

Medical Necessity Guideline: Using Large Genetic Testing Panels	Creation Date: 10/10/2023	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
- A presumed predisposition to a defined disease (e.g., using large screening panels)

DEFINITIONS: (underline and list in alphabetic order)

Allowed Practitioner: a Texas Medicaid enrolled physician, a physician assistant, or an advanced practice registered nurse 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 occurring during intrauterine life. Also called birth defects, genetic disorders, or congenital malformations, these conditions develop prenatally and are identified before delivery, at birth, or later in life.

Carrier: This individual carries and can pass on a genetic mutation associated with a disease and may or may not display the disease.

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.

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.

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

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** if:

1. The member displays clinical features, or is at direct risk of inheriting the mutation in question, and
2. The test results will be used to develop a clinically useful approach or course of treatment, or to cease unnecessary monitoring or treatments for the individual being tested. Clinically useful test results allow providers to do at least one of the following:
 - a. Inform interventions that could prevent or delay disease onset,
 - b. Detect disease at an earlier stage when treatment is more effective,
 - c. Manage the treatable progression of an established disease,
 - d. Treat current symptoms significantly affecting a member's health,
 - e. Guide decision making for the member's current or planned pregnancy; and
3. The genetic disorder could not be diagnosed through completion of conventional diagnostic studies, pedigree analysis and genetic counseling consistent with the community standards; and
4. The member has not previously undergone genetic testing for the disorder unless significant changes in testing technology or treatments indicate that test results or outcomes may change due to repeat testing.
5. When using testing panels, including but not limited to, multiple genes or multiple conditions, and in cases where a tiered approach/method is clinically available, testing would be covered **ONLY** for the number of genes or tests deemed medically necessary to establish a diagnosis, and
6. The use of testing panels, including but not limited to, multiple genes or multiple conditions, will be considered **ONLY** after the requesting physician provides historical, physical, and laboratory features that are suggestive of the disease(s) suspected, and
7. Clinical performance of the genetic test is supported by published peer-reviewed medical literature, and

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

8. Will **ONLY** be considered after genetic counseling, which encompasses all of 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

Documentation Requirements:

1. Documentation of the clinical features that have led the requesting physician to suspect the presence of a genetic condition and/or the direct risk factors leading the requesting physician to suspect the member is at risk of inheriting the mutation in question.
2. Documentation that the suspected genetic disorder could not be diagnosed through completion of conventional diagnostic studies, pedigree analysis and genetic counseling consistent with the community standards.
3. Documentation that the member has not previously undergone genetic testing for the disorder unless significant changes in testing technology or treatments indicate that test results or outcomes may change due to repeat testing.
4. When panel testing is requested, the requesting physician must provide documentation that justifies testing for multiple genes rather than using a tiered approach/method testing only for the genes that are deemed medically necessary to establish the diagnosis.
5. The use of testing panels, including but not limited to, multiple genes or multiple conditions, will be considered **ONLY** after the requesting physician provides historical, physical, and laboratory features that are suggestive of the disease(s) suspected.
6. Documentation that the performance of the requested testing is supported by published peer-reviewed medical literature, and
7. Documentation that genetic counseling has been conducted, enumerating in detail: the following:
 - 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

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

8. 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 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

Genetic testing identifies changes in chromosomes, genes, or proteins that may cause illness or disease. The results of a genetic test can confirm or rule out a suspected genetic condition. Carrier screening is performed to identify members at risk of having offspring with a genetic disease. Carriers are usually not at risk of developing the disease but have a risk of passing a pathogenic gene mutation to their offspring.²

Genetic testing is a procedure that has both risks and benefits. Both patient and clinician must consider how best to strike a balance between those risks and benefits before genetic testing. This involves informed consent. As with any procedure, the clinical utility of the genetic test must be considered along with its psychological and sociologic implications.³ Genetic counselors are specifically trained to provide a patient-centered interpretation of genetic testing results. These professional help patients understand and adapt to the medical, psychological, and familial implications of genetic contributions to disease and how the information obtained via genetic testing might affect them or their families.⁴ Genetic counselors are typically specialized in a variety of areas in medicine (e.g., prenatal, pediatric, oncology, neurology, ophthalmology, psychiatry, and many other areas). Furthermore, physicians have varying levels of knowledge on how to interpret genetic and genomic information and Genetic counselors are ideally suited and trained to provide the information a patient needs in interpreting the results of genetic testing.⁵

The past decade has seen a phenomenal increase in the numbers and types of genetic tests available and the number of companies offering genetic testing, leading to many different types of business models and settings where consumers access genetic tests. This access to genetic testing comes through direct-to-consumer channels and from full-service commercial laboratories, for-profit specialized laboratories, or not-for-profit laboratories, such as those associated with academic medical centers.⁶ The end result has been increasing interest in using de-identified data from genetic testing for use in research and discovery and other business purposes beyond how this information is applied to an individual patient (e.g., using genetic information to fuel a trend of generating larger testing using multiple panels of genes). In some

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

instances, genetic counselors, traditionally trained to counsel patients in healthcare settings prior to germline testing for diseases with a Mendelian inheritance pattern, have now taken their education and skills to assist in providing genetic testing services via telehealth. A few have now become employed by laboratories working under various distinct business models.⁶

The rapid expansion of genetic testing technology has begun to generate huge amounts of data increasing the potential for uncertainty in managing and adapting to this information. Clinicians, many of whom are not sufficiently prepared, are now tasked with accurately interpreting and communicating information about test validity and the reliability of test results, as well as the probability for individual patient benefit.⁷ The incidental findings that are now being discovered are also overwhelming. While genetic counselors are an invaluable resource, they are also becoming overwhelmed simply because they are in short supply.⁸ The result is a system of care stretched beyond its limits to respond effectively. Further research is needed regarding the use of clinical practice tools to enhance patient care and uphold the clinical and ethical ideals of medical care in this complicated realm of care delivery.

Finally, numerous guidelines exist for when to perform genetic screening for specific conditions (i.e., cancer, neuromuscular disorders). These guidelines specify that a thorough family history should be taken first and referral only when the history, physical, and laboratory findings causes the clinician to be highly suspicious for a hereditary condition. It is up to the referring physician to make a carefully informed decision about who should and should not be referred. Whole exome testing, polygenic risk scores, non-specific gene panels, and testing persons with a non-contributory history is not an indication for “random” genetic testing.⁹

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

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

81208	CHG BRAF GENE ANALYSIS V600 VARIANT(S)
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)

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

81270	CHG KRAS GENE ANALYSIS VARIANTS IN EXON 2
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

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

81374	CHG HLA CLASS II TYPING LOW RESOLUTION ONE LOCUS EA
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,MOAICISM
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

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

88283	CHG CHROMOSOME STUDY:ADDN HI RES
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

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

81317	PR PMS2 GENE ANALYSIS FULL SEQUENCE
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

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

81507	CHG FETAL ANEUPLOIDY 21 18 13 SEQ ANALY TRISOM RISK
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. MedlinePlus [Internet]. Bethesda (MD): National Library of Medicine (US); [updated Jun 24; cited 2024 May 22]. Available from: <https://medlineplus.gov/>. What are the different types of genetic tests?
3. Knob AL. Principles of genetic testing and genetic counseling for renal clinicians. *Semin Nephrol.* 2010;30(4):431-7. Epub 2010/09/03. PMID: 20807616
4. Patch C, Middleton A. Genetic counselling in the era of genomic medicine. *Br Med Bull.* 2018;126(1):27-36. Epub 2018/04/05. PMID: 29617718
5. Gray SW, Hicks-Courant K, Cronin A, et al. Physicians' attitudes about multiplex tumor genomic testing. *J Clin Oncol.* 2014;32(13):1317-23. Epub 2014/03/26. PMID: 24663044
6. Scheuner MT, Douglas MP, Sales P, et al. Laboratory business models and practices: implications for availability and access to germline genetic testing. *Genet Med.* 2021;23(9):1681-8. Epub 2021/05/08. PMID: 33958748
7. Pollard S, Sun S, Regier DA. Balancing uncertainty with patient autonomy in precision medicine. *Nat Rev Genet.* 2019;20(5):251-2. Epub 2019/03/16. PMID: 30872766
8. Borno HT, Rider JR, Gunn CM. The Ethics of Delivering Precision Medicine-Pretest Counseling and Somatic Genomic Testing. *JAMA Oncol.* 2020;6(6):815-6. Epub 2020/03/13. PMID: 32163096
9. Hampel H, Bennett RL, Buchanan A, Pearlman R, Wiesner GL; Guideline Development Group, American College of Medical Genetics and Genomics Professional Practice and Guidelines Committee and National Society of Genetic Counselors Practice Guidelines Committee. A practice guideline from the American College of Medical Genetics and Genomics and the National Society of Genetic Counselors: referral indications for cancer predisposition assessment. *Genet Med.* 2015;17(1):70-87. <https://doi:10.1038/gim.2014.147>

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 (last 5 years)</i>				
Medical Director	10/10/2023	05/31/2024 & 08/19/2024			
CMO	12/13/2023	06/11/2024 & 08/19/2024			
Medical Policy Workgroup	12/13/2023	06/11/2024 & 08/19/2024			
Utilization Management & Appeals Workgroup	12/13/2023	06/18/2024 & 08/20/2024			
Provider Advisory Committee (PAC)	12/13/2023	07/01/2024 & 07/22/2024			
Clinical Management Committee	01/24/2024	07/24/2024 & 09/06/2024			
Executive Quality Committee	01/30/2024	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

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

<i>Review/Revision Date</i>	<i>Review/Revision Information, etc.</i>
10/10/2023	Created by Dr. Fred McCurdy
12/13/2023	Reviewed and edited by the Medical Policy Committee
01/30/2024	Title of document revised to Using Large Genetic Testing Panels
05/22/2024	Reviewed and revised by Drs. Lenore Depagter and Fred McCurdy
08/19/2024	Revised by Dr. Doucet, removed statement “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