Medical Policy

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

Genetic Testing and Genetic Counseling

Policy Number: PG0041
Last Reviewed Date: 03/01/2025
Revised Date: 03/01/2025

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE:

X Professional
X Facility

DESCRIPTION:

Genetic Testing

A genetic test is the analysis of human DNA, RNA, chromosomes, proteins, or certain metabolites in order to detect alterations related to a heritable or acquired disorder. This can be accomplished by directly examining the DNA or RNA that makes up a gene (direct testing), looking at markers co-inherited with a disease-causing gene (linkage testing), assaying certain metabolites (biochemical testing), or examining the chromosomes (cytogenetic testing). Clinical genetic tests are those in which specimens are examined and results reported to the provider or patient for the purpose of diagnosis, prevention or treatment in the care of individual patients.

Genetic testing is performed for a variety of intended uses:

- Diagnostic testing (to diagnose disease)
- Predictive testing (generally performed to gather genetic data that can assist in clinical management, including therapeutic decision for an individual.
- Pre-symptomatic genetic testing (to predict future disease)
- Carrier testing (to identify carriers of genetic mutations)
- Prenatal testing (offered during pregnancy to identify fetuses that have certain diseases)
- Pre-implantation genetic testing (done in conjunction with in vitro fertilization to determine whether embryos for implantation carry a gene mutation that could cause disease)
- Newborn screening (to test newborns shortly after birth to determine whether they have certain diseases known to cause problems with health and development)
- Pharmacogenetic testing (to determine the likelihood of an individual being responsive to a particular drug and/or to predict serious toxicity from a drug in order to optimize drug selection or drug dosage)
- Research genetic testing (used to help with research and development of gene-based therapy)

Several hundred genetic tests are currently in use, and more are being developed. Although genetic testing can provide helpful information for diagnosing, treating, and preventing illness, there are limitations. For example, in a healthy patient, a positive result from a genetic test does not always mean the patient will develop a disease. On the other hand, in some situations, a negative result does not guarantee the patient will not have a certain disorder.

Genetic Counseling

Genetic counseling is a service provided by trained, qualified professionals involving assessment and education of an individual about presence or absence of an inherited genetic disease. This process is intended to assist individuals in understanding and adapting to the medical, psychological and familial implications of genetic contributions to health risks, health conditions/disease and management/treatment responses.

Appropriate genetic counseling is medically necessary for consideration of, or provided in conjunction with, medically necessary genetic testing, and in accordance with the guidelines of the American College of Medical Genetics and Genomics (ACMG). The individual providing the genetic counseling must be free of commercial bias and disclose all potential and/or real financial and intellectual conflicts of interest. Paramount follows InterQual Care Guidelines for genetic counseling requirements. If InterQual Care Guidelines for a genetic test do not include genetic counseling requirements, then no genetic counseling is necessary.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Paramount uses the following clinical criteria to ensure appropriateness of care and service:

- **Centers for Medicare & Medicaid Service (CMS) for national coverage determinations (NCD). CGS Administrators, LLC., Jurisdiction A/B, and Wisconsin Physicians Service Insurance Corporation for local coverage determinations (LCD).**
- **InterQual Coverage Criteria**
- **Other Paramount Health Care-approved medical policies**
- **In cases of a discrepancy between InterQual and Paramount Medical policies, InterQual will supersede Medical Policy language.**

- **All genetic testing procedure codes are considered noncovered unless otherwise noted within the medical policy.**
- **Prior authorization is required for all covered genetic testing procedure codes unless otherwise noted, (no matter the diagnosis).**
- **Refer to the code listing on the PRIOR AUTHORIZATION – EXPERIMENTAL/INVESTIGATIONAL – NONCOVERED SERVICES, excel spreadsheet, found at: https://www.paramounthealthcare.com/providers/claims-and-authorizations/outpatient-prior-authorization**
- **To access the InterQual Care Guidelines, click on the following link and follow access instructions: https://identity.onehealthcareid.com/oneapp/index.html#/login**
- **Prior authorization is required for all Non-Par Providers for ALL genetic testing procedure codes.**
- **Genetic counseling (96041) provided by a medical geneticist, a genetic counselor, or a provider with recognized expertise in the area being assessed does not require a prior authorization, when the coverage criteria below are met.**

NOTE: The Company had determined that the laboratory tests not determined to be medically necessary using InterQual Guidelines have not demonstrated equivalency or superiority to currently accepted standard means of testing, unless otherwise documented within a separate medical policy. The Company considers all other molecular diagnostic testing not medically necessary and not eligible for reimbursement.

Paramount does not cover experimental/investigational medical or surgical procedures that are not medically necessary and have not been strongly supported in research and for which there is a safe and medically accepted alternative available.

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Genetic Testing

Coverage and authorization for genetic testing is determined by review. The testing must have direct effect on the management and clinical care of the individual being tested, and must contain All of the following criteria:

- Testing is FDA/CLIA approved
- Individual has not previously received genetic testing for the disorder. In general, genetic testing for a particular disorder should be performed once per lifetime; however, there are rare instances in which testing may be performed more than once in a lifetime (e.g., previous testing methodology is inaccurate, a new discovery has added significant relevant mutations for a disease, significant changes in technology or treatments indicate that test results or outcomes may change because of repeat testing)
- The genetic disorder is associated with a significant disability or has a lethal natural history
- The risk of the significant disability or lethality from the genetic disorder cannot be determined through other diagnostic testing
- A specific mutation, or set of mutations, has been proven valid in the scientific literature to be reliable, associated with the disease
- The results of the genetic test could impact the medical management of the individual being tested
- The genetic test will likely result in an anticipated improvement in net health outcomes for the individual being tested (i.e., the disease is treatable or preventable)
- Panels including, but may not limited to, multiple genes or multiple conditions, and in cases where a tiered approach/method is clinically available, may be covered ONLY for the number of genes or tests deemed medically necessary to establish a diagnosis
- The testing is supported by clinical criteria (e.g., InterQual Care Guidelines)

When requesting prior authorization review, the patient's medical history/record and details of the lab facility providing the requested service must be provided. An approved request will only be given to a specific lab for a specific provider for a specific service. Genetic testing may be denied as experimental/investigational or not medically necessary based on the information submitted.

The physician, lab or facility ordering the service will be financially responsible if prior authorization is not obtained. Members who choose to precede with unauthorized genetic testing bear the responsibility for the cost. The provider should always secure a Waiver of Responsibility prior to providing the testing to assure member understanding of their financial responsibility.

Genetic testing is considered not medically necessary and not eligible for reimbursement for any of, but not limited to, the following:

- Routine, ongoing or long-term genetic counseling; or
- Determining paternity of a child; or
- Determining the sex of a child (except when medically indicated); or
- General population screening for genetic disorders (e.g., cystic fibrosis).

Genetic Counseling

Coverage for genetic counseling is dependent on benefit plan language. Many benefit plans limit coverage of genetic counseling to two (2) visits per year for both pre and post genetic testing. Please refer to the applicable benefit plan language to determine benefit availability and terms, conditions, and limitations of coverage.

If coverage is available for genetic counseling, the following conditions of coverage apply:
Paramount covers pre- and post-test genetic counseling as medically necessary by a medical geneticist, a genetic counselor, or a provider with recognized expertise not employed by a commercial genetic testing laboratory for EITHER of the following:

- an individual undergoing genetic testing; or
- an individual who is a potential candidate for genetic testing.

Genetic Counseling is a communication process, involving an individual and/or family, to help understand the testing and is comprised of ALL of the following:

- Explanation of potential benefits, risks, and limitations of testing; and
- Documented informed consent occurs before testing; and

- Comprehend the medical facts, including the diagnosis, the probable course of the disorder, and the available management; and
- Discussion the way heredity contributes to the disorder, and the risk of recurrence in specified relatives; and
- Discussion of impacts of testing (e.g., psychological, social, limitations of nondiscrimination statutes); and
- Discussion of possible test outcomes (i.e., positive, negative, variant of uncertain significance); and
- Explanation of purpose of evaluation (e.g., to confirm, diagnose, or exclude genetic condition); and
- Identification of medical management issues, including available prevention, surveillance, and treatment options and their implications.

Paramount will not reimburse genetic counseling (96041) when reported by a Physician, because this code is intended for use by non-physician health care professionals. Physicians who provide genetic counseling should report these services using evaluation and management codes.

Genetic counseling students cannot independently bill using code 96041.

Code 96041 cannot be used for group appointments or appointments seeing multiple patients at the same time.

Code 96041 is only allowable for time spent in service of a patient on the same day of an inperson, video, or audio-only patient interaction and cannot be used solely for electronic communication, such as email or direct EHR messaging, outside that time period.

CODING/BILLING INFORMATION:
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODE	
96040	Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family Deleted effective 01/01/2025
96041	Medical genetics and genetic counseling services, each 30 minutes of total time provided by the genetic counselor on the date of the encounter. New Code Effective 01/01/2025
Genetic Procedure Codes: Refer to the code listing on the PRIOR AUTHORIZATION – EXPERIMENTAL/INVESTIGATIONAL – NONCOVERED SERVICES, excel spreadsheet, found at: https://www.paramounthealthcare.com/providers/claims-and-authorizations/outpatient-prior-authorization	

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 01/01/2012

Date	Explanation & Changes
01/01/13	• Updated
07/08/13	• Per Medical Director Review, genetic subcommittee, the following genetic codes will not require a prior authorization; 81206-81208, 81210, 81220-81223, 81240-81245, 81250-81251, 81255-81256, 81261-81268, 81270, 81275, 81291, 81310, 81315-81316, 81340-81342, 81350, 81355, 81378-81383.
12/31/13	• Per 2014 new code review, updated the configuration code sets to include procedures G0452 and 81287 to require prior authorization, and procedures 81504 and 81507 to be denied as non-covered.
05/13/14	• Added codes 81161, 84999, 85999, 86849, 87999, 88199, 88299, 88380, 88381, 88399, 89398 • Removed code S3870 • Changed title of medical policy from Genetic and Experimental Laboratory Services to Genetic Testing • Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee

01/13/15	• Added reference to PG0296 Comparative Genomic Hybridization (CGH) for codes 81228 & 81229 per Medical Policy Steering Committee
06/09/15	• Added code effective 1/1/15: 81246, 81288, 81313, 81410, 81411, 81415-81417, 81420, 81425-81427, 81430, 81431, 81435, 81436, 81440, 81445, 81450, 81455, 81460, 81465, 81470, 81471, 81519 • Updated descriptions for revised codes effective 1/1/15: 81402-81405 • Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee
10/26/15	• For multianalyte assay with algorithmic analyses code 81519 refer to PG0301 Genetic Expression Assays for Breast Cancer Prognosis for coverage determination
02/26/16	• Added effective 1/1/16 o new codes 81162, 81432, 81433, 81434 that require prior authorization; o 81170, 81218, 81219, 81272, 81273, 81276, 81311, 81314, 81412, 81437, 81438, 81442, 81528, 81545, 81595 that do not require prior authorization; and o 81490, 81493, 81525, 81535, 81536, 81538, 81540 that are non-covered. • Updated effective 1/1/16 revised codes 81210, 81275, 81355, 81435, 81436, 81445, 81450, & 81455. • Added codes 88230-88299, and 0001M-0010M. • Code 88271 has a limit of 25 units per 365 days. • Removed codes 88380 & 88381. • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
03/25/16	• Coverage changes made per CMS guidelines: • Non-covered for all product lines – 81161, 81507, 0009M; • Non-covered for HMO, PPO, Individual Marketplace, Elite and covered with prior authorization for Advantage – 81200. 81205, 81209, 81224, 81252, 81253, 81254, 81257, 81260, 81290, 81324, 81325, 81326, 81330, 81331, 81410, 81411, 81412, 81415, 81416, 81417, 81425, 81426, 81427, 81430, 81431, 81433, 81434, 81438, 81440, 81442, 81460, 81465, 81470, 81471; • Covered with prior authorization for HMO, PPO, Individual Marketplace, Elite and Non-covered for Advantage – 81490, 81504, 81525, 81540; • Covered with prior authorization for Elite and Non- covered for HMO, PPO, Individual Marketplace, Advantage – 81493. • Policy reviewed and updated to reflect most current clinical evidence per TAWG
04/22/16	• Codes 81242, 81251, 81302, 81303, 81304 are covered with prior authorization for HMO, PPO, Individual Marketplace, & Advantage and are non-covered for Elite per CMS guidelines. • Added specific non- covered genes/gene components determination for 81400-81408, & 81479 per CMS guidelines as non-covered for all product lines. • Added myRisk test (81479) as non-covered for all product lines per CMS guidelines. • Added reference to new policies: o PG0355 Genetic Testing for Hereditary Thrombophilia (81240, 81241, 81291), o PG0357 Gene Expression Profiling for Colorectal Cancer (81525), PG0360 Genetic Testing for FMR1 Mutations Including Fragile X Syndrome (81243, 81244), PG0363 CORUS® CAD (81493), o PG0364 Cancer Type ID (81540), & o PG0368 GeneSight® Assay for Refractory Depression (81479). • Policy reviewed and updated to reflect most current clinical evidence per TAWG
6/24/16	• Policy updated per TAWG determination for PG0298 Afirma® Thyroid FNA Analysis, PG0334 ThyroSeq® v.2 Next Generation Sequencing, and PG0367 Gene Expression Analysis for Prostate Cancer
10/28/16	• CPT code 81224 is now covered without prior authorization for HMO, PPO, Individual Marketplace, & Elite, in addition, to Advantage.

	• Policy reviewed and updated to reflect most current clinical evidence per TAWG
03/24/17	• Added effective 01/01/17 new CPT code 81327 per PG0065 Colorectal Cancer Screening. • Added effective 01/01/17 new CPT codes 81413, 81414, 81439 per PG0280 Genetic Testing for Cardiac Conditions. • Added effective 01/01/17 new CPT code 81422 per PG0287 Cell-Free DNA Tests For Fetal Aneuploidy. • Added CPT code S3854 per PG0301 Genetic Expression Assays for Breast Cancer Prognosis. • Added CPT codes S3861- S3866 per PG0280 Genetic Testing for Cardiac Conditions. • Added CPT code S3870 per PG0296 Comparative Genomic Hybridization (CGH). • Added effective 01/01/17 new CPT codes 81539 as requires prior authorization for Advantage & non-covered for HMO, PPO, Individual Marketplace, & Elite. • Added CPT codes S3800-S3853 as non- covered for all product lines. • Deleted effective 12/31/16 CPT code 0010M (replaced by 81539). • Deleted effective 12/31/16 CPT codes 81280-81282 per PG0280 Genetic Testing for Cardiac Conditions. • Effective 01/01/17 code 81595 is now non-covered for Advantage per ODM guidelines (continues to be covered without prior authorization for HMO, PPO, Individual Marketplace, & Elite) for PG0340 AlloMap™ Molecular-Expression Blood Test. • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
01/25/18	• Added effective 01/01/18 new CPT codes 81520 & 81521 per PG0301 Genetic Expression Assays for Breast Cancer Prognosis. • Added effective 01/01/18 new CPT codes 81541 & 81551 per PG0367 Gene Expression Analysis for Prostate Cancer. • Effective 12/31/17 deleted code 0008M (replaced by 81520) per PG0301 Genetic Expression Assays for Breast Cancer Prognosis. • Added Proprietary Laboratory Analyses (PLA) Codes 0001U- 0034U per PG0417 Proprietary Laboratory Analyses (PLA) Codes & PG0367 Gene Expression Analysis for Prostate Cancer. • Revised effective 01/01/18 codes 81257, 81432, & 81439. • Added effective 01/01/18 new codes 81105, 81106, 81107, 81108, 81109, 81110, 81111, 81112, 81120, 81121, 81175, 81176, 81238, 81247, 81248, 81249, 81283, 81334, 81335, 81346, 81448 as covered with prior authorization for all product lines per CMS & ODM guidelines. • Added effective 01/01/18 new codes 81230, 81231, 81232 as covered with prior authorization for Advantage per ODM guidelines and non-covered for HMO, PPO, Individual Marketplace, & Elite per CMS guidelines. • Added effective 01/01/18 new codes 81258, 81259, 81269, 81328, 81361, 81362, 81363, 81364 as covered with prior authorization for HMO, PPO, Individual Marketplace, & Advantage and non-covered for Elite per CMS guidelines. • Added code G9143 per PG0390 Genetic Testing for Warfarin Dose. • Refer to PG0390 Genetic Testing for Warfarin Dose for coverage determination of codes G9143, 81227 & 81355. • Refer to PG0367 Gene Expression Analysis for Prostate Cancer for coverage determination of codes 81313 & 81539. • Refer to PG0375 Molecular Cytogenetic Testing for coverage determination of code 88271. • Refer to PG0411 Genetic Testing for Duchenne and Becker Muscular Dystrophy for coverage determination of codes 81161 & 81408. • Codes 81432, 81435, 81436, 81445, 81455 removed from PG0336 PTEN Hamartoma Tumor Syndrome.

	• Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
08/23/18	• Added reference to these genetic policies: o PG0358 Genetic Counseling; o PG0364 Gene Expression Profiling for Cancers of Unknown Primary Site (81504, 81540); o PG0374 Verifi Prenatal Test (81420, 81507, 0009M); o PG0387 Genetic Testing for Cystic Fibrosis (81220-81224); o PG0391 UGT1A1 Targeted Mutation Analysis for Irinotecan Response (81350); o PG0398 Genetic Testing for Spinal Muscular Atrophy (81400, 81401, 81403, 81405); o PG0412 Genetic Testing for Macular Degeneration (81401, 81405, 81408); PG0436 CYP2C19 & CYP2D6 Pharmacogenetic Testing (81225, 81226); o PG0437 HLA-B1502 & HLA-B5701 Pharmacogenetic Testing (81381); & o PG0438 Next Generation Sequencing (NGS) Tests for Advanced Cancer (81455, 81479); o PG0442 Carrier Screening for Genetic Diseases. • Updated title PG0298 from Afirma® Thyroid FNA Analysis to Molecular Markers in Fine Needle Aspirates of Thyroid Nodules. • Removed PG0334 ThyroSeq® v.2 Next Generation Sequencing (added to PG0298). • Removed Proprietary Laboratory Analyses (PLA) Codes (0001U-0044U) from this policy, refer to PG0417 Proprietary Laboratory Analyses (PLA) Codes. • Added effective 1/1/18 new Proprietary MAA code 0011M as non-covered for all product lines. • Added effective 4/1/18 new Proprietary MAA codes 0012M & 0013M as non- covered for all product lines. • Codes 81250 & 81255 are now non-covered for Elite per CMS guidelines. • Code 81438 is now covered with prior authorization for Elite per CMS guidelines. • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
7/22/19	• Added reference to genetic policy PG0453 Germline Multi-Gene Panel Testing. • Updated references to the following genetic policies: o PG0296 Comparative Genomic Hybridization (CGH)/Chromosomal Microarray Analysis (CMA), o PG0067 Genetic Testing for Hereditary Breast and Ovarian Cancer syndrome (HBOC), o PG0302 Genetic Testing for Lynch syndrome/Polyposis Syndromes, o PG0336 PTEN Genetic Testing, o PG0287 Non-Invasive Prenatal Screening (NIPS)/Cell-Free Screening for Fetal Aneuploidy, o PG0387 Cystic Fibrosis Genetic Testing, PG0398 Genetic Testing for Spinal Muscular Atrophy, o PG0360 Fragile X-Related Disorders, o PG0411 Genetic Testing for Dystriphinopathies (Duchenne and Becker Muscular Dystrophy), o PG0375 Molecular Cytogenetic Testing, and o PG0442 Carrier Screening for Genetic Disease. • Deleted specific gene names under 81400-81408, 81479 that were listed as not meeting medical necessity. • Added CPT codes 81163-81167, 81329, 81336, and 81337, which all require prior authorization. • Deleted CPT codes 81211, 81213, and 81214 to reflect changes in the CPT Coding Expert Manual.

	• CPT codes 81410, 81412, 81430-81436, 81438, 81440, 81442, 81460, 81465, 81470, 81471 were Previously non-covered for HMO, PPO, Individual, Marketplace, and Elite plans. • The policy was updated to reference PG0453 Germline Multi-Gene Panel Testing. • Deleted reference to 0004M as medical policy PG0125 has been retired
4/1/2020	• Updated policy with all active genetic codes related to the policy, including CPT genetic PLA U-codes
5/8/2020	• Policy corrections and updates. • Procedure G0452 was switched from Prior Authorization required to Non-covered for the Advantage Product line in error. Correction made. • Additionally, a review/determination made to allow coverage for the Commercial product lines with a Prior Authorization. • Additionally procedures 0111U and 0171U were added as covered with a Prior Authorization for the Elite Product line per https://www.cms.gov/files/document/mm11749.pdf , and click on this link, https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/CR11749.zip. • Additional review/determination to also allow coverage for 0171U for the Commercial product lines
12/14/2020	• Medical policy placed on a new Paramount medical policy format
02/21/2021	• 2021 new codes added to the medical policy along with coverage and prior authorizations determinations-see table above. o Procedure 0047U coverage change from Non-Covered to requires a Prior Authorization required for the Advantage Product line, effective 04/01/2021. o Procedures 81168, 81191, 81192, 81193, 81194, 81351, 81353, require a prior authorization, ALL product lines, effective 04/01/2021. o Procedures 81278, 81279, 81338, 81339, 81347, 81348, 81352, 81357, 81360, do not require a prior authorization, ALL product lines, effective 01/01/2021. o Procedures 81554, 0173U, 0174U, 0175U, 0177U, 0179U, 0180U, 0181U, 0182U, 0183U, 0184U, 0185U, 0186U, 0187U, 0188U, 0189U, 0190U, 0191U, 0192U, 0193U, 0194U, 0195U, 0196U, 0197U, 0198U, 0199U, 0200U, 0201U, 0203U, 0204U, 0205U, 0208U, 0209U, 0211U, 0212U, 0213U, 0214U, 0215U, 0216U, 0217U, 0218U, 0220U, 0221U, 0222U, 0229U, 0230U, 0231U, 0232U, 0233U, 0234U, 0235U, 0236U, 0237U, 0238U, 0239U are Non-Covered, ALL product lines, effective 01/01/2021. o Procedure 0172U requires a prior authorization for Commercial and Elite/ Medicare product lines, effective 04/01/2021. Procedure 0172U is Non-Covered, Advantage product line, effective 01/01/2021.
02/26/2021	• Per updated ODM 4/1/2021 fee schedule, procedures 0090U, 0172U and 81554 now require a prior authorization coverage for the Advantage product line. • Add procedure 0245U, effective 04/01/2021 • Procedure 0208U changed to require a prior authorization for Commercial and Elite/ Medicare per CMS coverage determination. • Procedure 81552 added to/addressed in medical policy PG0119 Gene Expression Profiling of Melanomas. Additionally, procedures 0090U and 81529 addressed in medical policy PG0019 Gene Expression Profiling of Melanomas. • Procedures 81210, 81406, 81445, 81479, 81545, 81546, 81599, 0018U, 0026U, 0204U, 0208U, 0245U addressed in updated/revised medical policy PG0298 Molecular Markers in Fine Needle Aspirates of Thyroid Nodules • Procedure 81419 added to medical policy PG0041 and to medical policies, PG0453 & PG0467 as covered prior authorization required effective 5/1/2021. • Procedure 81546 replaced for end-dated procedure 81545

	• Additionally medical policy PG0298 Molecular Markers in Fine Needle Aspirates of Thyroid Nodules updated with procedure 81546
04/11/2021	• Added unlisted procedure 81479 to the table, indicating prior authorization required for all product lines. Note: it was already listed in the green box under other medical policies as requiring a prior authorization.
08/06/2021	• Added documentation indicating that a prior authorization is required for all genetic testing unless specifically indicated otherwise, no matter the diagnosis.
01/04/2022	• <u>2022 new genetic codes added to the medical policy along with coverage and prior authorizations determinations changes-see table below.</u> o Added new 2022 procedure codes, 81349, 81523, 81560, 0229U, 0230U, 0231U, 0232U, 0233U, 0234U, 0235U, 0236U, 0237U, 0238U, 0239U, 0242U, 0245U, 0246U, 0250U, 0252U, 0253U, 0254U, 0258U, 0260U, 0262U, 0264U, 0265U, 0266U, 0267U, 0268U, 0269U, 0270U, 0271U, 0272U, 0273U, 0274U, 0276U, 0277U, 0278U, 0282U, 0285U, 0286U, 0287U, 0288U, 0289U, 0290U, 0291U, 0292U, 0293U, 0294U, 0295U, 0296U, 0297U, 0298U, 0299U, and 0300U. • Effective 1/1/2022 procedures 81331, S3854, S3865, S3866, and S3870 coverage change from Non-Covered to Covered with a Prior Authorization, for the Commercial product lines. • Effective 1/1/2022 procedures 81503, 0012M, 0013M, 0005U, 0018U, 0026U, and 0111U to change from Non-Covered to Covered with a Prior Authorization, for the Elite product. • Effective 1/1/2022 procedures 81355, 0171U, and G0452, to change from Non-Covered to Covered with a Prior Authorization, for the Commercial and Elite/ Medicare Plan products. • Effective 1/1/2022 procedures 0037U and 0047U to change from Non-Covered to Covered with a Prior Authorization, for the Advantage product. • Effective 4/1/2021 procedures 0090U and 0172U to change from Non-Covered to Covered with a Prior Authorization, for the Advantage product. • Effective 1/1/2022 procedure 0179U to change from Non-Covered to Covered with a Prior Authorization, for All products.

02/01/2022	• Policy updated to coordinate coverage indicated in medical policy PG0367 Genetic and Protein Biomarkers for Diagnosis and Risk Assessment of Prostate Cancer
	  o The unlisted procedure 81479 for Deciper updated to procedure 81542
	  o Advantage coverage for procedure 0047U, 81541, 81542, 81551 changed from non-covered to covered with a prior authorization
	  o Elite/ Medicare Plan coverage for procedure 81539 changed from non-covered to covered with a prior authorization
	  o Procedure 0005U added: non-covered for HMO, PPO, Individual Marketplace, and Advantage
	  o Procedure 0005U added: coverage with prior authorization for Elite/ Medicare Plan
	• Added the following new U-codes, 0306U, 0307U, 0313U, 0314U, 0315U, 0317U, 0318U, 0319U, and 0320U, effective 4/1/2022

02/23/2022	• Added procedures 0016M and 0017M • Changed coverage for procedure 0244U from noncoverage to covered with a prior authorization, effective 4/1/2022, per ODM
06/24/2022	• Changed coverage for procedure 0026U from noncoverage to covered with a prior authorization, for the Commercial product lines, HMO, PPO, Individual Marketplace, effective 6/1/2022

08/08/2022	• Added procedures 0326U, 0327U, 0329U, 0331U, 0332U, 0333U, 0334U, 0335U, 0336U, 0337U, 0338U, 0339U, 0340U, 0341U, 0343U, 0345U, 0347U, 0348U, 0349U, 0350U.
10/01/2022	• Added, Effective 10/01/2022 procedure 81420 does not require a prior authorization of the Advantage product line, PG0287 Non-Invasive Prenatal Screening (NIPS)/ Cell-Free DNA Screening for Fetal Aneuploidy
10/18/2022	• Medical Policy updated to allow procedure 81539 coverage with a prior authorization for the HMO, PPO, Individual Marketplace product lines, effective 11/1/2022
10/21/2022	• Corrected a typo for the date above in the table, for the effective date that procedure 81539 went from noncovered to covered with a prior authorization; typo-1/11/2022 to the correction 11/1/2022.
01/16/2023	• Added procedures 81418, 81441, 81449, 81451, 81456, 0355U, 0356U, 0362U, 0363U, 0364U, 0368U, 0378U, 0379U, 0380U, 0386U.
01/31/2023	• Paramount added the new 2023 Genetic Codes, indicating coverage/noncoverage/prior authorization criteria (procedure codes 81418, 81441, 81449, 81451, 81456, 0355U, 0356U, 0362U, 0363U, 0364U, 0368U, 0378U, 0379U, 0380U, 0386U) • Removed deleted procedure code 81545 • Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
05/01/2023	• Documentation added indicating that procedure codes 0013U, 0014U, 0056U, 0208U ARE deleted codes effective 01/01/2023. • Added procedure codes 0388U, 0389U, 0391U, 0392U, 0396U, 0397U, 0398U, 0400U, and 0401U indicating coverage/noncoverage/prior authorization criteria, effective 07/01/2023
05/05/2023	• Documented the deletion date July 1, 2023 for procedure 0053U
06/01/2023	• Clarified coverage detail for procedure codes 81381, 88230-88299
07/17/2023	• Changed procedure 0118U, for the Medicare Advantage Plans, from non-covered to requires a prior authorization effective 9/1/2023-PG0525 Molecular Testing for Solid Organ Allograft Rejection • PG0340 AlloMap™ Molecular-Expression Blood Test-Archived and Added to medical policy PG0525 Molecular Testing for Solid Organ Allograft Rejection
07/31/2023	• Changed procedure 0326U coverage for the Paramount Commercial Insurance plans from prior authorization to noncoverage, per SB genetic counselor review. Medical policy PG0500 update review.
11/07/2023	• Added Percepta Genomic Sequencing Classifier (81479) coverage classification to the medical policy, covered with a prior authorization for the Medicare plans and non-covered for the Commercial plans
02/01/2024	• Medical Policy placed on new Paramount Medical Policy Format • Revised coverage on procedures 0047U, 81541, 81551, 0005U. 0339U. • Added noncovered codes 0021U, 0113U, 0133U, 0228U, 0359U, 0376U, 0403U, 0424U, 0433U
02/13/2024	• Effective 02/01/2024 new policy created PG0533 Genetic Testing for Neurodegenerative Disorders, procedures 81271, 81274 and 0233U now covered with a prior authorization
03/13/2024	• Clarified procedure 0326U was removed from medical policy PG0500, as it does not apply
04/08/2024	• Added Effective 04/01/2024 PRIOR AUTHORIZATION REQUIRED for the following procedure codes 81415, 81416, 81417 for the Medicare Advantage Plans, and 81425, 81426, 81427, 0094U, 0209U, 0212U, 0213U, 0214U, 0215U, 0287U, 0298U, 0299U, 0300U, 0410U, 0413U, 0417U, 0425U, 0426U for all product lines.
06/01/2024	• Changed the medical policy name from Genetic Testing to Genetic Testing and Genetic Counseling

	• Updated the medical policy to only include genetic testing coverage criteria • The genetic code table has been deleted and placed on the Paramount PRIOR AUTHORIZATION – EXPERIMENTAL/INVESTIGATIONAL – NONCOVERED SERVICES excel spreadsheet • Medical policy PG0358 Genetic Counseling archived, and the documentation added to this medical policy PG0041 Genetic Testing and Genetic Counseling
09/01/2024	• Removed the Paramount Related Genetic Medical Policies listings as this information is documented in the code listing on the PRIOR AUTHORIZATION – EXPERIMENTAL/INVESTIGATIONAL – NONCOVERED SERVICES, excel spreadsheet, found at: https://www.paramounthealthcare.com/providers/claims-and-authorizations/outpatient-prior-authorization
03/01/2025	• The new code, 96041, will replace 96040 on January1, 2025 • Updated the medical policy with the updated genetic counseling code 96041, effective 01/01/2025 • Genetic counseling code 96040 deleted effective 01/10/2025

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

Centers for Disease Control and Prevention. (June, 2022). *Genetic Counseling.* Retrieved from: https://www.cdc.gov/genomics/gtesting/genetic_counseling.htm.

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/
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Hayes, Inc., Lansdale, PA: Author. Health Technology Assessments., https://www.hayesinc.com/

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