PROVIDER POLICIES & PROCEDURES

GENETIC TESTING

The purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for genetic testing. By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

Genetic testing provides information that can be used to diagnose genetic diseases and susceptibility to diseases or conditions that are inherited. Such testing includes studying chromosomes to the level of individual genes, biochemical testing for the possible presence of genetic diseases, and identifying mutant forms of genes associated with increased risk of developing genetic disorders. The results of a genetic test can be used to confirm or rule out a genetic condition or to help determine an individual's chance of developing a genetic condition or passing on a genetic disorder. Results can provide individuals and families with the information necessary to make fully informed health-care decisions and are often used to influence choices about health care and management of an identified genetic disorder or susceptibility to one.

HUSKY Health uses McKesson's InterQual® Molecular Diagnostics Criteria when reviewing prior authorization requests for coverage of most genetic tests. HUSKY Health will use this policy to review requests for genetic tests for which InterQual® Molecular Diagnostics Criteria are not available.

CLINICAL GUIDELINE

Coverage guidelines for genetic testing are made in accordance with the DSS definition of Medical Necessity. The following criteria are guidelines *only*. Coverage determinations are based on an individual assessment of the member and their unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

Genetic Testing

Genetic testing is typically considered medically necessary when:

1. The member falls within a high-risk group for a particular disease based on personal history, family history, documentation of a genetic mutation, and/or ethnic background; AND
2. The test is ordered by a physician, advanced practice registered nurse (APRN) or certified nurse midwife (CNM) with expertise in clinical genetics or in the treatment of the targeted disease; AND
3. Genetic counseling has been performed prior to testing; AND
4. Genetic counseling will be performed post-testing; AND
5. A specific mutation or set of mutations has been identified and broadly accepted by credible medical societies to be reliably associated with the condition (i.e., the genotypes to be detected by a genetic test must be shown by scientifically valid methods to be associated with the occurrence of a specific disease, and the observations must be independently replicated and subject to peer review); AND
6. The genetic disorder cannot be diagnosed or ruled out through means other than genetic testing,

including but not limited to: clinical examination, imaging, other laboratory testing or other testing; AND

7. Patient history, physical examination and other diagnostic testing do not result in a definitive diagnosis of the suspected disorder; AND
8. The clinical utility of the requested test has been established. There is reliable evidence in the peer-reviewed scientific literature that the results of the genetic test are likely to materially impact the medical management of the member or current offspring or potential future offspring, with resulting improvement in health outcomes. That is, performing the genetic test has a reasonable likelihood of resulting in improved clinical outcomes as compared with ordinary care without the test, due to any of the following: improving or altering decision-making, preventing unnecessary diagnostic tests, altering therapy, etc.; AND
9. The individual has not previously received genetic testing for the disease/condition. (In general, diagnostic genetic testing for a disease should be performed once in a lifetime.) Exceptions include clinical scenarios whereby:
    a. Repeat testing of somatically-acquired mutations (for example, pre- and post- therapy) may be required to inform appropriate therapeutic decision-making; and
    b. Repeat testing may be necessary when a test has been updated and will provide new information related to the disease/condition that was not included in the previous test. This must be clearly outlined in the documentation submitted by the ordering provider.

Genetic Testing Panels

Genetic testing panels are typically considered investigational based on a lack of evidence supporting the clinical validity and clinical utility of these tests and are therefore not medically necessary but may be considered medically necessary when the following criteria are met:

1. Criteria 1-9 above are met; AND
2. All components of the genetic testing panel demonstrate clinical utility for the condition being evaluated*; AND
3. All components of the panel offer significant advantages in efficiency compared to sequential analysis of individual genes; AND
4. The provider has had a discussion with the patient regarding the scope of the genetic testing panel being ordered and the impact of variants of unknown significance.

*The ordering provider must validate the clinical utility by considering all of the following:

- Will the panel testing offer significant advantages compared to sequential analysis of individual genes (i.e., a genetic testing panel that addresses the disorder in question, rather than the disorder in question plus other disorders)?
- How will the panel testing results be used in patient care decision making?
- Will the ancillary findings lead to further testing or management changes?
- Is there reliable evidence in the peer-reviewed scientific literature that health outcomes will be improved as a result of treatment decisions based on molecular genetic testing findings?

Note: If a genetic testing panel was previously performed for medically necessary indications and a larger panel is developed and requested, only the testing for previously untested genes will be considered medically necessary if the above criteria are met.

Whole Exome and Whole Genome Sequencing

Reference: HUSKY Health Provider Policy Whole Exome and Whole Genome Sequencing

Non-Covered

The following are typically not covered but may be covered based on an assessment of the individual and their unique clinical needs:

- Genetic tests whose clinical utility has not been established
- Testing for the purposes of confirming a suspected diagnosis of a disorder that can be diagnosed based on clinical evaluation alone
- Testing for conditions which cannot be altered by treatment or prevented by specific interventions
- Testing solely for the purpose of informing the care or management of the individual's family member
- For testing panels, including but not limited to, multiple genes or multiple conditions, and in cases where a tiered approach/method is clinically available, testing will be covered only for the number of genes or tests deemed medically necessary to establish a diagnosis

NOTE: EPSDT Special Provision
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE
Prior authorization is required for genetic testing with the exception of those tests used for cystic fibrosis screening during pregnancy*****.

Requests for coverage of genetic testing will be reviewed in accordance with procedures in place for reviewing requests for genetic testing. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

*****Cystic fibrosis transmembrane conductance regulator (CFTR) gene analysis:
Prior authorization will NOT be required for cystic fibrosis testing (CPT codes 81220-81224) occurring during the prenatal period when billed with one of the pregnancy diagnosis codes listed in Table 11 of the Connecticut Department of Social Services Fee Schedule Instructions located at www.ctdssmap.com → Provider → Provider Fee Schedule Download → Fee Schedule Instructions → Table 11.

The following information is needed to review requests for genetic testing:

- Fully completed Genetic Testing Prior Authorization Form or fully completed Fetal Aneuploidy Testing Prior Authorization Form
  Note: The prior authorization form is considered a certificate of medical necessity. The form should not be submitted unless it has been fully completed and signed by the ordering physician.
- Documentation describing:
  - Why the individual was referred for this specific test (documentation must identify the algorithm/evidence-based clinical guidelines that were used to aid in decision making e.g., NCCN Guidelines®)
  - A statement listing all other examinations, laboratory tests, imaging and diagnostic studies that have been completed as part of the evaluation of the individual's clinical scenario
  - How the results of genetic testing will have a material impact on the plan of care and improve health outcomes for the individual (i.e., whether to perform surgery, determine chemotherapy treatment, etc.)

- Medical records relevant to the testing being performed to include:
  - A comprehensive history and physical examination by the referring physician
  - Results of all lab tests/imaging/diagnostic studies pertinent to the requested genetic test
  - Family history, if applicable
  - Conservative treatment provided, if applicable
- Test information:
  - The specific name of the test/panel
  - Name of performing CLIA-accredited laboratory
  - The exact gene(s) and/or mutations being tested
- Other information as requested by CHNCT.

EFFECTIVE DATE
This Policy is effective for prior authorization requests for genetic testing for individuals covered under the HUSKY Health Program on or after November 1, 2018.

LIMITATIONS
Not Applicable

CODES:
A complete listing of molecular pathology and molecular diagnostic procedures requiring prior authorization may be found on the "Lab Fee Schedule" located on the DSS Connecticut Medical Assistance (CMAP) website www.ctdssmap.com, under "Provider Fee Schedule Download".

DEFINITIONS
1. **HUSKY A**: Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
2. **HUSKY B**: Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
3. **HUSKY C**: Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D**: Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
6. **HUSKY Limited Benefit Program or HUSKY, LBP**: Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
7. **HUSKY Plus Physical Program (or HUSKY Plus Program):** A supplemental physical health program pursuant to Conn. Gen. Stat. § 17b-294, for medically eligible members of HUSKY B in Income Bands 1 and 2, whose intensive physical health needs cannot be accommodated within the HUSKY Plan, Part B.

8. **Medically Necessary or Medical Necessity**: (as defined in Connecticut General Statutes § 17b-259b) 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.
9. **Prior authorization**: A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

ADDITIONAL RESOURCES AND REFERENCES:

- American College of Medical Genetics (ACMG) www.acmg.net
- American College of Obstetricians and Gynecologists Committee on Genetics. ACOG Committee Opinion No. 442: Preconception and prenatal carrier screening for genetic diseases in individuals of Eastern European Jewish descent. Obstet Gyecol. 2009; 114(4):950-953.
- American Medical Association, Current Procedural Terminology Manual: 2018
- Centers for Medicare and Medicaid Services. LCD for Molecular Pathology Procedures (L35000). Medicare Coverage Database. Retrieved on August 2, 2018 at: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35000
- Choosing Wisely®, an initiative of the American Board of Internal Medicine (AIBM) Foundation. Five things physicians and patients should question. The American College of Medical Genetics and Genomics. July 10, 2015. Accessed on August 2, 2018 at: http://www.choosingwisely.org/societies/american-college-of-medical-genetics-and-genomics/
- Miller CE, Krautscheid P, Baldwin EE, Tvrdik T, Openshaw AS, Hart K, Lagrave D. Genetic counselor review of genetic test orders in a reference laboratory reduces unnecessary testing. Am J Med Genet A. 2014 May; 164A (5):1094-101.
- Need AC, Shashi V, Hitomi Y, et al. Clinical application of exome sequencing in undiagnosed genetic conditions. *J Med Genet* 2012;49:353–361.
- Shashi V, McConkie-Rosell A, Rosell B, Schoch K, Vellore K, McDonald M, Jiang YH, Xie P, Need A, Goldstein DB. The utility of the traditional medical genetics diagnostic evaluation in the context of next-generation sequencing for undiagnosed genetic disorders. Genet Med. 2014 Feb; 16(2):176-82.
- U.S. National Library of Medicine. What are the types of genetic tests? Genetics Home Reference. Retrieved on August 2, 2018 from: https://ghr.nlm.nih.gov/primer/testing/uses
- U.S. Preventive Services Task Force www.uspreventiveservicestaskforce.org

PUBLICATION HISTORY

Status	Date	Action Taken

Original publication		Approved by the CHNCT Medical Policy Review Committee on September 12, 2018. Approved by the CHNCT Clinical Quality Subcommittee on September 17, 2018. Approved by DSS on September 19, 2018.
Update	December 2018	Updated Clinical Guideline section to clarify that genetic counseling must be performed pre- and post-testing. Added Fetal Aneuploidy Testing Prior Authorization Form to Procedure section. Changes approved at the December 12, 2018 Medical Reviewer meeting. Changes approved by the CHNCT Clinical Quality Subcommittee on March 18, 2019. Approved by DSS on March 27, 2019.
Update	June 2019	Update to the *Clinical Guideline* section. Changed requirements for ordering provider to "The test is ordered by a physician, advanced practice registered nurse (APRN) or certified nurse Midwife (CNM) with expertise in clinical genetics or In the treatment of the targeted disease". Added "Repeat testing may be necessary when a test has been updated and will provide new information related to the disease/condition that was not included in the previous test. This must be clearly outlined in the documentation submitted by the ordering provider." Update to the *Procedure* section. Added to the section outlining documentation required for review: "Documentation describing why the individual was referred for test including algorithm/evidence-based clinical guidelines used to aid decision making, information on examinations, testing, imaging and other diagnostic studies completed as part of evaluation." Reworded third bullet to state "How the results of genetic testing will have a material impact on the plan of care and improve the health outcomes of the individual." Added need for "Results of all lab tests and diagnostic studies pertinent to the requested genetic test" under "Medical records relevant to the testing performed" Changes approved at the June 12, 2019 Medical Reviewer meeting.

		Changes approved by the CHNCT Clinical Quality Subcommittee on June 19, 2019. Approved by DSS on June 21, 2019.

Please note that authorization is based on medical necessity at the time the authorization is issued and is not a guarantee of payment. Payment is based on the individual having active coverage, benefits and policies in effect at the time of service.

To determine if a service or procedure requires prior authorization, CMAP Providers may refer to the *Benefit and Authorization Grids* summaries on www.ct.gov/hh by clicking on "For Providers" and selecting "Benefit Grids" from the 'Medical Management" sub-menu. For a definitive list of benefits and service limitations, CMAP Providers may access the CMAP provider fee schedules and regulations at www.ctdssmap.com.