IHCP *bulletin*

INDIANA HEALTH COVERAGE PROGRAMS BT201459 DECEMBER 2, 2014

IHCP announces a general coverage policy for genetic testing services

Effective January 1, 2015, the Indiana Health Coverage Programs (IHCP) will implement a new general policy regarding coverage of genetic testing services. This policy will address IHCP's coverage of genetic testing services overall. Coverage policies issued regarding specific genetic tests or techniques will supplement this policy.

The National Human Genome Research Institute defines genetic testing as follows:

> *The term "genetic testing" covers an array of techniques including analysis of human DNA, RNA or protein. Genetic tests are used as a healthcare tool to detect gene variants associated with a specific disease or condition, as well as for non-clinical uses such as paternity testing and forensics. In the clinical setting, genetic tests can be performed to confirm a suspected diagnosis, to predict the possibility of future illness, to detect the presence of a carrier state in unaffected individuals (whose children may be at risk), and to predict response to therapy. They are also performed to screen fetuses, newborns or embryos used in in-vitro fertilization for genetic defects.*

Coverage requirements

The IHCP provides coverage for a variety of genetic tests when provided in compliance with IHCP coverage and billing guidelines. The following circumstances apply for any genetic testing service to be covered:

- The genetic disorder must be associated with a potentially significant disability; and
- The risk of the significant disability from the genetic disorder cannot be identified through biochemical or other testing (for example, ultrasound screening for aortic disease in Marfan's syndrome); and
- A specific mutation, or set of mutations, has been established in scientific literature to be reliably associated with the disease; and
- The results of the genetic test could impact the medical management of the individual with improved net-health outcomes; and
- No determinable diagnosis can be gathered from the history, physical examination, pedigree analysis, genetic counseling, and completion of conventional diagnostic studies
- Prior authorization is obtained, if required

Under the following circumstances, genetic testing services are not covered:

- Testing for the sole convenience of information for the patient without impacting treatment
- All screening tests, except those listed under the State's required Newborn Screening
- Tests performed for the medical management of other family members unless otherwise specified in policy
- History, physical examination, pedigree analysis, genetic counseling, or completion of conventional diagnostic studies has given a definitive diagnosis
- The genetic test was previously performed for the member to provide a conclusive diagnosis of the same genetic disorder
- Testing to establish paternity

Additional guidelines for coverage of certain categories of genetic testing are included in the following subsections.

Molecular pathology

Molecular pathology procedures are medical laboratory procedures involving the analyses of nucleic acid to detect variants in genes that may be indicative of germline (for example, constitutional disorders) or somatic (for example, neoplasia) conditions, or to test for histocompatibility antigens, such as HLA. This is the largest group of genetic tests.

Many molecular genetic tests are IHCP-covered services. To be covered, these tests must meet the general criteria previously stated as well as meet all test-specific guidelines established by the American College of Medical Genetics.

Cytogenetics

The National Human Genome Research Institute defines cytogenetics as "the branch of genetics that studies the structure of DNA within the cell nucleus. This DNA is condensed during cell division and form chromosomes. Cytogenetics studies the number and morphology of chromosomes. Using chromosome banding techniques (classical cytogenetics) or hybridization fluorescently labeled probes (molecular cytogenetics)."

Most cytogenetic tests are IHCP-covered services. To be covered, these tests must meet the general criteria previously stated as well as meet all test-specific guidelines established by the American College of Medical Genetics.

Multianalyte Assays with Algorithmic Analyses

Multianalyte Assays with Algorithmic Analyses (MAAAs) are procedures that use multiple results derived from assays of various types, including molecular pathology assays, fluorescent in situ hybridization assays, and non-nucleic acid-based assays, such as proteins, polypeptides, lipids, and carbohydrates. Algorithmic analysis using the results of these assays as well as other patient information is then performed and reported typically as a numeric score or a probability.

In general, MAAA procedures are noncovered services, because they do not provide a definitive diagnosis or change the course of treatment. Policy exceptions may be established for specific MAAA procedures.

Genetic tests for cancer susceptibility

Several genetic tests exist for a determination or risk score associated with inheritable cancer susceptibility, such as BRCA or HNPCC testing. Providers should check the IHCP Fee Schedule at indianamedicaid.com for coverage of specific tests. Cancer-susceptibility genetic testing is a covered service when the general criteria **and** the following conditions are met:

- A specific mutation, or set of mutations, has been established in the scientific literature to be reliably associated with the risk of developing malignancy; and
- The results of the genetic test must potentially affect at least one of the management options considered by the referring, ordering, or treating physician in accordance with accepted standards of medical care, including any one of the following:
  - Surgery, or the extent of surgery; or
  - A change in surveillance; or
  - Hormonal manipulation; or
  - A change in standard therapeutic or adjuvant chemotherapy
- All criteria set forth in test-specific coverage policies must also be met.

Genetic testing panels

Genetic testing panels are not covered.

Prior authorization requirements

Prior authorization (PA) is always required unless otherwise noted within the IHCP Fee Schedule or by test-specific coverage policy.

PAs are test-specific and providers must follow all available guidelines established by the American College of Medical Genetics. If no guidelines are available, providers should follow commonly accepted medical guidelines, such as Amsterdam II or revised Bethesda guidelines for HNPCC. All IHCP policy guidelines must also be met for PA approval. The following documentation is required for PA review:

- Documentation outlining medical necessity, specifically stating the impact on the patient's treatment
- Documentation that genetic counseling has been performed prior to testing
- Results from any commonly used conventional diagnostic testing showing inconclusive diagnosis
- All other general documentation required for PA

Billing requirements

Providers are reminded that genetic tests specific to a gene or a condition are limited to once per member, per lifetime unless otherwise specified in a test-specific coverage policy. For genetic tests not specific to a gene or a condition, providers must have medical documentation on file, which identifies each testing procedure is for a separate and distinct diagnosis.

Providers should see the IHCP Fee Schedule, the *IHCP Provider Manual*, or IHCP publications for billing guidelines.

In accordance with these new coverage policies, the following billing changes will apply for claims with dates of service (DOS) on or after January 1, 2015:

- Adding coverage for the procedure codes listed in Table 1. Coverage applies to all IHCP programs, subject to limitations established for certain benefit packages.
- Ending coverage for procedure codes listed in Table 2. Please note that the genetic counseling procedure code S0265 has been replaced with Current Procedural Terminology (CPT®[1]) code 96040 – *Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family*. Because genetic counselors are not enrolled as IHCP billing or rendering providers, this code must be billed by the supervising physician.
- Adding a PA requirement and in some instances revenue codes for the IHCP-covered genetic testing codes listed in Table 3.

These coverage and PA changes will be reflected in the next monthly update to the IHCP Fee Schedule at indianamedicaid.com. PA, reimbursement, and billing information applies to services provided under the fee-for-service (FFS) delivery system. Individual managed care entities (MCEs) establish and publish PA, reimbursement, and billing criteria within the risk-based managed care (RBMC) delivery system. Questions about FFS-PA should be directed to ADVANTAGE Health Solutions℠ at 1-800-269-5720. Questions about RBMC-PA should be directed to the MCE with which the member is enrolled.

Table 1 – Codes covered for DOS on or after January 1, 2015

CPT code	Description	PA required
81201	APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; full gene sequence	Yes
81202	APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; known familial variants	Yes
81203	APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; duplication/deletion variants	Yes
81220	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; common variants (eg, ACMG/ACOG guidelines)	Yes
81243	FMR1 (fragile x mental retardation 1) (eg, fragile x mental retardation) gene analysis; evaluation to detect abnormal (eg, expanded alleles)	Yes
81244	FMR1 (fragile x mental retardation 1) (eg, fragile x mental retardation) gene analysis; characterization of alleles (eg, expanded size and methylation status	Yes
81257	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, HB Bart Hydrops Fetalis syndrome, HBH disease), gene analysis, for common deletions or variant (eg, Southeast Asian, Thai, Filipino, Mediterranean, alpha3.7, alpha4.2, alpha20.5, and constant spring)	Yes
81292	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary nonpolyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	Yes

[1] *CPT copyright 2013 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.*

Table 1 – Codes covered for DOS on or after January 1, 2015 (Continued)

CPT code	Description	PA required
81293	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary nonpolyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants	Yes
81294	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary nonpolyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants	Yes
81295	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	Yes
81296	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants	Yes
81297	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants	Yes
81298	MSH6 (mutS homolog 6) [e. Colo]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	Yes
81299	MSH6 (mutS homolog 6) [e. Colo]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants	Yes
81300	MSH6 (mutS homolog 6) [e. Colo]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants	Yes
81301	Microsatellite instability analysis (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) of markers for mismatch repair deficiency (eg, bat25, bat26), includes comparison of neoplastic and normal tissue, if performed	Yes
81302	MECP2 (methyl CPG binding protein 2) (eg, Rett syndrome) gene analysis; full sequence analysis	Yes
81303	MECP2 (methyl CPG binding protein 2) (eg, Rett syndrome) gene analysis; known familial variants	Yes
81304	MECP2 (methyl CPG binding protein 2) (eg, Rett syndrome) gene analysis; duplication/deletion variants	Yes
81310	NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, exon 12 variants	Yes
81315	PML/raralpha, (t(15;17)), promyelocytic leukemia/retinoic acid receptor alpha) eg, promyelocytic leukemia) translocation analysis; common breakpoints (eg, intron 3 and intron 6), qualitative or quantitative	Yes
81316	PML/raralpha, (t(15;17)), promyelocytic leukemia/retinoic acid receptor alpha) eg, promyelocytic leukemia) translocation analysis; single breakpoint (eg, intron 3, intron 6 or exon 6), qualitative or quantitative	Yes
81317	PMS2 (postmeiotic segregation increased 2 [s. Cerevisiae]) (eg, hereditary non=polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	Yes

Table 1 – Codes covered for DOS on or after January 1, 2015 (Continued)

CPT code	Description	PA required
81318	PMS2 (postmeiotic segregation increased 2 [s. Cerevisiae]) (eg, hereditary non=polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants	Yes
81319	PMS2 (postmeiotic segregation increased 2 [s. Cerevisiae]) (eg, hereditary non=polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants	Yes
81330	SMPD1(sphingomyelin phosphodiesterase 1, acid lysosomal) (eg, Niemann-Pick disease, type A) gene analysis, common variants (eg, R496l, L302P, FSP330)	Yes
96040	Medical genetics and genetic counseling services, each 30 minutes face-to -face with patient/family	No

Table 2 – Codes noncovered for DOS on or after January 1, 2015

Procedure code	Description	Possible alternate or replacement code
S0265	Genetic counseling, under physician supervision, each 15 minutes	Replacement code: 96040
S3845	Genetic testing for alpha-thalassemia	Possible alternate code: 81257
S3849	Genetic testing for Niemann-Pick disease	Possible alternate code: 81330

Table 3 – Codes with PA added and revenue codes assigned for DOS on or after January 1, 2015

Procedure code	Description	New revenue code linkages
S3842	Genetic testing for Von-Hippel Lindau syndrome (VHL)	310, 319
S3844	DNA analysis of the connexin 26 gene (GJB2) for susceptibility to congenital, profound deafness	310, 319
S3846	Genetic testing for beta-thalassemia	310, 319
S3850	Genetic testing for sickle cell anemia	310, 319
S3853	Genetic testing for myotonic muscular dystrophy	310, 319
81200	ASPA (aspartoacyclase) (eg, Canavan disease) gene analysis, common variants (eg, e285a, y231x)	N/A
81251	GBA (glucosidase, beta, acid) (eg, Gaucher disease) gene analysis, common variants (eg, n370s, 84gg, l444p, ivs2+1g>a)	N/A
81504	Oncology (tissue of origin), microarray gene expression profiling of >2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores	N/A

QUESTIONS?

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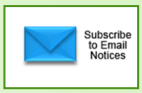

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