicin, Ifosfamide, and Mesna, terminated due to the progression of the disease on standard chemotherapy. (Exhibit 1:

Prior Authorization Request, Exhibit 14: Medical Records, Exhibit 18: Medical Review Request, and Appellant's Testimony)

- 16. Mid 2017, the Appellant began a new chemotherapy regimen taking Pazopanib daily in the morning with pelvic pain controlled with OxyContin. (Appellant's Testimony and Exhibit 17: Letter of Medical Necessity)
- 17. Pazopanib is a chemotherapy drug used to block tumor growth. (Appellant's Testimony)
- 18. On 2017, CHN received a prior authorization request from the YMCC oncologist for Tumor Sequencing, 143 Gene Oncomine Cancer Panel CPC (current procedure terminology) 81455 ("genetic sequence analysis test") for diagnosis of recurrent metastatic chondrosarcoma. (Exhibit 1: Prior Authorization Request, Exhibit 2: Medical Review, and Hearing Summary)
- 19. On _______ 2018, the Appellant met with the SFHMC oncologist. The SFHMC oncologist comments: "Progression in pelvis and lung despite adri/ifos chemo, now on Pazopanib. Tolerating therapy well; this will be continued. Will plan to repeat imaging after 2 months of therapy unless an attractive molecular option presents. Return 3 weeks to check counts." (Exhibit 14: Medical Records)
- 20. CHNCT denied the Appellant's request for prior authorization of genetic sequence analysis test based on the HUSKY Health Policy for "Genetic Cancer Susceptibility Panels Using Next Generation Sequencing" ("NGS Guidance"). This document went into effect on 2017 and sets forth coverage guidelines for genetic cancer susceptibility panels using NGS (next generation sequencing). (Exhibit 2: Medical Review)
- 21. The purpose of the NGS Guidance is "to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for genetic cancer susceptibility panels using next generation sequencing (NGS). allows the sequencing of large stretches of DNA compared to a focused method of testing for well-characterized mutations or panel testing which tests for multiple mutations in multiple genes at the same time. NGS quidelines follow the DSS definition of Medical Necessity. The guidelines are as follows: "Genetic cancer susceptibility panels using NGS are typically considered investigational based on a lack of evidence supporting the clinical validity and clinical utility of these tests and therefore are typically considered to be not medically necessary." The NGS Guidance includes the code for the testing requested for the Appellant: CPC 81455, targeted aenomic sequence analysis panel, solid organ

hematolymphoid neoplasm, DNA analysis, and RNA analysis when performed, 51 or greater genes, interrogation for sequence variants and copy number variants or rearrangements, if performed. (Exhibit 2: Medical Review)

- 22. On CHNCT denied the prior authorization request for the genetic sequence analysis test and notified the Appellant. The notice states that the service requested is "not medically necessary, per Connecticut law because is not the right type of service for you. Specifically, there is not enough medical evidence to show that doing this extensive genetic test is going to help your doctor to develop a plan of care for you or improve your health outcomes." (Exhibit 3: Notice of Action)
- 23. On ______, 2018, CHNCT issued a notice of confirmation of the verbal request for appeal to the Appellant. The notice provided the Appellant with information regarding his request for appeal and confirmed the name of the CHNCT representative who would coordinate the appeal. (Exhibit 5: Acknowledgement Letter)
- 25. On 2018, CHNCT requested from SFHMC oncologist the following information: "complete and legible copy of progress note for office visit with [SFHMC oncologist]sic on documentation of current medical evidence to show that the results of this extensive cancer genetic test will assist in developing a plan care for the member or improve the member's health outcomes, letter of medical necessity supporting the medical need for a genetic sequence analysis test for this member. CHNCT listed the due date for the information as January 26, 2018. (Exhibit 8: Medical Record Request)
- 26.On 2018, CHNCT issued a notice of confirmation of the administrative hearing request to the Appellant. The notice provided the Appellant with information regarding his request for appeal and an opportunity to submit additional medical documentation to CHNCT. (Exhibit 10: Acknowledgement Letter)



response in sarcomas with these abnormalities. Notch and hedgehog pathway mutations allow the treatment of vismodegib to be considered."

(Exhibit 16: Letter of Medical Necessity)

- 33. On 2018, CHNCT received a letter of medical necessity from the SFHMC oncologist on behalf of the Appellant. The SFHMC oncologist writes, "Standard treatment options for him are very limited. Some patients with advanced sarcoma, when their tumors are analyzed for genetic mutations, are found to have specific mutations which can be targeted by a molecularly tailored agent available on a clinical trial. Molecular testing of his tumor is requested to see if he is potentially eligible for such a clinical trial. Molecularly targeted therapy has potential for extended control of his disease which currently would not be available with any standard agents. The information available from this testing could potentially identify a clinical trial which might have a significant impact on both the quality of his life and his survival." (Exhibit 17: Letter of Medical Necessity)
- 2018, CHNCT requested a clinical review of the prior 34. On I authorization request for genetic sequence analysis test from MCMC. MCMC is a contractor that provides independent clinical reviews for CHNCT regarding medical necessity appeals. CHNCT submitted the following documents for review to MCMC: appeal summary, prior authorization request, administrative hearing request, progress notes and letters of medical necessity, and the Department's definition of medical necessity as per regulations Section 17b-259b. CHNCT writes, "Based on the information presented, is the requested genetic sequence analysis test (81455) considered medically necessary for this member in accordance with the DSS Definition of Medical Necessity provided above? If the requested genetic sequence analysis test (81455) is considered medically necessary for this member, how will the information obtained from the test impact treatment decisions? If it is not considered medically necessary for this member, please explain." (CHNCT's Representative's Testimony, Exhibit 18: Medical Review Request, and Exhibit 19: Medical Review Results)
- 35. A board certified medical doctor of Internal Medicine/Medical Oncology completed the review of the Appellant's prior authorization request for genetic sequence analysis testing for MCMC. Citing studies completed in 2014, 2015, and guidelines from the NCCN, the doctor concludes, "Based on the information presented, the requested genetic sequence analysis test (CPT 81455) is not considered medically necessary for this member in accordance with the DSS Definition of Medical Necessity provided. The standard of care in the United States does not yet include selecting chemotherapy for cancer based on the somatic mutation profile of the tumor." The October 2015 study cites, "The use of molecularly targeted agents outside their indications does not improve progression-free survival compared with treatment at physician's choice in heavily pretreated patients with cancer. Off-label use of molecularly targeted agents should be discouraged, but enrollment in clinical trials should be encouraged to

assess predictive biomarkers of efficacy." The April 2015 study suggests "that as many of 31 % of 'actionable' mutations in panels such as the FoundatioOne® test might be 'false positive." The May 2014 study cites, there is little information available on the post-analytic processes unique to next-generation sequencing platforms used by the companies offering these tests. To date, there is no published data of improved outcomes when using the commercially available tests to guide treatment decisions." The National Comprehensive Cancer Network ("NCCN") guidelines for the treatment of chondrosarcoma do not include Guardiant360® testing (NCCN Guidelines™Version 1.2018, Bone Cancers)." (Exhibit 19: Medical Review Results)

- 36. On 2018, CHNCT issued a notice of denial to the Appellant. The notice stated that "your appeal to the HUSKY Health Program of the denial of authorization for genetic sequence analysis test that you or your provider requested has been denied." CHNCT cites the principal reason to uphold the denial is that the medical information does not support the medical necessity for the requested genetic sequence analysis test because there is not enough medical evidence to show that extensive genetic tests lead to improved outcomes when used to guide treatment. The current standard of care does not include selecting chemotherapy for cancer based on the genetic profile of the tumor. The denial of such genetic sequence analysis test is based on Connecticut General Statutes 17b-259b(a)(1), not consistent with generally accepted standards, and (2) as set forth in the Notice of Action that was already sent to you. (Exhibit 20: Determination Letter)
- 37. The Appellant's most recent CT scan showed no tumor growth while on Pazopanib. (Appellant's Testimony)
- 38. On Parameter, Pazopanib chemotherapy terminated. The Appellant has open wounds that were not healing. Pazopanib stopped to promote healing. (Appellant's Testimony)
- 39. The Appellant seeks prior authorization approval for genetic sequence analysis test to assist both himself and his oncologists in determining the best course of treatment including enrollment in a clinical trial that is contingent upon meeting criteria which can only be determined by genetic sequence analysis test. (Appellant's Testimony)

CONCLUSIONS OF LAW

1. Section 17b-2(a)(6) of the Connecticut General Statutes provides that the Department of Social Services is designated as the state agency for the

- administration of the Medicaid program pursuant to Title XIX of the Social Security Act.
- 2. State statute provides that 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 physicianspecialty 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)]
- State statute provides that clinical policies, medical policies, 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)]
- 4. State statute provides that upon denial of a request for authorization of services based on medical necessity, the individual shall be notified that, upon request, the Department of Social Services shall provide a copy of the specific guideline or criteria, or portion thereof, other than the medical necessity definition provided in subsection (a) of this section, that was considered by the department or an entity acting on behalf of the department in making the determination of medical necessity. [Conn. Gen. Stat. § 17b-259b(c)]
- 5. State statute provides that the Department of Social Services shall amend or repeal any definitions in the regulations of Connecticut state agencies that are inconsistent with the definition of medical necessity provided in subsection (a) of this section, including the definitions of medical appropriateness and medically appropriate, that are used in administering the department's medical assistance program. The commissioner shall

implement policies and procedures to carry out the provisions of this section while in the process of adopting such policies and procedures in regulation form, provided notice of intent to adopt the regulations is published in the Connecticut Law Journal not later than twenty days after implementation. Such policies and procedures shall be valid until the time the final regulations are adopted. [Conn. Gen. Stat. § 17b-259b(d)]

- 6. Regulations of Connecticut State Agencies § 17b-262-641 provides that sections 17b-262-641 through 17b-262-650, inclusive, of the Regulations of Connecticut State Agencies set forth the Department of Social Services requirements for payment of laboratory services provided by licensed clinical laboratories, in settings other than hospital inpatient or outpatient departments or a physician's, nurse-midwife's, or nurse practitioner's office, for clients who are determined eligible to receive services under Connecticut's Medicaid Program pursuant to section 17b-262 of the Connecticut General Statutes (CGS).
- 7. State regulation defines Panel or Profile Tests as certain multiple tests performed on a single specimen or material derived from the human body which are related to a condition, disorder, or family of disorders, which when combined mathematically or otherwise, comprise a finished identifiable laboratory study or studies. [Conn. State Agencies Regs. § 17b-262-642(12)]
- 8. State regulation defines Prior Authorization as approval for the provision of a service or the delivery of goods from the department before the provider actually provides the service or delivers the goods. [Conn. State Agencies Regs. § 17b-262-642(13)]
- 9. State regulation provides payment for independent clinical laboratory services shall be available on behalf of all persons eligible for the Medicaid Program subject to the conditions and limitations which apply to these services. [Conn. State Agencies Regs. § 17b-262-644]
- 10. State regulation provides that the Department shall pay for the following: (1) medically appropriate and medically necessary clinical laboratory services, for which the laboratory holds certification according to the provisions of CLIA, which are listed in the department's fee schedule. [Conn. State Agencies Regs. § 17b-262-645(a)(1)]
- 11. State regulation provides for limitations on covered services shall be as follows: (4) payment shall not be made for any procedures or services of an unproven educational, social research, experimental, or cosmetic nature; for services in excess of those deemed medically necessary and medically appropriate to treat the client's condition; or for services not

- directly related to the client's diagnosis, symptoms, or medical history. [Conn. State Agency Regs. § 17b-262-645(b)(4)]
- 12. State regulation provides that the department shall pay for medically necessary and medically appropriate testing and analysis services only when ordered by a licensed physician or other licensed practitioner of the healing arts. [Conn. State Agencies Regs. § 17b-262-646]
- 13. State regulation provides for prior authorization, to determine medical appropriateness and medical necessity, shall be required as a condition of payment for certain Medical Assistance Program goods or services as set forth in the regulations of the department governing specific provider types and specialties. The department shall not make payment for such goods and services when such authorization is not obtained by the provider of the goods or services. [Conn. State Agencies Regs. § 17b-262-528(a)]
- 14. The genetic sequence analysis test is medically necessary for the Appellant. The genetic sequence analysis test is necessary to identify, diagnose and treat the Appellant's medical condition in order to attain or maintain his achievable health and independent functioning. Peer reviewed medical literature cited by the MCMC oncologist states enrollment in clinical trials should be encouraged. The genetic sequence analysis identify genetic mutations associated chondrosarcoma and/or other cancers which will guide the treating oncologists in the course of treatment prescribed as outlined by both the YMCC oncologist and SFHMC oncologist letters of medical necessity. As outlined in the YMCC oncologist letter of medical necessity, patients with advanced chondrosarcomas are routinely tested for genetic sequencing. Test results can offer additional treatment options which are not available without genetic sequencing test results, such as FDA approved pembrolizumab, or entrectenib and larotrectenib for NTRK fusion abnormalities, or vismodegib for Notch and Hedgehog pathway mutations. The SFHMC oncologist notes, standard treatment options are very limited. Medical evidence provided outlines the treatment the Appellant has received since diagnosis; surgery and two separate chemotherapy trials resulting in the recurrent tumor(s) and tumor growth. In addition to medically necessary regulations, CHNCT cites HUSKY Health Provider Policy and Procedures document titled Genetic Cancer Susceptibility Panels Using Next Generation Sequencing as a basis for denial. Although the genetic sequencing analysis test is cited as a test under this document, the document refers to "genetic testing for cancer susceptibility may be performed using a focused method of testing for wellcharacterized mutations based on a clinical suspicion of which gene(s) may be the cause of a familial cancer. Cancer susceptibility mutation panels may test for multiple mutations associated with a specific type of cancer or may include mutations associated with a wide variety of

cancers. The mutations tested for in these panels are associated with varying degrees of risk of developing cancer and only some of the mutations included on such panels are associated with a high risk of developing a well-defined cancer syndrome for which there are established clinical management guidelines." The prior authorization request for genetic sequence analysis test is requested to review treatment options for the Appellant's chondrosarcoma; it has not been requested to review the Appellant's risk of developing a familial cancer as outlined under this document.

15. CHNCT was incorrect to deny the prior authorization request because the genetic sequence analysis test meets the medical necessity criteria in accordance with state statutes and regulations.

DECISION

The Appellant's appeal is **GRANTED**.

ORDER

1.	CHNCT must rescind the denial of the authorization request for the (genetic sequence analysis test).
2.	CHNCT must approve the 2017 prior authorization request for the genetic sequence analysis test.
3.	Compliance is due, 2018.
	LisaA.Nysen Lisa A. Nyren Fair Hearing Officer

CC: Robin Goss, R.N., B.S.N., appeals@chnct.org
Fatmata Williams, Department of Social Services

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 what 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 Administrative Hearings and Appeals, 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 the Commissioner's 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.