**LETTER OF MEDICAL NECESSITY**

**FRAGILE X DNA ANALYSIS (*FMR1*)**

Date: Date of service/claim

To: Utilization Review Department

Insurance Company Name, Address, City, State

Re: Patient Name, DOB, ID #

ICD-10 Codes:

The ICD-10 codes listed below are commonly received by Ambry from ordering providers for the testing described in this letter. Ambry provides this information as a customer service but makes no recommendations regarding the use of any diagnosis codes. As a reminder, it is the ordering provider’s responsibility to always determine, for the specific date of service, the appropriate diagnostic codes based on the patient’s signs and symptoms.

Code Description

F84.0 AUTISTIC DISORDER

F80.9 DEVELOPMENTAL DISORDER OF SPEECH AND LANGUAGE, UNSPECIFIED

R62.50 UNSPECIFIED LACK OF EXPECTED NORMAL PHYSIOLOGICAL DEVELOPMENT IN CHILDHOOD

F82 SPECIFIC DEVELOPMENTAL DISORDER OF MOTOR FUNCTION

Z84.81 FAMILY HISTORY OF CARRIER OF GENETIC DISEASE

This letter is regarding my patient and your subscriber, referenced above, to request full coverage of medically indicated fragile X DNA analysis (*FMR1*) to be performed by Ambry Genetics Corporation.

*FMR1* disorders include fragile X syndrome (FXS), fragile X-associated tremor/ataxia syndrome (FXTAS), and fragile X-associated primary ovarian insufficiency (FXPOI). Fragile X syndrome (FXS), which is caused by a mutation in the *FMR1* gene, is the most common form of inherited intellectual disability and affects approximately 1 in 3,600 males and 1 in 4,000 females.1 Individuals with FXS may have autistic features, behavioral manifestations, connective tissue anomalies, developmental delay, dysmorphic facial features, intellectual disability, macroorchidism and/or seizures. In addition, individuals who carry an *FMR1* premutation are at risk for fragile X-associated tremor/ataxia syndrome (FXTAS), and women with a premutation are also at risk for fragile X-associated premature ovarian insufficiency (FXPOI).2

**Significant aspects of my patient’s personal and/or family medical history that suggest a reasonable probability of an *FMR1* disorder, are outlined below: [Check all that apply]**

* Autism spectrum disorder
* Unexplained developmental delay/intellectual disability
* Primary ovarian insufficiency/premature ovarian failure
* Progressive cerebellar ataxia and intention tremor in individuals over age 50
* A relative with any form of *FMR1* disorder

**According to American College of Medical Genetics (ACMG) and American College of Obstetrics and Gynecology (ACOG) recommendations, fragile X DNA analysis is warranted.**2-5

***FMR1* genetic testing will directly impact my patient’s care and management**. A positive genetic test result can:

* Aid in diagnosis and tailor medical treatment for those with FXS, FXTAS, and FXPOI
* Allow my patient to participate in clinical trials for medications or other treatments aimed at reducing the cognitive and social deficits in those with FXS
* Help clarify/inform reproductive decision making for at-risk family members (including prenatal genetic testing)

**As such, I am ordering this testing as medically necessary and affirm that my patient has provided informed consent for genetic testing.** I request that you approve coverage of fragile X DNA analysis (*FMR1*) in my patient.

Thank you for your time and please don’t hesitate to contact me with any questions.

Sincerely,

Ordering Clinician Name (Signature Provided on Test Requisition Form)

(MD/DO, Clinical Nurse Specialist, Nurse-Midwives, Nurse Practitioner, Physician Assistant, Genetic Counselor\*)

\*Authorized clinician requirements vary by state

**Test Details**

CPT codes: 81243

Laboratory: Ambry Genetics Corporation (TIN 33-0892453 / NPI 1861568784), a CAP-accredited and CLIA-certified laboratory located at 1 Enterprise, Aliso Viejo, CA 92656

**References**

1. Seltzer M, *et al*. Prevalence of CGG expansions of the *FMR1* gene in a US population-based sample. Am J Med Genet B Neuropsychiatr Genet. 2012 Jul;159B(5):589-97.
2. Sherman S, Pletcher BA, Driscoll DA. ACMG Practice Guideline. Fragile X syndrome: diagnostic and carrier testing. Genet Med. 2005;7(8):584–7.
3. American Congress (formerly College) of Obstetricians and Gynecologists Committee on Genetics. ACOG Committee Opinion No. 469: Carrier screening for fragile X syndrome. Obstet Gynecol. 2010 Oct;116(4):1008–10.
4. American College of Obstetricians and Gynecologists Committee on Genetics. ACOG Committee Opinion No. 691: Carrier screening for genetic conditions. Obstet Gynecol. 2017;129:e41-55.
5. Hersh JH, Saul RA; Committee on Genetics. Health supervision for children with fragile X syndrome. Pediatrics. 2011 May;127(5):994-100.