

Medical Necessity Guideline: Genetic Testing for Suspected Disability	Creation Date: 05/16/2023	Review Date: 08/07/2024	Effective Date: 08/19/2024
---	-------------------------------------	-----------------------------------	--------------------------------------

PURPOSE:

To detail the authorization requirements for genetic testing in any member who has, or is suspected of having:

- A genetic disorder
- A congenital anomaly
- Developmental delay
- An intellectual disability

DEFINITIONS: (underline and list in alphabetic order)

Allowed Practitioner: a Texas Medicaid enrolled physician, a physician assistant, or an advanced practice registered nurse who is licensed as a certified nurse practitioner (CNP) or clinical nurse specialist (CNS) also enrolled in Texas Medicaid.

Chromosomal microarray analysis (CMA): A cytogenetic test used to determine if there are chromosomal imbalances, either large (e.g., whole extra or missing chromosomes, also detected by standard karyotype) or smaller extra (micro-duplication) or missing (micro-deletion) pieces of genetic information, also called copy number variants (CNV).

Congenital anomaly (CA): Structural or functional anomalies that occur during intrauterine life. Also called birth defects, congenital disorders, or congenital malformations, these conditions develop prenatally and may be identified before or at birth, or later in life.

Developmental Disability (DD): A group of conditions due to an impairment in physical, learning, language, or behavior areas. These conditions begin during the developmental period, may impact day-to-day functioning, and usually last throughout a person’s lifetime.

Global Developmental Delay (GDD): A group of conditions due to an impairment in physical, learning, language, or behavior areas that occur in children <5 years of age and are expected to persist throughout the person’s entire lifetime.

Intellectual Disability (ID): A term used when there are limits to a person’s ability to learn at an expected level and function in daily life. Levels of intellectual disability vary greatly in children.

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

Non-syndromic genetic disorder: Not a part of a syndrome (e.g., lacking signs, symptoms, and clinicopathological characteristics of a known syndrome); such as hearing loss can be a part of a syndrome, or it may occur without other known syndromic features; the same can be true for individuals with intellectual disabilities (IDD).

Syndromic genetic disorder: A group of signs, symptoms, and clinicopathological characteristics that may or may not have a genetic basis and collectively define an abnormal condition.

Whole exome sequencing (WES): A laboratory method that is used to learn the exact order of all the building blocks that make up the pieces of a person's DNA that contain information for making proteins. These pieces, called exons, are thought to make up about 1% of a person's genome (complete set of DNA). Whole exome sequencing is used to find mutations (changes) in genes that may cause diseases, such as cancer. Also called WXS.

Whole genome sequencing (WGS): A laboratory process that is used to determine nearly all the approximately 3 billion nucleotides of an individual's complete DNA sequence, including the non-coding sequence.

GUIDELINE:

In general, genetic testing is considered medically necessary only:

1. When the results of testing would confirm or establish a clinical diagnosis that may lead to changes in management; and
2. After genetic counseling, which encompasses all the following components, has been performed and enumerated in detail in the clinical record:
 - a. Interpretation of family and medical histories to assess the probability of disease occurrence or recurrence; and
 - b. Education about inheritance, genetic testing, disease management, prevention, and resources; and
 - c. Counseling to promote informed choices and adaptation to the risk or presence of a genetic condition; and
 - d. Counseling for the psychological aspects of genetic testing ¹

Chromosomal microarray analysis (CMA) is considered medically necessary as a first-line test in the initial evaluation of individuals with the following:

- A. Multiple anomalies not specific to a well-delineated genetic syndrome; or
- B. Apparently, non-syndromic GDD/intellectual or developmental disability (IDD); or

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

- C. Autism spectrum disorders (ASD) as established by the Diagnostic Criteria from the DSM V (see the Background below for further details on establishing the diagnosis of ASD).

Whole exome sequencing (WES) is considered medically necessary as a second-tier test in the evaluation of an individual who meets both of the following criteria:

1. Multiple anomalies not specific to a well-delineated genetic syndrome apparent before 1 year of age; or
2. Apparently non-syndromic GDD/IDD with onset prior to 18 years of age.

Documentation Requirements:

1. Documentation that the member meets DSM V criteria for ASD (see the Background below for further details on establishing the diagnosis of ASD). This diagnosis must be performed by an appropriate specialist with appropriate documentation of tests performed. These are typically done by specialists (e.g., neurodevelopmental pediatricians, developmental-behavioral pediatricians, child neurologists, geneticists, and early intervention programs that provide assessment services).

Selected examples of specific diagnostic tools are:

- Autism Diagnosis Interview-Revised (ADI-R)
 - Autism Diagnostic Observation Schedule – Generic (ADOS-G)
 - Childhood Autism Rating Scale (CARS)
 - Gilliam Autism Rating Scale – Second Edition (GARS-2) ².
2. Documentation that the member, <5 years of age, meets DSM V criteria for Global Developmental Delay (GDD) - delay in two or more developmental domains:
 - a. gross motor/fine motor
 - b. cognitive
 - c. speech/language
 - d. personal/social
 - e. activities of daily living ³ **or**
 3. Documentation that the member meets DSM V criteria for IDD (i.e., intellectual disabilities as neurodevelopmental disorders that begin in childhood and are characterized by intellectual difficulties as well as conceptual, social, and practical areas of living and satisfy the following criteria:
 - a. Deficits in intellectual functioning – reasoning, problem-solving planning, abstract thinking, judgment, academic learning, and learning from experience – confirmed by clinical evaluation and individualized standard IQ testing.

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

- b. Deficits in adaptive functioning that significantly hamper conforming to developmental and sociocultural standards for the individual's independence and ability to meet their social responsibility; and
 - c. The onset of these during childhood ⁴.
4. These assessments are performed by the appropriate specialists (e.g., neurodevelopmental pediatricians, developmental-behavioral pediatricians, child neurologists, geneticists, and early intervention programs that provide assessment services).
5. Any request for genetic testing **must be signed by an allowed provider**.

BACKGROUND:

The Texas Medicaid Provider Procedures manual lays out general guidelines for genetic testing. Diagnostic tests to check for genetic abnormalities must be performed only if the test results will affect treatment decisions or provide prognostic information. Furthermore, any genetic testing and screening procedure must be accompanied by appropriate non-directive counseling, both before and after the procedure. And finally, testing performed on a client to provide genetic information for a family member and testing performed on a non-Medicaid client to provide genetic information for a Medicaid client are not benefits of Texas Medicaid. ¹

Children with neurodevelopmental disorders, including developmental delay, intellectual disability, autism spectrum disorder (ASD), or congenital anomalies, may have genetic abnormalities that traditionally were detected using G-banded karyotype analysis. Karyotyping identifies clinically relevant genetic abnormalities in approximately 5% of children with these disorders. However, Karyotyping has now been replaced by chromosomal microarray analysis (CMA), which detects unbalanced chromosomal rearrangements like G-banded karyotyping but also detects smaller chromosome abnormalities, increasing the diagnostic yield to approximately 20% of patients. Because of its greater sensitivity, CMA tests should now be considered by any clinician evaluating a child with otherwise unexplained developmental delay, intellectual disability, ASD, or congenital anomalies ⁵.

CMA is now the recommended first-line genomic test for children with neurodevelopmental disorders, including ASD, irrespective of having concomitant congenital anomalies. Precise genomic information from CMA testing can detect a genetic cause for a child's clinical presentation and may help tailor further evaluations and target clinical management. For example, those with 22q11.2 deletion syndrome (DiGeorge Syndrome) can exhibit clinical features including developmental or learning disabilities, ASD, conotruncal cardiac anomalies, dysmorphic facial features, palatal defects, hypernasal speech, immunodeficiency, hypocalcemia, and psychiatric illness. Once 22q11.2 deletion is diagnosed, specific medical assessments for children and adults, such as having immunologic evaluations (\leq age 5 years) and monitoring calcium levels throughout the lifespan, have been defined to help manage clinical care. In

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

addition, because patients with 22q11.2 deletions have a 25% to 30% lifetime risk for schizophrenia, specific guidelines exist for monitoring change from baseline symptoms that may suggest a treatable psychiatric illness ⁵.

Congenital anomalies (CA), developmental delay (DD), and intellectual disability (ID) are among the most common indications for genetic referral in the pediatric population and comprise a heterogeneous group of conditions that can impact a child's physical, learning, or behavioral function. Identification of an underlying diagnosis for CA/DD/ID can lead to changes in management that will influence mortality, morbidity and reduce the burden on patients and families searching for answers (sometimes referred to as the "diagnostic odyssey"). As noted above, the current standard of practice, based on recommendations from the American College of Medical Genetics and Genomics (ACMG), is to perform chromosomal microarray (CMA) as the first-tier genetic test for individuals with CA/DD/ID. Diagnostic yield for CMA has typically focused on cohorts of mixed phenotypes of CA/DD/ID, and autism spectrum disorder (ASD). Yields averaged 12.2% in the early literature. More recent studies on cohorts of patients with CA/DD/ID have documented diagnostic yields ranging from 16% to 28%. As a result, CMA is a well-established tool in clinical practice, yet this testing will not capture single nucleotide variations (SNVs) or small insertion/deletions (indels), smaller structural variants, and other pathogenic variant types contributing to CA/DD/ID ⁶.

Whole exome sequencing (WES) is now becoming more widely available. The recommendations to perform CMA as a first-line test for CA/DD/ID occurred prior to this wider availability. Studies using WES have shown that patients with CA/DD/ID may have an even larger diagnostic yield ranging from 28% to 68% than was possible with CMA alone. But the caveat here is that the patients studied with WES were those who had previously been identified to have CA/DD/ID. Currently, WES is considered a second-tier genetic test, and its interpretation is best done by a physician trained in medical genetics ⁶.

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

Further Details on the DSM V Criteria for Autism

ASD is a neurodevelopmental disorder that is characterized by challenges in social communication and interaction and the presence of restrictive, repetitive behaviors, interests, or activities ⁷. There is no single, objective, criterion standard test for ASD, and the diagnosis is based on clinicians' best estimates, often informed by standardized tests.

To meet diagnostic criteria for ASD according to DSM-5, a child **must** have persistent deficits in each of three areas of social communication and interaction (see A.1. through A.3. below) plus at least two of four types of restricted, repetitive behaviors (see B.1. through B.4. below).

- A. Persistent deficits in social communication and social interaction across multiple contexts:
 1. Deficits in social-emotional reciprocity.
 2. Deficits in nonverbal communicative behaviors used for social interaction.
 3. Deficits in developing, maintaining, and understanding relationships.
- B. Restricted, repetitive patterns of behavior, interests, or activities, as manifested by at least two of the following:
 1. Stereotyped or repetitive motor movements, use of objects, or speech.
 2. Insistence on sameness, inflexible adherence to routines, or ritualized patterns of verbal or nonverbal behavior.
 3. Highly restricted, fixated interests that are abnormal in intensity or focus.
 4. Hyper- or hypo-reactivity to sensory input or unusual interest in sensory aspects of the environment.

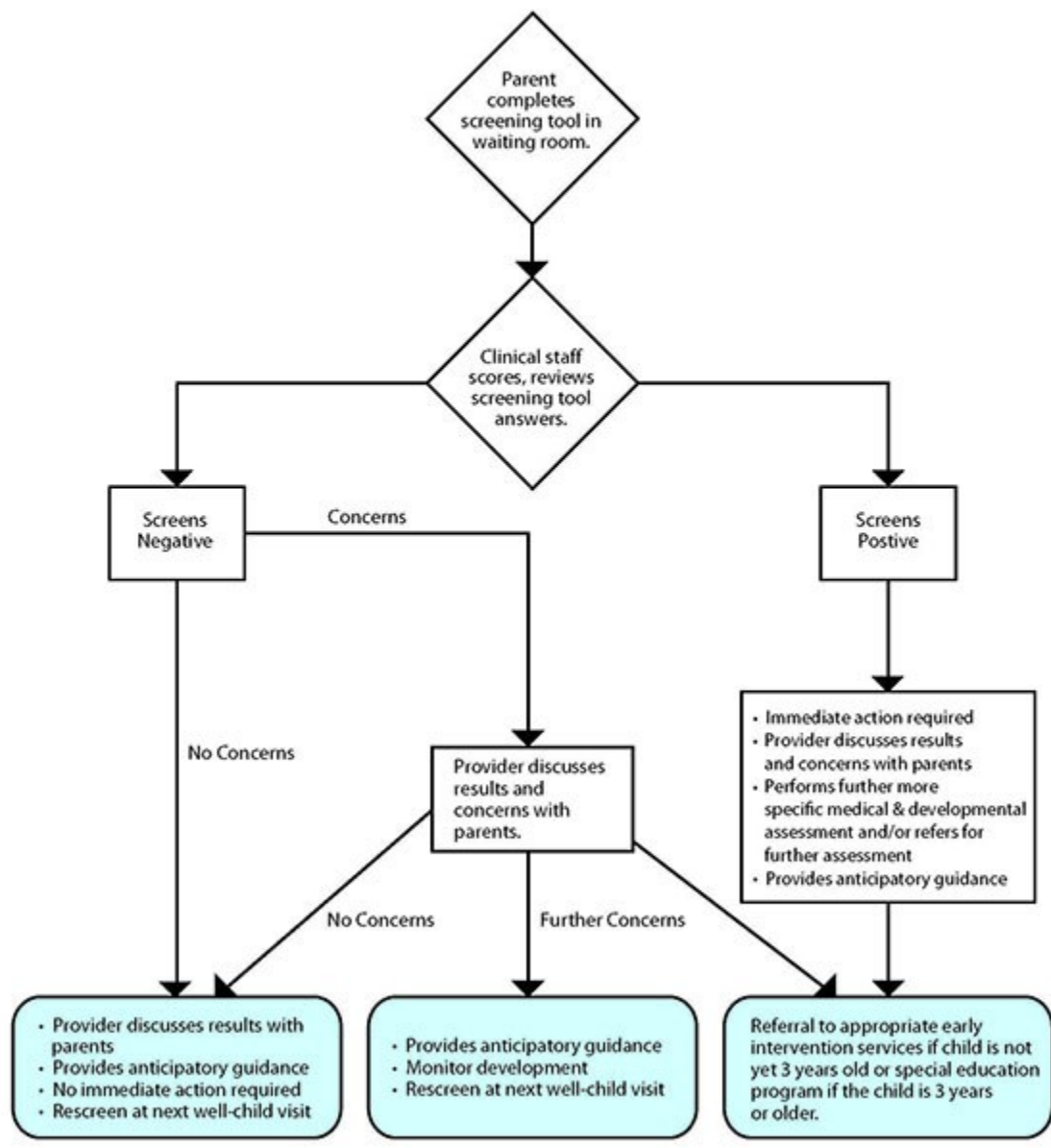
Autism is screened for by using developmental screening tools. Selected examples are:

- Ages and Stages Questionnaire (ASQ)
- Communication and Symbolic Behavior Scales (CSBS)
- Parent's Evaluation of Development Status (PEDS)
- Modified Checklist for Autism in Toddlers (MCHAT)
- Screening Tool for Autism in Toddlers and Young Children (STAT)

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

Pediatric Developmental Screening Flowchart



Medical Necessity Guideline: STAR, CHIP, STAR Kids

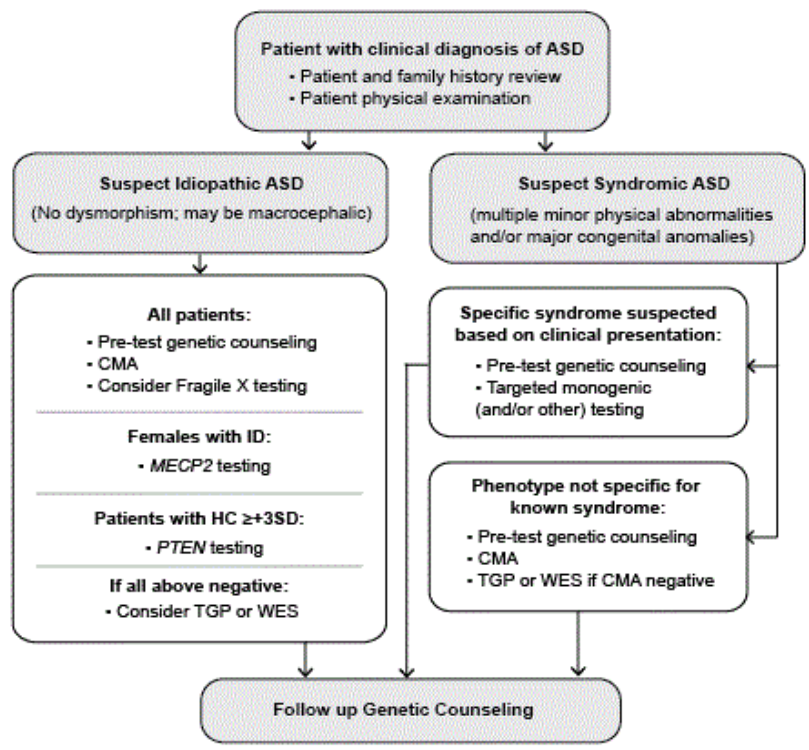
Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

Next are diagnostic tools. These are typically done by specialists (e.g., neurodevelopmental pediatricians, developmental-behavioral pediatricians, child neurologists, geneticists, and early intervention programs that provide assessment services).

Selected examples are:

- Autism Diagnosis Interview-Revised (ADI-R)
- Autism Diagnostic Observation Schedule – Generic (ADOS-G)
- Childhood Autism Rating Scale (CARS)
- Gilliam Autism Rating Scale – Second Edition (GARS-2) ².

Once it is determined that the criteria for ASD have been met according to the DSM V, then the following process should be followed ⁸:



Key: CMA, chromosomal microarray; HC, head circumference; ID, intellectual disability; TGP, targeted gene panel; WES, whole exome sequencing.

Figure 1. Suggested diagnostic pathways for medical genetic assessment and testing of patients who have met clinical diagnostic criteria for autism spectrum disorder (ASD), with focus on idiopathic ASD.
Adapted from Fernandez and Scherer, 2017 and Jiang et al., 2014.

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

Driscoll Health Plan Medical Necessity Guideline

PROVIDER CLAIMS CODES:

[LIST ALL CLAIM CODES INCLUDING MODIFIERS THAT ARE PERTINENT TO THE TOPIC OF THE POLICY OR GUIDELINE.]

CPT Code	Description <\$300.00
81105	CHG HPA-1 GENOTYPING GENE ANALYSIS COMMON VARIANT
81106	CHG HPA-2 GENOTYPING GENE ANALYSIS COMMON VARIANT
81107	CHG HPA-3 GENOTYPING GENE ANALYSIS COMMON VARIANT
81108	CHG HPA-4 GENOTYPING GENE ANALYSIS COMMON VARIANT
81109	CHG HPA-5 GENOTYPING GENE ANALYSIS COMMON VARIANT
81110	CHG HPA-6 GENOTYPING GENE ANALYSIS COMMON VARIANT
81111	CHG HPA-9 GENOTYPING GENE ANALYSIS COMMON VARIANT
81112	CHG HPA-15 GENOTYPING GENE ANALYSIS COMMON VARIANT
81120	CHG IDH1 COMMON VARIANTS
81121	CHG IDH2 COMMON VARIANTS
81161	CHG BRCA1 GENE ANALYSIS FULL SEQUENCE ANALYSIS
81165	CHG BRCA2 GENE ANALYSIS FULL DUP/DEL ANALYSIS
81167	CHG ABL1 GENE ANALYSIS KINASE DOMAIN VARIANTS
81170	CHG ATN1 GENE ANALYSIS EVAL DETECT ABNORMAL ALLELES
81177	CHG ATXN1 GENE ANALYSIS EVAL DETECT ABNORMAL ALLELES
81178	CHG ATXN2 GENE ANALYSIS EVAL DETECT ABNORMAL ALLELES
81179	CHG ATXN3 GENE ANALYSIS EVAL DETECT ABNORMAL ALLELES
81180	CHG ATXN7 GENE ANALYSIS EVAL DETECT ABNORMAL ALLELES
81181	CHG CACNA1A GENE ANALYSIS EVAL DETECT ABNOR ALLELES
81184	CHG CACNA1A GENE ANALYSIS KNOWN FAMILIAL VARIANT
81186	PR ASPA GENE ANALYSIS COMMON VARIANTS
81200	CHG APC GENE ANALYSIS KNOWN FAMILIAL VARIANTS
81202	CHG APC GENE ANALYSIS DUPLICATION/DELETION VARIANTS
81203	PR BCKDHB GENE ANALYSIS COMMON VARIANTS
81205	PR BCR/ABL1 MAJOR BREAKPNT QUALITATIVE/QUANTITATIVE
81206	PR BCR/ABL1 MINOR BREAKPNT QUALITATIVE/QUANTITATIVE
81206	PR BCR/ABL1 OTHER BREAKPNT QUALITATIVE/QUANTITATIVE
81207	PR BLM GENE ANALYSIS 2281DEL6INS7 VARIANT
81208	CHG BRAF GENE ANALYSIS V600 VARIANT(S)

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

Driscoll Health Plan Medical Necessity Guideline

81209	CHG BRCA2 GENE ANALYSIS FULL SEQUENCE ANALYSIS
81210	CHG CEBPA GENE ANALYSIS FULL GENE SEQUENCE
81216	CHG CALR GENE ANALYSIS COMMON VARIANTS IN EXON 9
81218	PR CFTR GENE ANALYSIS KNOWN FAMILIAL VARIANTS
81219	PR CFTR GENE ANALYSIS INTRON 8 POLY-T ANALYSIS
81221	PR CYP2C19 GENE ANALYSIS COMMON VARIANTS
81224	PR CYP2C9 GENE ANALYSIS COMMON VARIANTS
81225	CHG BTK GENE ANALYSIS COMMON VARIANTS
81227	CHG EZH2 GENE ANALYSIS COMMON VARIANTS
81233	PR F2 GENE ANALYSIS 20210G >A VARIANT
81237	PR F5 COAGULATION FACTOR V ANAL LEIDEN VARIANT
81240	PR FANCC GENE ANALYSIS COMMON VARIANT
81241	PR FMR1 ANALYSIS EVAL TO DETECT ABNORMAL ALLELES
81242	CHG FMR1 GENE ANALYSIS CHARACTERIZATION OF ALLELES
81243	CHG FLT3 GENE ANALYSIS INTERNAL TANDEM DUP VARIANTS
81244	CHG FLT3 GENE ANALYSIS TYROSINE KINASE DOMAIN VARIANTS
81245	CHG G6PD GENE ANALYSIS COMMON VARIANTS
81246	PR G6PC GENE ANALYSIS COMMON VARIANTS
81247	PR GBA GLUCOSIDASE/BETA/ACID ANAL COMM VARIANTS
81250	CHG GJB2 GENE ANALYSIS FULL GENE SEQUENCE
81251	CHG GJB2 GENE ANALYSIS KNOWN FAMILIAL VARIANTS
81252	CHG GJB6 GENE ANALYSIS COMMON VARIANTS
81253	PR HEXA GENE ANALYSIS COMMON VARIANTS
81254	PR HFE HEMOCHROMATOSIS GENE ANAL COMMON VARIANTS
81255	CHG HBA1/HBA2 GENE ANALYSIS COMMON DELETIONS/VARIANT
81256	PR IKBKAP GENE ANALYSIS COMMON VARIANTS
81257	PR IGH@ REARRANGE ABNORMAL CLONAL POP AMPLIFIED
81260	PR IGH@ REARRANGE ABNORMAL CLONAL POP DIRECT PROBE
81261	PR IGH@ VARIABLE REGION SOMATIC MUTATION ANALYSIS
81262	PR IGK@ GENE REARRANGE DETECT ABNORMAL CLONAL POP
81263	PR COMPARATIVE ANAL STR MARKERS PATIENT&COMP SPEC
81264	PR CHIMERISM W/COMP TO BASELINE W/O CELL SELECTION
81265	PR CHIMERISM W/COMP TO BASELINE W/CELL SELECTION EA
81267	CHG HBA1/HBA2 GENE ANALYSIS DUP/DEL VARIANTS
81268	PR JAK2 GENE ANALYSIS P.VAL617PHE VARIANT
81269	CHG KIT GENE ANALYSIS D816 VARIANT(S)
81270	CHG KRAS GENE ANALYSIS VARIANTS IN EXON 2

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

Driscoll Health Plan Medical Necessity Guideline

81273	CHG KRAS GENE ANALYSIS ADDITIONAL VARIANT(S)
81275	CHG IGH@/BCL2 TLCJ ALYS MBR & MCR BP QUAL/QUAN
81276	CHG MGMT GENE PROMOTER METHYLATION ANALYSIS
81278	CHG MLH1 GENE ANALYSIS PROMOTER METHYLATION ANALYSIS
81287	PR MCOLN1 MUCOLIPIN1 GENE ANALYSIS COMMON VARIANTS
81288	PR MTHFR GENE ANALYSIS COMMON VARIANTS
81290	PR MLH1 GENE ANALYSIS DUPLICATION/DELETION VARIANTS
81291	PR MSH2 GENE ANALYSIS DUPLICATION/DELETION VARIANTS
81294	PR MSH6 GENE ANALYSIS DUPLICATION/DELETION VARIA
81297	PR MECP2 GENE ANALYSIS KNOWN FAMILIAL VARIANT
81300	PR MECP2 GENE ANALYSIS DUPLICATION/DELETION VARIANT
81303	PR NPM1 NUCLEOPHOSMIN GENE ANAL EXON 12 VARIANTS
81304	CHG PCA3/KLK3 PROSTATE SPECIFIC ANTIGEN RATIO
81310	PR PML/RARALPHA COMMON BREAKPOINTS QUAL/QUANT
81313	PR PML/RARALPHA SINGLE BREAKPOINT QUAL/QUAN
81315	PR PMS2 GENE ANALYSIS DUPLICATION/DELETION VARIANTS
81316	CHG PTEN GENE ANALYSIS KNOWN FAMILIAL VARIANT
81319	CHG PTEN GENE ANALYSIS DUPLICATION/DELETION VARIANT
81322	CHG PMP22 GENE ANALYSIS KNOWN FAMILIAL VARIANT
81323	CHG SEPT9 GENE PROMOTER METHYLATION ANALYSIS
81326	CHG SMN1 GENE ANALYSIS DOSAGE/DELET ALYS W/SMN2 ALYS
81327	PR SMPD1 GENE ANALYSIS COMMON VARIANTS
81329	PR SNRPN/UBE3A METHYLATION ANALYSIS
81330	PR SERPINA1 GENE ANALYSIS COMMON VARIANTS
81331	CHG SMN1 GENE ANALYSIS KNOWN FAMILIAL SEQ VARIANTS
81332	PR TRB@ REARRANGEMENT ANAL AMPLIFICATION METHOD
81337	PR TRB@ REARRANGEMENT ANAL DIRECT PROBE METHODOLOGY
81340	PR TRG@ GENE REARRANGEMENT ANALYSIS
81341	CHG UGT1A1 GENE ANALYSIS COMMON VARIANTS
81342	CHG HBB COMMON VARIANTS
81350	CHG HBB DUPLICATION/DELETION VARIANTS
81361	CHG VKORC1 GENE ANALYSIS COMMON VARIANT(S)
81363	PR HLA CLASS I TYPING LOW RESOLUTION ONE LOCUS EACH
81355	PR HLA I LOW RESOLUTION ONE ANTIGEN EQUIVALENT EACH
81373	PR HLA II LOW RESOLUTION HLA-DRB1/3/4/5 AND -DQB1
81374	CHG HLA CLASS II TYPING LOW RESOLUTION ONE LOCUS EA

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

Driscoll Health Plan Medical Necessity Guideline

81375	PR HLA II LOW RESOLUTION ONE ANTIGEN EQUIVALENT EA
81376	PR HLA CLASS I TYPING HIGH RESOLUTION ONE LOCUS EA
81377	PR HLA I TYPING HIGH RESOLUTION 1 ALLELE/ALLELE GRP
81380	CHG HLA CLASS II TYPING HIGH RESOLUTION ONE LOCUS EA
81381	PR HLA II HIGH RESOLUTION 1 ALLELE/ALLELE GROUP
81382	CHG MOLECULAR PATHOLOGY PROCEDURE LEVEL 1
81381	CHG MOLECULAR PATHOLOGY PROCEDURE LEVEL 2
81400	CHG MOLECULAR PATHOLOGY PROCEDURE LEVEL 3
81401	CHG MOLECULAR PATHOLOGY PROCEDURE LEVEL 4
81402	CHG MOLECULAR PATHOLOGY PROCEDURE LEVEL 5
81403	CHG MOLECULAR PATHOLOGY PROCEDURE LEVEL 7
81404	CHG NFCT DS BACTERAL VAGINOSIS RNA VAGINAL-FLUID ALG
81406	CHG NFCT DS BCT VAGINOSIS&VAGINITIS DNA VAG FLU ALG
81513	CHG TISSUE CULTURE, LYMPHOCYTE
81514	CHG TISSUE CULTURE, SKIN/BIOPSY
88230	CHG TISSUE CULTURE, PLACENTA
88233	CHG TISSUE CULTURE, BONE MARROW
88235	CHG TISSUE CULTURE, TUMOR
88237	CHG CELL CRYOPRESERVE/STORAGE
88239	CHG FROZEN CELL PREPARATION
88240	CHG CHROMOSOME ANAL:BREAKGE,20-25 CELLS
88241	CHG CHROMOSOME ANAL:BREAKGE,50-100 CELLS
88245	CHG CHROMOSOME ANAL:BREAKGE,100 CELLS
88248	CHG CHROMOSOME ANAL:5 CELLS,1 KARYOTYPE
88249	CHG CHROMOSOME ANAL:15-20,2 KARYOTYPES
88261	CHG CHROMOSOME ANAL:45 CELLS,MOSAICISM
88262	CHG CHROMOSOME ANALYSIS:20-25
88263	CHG CHROMOSOME ANALY:PLACENTA
88264	CHG CHROMOSOME ANALY:AMNIOTIC
88267	CHG CYTOGENETICS, DNA PROBE
88269	CHG CYTOGENETICS, 3-5
88271	CHG CYTOGENETICS, 10-30
88272	CHG CYTOGENETICS, 25-99
88273	CHG CYTOGENETICS, 100-300
88274	CHG CHROMOSOME KARYOTYPE STUDY
88275	CHG CHROMOSOME BANDING STUDY
88280	CHG CHROMOSOME COUNT:ADDN CELLS
88283	CHG CHROMOSOME STUDY:ADDN HI RES

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

Driscoll Health Plan Medical Necessity Guideline

88285	CHG BRCA1 GENE ANALYSIS FULL SEQUENCE ANALYSIS
88289	CHG BRCA2 GENE ANALYSIS FULL DUP/DEL ANALYSIS

CPT Code	Description >\$300.00
81162	CHG BRCA1 BRCA2 GENE ALYS FULL SEQ FULL DUP/DEL ALYS
81163	CHG BRCA1 BRCA2 GENE ANALYSIS FULL SEQUENCE ANALYSIS
81164	CHG BRCA1 BRCA2 GENE ANALYSIS FULL DUP/DEL ANALYSIS
81166	CHG BRCA1 GENE ANALYSIS FULL DUP/DEL ANALYSIS
81185	CHG CACNA1A GENE ANALYSIS FULL GENE SEQUENCE
81201	CHG APC GENE ANALYSIS FULL GENE SEQUENCE
81212	CHG BRCA1 BRCA 2 GEN ALYS 185DELAG 5385INSC 6174DELT
81215	CHG BRCA1 GENE ANALYSIS KNOWN FAMILIAL VARIANT
81217	CHG BRCA2 GENE ANALYSIS KNOWN FAMILIAL VARIANT
81220	PR CFTR GENE ANALYSIS COMMON VARIANTS
81222	PR CFTR GENE ANALYSIS DUPLICATION/DELETION VARIANTS
81223	PR CFTR GENE ANALYSIS FULL GENE SEQUENCE
81226	PR CYP2D6 GENE ANALYSIS COMMON VARIANTS
81229	CHG CYTOG ALYS CHRMOML ABNOR CPY NUMBER&SNP VRNT CGH
81235	CHG EGFR GENE ANALYSIS COMMON VARIANTS
81238	CHG F9 FULL GENE SEQUENCE
81248	CHG G6PD GENE ANALYSIS KNOWN FAMILIAL VARIANTS
81249	CHG G6PD GENE ANALYSIS FULL GENE SEQUENCE
81258	CHG HBA1/HBA2 GENE ANALYSIS KNOWN FAMILIAL VARIANT
81259	"CHG HBA1/HBA2 GENE ANALYSIS FULL GENE SEQUENCE
81266	PR COMPARATIVE ANAL STR MARKERS EA ADDL SPECIMEN
81272	CHG KIT GENE ANALYSIS TARGETED SEQUENCE ANALYSIS
81292	PR MLH1 GENE ANALYSIS FULL SEQUENCE ANALYSIS
81293	PR MLH1 GENE ANALYSIS KNOWN FAMILIAL VARIANTS
81295	PR MSH2 GENE ANALYSIS FULL SEQUENCE ANALYSIS
81296	PR MSH2 GENE ANALYSIS KNOWN FAMILIAL VARIANTS
81298	PR MSH6 GENE ANALYSIS FULL SEQUENCE ANALYSIS
81299	PR MSH6 GENE ANALYSIS KNOWN FAMILIAL VARIANTS
81301	PR MICROSATELLITE INSTAB ANAL MISMATCH REPAIR DEF
81302	PR MECP2 GENE ANALYSIS FULL SEQUENCE
81314	CHG PDGFRA GENE ANALYS TARGETED SEQUENCE ANALYS
81317	PR PMS2 GENE ANALYSIS FULL SEQUENCE

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

Driscoll Health Plan Medical Necessity Guideline

81318	PR PMS2 GENE ANALYSIS KNOWN FAMILIAL VARIANTS
81321	CHG PTEN GENE ANALYSIS FULL SEQUENCE ANALYSIS
81324	CHG PMP22 GENE ANAL DUPLICATION/DELETION ANALYSIS
81325	CHG PMP22 GENE ANALYSIS FULL SEQUENCE ANALYSIS
81334	CHG RUNX1 GENE ANALYSIS TARGETED SEQUENCE ANALYSIS
81336	CHG SMN1 GENE ANALYSIS FULL GENE SEQUENCE
81349	CHG CYTOG ALYS CHRMOML ABNOR LOW-PASS SEQ ALYS
81351	CHG TP53 GENE ANALYSIS FULL GENE SEQUENCE
81352	CHG TP53 GENE ANALYSIS TARGETED SEQUENCE ANALYSIS
81353	CHG TP53 GENE ANALYSIS KNOWN FAMILIAL VARIANT
81362	CHG HBB KNOWN FAMILIAL VARIANTS
81364	CHG HBB FULL GENE SEQUENCE
81370	PR HLA CLASS I&II LOW HLA-A -B -C -DRB1/3/4/5&-DQB1
81371	CHG HLA I&LI LOW RESOLUTION HLA-A -B&-DRB1
81372	PR HLA CLASS I TYPING LOW RESOLUTION COMPLETE
81378	PR HLA I&II HIGH RESOLUTION HLA-A -B -C AND -DRB1
81379	PR HLA CLASS I TYPING HIGH RESOLUTION COMPLETE
81405	CHG MOLECULAR PATHOLOGY PROCEDURE LEVEL 6
81407	CHG MOLECULAR PATHOLOGY PROCEDURE LEVEL 8
81408	CHG MOLECULAR PATHOLOGY PROCEDURE LEVEL 9
81410	CHG AORTIC DYSFUNCTION/DILATION GENOMIC SEQ ANALYSIS
81411	CHG AORTIC DYSFUNCTION/DILATION DUP/DEL ANALYSIS
81420	CHG FETAL CHROMOSOMAL ANEUPLOIDY GENOMIC SEQ ANALYS
81449	PR TARGETED GENOMIC SEQUENCE ANALYSIS PANEL, SOLID ORGAN NEOPLASM, 5-50 GENES (EG, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, MET, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), INTERROGATI
81450	CHG GEN SEQ ANALYS HEMATOLYMPHOID NEO 5-50 GENE
81451	PR TARGETED GENOMIC SEQUENCE ANALYSIS PANEL, HEMATOLYMPHOID NEOPLASM OR DISORDER, 5-50 GENES (EG, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NOTCH1, NPM1, NRAS), INT
81455	CHG GEN SEQ ANALYS SOL ORG/HEMTOLMPHOID NEO 51/> GEN
81456	PR TARGETED GENOMIC SEQUENCE ANALYSIS PANEL, SOLID ORGAN OR HEMATOLYMPHOID NEOPLASM OR DISORDER, 51>GREATER GENES (EG, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, ID
81507	CHG FETAL ANEUPLOIDY 21 18 13 SEQ ANALY TRISOM RISK

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

81519	CHG ONCOLOGY BREAST MRNA GENE EXPRESSION 21 GENES
81520	CHG ONC BREAST MRNA GENE XPRSN PRFL HYBRD 58 GENES
81528	CHG ONCOLOGY COLORECTAL SCREENING QUAN 10 DNA MARKRS

REFERENCES:

1. Texas Medicaid Provider Procedures Manual (Current Edition): Medical and Nursing Specialists, Physicians, and Physician Assistants Handbook; Section 5 (Geneticists); Subsection 5.2 (Services, Benefits, Limitations, and Prior Authorizations), May 2024.
2. CDC - Centers for Disease Control and Prevention; Autism Spectrum Disorder (ASD) Information on Autism Spectrum Disorder for Healthcare Providers found on the internet at URL: <https://www.cdc.gov/ncbddd/autism/hcp.html>.
3. Habibullah H, Albradie R, Bashir S. Identifying pattern in global developmental delay children: A retrospective study at King Fahad specialist hospital, Dammam (Saudi Arabia). *Pediatr Rep.* 2019;11(4):8251. Published 2019 Dec 2. doi:10.4081/pr.2019.8251.
4. Committee to Evaluate the Supplemental Security Income Disability Program for Children with Mental Disorders; Board on the Health of Select Populations; Board on Children, Youth, and Families; Institute of Medicine; Division of Behavioral and Social Sciences and Education; The National Academies of Sciences, Engineering, and Medicine; Boat TF, Wu JT, editors. *Mental Disorders and Disabilities Among Low-Income Children*. Washington (DC): National Academies Press (US); 2015 Oct 28. 9, *Clinical Characteristics of Intellectual Disabilities*. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK332877/>.
5. Martin CL, Ledbetter DH. Chromosomal Microarray Testing for Children With Unexplained Neurodevelopmental Disorders. *JAMA.* 2017;317(24):2545-2546. doi:10.1001/jama.2017.7272.
6. Malinowski J, Miller DT, Demmer L, et al. Systematic evidence-based review: outcomes from exome and genome sequencing for pediatric patients with congenital anomalies or intellectual disability. *Genet Med.* 2020;22(6):986-1004. doi:10.1038/s41436-020-0771-z.
7. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)*. American Psychiatric Association; 2013.
8. Hayes, *Clinical Utility of Genetic Testing to Aid in the Evaluation of Syndromic or Complex Autism Spectrum Disorder, Clinical Utility Evaluation*, First published August 22, 2018, Updated August 9, 2021.

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

DOCUMENT HISTORY:

DHP Committee that Approved	<i>Review Approval Date</i>				
Medical Director	06/01/2023	05/31/2024 & 08/19/2024			
CMO	06/06/2023	06/11/2024 & 08/19/2024			
Medical Policy Workgroup	06/06/2023	06/11/2024 & 08/19/2024			
Utilization Management & Appeals Workgroup	06/20/2023	06/18/2024 & 08/20/2024			
Provider Advisory Committee (PAC)	06/09/2023	07/01/2024 & 07/22/2024			
Clinical Management Committee	07/20/2023	07/24/2024 & 09/06/2024			
Executive Quality Committee	07/25/2023	07/30/2024 & 09/09/2024			

<i>Document Owner</i>	<i>Organization</i>	<i>Department</i>
Dr. Fred McCurdy, Medical Director	Driscoll Health Plan	Utilization Management

<i>Review/Revision Date</i>	<i>Review/Revision Information, etc.</i>
05/16/2023	Created by Dr. Fred McCurdy

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

Driscoll Health Plan Medical Necessity Guideline



05/28/2023	Reviewed and edited by the Medical Policy Committee
06/01/2023	Final edits performed by Drs. Karl Serrao and Fred McCurdy
01/30/2024	Title of document revised to Genetic Testing for Suspected Disability
05/31/2024	Reviewed and revised by Drs. Tessa Perz and Fred McCurdy
08/19/2024	Revised by Dr. Doucet, statement removed “Currently, Driscoll Health Plan considers whole genome sequencing to be Investigational and Not Medically Necessary.

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan