ForwardHealth
Wisconsin serving you

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Affected Programs: BadgerCare Plus, Medicaid
To: Hospital Providers, Independent Labs, Nurse Practitioners, Physician Assistants, Physician Clinics, Physicians, HMOs and Other Managed Care Programs

Coverage Policy for Emerging Molecular Pathology and Diagnostic Genetic Testing

Genetic testing is a covered service for Wisconsin Medicaid and BadgerCare Plus members when such testing is part of either routine or targeted clinical screening that has been determined to have a clinically useful impact on health outcomes. This *ForwardHealth Update* outlines the coverage policy for molecular pathology and diagnostic genetic tests.

Coverage Policy Effective July 1, 2014

Genetic testing is a covered service for Wisconsin Medicaid and BadgerCare Plus members when such testing is part of either routine or targeted clinical screening that has been determined to have a clinically useful impact on health outcomes. Resources used to make these determinations may include guidelines developed and endorsed by entities such as the National Comprehensive Cancer Network (NCCN), the American College of Medical Genetics and Genomics (ACMG), and the American Congress of Obstetricians and Gynecologists (ACOG) where those guidelines are published and are evidence based.

Wisconsin Medicaid and BadgerCare Plus do not cover genetic testing in situations where the results would not have a clinically useful impact on health outcomes. Screening tests requiring prior authorization (PA) will be evaluated individually with regard to their impact on clinical outcomes. Genetic testing is a rapidly evolving science and evidence of clinical utility for many tests is still being established. Refer to the Attachment of this *ForwardHeath Update* for a list of select molecular pathology and select diagnostic genetic testing *Current Procedural Terminology* (CPT) procedure codes addressed in this *Update* and associated PA requirements. For the most current information on coverage of genetic testing codes, refer to the maximum allowable fee schedule on the ForwardHealth Portal, available by clicking the Fee Schedules link in the Providers box on the Portal home page at *www.forwardhealth.wi.gov/*.

Wisconsin Medicaid and BadgerCare Plus do not cover full genome and exome sequencing.

Clinically Useful Criteria

Wisconsin Medicaid and BadgerCare Plus consider genetic testing medically necessary when the testing yields results that can be used specifically to develop a clinically useful approach or course of treatment or to cease unnecessary treatments or monitoring. Clinically useful tests allow providers to treat current symptoms significantly affecting a member's health or to manage the treatable progression of an established disease.

Tests will not be reimbursable for Wisconsin Medicaid and BadgerCare Plus members if the sole outcome would be labeling the disorder or categorizing symptoms that cannot or should not be treated.

Documentation

All providers who receive payment from Wisconsin Medicaid, including state-contracted managed care

organizations, are required to maintain records that fully document the basis of charges upon which all claims for payment are made, according to DHS 106.02(9)(a), Wis. Admin. Code. Records should clearly support the services rendered and the procedure codes being submitted on claims.

Prior Authorization

Wisconsin Medicaid and BadgerCare Plus require PA for some genetic testing in order for the testing to be covered. This requirement is in addition to meeting all other program requirements for covered services. When submitting a PA request for genetic testing, providers are required to submit both the Prior Authorization Request Form (PA/RF), F -11018 (05/13), and the Prior Authorization/Physician Attachment (PA/PA), F-11016 (07/12). Refer to the Attachment for a list of covered genetic testing services addressed in this *Update* and associated procedure codes, along with an indication regarding which services require PA.

For services requiring PA, in situations where published guidelines are not available or are inconclusive, Wisconsin Medicaid and BadgerCare Plus will request additional information be provided with the PA request, such as peer-reviewed journal articles or published studies, as evidence of the medical necessity of a particular test.

Note: The PA requirement information included in the Attachment is subject to change. For the most current information, providers are encouraged to refer to the maximum allowable fee schedule on the Portal, available by clicking the Fee Schedules link in the Providers box on the Portal home page.

Genetic Counseling Requirement

The provider ordering the testing is required to either be, or arrange for consultation with, a provider who has relevant education or training in genetics, such as a genetics counselor, a geneticist, or a physician/nurse practitioner specialist with knowledge of the genetic factors of disease within his/her specialty and the genetic testing process.

Providers who provide genetic counseling should review the following:

- Interpretation of the patient and family medical histories to assess the chance of disease occurrence.
- Education about inheritance, testing, management, prevention, and resources.
- Discussion of the ethical, legal, and psychosocial aspects of genetic testing.
- Support to make informed decisions.

Physicians or advanced practice nurse prescribers (APNPs) who provide counseling should follow CPT guidelines, reporting evaluation and management codes on professional claims as appropriate.

Claims Submission for Genetic Counseling

Genetic counselors cannot currently enroll independently with ForwardHealth and, therefore, cannot submit separate professional claims or be reimbursed for services provided in non-institutional settings. When genetic counseling services are provided by a trained genetic counselor, revenue code 510 (Clinic, General) and CPT procedure code 96040 (Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family) should be reported on the institutional claim form.

Guidelines for BRCA Testing (Excluding Familial Variant Testing)

Breast cancer susceptibility gene (BRCA) 1 and 2 testing requires PA. The PA requests will be adjudicated by Wisconsin Medicaid and BadgerCare Plus according to the guidelines established by the NCCN. Wisconsin Medicaid and BadgerCare Plus require PA for all BRCA tests except familial variant testing (refer to the Familial Variants section of this *Update*). The NCCN guidelines are available at *www.nccn.org/professionals/physician_gls/f_guidelines.asp#breast_screening*.

Documentation Requirements for Genetic Testing Services Not Requiring Prior Authorization

Wisconsin Medicaid and BadgerCare Plus do not require PA for the following tests, but the rendering provider is required to keep documentation that applicable criteria are met. In addition to test-specific criteria, genetic counseling prior to testing and informed patient choice must be documented in the ordering provider's clinical record.

Familial Variants

Some genetic tests focus on known familial variants within a patient's family that may relate to an increased risk of disease or disorder. The laboratory must be provided with a copy of the official laboratory results on a family member showing the variant in order for a laboratory to conduct these tests. For covered familial variant testing identified by individualized CPT procedure codes, Wisconsin Medicaid and BadgerCare Plus consider the family member's result with the variant as adequate evidence of the medical necessity of the test, and PA is not required. Documentation of the family member's result is required to be maintained by the laboratory, but providers are not required to submit those results along with the claim for familial variant testing.

Fetal Aneuploidy Testing Using Cell Free Fetal DNA

Wisconsin Medicaid and BadgerCare Plus cover cell free fetal DNA testing without PA for prenatal screening according to published ACOG guidelines, available on the ACOG Web site at *www.acog.org/*. Claims submitted for fetal aneuploidy testing are required to be submitted with CPT code 81507 (Fetal anueploidy [trisomy 21, 18, and 13] DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy), regardless of the nature of the results reporting or testing techniques.

Indications for cell free fetal DNA testing include at least one of the following:

- Maternal age will be 35 years or older at the time of delivery.
- Fetal ultrasonographic findings indicate an increased risk of aneuploidy.
- History of prior pregnancy with trisomy.
- Positive screening test for aneuploidy, including first trimester, sequential, or integrated screen, or a quadruple screen.
- Parental balanced robertsonian translocation with increased risk of fetal trisomy 13 or trisomy 21.

Other Tests Allowed Based on American College of Medical Genetics and Genomics Guidelines

Wisconsin Medicaid and BadgerCare Plus cover the following tests without PA, in cases which meet guideline criteria published by the ACMG:

- Cytogenomic constitutional (genome-wide) microarray analysis.
- Fragile X mental retardation 1 (FMR1) gene analysis for Fragile X syndrome.
- Gap junction protein beta 2, connexin 26 (GJB2) gene analysis for nonsyndromic hearing loss.

Documentation must be maintained by the provider that demonstrates adherence to ACMG guidelines.

Reporting Tier 2 and Unlisted Molecular Pathology Codes

Within the CPT procedure code set reserved for molecular pathology is a group of Tier 2 molecular pathology codes that cover a wide range of specific tests based upon the complexity of those tests. Both ordering providers and performing laboratories are required to use CPT procedure codes 81400-81408 only for the tests specifically listed in the descriptions of those codes. If a particular test does not have a specific Tier 1 code and is not listed in the description of any Tier 2 code, providers are required to use CPT procedure code 81479 (Unlisted molecular pathology procedure). Prior authorization is required for all Tier 2 molecular pathology codes.

Prescribing/Referring/Ordering Providers Required to Be Medicaid Enrolled

As a reminder, all physicians and other professionals who prescribe, refer, or order services for Wisconsin Medicaid and BadgerCare Plus members on and after July 15, 2013, are required to be Medicaid enrolled. Prior authorization requests received on and after July 15, 2013, and claims for dates of service on and after July 15, 2013, for services that are prescribed, referred, or ordered, will be returned or denied if they do not include the National Provider Identifier of a Medicaid-enrolled provider. For more information about enrollment options and requirements for prescribing/referring/ordering providers, refer to the Provider Enrollment Information home page of the ForwardHealth Portal and select the Prescribing/Referring/Ordering Providers link.

Information Regarding Managed Care Organizations

This *Update* contains fee-for-service policy and applies to services members receive on a fee-for-service basis only. For managed care policy, contact the appropriate managed care organization. Managed care organizations are required to provide at least the same benefits as those provided under fee-for-service arrangements.

The *ForwardHealth Update* is the first source of program policy and billing information for providers.

Wisconsin Medicaid, BadgerCare Plus, SeniorCare, and Wisconsin Chronic Disease Program are administered by the Division of Health Care Access and Accountability, Wisconsin Department of Health Services (DHS). The Wisconsin AIDS Drug Assistance Program and the Wisconsin Well Woman Program are administered by the Division of Public Health, Wisconsin DHS.

For questions, call Provider Services at (800) 947-9627 or visit our Web site at *www.forwardhealth.wi.gov/*.

P-1250

ATTACHMENT
Select Molecular Pathology and Diagnostic Genetic Test Procedure Codes and Prior Authorization Requirements

The following table contains a list of select molecular pathology and select diagnostic genetic testing *Current Procedural Terminology* (CPT) procedure codes that are covered by Wisconsin Medicaid and BadgerCare Plus to which the described coverage policy applies.

Note: This list is not a comprehensive list of covered genetic testing services. The information included in the table is subject to change. For the most current information, providers are encouraged to refer to the maximum allowable fee schedule on the ForwardHealth Portal, available by clicking the Fee Schedules link in the Providers box on the Portal home page.

Procedure Code	Description	Prior Authorization Required?
81161	*DMD (dystrophin)* (eg, Duchenne/Becker muscular dystrophy) deletion analysis, and duplication analysis, if performed	Yes
81200	*ASPA (aspartoacylase)* (eg, Canavan disease) gene analysis, common variants (eg, E285A, Y231X)	No
81201	*APC (adenomatous polyposis coli)* (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; full gene sequence	Yes
81202	known familial variants	No
81203	duplication/deletion variants	Yes
81205	*BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide)* (e.g., Maple syrup urine disease) gene analysis, common variants (eg, R183P, G278S, E422X)	No
81209	*BLM (Bloom syndrome, ReqcQ helicase-like)* (eg, Bloom syndrome) gene analysis, 2281del6ins7 variant	No
81211	*BRCA1, BRCA2 (breast cancer 1 and 2)* (eg hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants in BRCA1 (ie, exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)	Yes
81212	185delAG, 5385insC, 617delT variants	No
81213	uncommon duplication/deletion variants	Yes
81214	*BRCA1 (breast cancer 1)* (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants (ie, exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)	Yes
81215	known familial variant	No

Procedure Code	Description	Prior Authorization Required?
81216	*BRCA2 (breast cancer 2)* (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis	Yes
81217	known familial variant	No
81220	*CFTR (cystic fibrosis transmembrane conductance regulator)* (eg, cystic fibrosis) gene analysis; common variants (eg, ACMG/ACOG guidelines)	No
81221	known familial variants	No
81222	duplication/deletion variants	Yes
81223	full gene sequence	Yes
81224	intron 8 poly-T analysis (eg, male infertility)	No
81228	Cytogenomic contitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (eg, bacterial artificial chromosome [BAC] or oligo-based comparative genomic hybridization [CGH] microarray analysis)	No
81229	interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities	No
81242	*FANCC (Fanconi anemia, complementation group C)* (eg, Fanconi anemia, type C) gene analysis, common variant (eg, IVS4+4A>T)	No
81243	*FMR1 (fragile X mental retardation 1)* (eg, fragile X mental retardation) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	No
81244	characterization of alleles (eg, expanded size and methylation status)	No
81250	*G6PC (glucose-6-phosphatase, catalytic subunit)* (eg, Glycogen storage disease, Type 1a, von Gierke disease) gene analysis, common variants (eg, R83C, Q347X)	No
81251	*GBA (glucosidase, beta, acid)* (eg, Gaucher disease) gene analysis, common variants (eg, N370S, 84GG, L444P, IVS2+1G>A)	No
81252	*GJB2 (gap junction protein, beta 2, 26kDa; connexin 26)* (eg, nonsyndromic hearing loss) gene analysis; full gene sequence	No
81253	known familial variants	No
81254	*GJB6 (gap junction protein beta 6, 30kDa, connexin 30)* (eg, nonsyndromic hearing loss) gene analysis, common variants (eg, 309kb [del(GJB6-D13S1830)] and 232kb [del(GJB6-D13S1854)])	No
81255	*HEXA (hexosaminidase A [alpha polypeptide])*(eg, Tay Sachs disease) gene analysis, common variants (eg, 1278insTATC, 1421+1G>C, G269S)	No
81256	*HFE (hemochromatosis)* (eg, hereditary hemochromatosis) gene analysis, common variants (eg, C282Y, H63D)	No

Procedure Code	Description	Prior Authorization Required?
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)	No
81260	*IKBKAP (inhibitor of kappa light polypeptide gene enhancer in B-cells, kinase complex-associated protein)* (eg, familial dysautonomia) gene analysis, common variants (eg, 2507+6T>C, R696P)	No
81280	Long QT syndrome gene analyses (eg, KCNQ1, KCNH2, SCN5A, KCNE1, KCNE2, KCNJ2, CACNA1C, CAV3, SCN4B, AKAP, SNTA1, and ANK2); full sequence analysis	Yes
81281	known familial sequence variant	No
81282	duplication/deletion variants	Yes
81290	*MCOLN1 (mucolipin 1)* (eg, Mucolipidosis, type IV) gene analysis, common variants (eg, IVS3-2A>G, del6.4kb)	No
81292	*MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2)* (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	Yes
81293	known familial variants	No
81294	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	known familial variants	No
81297	duplication/deletion variants	Yes
81298	*MSH6 (mutS homolog 6 [E. coli])* (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	Yes
81299	known familial variants	No
81300	duplication/deletion analysis	Yes
81302	*MECP2 (methyl CpG binding protein 2)* (eg, Rett syndrome) gene analysis; full sequence analysis	Yes
81303	known familial variant	No
81304	duplication/deletion variants	Yes
81317	*PMS2 (postmeiotic segregation increase 2 [S. cerevisae])* (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	Yes
81318	known familial variants	No

Procedure Code	Description	Prior Authorization Required?
81319	duplication/deletion analysis	Yes
81321	*PTEN (phosphatase and tensin homolog)* (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; full sequence analysis	Yes
81322	known familial variants	No
81323	duplication/deletion variants	Yes
81324	*PMP22 (peripheral myelin protein 22)* (eg, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; duplication deletion analysis	Yes
81325	full sequence analysis	Yes
81326	known familial variant	No
81330	*SMPD1 (sphingomyelin phosphodiesterase 1, acid lysosomal)* (eg, Niemann-Pick disease, Type A) gene analysis, common variants (eg, R496L, L302P, fsP330)	No
81331	*SNRPN/UBE3A (small nuclear ribonucleoprotein polypeptide N and ubiquitin protein ligase E3A)* (eg, Prader-Willi syndrome and/or Angelman syndrome), methylation analysis	No
81400*	Molecular pathology procedure, Level 1 (eg, identification of single germline variant [eg, SNP] by techniques such as restriction enzyme digestion or melt curve analysis)	Yes
81401*	Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)	Yes
81402*	Molecular pathology procedure, Level 3 (eg, >10 SNPs, 2-10 methylated variants, or 2-10 somatic variants [typically using non-sequencing target variant analysis], immunoglobulin and T-cell receptor gene rearrangements, duplication/deletion variants of 1 exon, loss of heterozygosity [LOH], uniparental disomy [UPD])	Yes
81403*	Molecular pathology procedure, Level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)	Yes
81404*	Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis)	Yes
81405*	Molecular pathology procedure, Level 6 (eg, analysis of 6-10 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 11-25 exons), regionally targeted cytogenomic array analysis	Yes

Procedure Code	Description	Prior Authorization Required?
81406*	Molecular pathology procedure, Level 7 (eg, analysis of 11-25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 26-50 exons, cytogenomic array analysis for neoplasia)	Yes
81407*	Molecular pathology procedure, Level 8 (eg, analysis of 26-50 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of >50 exons, sequence analysis of multiple genes on one platform)	Yes
81408*	Molecular pathology procedure, Level 9 (eg, analysis of >50 exons in a single gene by DNA sequence analysis)	Yes
81479	Unlisted molecular pathology procedure	Yes
81504	Oncology tissue (tissue of origin), microarray gene expression profiling of > 2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores	No
81507	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy	No (diagnosis restricted)

* Refer to the CPT manual for a full list of genetic tests that are included under each Tier 2 Molecular Pathology code (81400-81408).