



| Medical Necessity Guideline: | Creation | Review | Effective |
|------------------------------------|------------|------------|------------|
| Using Large Genetic Testing Panels | Date: | Date: | Date: |
| | 10/10/2023 | 08/07/2024 | 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)

<u>DEFINITIONS</u>: (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





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 <u>ONLY</u> 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





- 8. Will <u>ONLY</u> 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 <u>ONLY</u> 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





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





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





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 | | |
| 01170 | ALLELES | | |
| 811/9 | ALLELES | | |
| 81180 | CHG ATXN7 GENE ANALYSIS EVAL DETECT ABNORMAL | | |
| 01100 | 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





| 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 ANLYS 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





| 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





| 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,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 |

Medical Necessity Guideline: STAR, CHIP, STAR Kids





| 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





| 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 |
| 01440 | ANALYS |
| 81449 | PR TARGETED GENOMIC SEQUENCE ANALYSIS PANEL, SOLID |
| | EPRE2 KIT KRAS MET NRAS DOGERA DOGERB DOR DIK3CA |
| | PTEN RET) INTERROGATI |
| 81450 | CHG GEN SEO ANALYS HEMATOLYMPHOID NEO 5-50 GENE |
| 81451 | PR TARGETED GENOMIC SEQUENCE ANALYSIS PANEL. |
| 01101 | 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





| 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 |

| CPT Code | Description >\$500.00 | | |
|----------|--|--|--|
| 81279 | CHG JAK2 TARGETED SEQUENCE ANALYSIS | | |
| 81305 | CHG MYD88 GENE ANALYSIS P.LEU265 (L265P) VARIANT | | |
| 81307 | CHG PALB2 GENE ANALYSIS FULL GENE SEQUENCE | | |
| 81320 | CHG PLCG2 GENE ANALYSIS COMMON VARIANTS | | |
| 81345 | CHG TERT GENE ANALYSIS TARGETED SEQUENCE ANALYSIS | | |
| 81425 | CHG GENOME SEQUENCE ANALYSIS | | |
| 81426 | CHG GENOME SEQUENCE ANALYSIS EACH COMPARATOR | | |
| | GENOME | | |
| 81427 | CHG GENOME RE-EVALUATION OF PREC OBTAINED | | |
| | GENOME SEQ | | |
| 81443 | CHG GENETIC TESTING FOR SEVERE INHERITED | | |
| | CONDITIONS | | |
| 81457 | GENOMIC SEQUENCE ANALYSIS PANEL OF DNA FOR | | |
| | MICROSATELLITE | | |
| 81458 | GENOMIC SEQUENCE ANALYSIS PANEL OF DNA | | |
| 81459 | GENOMIC SEQUENCE ANALYSIS PANEL OF DNA OR | | |
| | COMBINED DNA A | | |
| 81462 | GENOMIC SEQUENCE ANALYSIS OF DNA OR COMBINED | | |
| | DNA AND RNA IN PLASMA | | |
| 81463 | GENOMIC SEQUENCE ANALYSIS OF DNA IN PLASMA FOR | | |
| | COPY NUMBER VARIANTS AND MICROSATELLITE | | |
| 81464 | GENOMIC SEQUENCE ANALYSIS OF DNA OR COMBINED | | |
| | DNA AND RNA IN PLASMA FOR COPY NUMBER VARIANTS | | |

<u>REFERENCES</u>:

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.

Medical Necessity Guideline: STAR, CHIP, STAR Kids





- 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
- 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
- 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. <u>Https://doi:10.1038/gim.2014.147</u>

Medical Necessity Guideline: STAR, CHIP, STAR Kids





DOCUMENT HISTORY:

| DHP Committee that Approved | Review Approval Date (last 5 years) | | |
|-----------------------------------|-------------------------------------|------------|--|
| | | | |
| Medical | 10/10/2023 | 05/31/2024 | |
| Director | | & | |
| | | 08/19/2024 | |
| СМО | 12/13/2023 | 06/11/2024 | |
| | | & | |
| | | 08/19/2024 | |
| Medical Policy | 12/13/2023 | 06/11/2024 | |
| Workgroup | | & | |
| | | 08/19/2024 | |
| Utilization | 12/13/2023 | 06/18/2024 | |
| Management & | | & | |
| Appeals | | 08/20/2024 | |
| Workgroup | | | |
| Provider | 12/13/2023 | 07/01/2024 | |
| Advisory | | & | |
| Committee | | 07/22/2024 | |
| (PAC) | | | |
| Clinical | 01/24/2024 | 07/24/2024 | |
| Management | | & | |
| Committee | | 09/06/2024 | |
| Executive | 01/30/2024 | 07/30/2024 | |
| Quality | | & | |
| Committee | | 09/09/2024 | |

| Document Owner | Organization | Department |
|---------------------------------------|----------------------|------------------------|
| Dr. Fred McCurdy, Medical Director | Driscoll Health Plan | Utilization Management |

Medical Necessity Guideline: STAR, CHIP, STAR Kids





| Review/Revision Date | Review/Revision Information, etc. |
|-------------------------|--|
| 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

4525 Ayers St. Corpus Christi, Texas 78415 Telephone (877) 455-1053 Fax (866) 741-5650