**Letter of Medical Necessity for Chromosomal Microarray**

**Patient Information**

**Date:**

**Patient Name:**

**Patient DOB:**

**Insurance Company Name, Address, City, State:**

**Policy Number:**

**Group Number:**

**ICD10 Codes:**

**Test Information**

**Test Name:** Chromosomal Microarray

**CPT Codes:** 81229x1

**Laboratory:**

GeneDx, Inc.

(NPI#1487632998 / TAXID#205446298 / CLIA#21D0969951)

207 Perry Parkway

Gaithersburg, MD 20877

Telephone: (301) 519-2100

Fax: (201) 421-2010

This letter is in regards to my patient, [FIRST NAME LAST NAME], to request full coverage for the Chromosomal microarray test to be performed by GeneDx. It is my professional determination that testing is medically necessary and will have a direct impact on this patient’s treatment and management.

**Patient Clinical and Family History**

This testing is requested due to this patient’s personal medical history, which includes the following clinical findings:

* Add Phenotype
* Add Phenotype
* Add Phenotype

The patient’s family history is negative for related conditions / unknown / remarkable for the following related clinical features:

The patient has previously had the following uninformative genetic and other testing:

* Add test
* Add test
* Add test

**Clinical Evidence and Guidelines for Testing**

Chromosomal abnormalities are a common cause of developmental delay, intellectual disability, autism spectrum disorders (ASDs), seizures, and birth defects.1,2,3 In particular, small chromosomal microdeletions and microduplications, collectively referred to as copy number variants (CNVs), account for a significant proportion of pathogenic chromosomal abnormalities. Many CNVs are too small to be detected by conventional cytogenetic testing and require other detection methods such as microarray.

Evidence based medical literature and national standards support the use of this testing. The American College of Medical Genetics (ACMG), American Academy of Pediatrics (AAP), and the American Academy of Neurology (AAN) all support chromosomal microarray analysis as first-tier diagnostic testing for individuals with developmental delay or intellectual disability, autism spectrum disorders, birth defects, and/or dysmorphic features.1,2,4,5

Whole genome chromosomal microarray analysis is currently the most comprehensive and cost-effective method for detection of CNVs and provides much greater resolution than conventional cytogenetics.1,2,4 The clinical sensitivity of chromosomal microarray testing ranges from 8-20% for individuals with developmental delay/intellectual disability, ASDs, and/or multiple congenital anomalies, compared to ~3% for G-banded karyotyping to evaluate for large chromosome aberrations.1,4

**Patient Clinical Utility and Medical Management Implications**

The test results will guide and tailor appropriate medical management and treatment for this patient, which would not be possible without this testing. The results of chromosomal microarray analysis have been shown to significantly impact medical management.1,2 Identification of a definitive genetic diagnosis enables health care providers to identify associated medical risks that may require intervention or ongoing management and to select appropriate therapeutic interventions.1 Confirmation of the diagnosis also prevents additional, unnecessary diagnostic testing and provides information about future prognosis and recurrence risk. 1,2

Specifically for this patient, the results of chromosomal microarray will {ADD ADDITIONAL INFORMATION}

**Summary**

The Chromosomal Microarray at GeneDx is a highly sensitive and cost-effective genetic test. I am requesting coverage for this medically necessary test in order to establish appropriate medical management for this patient. Without testing, treatment would be suboptimal, subjecting this patient to increased morbidity and potentially early mortality.

Thank you for your review and consideration. If you have questions, or if I can be of further assistance, please do not hesitate to call me at (XXX) XXX-XXXX.

Sincerely,

Signature

Ordering Provider’s Name

1. Schaefer et al. (2013) Professional Practice and Guidelines Committee. Clinical genetics evaluation in identifying the etiology of autism spectrum disorders: 2013 guideline revisions. Genetics In Medicine: Official Journal Of The American College Of Medical Genetics 15 (5):399-407 (PMID: 23519317)
2. Ellison et al. (2012) Clinical utility of chromosomal microarray analysis. *Pediatrics* 130 (5):e1085-95 (PMID: 23071206)
3. Olson et al. (2014) Copy number variation plays an important role in clinical epilepsy. *Ann. Neurol.* 75 (6):943-58 (PMID: 24811917)
4. Miller et al. (2010) Consensus statement: chromosomal microarray is a first-tier clinical diagnostic test for individuals with developmental disabilities or congenital anomalies. *American Journal Of Human Genetics* 86 (5):749-64 (PMID: 20466091)
5. Michelson et al. (2011) Evidence report: Genetic and metabolic testing on children with global developmental delay: report of the Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. *Neurology* 77 (17):1629-35 (PMID: 21956720)