**Letter of Medical Necessity for Autism/Intellectual Disability (ID) Xpanded Panel**

**Patient Information**

**Date:**

**Patient Name:**

**Patient DOB:**

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

**Policy Number:**

**Group Number:**

**ICD10 Codes:**

**Test Information**

**Test Name:** Autism/Intellectual Disability (ID) Xpanded Panel

**CPT Codes:** 81470x1, 81471x1

**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 Autism/Intellectual Disability (ID) Xpanded Panel 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**

Neurodevelopmental disorders (NDDs) including autism, intellectual disability (ID), and global developmental delay affect more than 3% of children.1,2 Over half of children with autism also have ID. Many individuals with ASD and/or ID are diagnosed with global developmental delay in early childhood.3 NDDs are clinically and genetically heterogeneous, and pathogenic variants in many different genes can cause nearly identical clinical presentations. Therefore, it is typically necessary to perform testing of multiple genes to identify the underlying genetic cause in an individual with ASD and/or ID. New genes known to cause NDD are being discovered regularly, making it challenging for clinical laboratories to keep traditional testing panels updated.4,5 Additionally, interpretation of the clinical significance of variants in these newly discovered genes is often difficult in the absence of parental testing to clarify which variants are de novo or inherited.

To address the challenges with traditional genetic testing approaches for NDDs, the Autism/ID Xpanded Panel uses a trio approach that includes concurrent analysis of the affected proband and both parents, which increases the likelihood of identifying a definitive genetic explanation for ASD and/or ID. The Autism/ID Xpanded Panel includes targeted analysis of a list of approximately 2300 genes currently associated with ASD, ID, and global developmental delay. The design of the panel allows for a comprehensive, dynamic gene list that is updated regularly to ensure inclusion of genes recently associated with these phenotypes. The yield is higher with a trio approach compared to the proband-only testing approach that is commonly used for multi-gene testing panels.6

**Patient Clinical Utility and Medical Management Implications**

Knowledge of the specific genetic etiology can provide important information about the risk for associated medical and psychiatric problems and provide important information to guide medical management.7-11 NDDs may be isolated or may occur in individuals who have a syndromic clinical presentation that also includes birth defects, dysmorphic features, and/or an increased risk for other associated health problems, such as seizures, psychiatric disorders, and vision or hearing problems. Additionally, in some cases, knowledge of the specific genetic etiology may enable initiation of an effective treatment or may assist in the decision to discontinue a treatment that ineffective or harmful.7,9,11 Knowledge of the specific genetic cause of NDDs has been shown to lead to direct changes in medical management in approximately half of individuals who received a genetic diagnosis, including changes to medications, dietary treatments, surgical interventions, surveillance regimens, or preventative measures.7,10

Specifically for this patient, the results of this test will also {ADD ADDITIONAL INFORMATION}

**Summary**

The Autism/Intellectual Disability (ID) Xpanded Panel 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

References:

1. CDC (Centers for Disease Control and Prevention) (2014) Morbidity and Mortality Weekly Report 63(SS02) 1-21; [www.cdc.gov/mmwr](http://www.cdc.gov/mmwr)
2. Mefford H et al. Genomics, Intellectual Disability, and Autism NEJM 2012 366(8): 733-743.
3. Moeschler et al. Comprehensive evaluation the child with intellectual disability or global developmental delay. Pediatrics 2014 134(3): e903-e918.
4. Fitzgerald et al. Large-scale discovery of novel genetic causes of developmental disorders. Nature 2015 519 (7542):223-8.
5. Vissers LE et al. Genetic studies in intellectual disability and related disorders. Nat Rev Genet 2016 17(1): 9-18.
6. Retterer K et al. Clinical application of whole-exome sequencing across clinical indications. Genet Med*.* 2016 18(7):696-704.
7. Thevenon J et al. Diagnostic odyssey in severe neurodevelopmental disorders: toward clinical whole exome sequencing as a first-line diagnostic test. Clin Genet2016 89:700–707
8. Soden SE et al. Effectiveness of exome and genome sequencing guided by acuity of illness for diagnosis of

neurodevelopmental disorders. Sci Transl Med. 2014 3;6(265):265.

1. Iglesias A et al. The usefulness of whole-exome sequencing in routine clinical practice. Genet Med. 2014 16(12):922-31
2. Srivastava S et al. Clinical whole exome sequencing in child neurology practice. Ann Neurol 2015 77(3):553.
3. Schaefer et al. 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 2013 15 (5):399-407.