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Commercial Medical Policy



Medical Policy Bulletin

Title:

Genetic Testing (AmeriHealth Administrators)

Policy #:

06.02.35ao

The Company makes decisions on coverage based on Policy Bulletins, benefit plan documents, and the member's medical history and condition. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Medical Policy Bulletin document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged or new medical literature may have been published. This Medical Policy Bulletin will be reviewed regularly and be updated as scientific and medical literature becomes available. For more information on how Medical Policy Bulletins are developed, go to the Policy Types and Descriptions section of this Medical Policy Web site.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's contract.

This policy only applies to members for whom AmeriHealth Administrators serves as the claims administrator and whose group has not enrolled in the UM vendor program. For those groups who have been given the option to enroll in the UM vendor program, this policy is no longer applicable upon their renewal effective date. Individual member benefits must be verified before/prior to providing services.

The intent of this policy is to communicate the coverage positions for genetic testing.

For information on policies related to this topic, refer to the Cross References section in this policy.

Refer to Attachment A for a list of codes and services that may represent medically necessary genetic testing and may be covered for an individual when the testing has a direct effect on the management and clinical care of the individual being tested.

Refer to Attachment B for a list of codes and services that may represent medically necessary genetic testing and may be covered for an individual when the testing has a direct effect on the management and clinical care of the individual being tested and if test-specific criteria are met.

Refer to Attachment C for a list of codes and services that represent genetic testing for indications that the Company considers experimental/investigational. The peer-reviewed literature does not support at least one of the following for the testing:

- The analytical validity and/or

- The clinical validity and/or
- Direct effect on the management and clinical care of the individual being tested based upon the test's results (i.e. clinical utility).

Any genetic testing not addressed in this policy may be considered medically necessary, and, therefore, covered when all of the following criteria are met:

- The testing is used for individuals at risk by pedigree for a specific hereditary disease among other physiological and environmental factors, and when this testing is intended for screening, diagnosis, prognosis, predictive testing (pharmacogenomic), risk assessment, neonatal screening, and reproductive decision-making.
- The analytical (technical) validity of the test has been confirmed (e.g., reliability and repeatability of the test are established through standard protocols).
- Biological and clinical validity, (i.e. genotype to phenotype correlation), of the test have been established through the peer-reviewed literature.
- Peer-reviewed support and data establish the objective effect(s) of the test results on direct management and care of the individual for all applicable indications and clinical situations to verify clinical utility of the test.

When a benefit exists, genetic testing is an eligible service for individuals who have a Company benefit and the genetic testing is used only for the covered individual's clinical benefit. Testing of associated family members, without a Company benefit, is not eligible for reimbursement.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the service.

BILLING REQUIREMENTS

The "stacking code" method (and associated modifiers usage) of reporting genetic testing should not be used, since these codes and modifiers have been retired as of 01/01/2013. Where available, the most specific CPT or HCPCS codes must be used for billing.

The specific genetic test(s) being performed should be reported when using CPT codes 81400-81408.

Guidelines

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, genetic testing is covered under the medical benefits of the Company's products when the medical necessity criteria listed in this medical policy are met.

However, services that are identified in this policy as experimental/investigational OR not medically necessary are not eligible for coverage or reimbursement by the Company.

US FOOD AND DRUG ADMINISTRATION STATUS

Genetic testing is a laboratory procedure and is historically not regulated by the US Food and Drug Administration (FDA). Clinical Laboratory Improvement Amendments (CLIA) establishes quality standards for all laboratory testing. However, recently, the FDA is reported to be involved in the evaluation of the service of genetic testing.

Description

Genetic testing identifies changes in chromosomes, genes, or proteins. The term "genetic testing" covers an array of techniques, including analysis of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), genes, or gene products (e.g., enzymes and other types of protein).

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 decisions 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 genes 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).

The Centers for Disease Control and Prevention (CDC) Office of Public Health Genomics helped to establish and support the ACCE Model Project, which has become the standard for evaluating scientific data on new genetic tests. The ACCE Model System* for Collecting, Analyzing and Disseminating Information on Genetic Tests provides an evaluation framework that is applicable to a variety of genetic tests. The Evaluation of Genomic Applications in Practice and Prevention (EGAPP) used the ACCE framework and established this process as a way of evaluating an evidence-based method for assessing genetic tests and other types of genomic technology as it has transitioned from the research arena to the practice arena. The ACCE evaluation framework examines:

- **Analytical validity:** Measures the specific genotypic test performance characteristics and whether the test accurately and reliably detects the gene marker(s) of interest. This refers to how well a test performs in the laboratory and how well the test measures the property or characteristic it is intended to measure. If the test does what its makers claim, it must produce the same results repeatedly and in different laboratories given the same set of procedures.
- **Clinical validity:** Refers to the associations of the test result(s) with patient outcomes of interest, and may be expressed as clinical sensitivity, specificity, and predictive value for the outcome. Evidence is usually retrospective. This component refers to the accuracy with which a test predicts the presence or absence of a clinical condition or predisposition. Initially, the test has to be conducted on individuals who are known to have the condition (as well as those who do not) to determine its success rate.
- **Clinical utility:** Clinical utility determines whether the use of genetic testing to modify medical management decisions improves patient outcomes. Best evidence is prospective, from randomized clinical trials of standard management procedures versus genetic test--directed management. Evidence may also be derived using banked samples from already completed clinical trials, or by constructing an indirect chain of evidence linking test results to clinical outcome. If a test has utility, it means that the result (positive or negative) provides information that can be used in the formulation of an effective treatment or preventive strategy.
- **Ethical, Legal, and Social Implications:** Determines what, if any, ethical, legal, or social implications may arise from the use of this test and its results.

*From: Haddow JE, Palomaki GE. ACCE: A Model Process for Evaluating Data on Emerging Genetic Tests. In: *Human Genome Epidemiology: A Scientific Foundation for Using Genetic Information to Improve Health and Prevent Disease*. Khoury M, Little J, Burke W (eds.), Oxford University Press, pp. 217-233, 2003.

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Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)

See Attachments A, B, and C.

ICD - 10 Procedure Code Number(s)

N/A

ICD - 10 Diagnosis Code Number(s)

N/A

HCPCS Level II Code Number(s)

See Attachments A, B, and C.

Revenue Code Number(s)

N/A

Cross Reference

Attachment A: Genetic Testing (AmeriHealth Administrators)

Description: Services that are Considered Medically Necessary

Attachment B: Genetic Testing (AmeriHealth Administrators)

Description: Services that are Considered Medically Necessary with Criteria

Attachment C: Genetic Testing (AmeriHealth Administrators)

Description: Services that are Considered Experimental/Investigational

Policy History

Revisions From 06.02.35ao:

07/01/2024	<p>This version of the policy is a result of code updates effective 07/01/2024.</p> <p>Following procedure code has been deleted from this policy because it has been retired.</p> <p>0204U</p> <p>Following procedure codes are being added to this policy:</p> <p>0020M, 0452U, 0453U, 0454U, 0455U, 0456U, 0460U, 0461U, 0463U, 0465U, 0466U, 0467U, 0469U, 0470U, 0471U, 0473U, 0474U, and 0475U</p>
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Revisions From 06.02.35an:

05/29/2024	This policy has been reissued in accordance with the Company's annual review process.
04/01/2024	<p>This version of the policy is a result of code updates effective 04/01/2024.</p> <p>Following procedure codes are being added to this policy:</p> <p>0439U, 0440U, 0444U, 0448U, and 0449U</p> <p>Following procedure code has been deleted from this policy because it has been retired:</p> <p>0354U</p>

Revisions From 06.02.35am:

01/01/2024	<p>This version of the policy is a result of code updates effective 01/01/2024.</p> <p>Narratives for the following procedure codes have been revised:</p> <p>0356U, 81171, 81172, 81243, 81244, 81445, 81449, 81450, 81455, 81456</p> <p>Following procedure codes are being added to this policy:</p> <p>0420U, 0421U, 0422U, 0423U, 0424U, 0428U, 0429U, 0433U, 0434U, 0437U, 0438U, 81457, 81458, 81459, 81462, 81463, 81464, 87523</p>
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Revisions From 06.02.35al:

10/01/2023	<p>This version of the policy is a result of code updates effective 10/01/2023.</p> <p>Narratives for the following procedure codes have been revised: 0269U, 0271U, 0272U, 0274U, 0277U, 0278U, & 0362U</p> <p>Following procedure code has been deleted from this policy because it has been retired. 0386U</p> <p>Following procedure codes are being added to this policy: 0403U, 0405U, 0406U, 0409U, 0410U, 0411U, 0413U, 0414U, 0418U, & 0419U</p>
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Revisions From 06.02.35ak:

07/01/2023	<p>This version of the policy is a result of code updates effective 07/01/2023.</p> <p>Following procedure code was added to Attachment B of the policy: 0397U</p> <p>Following procedure codes were added to Attachment C of the policy: 0388U, 0389U, 0391U, 0392U, 0395U, 0396U, 0398U, 0400U, 0401U</p> <p>Narrative for the following procedure codes in Attachment C was revised in the policy: 0113U</p> <p>Following procedure code was deleted from Attachment C of the policy because it was termed: 0053U</p>
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Revisions From 06.02.35aj:

05/31/2023	This policy has been reissued in accordance with the Company's annual review process.
04/01/2023	<p>This version of the policy is a result of code updates effective 04/01/2023.</p> <p>The following procedure codes were added to the policy: 0364U, 0368U, 0369U, 0370U, 0371U, 0372U, 0373U, 0374U, 0378U, 0379U, 0380U, and 0386U</p> <p>Narrative for the following procedure code was revised: 0022U</p>

Revisions From 06.02.35ai:

01/01/2023	<p>This policy has been identified for the code updates effective 01/01/2023.</p> <p>The following procedure codes are being added to this policy:</p> <p>81418 81441 81449 81451 81456 87468 87469 87478 87484 0355U 0356U 0362U 0363U</p>
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Revisions From 06.02.35ah:

10/01/2022	<p>This version of the policy is a result of code updates effective 10/01/2022.</p> <p>Following procedure codes were added to the policy:</p> <p>0332U, 0333U, 0334U, 0335U, 0336U, 0339U, 0340U, 0341U, 0343U, 0345U, 0347U, 0348U, 0349U, 0350U, 0352U, 0353U, & 0354U</p> <p>Narratives for the following procedure codes were revised in the policy:</p> <p>0276U & 0296U</p> <p>Following procedure codes were deleted from the policy because they were termed:</p> <p>0012U, 0013U, 0014U, & 0056U</p>
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Revisions From 06.02.35ag:

07/01/2022	<p>This version of the policy is a result of code updates effective 07/01/2022.</p> <p>Following procedure codes were added to Attachment B of this policy:</p> <p>0326U & 0327U</p> <p>Following procedure codes were added to Attachment C of this policy:</p> <p>0323U, 0329U, 0330U, & 0331U</p> <p>Narratives for the following procedure codes were revised:</p> <p>0229U</p> <p>Furthermore:</p> <p>The following disclaimer language...:</p> <p><i>This policy only applies to members for whom AmeriHealth Administrators serves as the claims administrator and whose group has not enrolled in the UM vendor program. For those groups who have been given the option to enroll in the UM vendor program, this policy is no longer applicable upon their renewal effective date. Individual member benefits must be verified before/prior to providing services.</i></p> <p>... is replacing this disclaimer language...:</p> <p><i>This policy only applies to members for whom AmeriHealth Administrators serves as the claims administrator. For all other Independence members, refer to the policy entitled eviCore Lab Management Program.</i></p>
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Revisions From 06.02.35af:

06/01/2022	This policy has been reissued in accordance with the Company's annual review process.
04/01/2022	<p>This version of the policy is a result of code updates effective 04/01/2022.</p> <p>Following procedure codes were added to the policy:</p> <p>0306U, 0307U, 0311U, 0313U, 0314U, 0315U, 0317U, 0318U, 0319U, 0320U, and 0321U</p> <p>Narrative for the following procedure code was revised in this policy:</p> <p>0022U</p> <p>Following procedure codes were deleted from this policy due to termination of the codes:</p> <p>0097U and 0151U</p>

Revisions From 06.02.35ae:

01/01/2022	<p>This version of the policy is a result of code updates effective 01/01/2022.</p> <p>Following procedure codes were added to Attachment B of this policy:</p> <p>0287U, 0301U, 0302U, 81349, & 87154</p> <p>Following procedure codes were added to Attachment C of this policy:</p> <p>0285U, 0286U, 0288U, 0289U, 0290U, 0291U, 0292U, 0293U, 0294U, 0296U, 0297U, 0298U, 0299U, and 0300U</p> <p>Narratives for the following procedure codes were revised:</p> <p>81228, 81229, 0090U, 0152U</p> <p>Following procedure code was deleted:</p> <p>0208U</p>
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Revisions From 06.02.35ad:

11/03/2021	This policy has been reissued in accordance with the Company's annual review process.
10/01/2021	<p>This version of the policy is a result of code updates effective 10/01/2021.</p> <p>Following procedure codes were added:</p> <p>0258U 0260U 0262U 0264U 0265U 0266U 0267U 0268U 0269U 0270U 0271U 0272U 0273U 0274U 0276U 0277U 0278U 0282U</p>

Revisions From 06.02.35ac:

07/01/2021	<p>This version of the policy is effective as of 07/01/2021, and is in place due to coding updates.</p> <p>The following procedure codes has been added to Attachment C of this policy:</p> <p>0250U, 0252U, 0253U, & 0254U</p>
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Revisions From 06.02.35ab:

04/01/2021	<p>This version of the policy is effective as of 04/01/2021, and is in place due to coding updates.</p> <p>The following procedure codes have been added to Attachment B of this policy:</p> <p>0242U, 0245U, & 0246U</p> <p>The following procedure code has been added to Attachment C of this policy:</p> <p>0244U</p> <p>The following procedure codes have been deleted from this policy:</p> <p>0098, 0099U, & 0100U</p> <p>-- Also, procedure code 0026U has been moved from Attachment C of this policy to Attachment B of this policy.</p>
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Revisions From 06.02.35aa:

01/01/2021	<p>This version of the policy went through a code update process effective 01/01/2021.</p> <ul style="list-style-type: none"> • Procedure codes 81168, 81191, 81192, 81193, 81194, 81278, 81279, 81338, 81339, 81347, 81348, 81351, 81352, 81353, 81357, 81360, 81419, 81546, 0230U, 0231U, 0232U, 0233U, 0234U, 0235U, 0236U, 0237U, 0238U and 0239U were added to Attachment B. • Procedure codes 81513, 81524, 81529, 81554, 0228U, 0229U and 0017M were added to Attachment C. • Procedure code 81545 was deleted from attachment B per code update process effective 01/01/2021.
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Revisions From 06.02.35z:

10/01/2020	<p>This version of the policy became effective on 10/01/2020.</p> <p>The following changes have been made due to code updates:</p> <ul style="list-style-type: none"> • Procedure codes 0208U, 0214U, 0215U, 0216U, 0217U, 0218U, 0219U, 0221U and 0222U were added to Attachment B. • Procedure codes 0016M, 0203U, 0204U, 0205U, 0209U, 0211U, 0212U, 0213U and 0220U were added to Attachment C. <p>Additionally, procedure codes 87506 and 87507 have been moved from attachment C, and added to attachment B of this policy.</p>
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Revisions From 06.02.35y:

07/01/2020	<p>This version of the policy is effective of as of 07/01/2020.</p> <p>The following changes have been made due to code updates:</p> <ul style="list-style-type: none"> • Procedure codes 0177U, 0180U, 0181U, 0182U, 0183U, 0184U, 0185U, 0186U, 0187U, 0188U 0189U, 0190U, 0191U, 0192U, 0193U, 0194U, 0195U, 0196U, 0197U, 0198U, 0199U, 0200U and 0201U have been added to Attachment B of this policy. • Procedure codes 0173U, 0175U and 0179U have been added to Attachment C of this policy. <p>Additionally, procedure codes 81415, 81416 and 81417 have been moved from Attachment C of this policy and added to Attachment B of this policy.</p>
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Revisions From 06.02.35x:

04/01/2020	<p>This version of the policy went through a code update process effective 04/01/2020:</p> <ul style="list-style-type: none"> • Code narrative for procedure codes 0154U and 0155U were revised. • Procedure codes 0169U, 0170U, and 0171U were added this policy.
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Revisions From 06.02.35w:

03/25/2020	This policy has been reissued in accordance with the Company's annual review process.
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01/01/2020	<p>This version of the policy will become effective on 01/01/2020 due to coding updates.</p> <p>The following codes are being deleted from the policy:</p> <p>0081U, 0009M</p> <p>Narratives for the following codes are being revised in the policy:</p> <p>81350 0011M 81404 81406 81407</p> <p>The following codes are being added to the policy:</p> <p>0140U 0141U 0142U 0151U 0152U 0153U 0154U 0155U 0156U 0157U 0158U 0159U 0160U 0161U 0162U 81277 81307 81308 81309 81522 81542 81552 87563</p>
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Revisions From 06.02.35v:

11/06/2019	This policy has been reissued in accordance with the Company's annual review process.
10/01/2019	<p>This version of the policy went through a code update process effective 10/01/2019:</p> <ul style="list-style-type: none"> • Procedure code 0104U was deleted from this policy. • Procedure codes 0109U, 0111U, 0112U, 0113U, 0114U, 0115U, 0118U, 0120U, 0129U, 0130U, 0131U, 0132U, 0133U, 0134U, 0135U, 0136U, 0137U, and 0138U were added to Attachment C of this policy.

Revisions From 06.02.35u:

07/01/2019	<p>This version of the policy went through a code update process effective 07/01/2019:</p> <ul style="list-style-type: none">• Procedure code 0057U was deleted from this policy.• Procedure codes 0084U, 0096U and 0098U were added to Attachment B of this policy.• Procedure codes 0086U, 0087U, 0088U, 0089U, 0090U, 0094U, 0097U, 0099U, 0100U, 00101U, 00102U, 00103U and 00104U were added to Attachment C of this policy.
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Revisions From 06.02.35t:

01/01/2019	<p>Effective 01/01/2019, the following CPT codes have been added to Attachment B for this policy due to coding updates. The services represented by these procedure codes are considered medically necessary only when criteria are met:</p> <p>81163 81164 81165 81166 81167 81171 81172 81173 81174 81177 81178 81179 81180 81181 81182 81183 81184 81185 81186 81187 81188 81189 81190 81204 81233 81234 81236 81237 81239 81271 81274 81284 81285 81286 81289 81305 81306 81312 81320 81329 81333 81336 81337 81343 81344 81345 81443 81518 0081U</p>
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	<p>Effective 01/01/2019, narratives for the following CPT codes have been revised in Attachment B for this policy due to coding updates. The services represented by these procedure codes are considered medically necessary only when criteria are met:</p> <p>81162, 81212, 81215, 81216, 81217, 81244, 81287</p> <p>Effective 01/01/2019, the following CPT code narrative has been revised in Attachment C for this policy due to coding updates. The services represented by these procedure codes are considered experimental/investigational:</p> <p>81327</p> <p>Effective 01/01/2019, the following CPT codes have been deleted from Attachment B for this policy due to coding updates:</p> <p>81211, 81213, 81214</p>
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Revisions From 06.02.35s:

11/21/2018	This policy has been reissued in accordance with the Company's annual review process.
10/01/2018	<p>Effective 10/01/2018, the following CPT codes have been added to Attachment B for this policy due to coding updates. The services represented by these procedure codes are considered medically necessary only when criteria are met:</p> <p>0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U</p> <p>Effective 10/01/2018, the following CPT codes have been added to Attachment C for this policy due to coding updates. The services represented by these procedure codes are considered experimental investigational:</p> <p>0067U, 0068U, 0069U, 0078U, 0079U</p> <p>Effective 10/01/2018, the following CPT code has been deleted from this policy due to coding updates:</p> <p>0028U</p>

Revisions From 06.02.35r:

07/01/2018	<p>Effective 07/01/2018, the following CPT codes have been added to Attachment B for this policy due to coding updates. The services represented by these procedure codes are considered medically necessary only when criteria are met:</p> <p>0046U, 0049U</p> <p>Effective 07/01/2018, the following CPT codes have been added to Attachment C for this policy due to coding updates. The services represented by these procedure codes are considered experimental investigational:</p> <p>0045U, 0047U, 0048U, 0050U, 0053U, 0055U, 0056U, 0057U, 0060U</p>
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Revisions From 06.02.35q:

04/01/2018	<p>Effective 04/01/2018, the following CPT codes have been added to Attachment B for this policy due to coding updates. The services represented by these procedure codes are considered medically necessary only when criteria are met:</p> <p>0040U</p> <p>Effective 04/01/2018, the following CPT codes have been added to Attachment C for this policy due to coding updates. The services represented by these procedure codes are considered experimental investigational:</p> <p>0036U, 0037U, 0012M, 0013M</p> <p>The following CPT codes have been deleted from Attachment C for this policy because of their termination by AMA:</p> <p>0004U, 0015U</p>
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Revisions From 06.02.35p:

01/01/2018	<p>Effective 01/01/2018, the following CPT codes have been added to Attachment B for this policy due to coding updates. The services represented by these procedure codes are considered medically necessary only when criteria are met:</p> <p>0500T, 81105, 81106, 81107, 81108, 81109, 81110, 81111, 81112, 81120, 81121, 81175, 81176, 81232, 81238, 81247, 81248, 81249, 81258, 81259, 81269, 81334, 81335, 81361, 81362, 81363, 81364, 81520, 81521, 81551, 87634, 87662, 0027U</p> <p>Effective 01/01/2018, the following CPT codes have been added to Attachment C for this policy due to coding updates. The services represented by these procedure codes are considered experimental investigational:</p> <p>81230, 81231, 81283, 81328, 81346, 81448, 81541, 0026U, 0028U, 0029U, 0030U, 0031U, 0032U, 0033U, 0034U, 0011M</p> <p>Effective 01/01/2018, the narratives for the following procedure codes have been revised due to coding updates:</p> <p>81257, 81432, 81439</p>
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Revisions From 06.02.35o:

11/22/2017	This policy has been reissued in accordance with the Company's annual review process.
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Effective 10/05/2017 this policy has been updated to the new policy template format.

Version Effective Date: 07/01/2024

Version Issued Date: 01/06/2025

Version Reissued Date: N/A