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 primarily uses 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, and/or documentation of a genetic mutation; AND
2. The test is ordered by:
    a. A board-certified medical geneticist or other board-certified physician with specific expertise in clinical genetics who is not employed or contracted with a commercial genetic testing laboratory; OR
    b. A physician, APRN, PA, or CNM with expertise in 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 clinical utility of the requested test has been established. There is sufficient 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
7. The individual has not previously had 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 repeat testing of somatically acquired mutations (for example, pre- and post- therapy) may be required to inform appropriate therapeutic decision-making.

Note: genetic testing is considered medically necessary as diagnostic confirmation for Infants with a positive newborn genetic screening.

Genetic Testing Panels

Genetic testing panels are considered medically necessary when the following criteria are met:

1. Criteria 1-7 above are met; AND
2. All components of the genetic testing panel demonstrate clinical utility for the condition being evaluated*; AND
3. 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:

- How will the genetic panel testing results be used in patient care decision making?
- Will the genetic testing panel results lead to further testing or management changes?
- Is there reliable evidence in the peer-reviewed scientific literature that health outcomes will be improved based on the genetic testing panel results?

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 Mitochondrial Genome Sequencing (81460 and 81465)

Whole mitochondrial genome sequencing (WmGS) is typically considered investigational and therefore not medically necessary; however, WmGS may be considered medically necessary in select instances and will be reviewed on a case-by-case basis.

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 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* (CPT codes 81220-81224), spinal muscular atrophy gene analysis** (CPT code 81329), and fetal aneuploidy screening (CPT codes 81420 and 81507) during pregnancy.**

*****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.

**Spinal muscular atrophy gene analysis:
Prior authorization will NOT be required for spinal muscular atrophy gene analysis (CPT code 81329) if billed with one of the diagnosis codes listed in Table 11A of the Connecticut Department of Social Services Fee Schedule Instructions located at www.ctdssmap.com → Provider → Provider Fee Schedule Download → Fee Schedule Instructions → Table 11A.

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.

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

- Fully completed Genetic Testing Prior Authorization
  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.
- Explanation of how the results of genetic testing are necessary to guide treatment decisions relevant to the member's personal medical history for positive patient outcome (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 laboratory tests and imaging studies
  - A three-generation pedigree
  - 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. **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.

8. **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: 2021
- 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.
- 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
- UpToDate. Intellectual Disability in Children: Evaluation for a Cause. Penelope Pivalizza M.D., Seema R. Lalani M.D. Topic last updated Jan 10, 2023.
- Parikh S, Goldstein A, Koenig MK, et al. Diagnosis and management of mitochondrial disease: a consensus statement from the Mitochondrial Medicine Society. *Genet Med*. 2015;17(9):689-701. doi:10.1038/gim.2014.177
- UpToDate. Next-generation DNA Sequencing (NGS): Principles and clinical applications. Peter J. Hulick, M.D. Topic last updated October 25, 2024.

PUBLICATION HISTORY

Status	Date	Action Taken
Original publication	September 2018	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	March 2019	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 2020	Removed "McKesson" before "InterQual". Moved language regarding InterQual criteria to first paragraph. Added APRNs and CNMs to list of providers that can order genetic testing. Changes approved at the May 13, 2020 Medical Reviewer meeting. Changes approved by the CHNCT Clinical Quality Subcommittee on June 15, 2020. Approved by DSS on June 19, 2020.
Update	September 2020	Update to policy as prior authorization no longer needed for fetal aneuploidy testing. Change approved at the September 9, 2020 MD Reviewer Meeting. Change approved by the CHNCT Clinical Quality Subcommittee on September 21, 2020. Approved by DSS on October 7, 2020.
Update	September 2021	Added language stating that testing for SMA no longer requires prior authorization. Change approved at the August 11, 2021 CHNCT Medical Reviewer meeting. Change approved by the CHNCT Clinical Quality Subcommittee on September 20, 2021. Change approved by DSS on September 30, 2021.
Review	September 2022	Reviewed and approved without changes at the July 13, 2022 CHNCT Medical Reviewer meeting. Reviewed and approved without changes by the CHNCT Clinical Quality Subcommittee on September 19, 2022. Approved by DSS on September 28, 2022.
Update	September 2023	Update to Clinical Guideline section: removed "ethnic background" from criteria point #1, removed "in treatment of" and "for molecular diagnostic testing only" from criteria point #2b, made note that "genetic testing is considered medically necessary as diagnostic confirmation for Infants with a positive newborn genetic screening", removed criteria point #3 from the genetic testing panels section "criteria related to all components of panel must have significant advantages over sequential testing of individual genes", updated section on considerations for clinical utility of panel testing, removed the following from list of non-

		covered services: testing for conditions which cannot be altered by treatment or prevented by specific interventions. Changes approved at the July 12, 2023, CHNCT Medical Reviewer meeting. Changes approved by the CHNCT Clinical Quality Subcommittee on September 18, 2023. Approved by DSS on October 2, 2023.
Update	November 2023	Update to Clinical Guidelines section to remove policy reference for Whole Exome Sequencing and Whole Genome Sequencing and to include Whole Mitochondrial Genome Sequencing criteria. Additional Resources and Reference section updated to include references for Whole Mitochondrial Genome Sequencing. Changes approved at the December 13, 2023 CHNCT Medical Reviewer meeting. Changes approved by the CHNCT Clinical Quality Subcommittee on December 18, 2023. Approved by DSS on January 03, 2024.
Updated	December 2024	Clinical Guideline updated to remove clinical requirements no longer used to determine medical necessity in current practice. Non-covered testing also updated to reflect current practice. Additional Resources and References updated to reflect new references. Changes approved at the December 11, 2024 CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on December 16, 2024. Approved by DSS on December 27, 2024.