# **Table of Contents**

Laboratory Services	. 1
1. Important Contacts	3
1.1. Gainwell Technologies	
1.2. Provider Relations Consultants	
1.3. Magellan Healthcare, Inc.	
1.4. Telligen, Inc.	
2. Provider Qualifications	-
2.1. Hospital Laboratory	
2.1.1. References: Hospital Laboratory	
2.2. Independent Laboratory 2.2.1. References: Independent Laboratory	
2.3. Physician Office Laboratory	
2.3.1. References: Physician Office Laboratory	
2.4. Reference Laboratory	
2.4.1. References: Reference Laboratory	13
2.5. Skilled Nursing Facility Laboratory	
2.5.1. References: Skilled Nursing Facility Laboratory	
3. Eligible Participants	17
3.1. Referrals	
3.2. Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Services	
4. Covered Services and Limitations	
4.1. References: Covered Services and Limitations	19
4.1. References: Covered Services and Limitations	19 19
4.1. References: Covered Services and Limitations         4.1.1. CMS Guidance         4.1.2. Federal Regulations	19 19 19
4.1. References: Covered Services and Limitations4.1.1. CMS Guidance4.1.2. Federal Regulations4.1.3. Idaho Medicaid Publications	19 19 19 19
<ul> <li>4.1. References: Covered Services and Limitations</li> <li>4.1.1. CMS Guidance</li> <li>4.1.2. Federal Regulations</li> <li>4.1.3. Idaho Medicaid Publications</li> <li>4.1.4. State Regulations</li> </ul>	19 19 19 19 20
<ul> <li>4.1. References: Covered Services and Limitations</li> <li>4.1.1. CMS Guidance</li> <li>4.1.2. Federal Regulations</li> <li>4.1.3. Idaho Medicaid Publications</li> <li>4.1.4. State Regulations</li> <li>4.2. Abortions</li> </ul>	19 19 19 19 20 21
<ul> <li>4.1. References: Covered Services and Limitations</li> <li>4.1.1. CMS Guidance</li> <li>4.1.2. Federal Regulations</li> <li>4.1.3. Idaho Medicaid Publications</li> <li>4.1.4. State Regulations</li> <li>4.2. Abortions</li> </ul>	19 19 19 20 21 22
<ul> <li>4.1. References: Covered Services and Limitations</li> <li>4.1.1. CMS Guidance</li> <li>4.1.2. Federal Regulations</li> <li>4.1.3. Idaho Medicaid Publications</li> <li>4.1.4. State Regulations</li> <li>4.2. Abortions</li> <li>4.3. Cervical Cancer Screening</li> <li>4.4. Controlled Substance and Drug Testing</li> <li>4.4.1. References: Controlled Substance and Drug Testing</li> </ul>	19 19 19 20 21 22 23 25
<ul> <li>4.1. References: Covered Services and Limitations</li> <li>4.1.1. CMS Guidance</li> <li>4.1.2. Federal Regulations</li> <li>4.1.3. Idaho Medicaid Publications</li> <li>4.1.4. State Regulations</li> <li>4.2. Abortions</li> <li>4.3. Cervical Cancer Screening</li> <li>4.4. Controlled Substance and Drug Testing</li> <li>4.4.1. References: Controlled Substance and Drug Testing</li> <li>4.4.2. Drug Testing for 15 or More Classes</li> </ul>	19 19 19 20 21 22 23 25 27
<ul> <li>4.1. References: Covered Services and Limitations</li> <li>4.1.1. CMS Guidance</li> <li>4.1.2. Federal Regulations</li> <li>4.1.3. Idaho Medicaid Publications</li> <li>4.1.4. State Regulations</li> <li>4.2. Abortions</li> <li>4.3. Cervical Cancer Screening</li> <li>4.4. Controlled Substance and Drug Testing</li> <li>4.4.1. References: Controlled Substance and Drug Testing</li> <li>4.4.2. Drug Testing for 15 or More Classes</li> <li>4.5. COVID-19 Testing</li> </ul>	19 19 19 20 21 22 23 25 27 30
<ul> <li>4.1. References: Covered Services and Limitations</li> <li>4.1.1. CMS Guidance</li> <li>4.1.2. Federal Regulations</li> <li>4.1.3. Idaho Medicaid Publications</li> <li>4.1.4. State Regulations</li> <li>4.2. Abortions</li> <li>4.3. Cervical Cancer Screening</li> <li>4.4. Controlled Substance and Drug Testing</li> <li>4.4.1. References: Controlled Substance and Drug Testing</li> <li>4.4.2. Drug Testing for 15 or More Classes</li> <li>4.5. COVID-19 Testing</li> <li>4.5.1. References: COVID-19 Testing</li> </ul>	19 19 19 20 21 22 23 25 27 30 30
<ul> <li>4.1. References: Covered Services and Limitations</li></ul>	<ol> <li>19</li> <li>19</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> <li>23</li> <li>25</li> <li>27</li> <li>30</li> <li>30</li> <li>30</li> </ol>
<ul> <li>4.1. References: Covered Services and Limitations</li></ul>	<ol> <li>19</li> <li>19</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> <li>23</li> <li>25</li> <li>27</li> <li>30</li> <li>30</li> <li>31</li> </ol>
<ul> <li>4.1. References: Covered Services and Limitations</li></ul>	19 19 19 20 21 22 23 25 27 30 30 30 31 31
<ul> <li>4.1. References: Covered Services and Limitations</li></ul>	<ol> <li>19</li> <li>19</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> <li>23</li> <li>25</li> <li>27</li> <li>30</li> <li>30</li> <li>31</li> <li>31</li> <li>32</li> </ol>
<ul> <li>4.1. References: Covered Services and Limitations</li> <li>4.1.1. CMS Guidance</li> <li>4.1.2. Federal Regulations</li> <li>4.1.3. Idaho Medicaid Publications</li> <li>4.1.4. State Regulations</li> <li>4.2. Abortions</li> <li>4.3. Cervical Cancer Screening</li> <li>4.4. Controlled Substance and Drug Testing</li> <li>4.4.1. References: Controlled Substance and Drug Testing</li> <li>4.4.2. Drug Testing for 15 or More Classes</li> <li>4.5. COVID-19 Testing</li> <li>4.5.1. References: COVID-19 Testing</li> <li>4.5.2. Molecular Testing for SARS-CoV-2</li> <li>4.5.3. Rapid Antigen Testing for SARS-CoV-2</li> <li>(a) References: Rapid Antigen Testing for SARS-CoV-2</li> <li>4.5.4. Coverage of Serologic Testing for SARS-CoV-2</li> <li>4.6.1. References: Fertility Testing</li> </ul>	19 19 19 20 21 22 23 25 27 30 30 31 31 32 33 33
<ul> <li>4.1. References: Covered Services and Limitations</li></ul>	19 19 19 20 21 22 23 25 27 30 30 30 31 31 31 32 33 33 34
<ul> <li>4.1. References: Covered Services and Limitations</li> <li>4.1.1. CMS Guidance</li> <li>4.1.2. Federal Regulations</li> <li>4.1.3. Idaho Medicaid Publications</li> <li>4.1.4. State Regulations</li> <li>4.2. Abortions</li> <li>4.3. Cervical Cancer Screening</li> <li>4.4. Controlled Substance and Drug Testing</li> <li>4.4.1. References: Controlled Substance and Drug Testing</li> <li>4.4.2. Drug Testing for 15 or More Classes</li> <li>4.5. COVID-19 Testing</li> <li>4.5.1. References: COVID-19 Testing</li> <li>4.5.2. Molecular Testing for SARS-CoV-2</li> <li>4.5.3. Rapid Antigen Testing for SARS-CoV-2</li> <li>(a) References: Rapid Antigen Testing for SARS-CoV-2</li> <li>4.5.4. Coverage of Serologic Testing for SARS-CoV-2</li> <li>4.6.1. References: Fertility Testing</li> </ul>	19 19 19 20 21 22 23 25 27 30 30 30 31 31 32 33 33 34 34

4.8.1. References: Genetic Testing	35
4.8.2. Genetic Counseling	
4.8.3. Genetic Testing for Alzheimer Disease	38
4.8.4. Genetic Testing for Pharmacogenetics	39
4.8.5. Genetic Testing for Hemochromatosis	
4.8.6. Genetic Testing for Hyperbilirubinemia	41
4.8.7. Genetic Testing for Mental Health Disorders	42
4.8.8. Genetic Testing for Thrombophilia	43
4.8.9. Molecular Pathology for Infants	44
4.9. Home Monitoring of Anticoagulant Therapy	45
4.9.1. References: Home Monitoring of Anticoagulant Therapy	45
4.10. Lead Screening	46
4.10.1. References: Blood Lead Screening	47
4.11. Newborn Screening	
4.11.1. References: Newborn Screening	
4.12. Non-Invasive Prenatal Testing	
4.12.1. References: Non-Invasive Prenatal Testing	
4.13. Papanicolaou Testing	
4.14. Pregnancy Testing	
4.14.1. References: Pregnancy Testing	
4.15. Proprietary Laboratory Analyses	
4.15.1. References: Proprietary Laboratory Analyses	
4.16. Refugee Screening	
4.16.1. References: Refugee Screening	
4.17. Specimen Collection and Handling	
4.17.1. References: Specimen Collection	56
5. Quality Assurance	57
5.1. References: Quality Assurance	57
5.1.1. Federal Regulations	57
5.1.2. State Regulations	57
6. Prior Authorization	58
7. Documentation	
7.1. References: Documentation Requirements	
7.1.1. CMS Guidance	
7.1.2. State Regulations	
8. Reimbursement	60
8.1. References: Reimbursement	61
8.1.1. Federal Regulations	61
8.1.2. Idaho Medicaid Publications	
8.1.3. State Regulations	61
8.2. Laboratory Modifiers	63
8.2.1. Modifier 90	
8.2.2. Modifier 91	64
8.2.3. Professional and Technical Components	65
Appendix A. Laboratory, Provider Handbook Modifications	66

# **Laboratory Services**

This Provider Handbook describes Medicaid-covered services provided as laboratory and pathology services. A laboratory is a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examinations of material derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease, or the impairment or assessment of human health. This handbook applies to the following provider types and specialties:

- <u>Hospital Laboratory;</u>
- <u>Independent Laboratory;</u>
- <u>Physician Office Laboratory</u>;
- <u>Reference Laboratory</u>; and
- <u>Skilled Nursing Facility Laboratory</u>.

Services must be within the scope of the laboratory's certification, and the training and qualifications of the performing technicians and analysts.

Should the handbook ever appear to contradict relevant provisions of Idaho or federal regulations, the regulations prevail. Any paper or digital copy of these documents is considered out of date except the version appearing on Gainwell Technologies' <u>Idaho Medicaid</u> website. Sections of the Idaho Medicaid Provider Handbook applicable in specific situations are listed throughout the handbook for provider convenience. Handbooks which always apply to this provider type include the following:

- <u>General Billing Instructions;</u>
- General Information and Requirements for Providers; and
- <u>Glossary</u>.

Handbooks can only be used properly in context. Providers must be familiar with the handbooks that affect them and their services. The numbering in handbooks is also important to make note of as subsections rely on the content of the sections above them.

#### Example

Section 1.2.3.a The Answer requires the reader to have also read Section 1, Section 1.2 and Section 1.2.3 to be able to properly apply Section 1.2.3.a.

References are included throughout the handbook for provider and staff convenience. Not all applicable references have been incorporated into the handbook. Not all references provided are equal in weight.

- Case Law: Includes references to court cases that established interpretations of law that states, and providers would be required to follow.
- CMS Guidance: These references reflect various Centers for Medicare and Medicaid Services (CMS) publications that Idaho Medicaid reviewed in the formulation of their policy. The publications themselves are not required to be followed for Idaho Medicaid services.
- Federal Regulations: These references are regulations from the federal level that affected policy development. Usually these include the Code of Federal Regulations, the Social Security Act, and other statutes. Providers are required to follow them.
- Idaho Medicaid Publications: These are communications from Idaho Medicaid to providers that were required to be followed when published. These are included in the handbook for historical reference. The provider handbook supersedes other

communications unless the documents are listed in the <u>Policies, Procedures, and</u> <u>Waivers</u> webpage under policies in <u>Medicaid Policies library</u>.

- Idaho State Plan: The State Plan is the agreement between the State of Idaho and the Centers for Medicare and Medicaid Services on how the State will administer its medical assistance program.
- Professional Organizations: These references reflect various publications of professional organizations that Idaho Medicaid reviewed in the formulation of their policy. Providers may or may not be required to follow these references, depending on the individual reference and its application to a provider's licensure and scope of practice.
- Scholarly Work: These references are publications that Idaho Medicaid reviewed in the formulation of their policy. The publications themselves are not required to be followed for Idaho Medicaid services.
- State Regulations: These references are regulations from the state level that affected policy development. They usually include statute and IDAPA. Providers are required to follow them.

Some citations may not be available on the internet. Copies of the documents may be requested with a <u>public records request</u>. Guidance for public records requests is available on the Department's website.

# **1. Important Contacts**

The <u>Directory</u>, Idaho Medicaid Provider Handbook contains a comprehensive list of contacts. The following contacts are presented here for provider convenience.

#### **1.1.** Gainwell Technologies

<u>Gainwell Technologies</u> is Idaho Medicaid's fiscal agent that handles all claims processing and customer service issues.

#### **Gainwell Technologies Contact Information**

Gainwell Technologies Provider Services P.O. Box 70082 Boise, ID 83707 Phone: 1 (888) 686-4272 Fax: 1 (877) 661-0974 IDProviderServices@gainwelltechnologies.com

The Medicaid Automated Call Service (MACS) is available 24 hours a day, seven days a week. Provider service representatives are available Monday through Friday, 7:00 A.M.-7:00 P.M. MT.

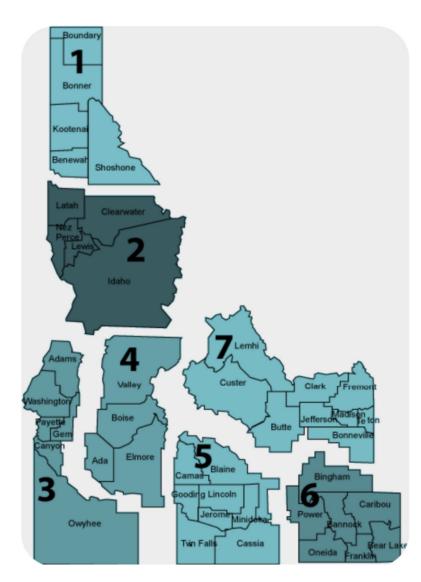
Provider Enrollment P.O. Box 70082 Boise, ID 83707 Phone: 1 (866) 686-4272 Fax: 1 (877) 517-2041 IDProviderEnrollment@gainwelltechnologies.com

Technical Services Phone: 1 (866) 686-4272 Fax: 1 (877) 517-2040 IDEDISupport@gainwelltechnologies.com

#### 1.2. Provider Relations Consultants

Gainwell Technologies Provider Relations Consultants help keep providers up-to-date on billing changes required by program policy changes implemented by the Division of Medicaid. Provider Relations Consultants accomplish this by:

- Conducting provider workshops;
- Conducting live meetings for training;
- Visiting a provider's site to conduct training; and
- Assisting providers with electronic claims submission



Region 1 and the state of Washington 1 (208) 202-5735 Region.1@gainwelltechnologies.com

Region 2 and the state of Montana 1 (208) 202-5736 Region.2@gainwelltechnologies.com

Region 3 and the state of Oregon 1 (208) 202-5816 Region.3@gainwelltechnologies.com

Region 4 1 (208) 202-5843 Region.4@gainwelltechnologies.com

Region 5 and the state of Nevada 1 (208) 202-5963 Region.5@gainwelltechnologies.com

Region 6 and the state of Utah 1 (208) 593-7759 Region.6@gainwelltechnologies.com

Region 7 and the state of Wyoming 1 (208) 609-5062 Region.7@gainwelltechnologies.com

Region 9 all other states (not bordering Idaho) 1 (208) 609-5115 Region.9@gainwelltechnologies.com

#### **1.3.** Magellan Healthcare, Inc.

Magellan Healthcare, Inc. is Idaho Medicaid's managed care contractor for the Idaho Behavioral Health Plan.

Magellan Healthcare, Inc. P.O. Box 1029 Maryland Heights, MO 63043 Phone: 1 (855) 202-0983 Fax: 1 (888) 656-9795 E-mail: <u>IdahoProvider@MagellanHealth.com</u> Website: <u>https://www.MagellanOfIdaho.com</u>

The Idaho Behavioral Health Plan does not cover Medicaid participants enrolled in Idaho Medicaid Plus (IMPlus) or Medicaid-Medicare Coordinated Plan (MMCP) duals health plans. These participants receive behavioral health services through their health plan.

# 1.4. Telligen, Inc.

Telligen, Inc. is Idaho Medicaid's quality improvement organization (QIO) that reviews prior authorization requests for laboratory services as listed on the <u>Numerical Fee Schedule</u> or when a prior authorization would otherwise be indicated.

Telligen 670 E Riverpark Ln. Suite 120 Boise, ID 83706 Phone: 1 (866) 538-9510 E-mail: <u>idmedicaidsupport@telligen.com</u>

# 2. Provider Qualifications

#### 2.1. Hospital Laboratory

A hospital laboratory is a laboratory located on the campus of a hospital. Hospital laboratories in any state are eligible to participate in the Idaho Medicaid Program. Laboratories must have a National Provider Identification (NPI). They must be licensed in the state where the services are performed, eligible for Medicare certification, and enroll as an Idaho Medicaid provider prior to submitting claims for services. The laboratory must have a Clinical Laboratory Improvement Amendments (CLIA) certificate valid for the dates of service on file with Idaho Medicaid. Payments will be denied for any laboratory services not covered by a CLIA certificate or rendered outside the effective dates of their CLIA certificate.

Laboratories are required to have their site credentialed. Should the laboratory have a change of address they must complete and submit a new W-9 form that reflects the new address, a new provider agreement and proof of the new site being credentialed before billing for services provided at the new location.

Hospital laboratories do not qualify as a reference laboratory or an independent laboratory. Specimens sent from hospital laboratories to an external laboratory for testing must be billed by the external laboratory.

See <u>General Information and Requirements for Providers</u>, Idaho Medicaid Provider Handbook for more information on enrolling as an Idaho Medicaid provider.

#### 2.1.1. References: Hospital Laboratory

#### (a) Federal Regulations

"Certificate Requirement." P.L. 100-578, "*Clinical Laboratory Improvement Amendments of 1988*," Sec. 353(b). Government Printing Office, https://www.govinfo.gov/content/pkg/STATUTE-102/pdf/STATUTE-102-Pg2903.pdf.

Condition of Participation: Laboratory Services, 42 C.F.R. Sec. 482.27 (2019). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol5/pdf/CFR-2019-title42-vol5-sec482-27.pdf</u>.

"Definitions of Services, Institutions, ETC..." Social Security Act, Sec. 1861(e)(9) (1935). Social Security Administration, <u>https://www.ssa.gov/OP\_Home/ssact/title18/1861.htm</u>.

Laboratory Requirements, 42 C.F.R. Sec. 493 (2019). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol5/pdf/CFR-2019-title42-vol5-part493.pdf</u>.

Laboratory Services, 42 C.F.R. Sec. 441.17(a)(2) (1998). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol4/pdf/CFR-2019-title42-vol4-sec441-17.pdf</u>.

"State Plans for Medical Assistance." Social Security Act, Sec. 1902(a)(9)(C) (1935). Social Security Administration, <u>https://www.ssa.gov/OP Home/ssact/title19/1902.htm</u>.

# (b) State Regulations

"Individual Providers – Requirements." IDAPA 16.03.09, "*Medicaid Basic Plan Benefits,"* Sec. 200. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"Laboratory and Radiology Requirements." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 654.01. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"Provider." IDAPA 16.03.09, "*Medicaid Basic Plan Benefits*," Sec. 012.09. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

#### **2.2.** Independent Laboratory

An independent laboratory is a laboratory not located on a hospital's campus or affiliated with a physician's office that receives specimens from a source other than another laboratory. Independent laboratories in any state are eligible to participate in the Idaho Medicaid Program. Laboratories must have a National Provider Identification (NPI). They must be licensed in the state where the services are performed, eligible for Medicare certification, and enroll as an Idaho Medicaid provider prior to submitting claims for services. The laboratory must have a Clinical Laboratory Improvement Amendments (CLIA) certificate valid for the dates of service on file with Idaho Medicaid. Payments will be denied for any laboratory services not covered by a CLIA certificate or rendered outside the effective dates of their CLIA certificate.

Laboratories are required to have their site credentialed. Should the laboratory have a change of address they must complete and submit a new W9 that reflects the new address, a new provider agreement and proof of the new site being credentialed before billing for services provided at the new location.

See <u>General Information and Requirements for Providers</u>, Idaho Medicaid Provider Handbook for more information on enrolling as an Idaho Medicaid provider.

#### 2.2.1. References: Independent Laboratory

#### (a) Federal Regulations

"Certificate Requirement." P.L. 100-578, "*Clinical Laboratory Improvement Amendments of 1988*," Sec. 353(b). Government Printing Office, https://www.govinfo.gov/content/pkg/STATUTE-102/pdf/STATUTE-102-Pg2903.pdf.

"Definitions of Services, Institutions, ETC..." Social Security Act, Sec. 1861(s)(16) (1935). Social Security Administration, <u>https://www.ssa.gov/OP\_Home/ssact/title18/1861.htm</u>.

"Definitions of Services, Institutions, ETC..." Social Security Act, Sec. 1861(s)(17) (1935). Social Security Administration, https://www.ssa.gov/OP\_Home/ssact/title18/1861.htm.

Laboratory Requirements, 42 C.F.R. Sec. 493 (2019). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol5/pdf/CFR-2019-title42-vol5-part493.pdf</u>.

Laboratory Services, 42 C.F.R. Sec. 441.17(a)(1) (1998). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol4/pdf/CFR-2019-title42-vol4-sec441-17.pdf</u>.

"State Plans for Medical Assistance." Social Security Act, Sec. 1902(a)(9)(C) (1935). Social Security Administration, <u>https://www.ssa.gov/OP Home/ssact/title19/1902.htm</u>.

### (b) State Regulations

"Independent Laboratory." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 650.01. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"Individual Providers – Requirements." IDAPA 16.03.09, "*Medicaid Basic Plan Benefits,*" Sec. 200. Department of Administration, State of Idaho, https://adminrules.idaho.gov/rules/current/16/160309.pdf.

"Laboratory and Radiology Requirements." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 654.01. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"Provider." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 012.09. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

#### **2.3.** Physician Office Laboratory

Physicians can bill Medicaid for clinical diagnostic laboratory services they personally performed or supervised in their office. This includes services provided in a Rural Health Clinic. These services do not constitute the services of a hospital, independent or reference laboratory per the definitions for those providers. Physician-owned laboratories may not bill for tests sent to independent or hospital laboratories nor may they send specimens to a reference laboratory.

Physician office laboratories in any state are eligible to participate in the Idaho Medicaid Program. Laboratories must have a National Provider Identification (NPI). They must be licensed in the state where the services are performed, eligible for Medicare certification, and enroll as an Idaho Medicaid provider prior to submitting claims for services. The laboratory must have a Clinical Laboratory Improvement Amendments (CLIA) certificate valid for the dates of service on file with Idaho Medicaid or a Certificate of Waiver for applicable tests. Payments will be denied for any laboratory services not covered by a CLIA certificate or waiver or rendered outside the effective dates of their CLIA certificate.

Laboratories with a CLIA certificate are required to have their site credentialed. Should the laboratory have a change of address they must complete and submit a new W-9 form that reflects the new address, a new provider agreement and proof of the new site being credentialed before billing for services provided at the new location.

See <u>General Information and Requirements for Providers</u>, Idaho Medicaid Provider Handbook for more information on enrolling as an Idaho Medicaid provider.

#### **2.3.1.** References: Physician Office Laboratory

### (a) Federal Regulations

"Certificate Requirement." P.L. 100-578, "*Clinical Laboratory Improvement Amendments of 1988*," Sec. 353(b). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/STATUTE-102/pdf/STATUTE-102-Pg2903.pdf</u>.

"Definitions of Services, Institutions, ETC..." Social Security Act, Sec. 1861(s)(16) (1935). Social Security Administration, <u>https://www.ssa.gov/OP\_Home/ssact/title18/1861.htm</u>.

"Definitions of Services, Institutions, ETC..." Social Security Act, Sec. 1861(s)(17) (1935). Social Security Administration, https://www.ssa.gov/OP\_Home/ssact/title18/1861.htm.

"Definitions of Services, Institutions, ETC..." Social Security Act, Sec. 1861(aa)(2)(G) (1935). Social Security Administration, <u>https://www.ssa.gov/OP\_Home/ssact/title18/1861.htm</u>.

Laboratory Requirements, 42 C.F.R. Sec. 493 (2019). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol5/pdf/CFR-2019-title42-vol5-part493.pdf</u>.

Laboratory Services, 42 C.F.R. Sec. 441.17(a)(3) (1998). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol4/pdf/CFR-2019-title42-vol4-sec441-17.pdf</u>. Provision of Services, 42 C.F.R. Sec. 491.9 (2019). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol5/pdf/CFR-2019-title42-vol5-sec491-9.pdf</u>.

"State Plans for Medical Assistance." Social Security Act, Sec. 1902(a)(9)(C) (1935). Social Security Administration, <u>https://www.ssa.gov/OP\_Home/ssact/title19/1902.htm</u>.

# (b) State Regulations

"Individual Providers – Requirements." IDAPA 16.03.09, "*Medicaid Basic Plan Benefits*," Sec. 200. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"Laboratory and Radiology Requirements." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 654.01. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"Provider." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 012.09. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

#### **2.4.** Reference Laboratory

Reference laboratories are laboratories that only accept specimens from other laboratories. A physician would never be or use a reference laboratory. Laboratories using reference laboratories are responsible for ensuring they meet all Idaho Medicaid requirements including rule, statute, and the Idaho Medicaid Provider Handbook.

Reference laboratories in any state are eligible to participate in the Idaho Medicaid Program. Laboratories must have a National Provider Identification (NPI). They must be licensed in the state where the services are performed, eligible for Medicare certification, and enroll as an Idaho Medicaid provider prior to submitting claims for services. The laboratory must have a Clinical Laboratory Improvement Amendments (CLIA) certificate valid for the dates of service on file with Idaho Medicaid. Payments will be denied for any laboratory services not covered by a CLIA certificate or rendered outside the effective dates of their CLIA certificate.

Laboratories are required to have their site credentialed. Should the laboratory have a change of address they must complete and submit a new W-9 form that reflects the new address, a new provider agreement and proof of the new site being credentialed before billing for services provided at the new location.

See <u>General Information and Requirements for Providers</u>, Idaho Medicaid Provider Handbook for more information on enrolling as an Idaho Medicaid provider.

#### 2.4.1. References: Reference Laboratory

# (a) Federal Regulations

"Certificate Requirement." P.L. 100-578, "*Clinical Laboratory Improvement Amendments of 1988*," Sec. 353(b). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/STATUTE-102/pdf/STATUTE-102-Pg2903.pdf</u>.

"Definitions of Services, Institutions, ETC..." Social Security Act, Sec. 1861(s)(16) (1935). Social Security Administration, https://www.ssa.gov/OP\_Home/ssact/title18/1861.htm.

"Definitions of Services, Institutions, ETC..." Social Security Act, Sec. 1861(s)(17) (1935). Social Security Administration, https://www.ssa.gov/OP\_Home/ssact/title18/1861.htm.

Laboratory Requirements, 42 C.F.R. Sec. 493 (2019). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol5/pdf/CFR-2019-title42-vol5-part493.pdf</u>.

"State Plans for Medical Assistance." Social Security Act, Sec. 1902(a)(9)(C) (1935). Social Security Administration, <u>https://www.ssa.gov/OP Home/ssact/title19/1902.htm</u>.

# (b) State Regulations

"Individual Providers – Requirements." IDAPA 16.03.09, "*Medicaid Basic Plan Benefits*," Sec. 200. Department of Administration, State of Idaho, https://adminrules.idaho.gov/rules/current/16/160309.pdf.

"Laboratory and Radiology Requirements." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 654.01. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>. "Provider." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 012.09. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"Use of Reference Laboratories." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 654.02. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"Reference Laboratory." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 650.05. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

### 2.5. Skilled Nursing Facility Laboratory

A skilled nursing facility laboratory is a laboratory located on the campus of a skilled nursing facility. Skilled nursing facility laboratories in any state are eligible to participate in the Idaho Medicaid Program. Laboratories must have a National Provider Identification (NPI). They must be licensed in the state where the services are performed, eligible for Medicare certification, and enroll as an Idaho Medicaid provider prior to submitting claims for services. The laboratory must have a Clinical Laboratory Improvement Amendments (CLIA) certificate valid for the dates of service on file with Idaho Medicaid. Payments will be denied for any laboratory services not covered by a CLIA certificate or rendered outside the effective dates of their CLIA certificate.

Laboratories are required to have their site credentialed. Should the laboratory have a change of address they must complete and submit a new W9 that reflects the new address, a new provider agreement and proof of the new site being credentialed before billing for services provided at the new location.

Skilled nursing facility laboratories do not qualify as a reference laboratory or an independent laboratory. Specimens sent from these laboratories to an external laboratory for testing must be billed by the external laboratory.

See <u>General Information and Requirements for Providers</u>, Idaho Medicaid Provider Handbook for more information on enrolling as an Idaho Medicaid provider.

#### 2.5.1. References: Skilled Nursing Facility Laboratory

#### (a) Federal Regulations

"Certificate Requirement." P.L. 100-578, "*Clinical Laboratory Improvement Amendments of 1988*," Sec. 353(b). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/STATUTE-102/pdf/STATUTE-102-Pg2903.pdf</u>.

"Definitions of Services, Institutions, ETC..." Social Security Act, Sec. 1861(s)(16) (1935). Social Security Administration, https://www.ssa.gov/OP\_Home/ssact/title18/1861.htm.

"Definitions of Services, Institutions, ETC..." Social Security Act, Sec. 1861(s)(17) (1935). Social Security Administration, <u>https://www.ssa.gov/OP\_Home/ssact/title18/1861.htm</u>.

Laboratory, Radiology, and Other Diagnostic Services, 42 C.F.R. Sec. 483.50 (2017). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol5/pdf/CFR-2019-title42-vol5-sec483-50.pdf</u>.

Laboratory Requirements, 42 C.F.R. Sec. 493 (2019). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol5/pdf/CFR-2019-title42-vol5-part493.pdf</u>.

Laboratory Services, 42 C.F.R. Sec. 441.17(a)(4) (1998). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol4/pdf/CFR-2019-title42-vol4/pdf/CFR-2019-title42-vol4-sec441-17.pdf</u>. "State Plans for Medical Assistance." Social Security Act, Sec. 1902(a)(9)(C) (1935). Social Security Administration, <u>https://www.ssa.gov/OP Home/ssact/title19/1902.htm</u>.

# (b) State Regulations

"Individual Providers – Requirements." IDAPA 16.03.09, "*Medicaid Basic Plan Benefits,*" Sec. 200. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"Laboratory and Radiology Requirements." *IDAPA 16.03.09*, "*Medicaid Basic Plan Benefits*," Sec. 654.01. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"Provider." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 012.09. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

# 3. Eligible Participants

Participants with Medicaid Basic and Enhanced Plans are eligible to receive services. When billing for participants enrolled with other eligibility segments, refer to <u>General Information</u> and <u>Requirements for Providers</u>, Idaho Medicaid Provider Handbook for coverage. Providers must check participant eligibility prior to delivery of the service by calling Idaho Medicaid Automated Customer Service (MACS) at 1 (866) 686-4272; or through the Trading Partner Account on Gainwell Technologies' <u>Idaho Medicaid</u> website.

### 3.1. Referrals

A referral from the primary care provider is not necessary for participants enrolled in the Healthy Connections (HC) program, Idaho's primary care case management (PCCM) model of managed care, to receive laboratory services.

# 3.2. Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Services

Services identified for participants under the age of 21 as a result of Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) which correct or ameliorate a defect will not be subject to the existing amount, scope, and duration limitations, and do not require prior authorization if identified on the AAP's periodicity schedule as "should be performed" or "A risk assessment to be performed" as part of a periodic or interperiodic medical screening. All other laboratory tests are subject to prior authorization. The medical necessity for the additional service must be documented. It must be proven safe, effective, and accepted as a medical practice or treatment for the condition being addressed. Additional information for EPSDT may be found in the <u>General Information and Requirements for Providers</u>, Idaho Medicaid Provider Handbook.

# 4. Covered Services and Limitations

Laboratory services are a covered benefit of Idaho Medicaid when performed in compliance with CLIA requirements. Coverage is limited to medically necessary diagnostic testing, and some select screening services discussed in this section. Coverage is not available for deceased participants including postmortem examinations. Diagnostic tests are laboratory services used in the presence of signs or symptoms that have results leading to treatment services, which control, correct, or ameliorate health problems. Screening services are those tests made in the absence of signs or symptoms.

Screening services generally are not covered by Idaho Medicaid due to statutory requirements for medical necessity. The Affordable Care Act requires certain screening services be covered including services with an "A" or "B" recommendation from the <u>U.S. Preventive Services Task</u> Force (USPSTF) and other standards as adopted by the Department. The Department has also adopted the <u>American Academy of Pediatrics (AAP)</u> Bright Futures Preventative Care Periodicity Schedule, and the Health Resources and Services Administration's <u>Women's Preventive Services Guidelines</u>. Any screening services outside these three organizations' applicable recommendations must be explicitly communicated by the Department as covered to be eligible for reimbursement. Additional information on screening services is available under the Medical Necessity section in the <u>General Information and Requirements for Providers</u>, Idaho Medicaid Provider Handbook.

The laboratory is responsible for ensuring all services are medically necessary and criteria are followed. Testing for sports participation, camp attendance, employment, driving licensure, admission to an educational institution, military recruitment, insurance coverage, paternity determination, adoption, immigration, probation, or marriage are not considered medically necessary and are not covered by Idaho Medicaid. Laboratory services are not considered medically necessary, non-covered, and not eligible for reimbursement if any of the following apply:

- Testing is not considered standard of care, such as when the clinical diagnosis can be made without the use of a genetic or other laboratory test;
- Testing is not clinically appropriate for the participant's condition;
- Testing is for family planning;
- Testing is only for genetic counseling; or
- The results of a test would not impact medical decision making or change a participant's treatment plan.

An example of ICD-10 diagnoses that would indicate to a laboratory that a test is not medically necessary include:

Non-medically Necessary ICD-10-CM Diagnoses		
ICD-10-CM	Description	
Z02.0	Encounter for examination for admission to educational institution	
Z02.1	Encounter for pre-employment examination	
Z02.2	Encounter for examination for admission to residential institution	
Z02.3	Encounter for examination for recruitment to armed forces	
Z02.4	Encounter for examination for driving license	
Z02.5	Encounter for examination for participation in sport	
Z02.6	Encounter for examination for insurance purposes	
Z02.81	Encounter for paternity testing	
Z02.82	Encounter for adoption services	
Z02.89	Encounter for other administrative examinations	

	Non-medically Necessary ICD-10-CM Diagnoses
ICD-10-CM	Description
Z04.8	Encounter for examination and observation for other specified reasons

Services not medically necessary or non-covered may not be billed to the participant unless the requirements in the Participant Financial Responsibility section of the <u>General Information</u> <u>and Requirements for Providers</u>, Idaho Medicaid Provider Handbook are followed.

All laboratory services require a physician or non-physician practitioner's order. Blanket, reflexive or standing orders do not meet the requirements for an order. A blanket order is considered any order not specific to the participant, such as orders a provider establishes for all patients under their care. If a clinical diagnostic test order does not require a signature, there must be signed medical documentation such as a progress note by the treating physician or non-physician practitioner. Some laboratory procedures may require a prior authorization, refer to the current <u>Numerical Fee Schedule</u> for CPT<sup>®</sup> and HCPCS codes that always require a prior authorization, and the reviewing authority.

#### 4.1. References: Covered Services and Limitations

#### 4.1.1. CMS Guidance

"Medical Documentation Signature Requirements." *Noridian Healthcare Solutions*, 10 June 2024, <u>https://med.noridianmedicare.com/web/jfb/cert-reviews/signature-requirements</u>.

#### 4.1.2. Federal Regulations

"Definitions." Social Security Act, Sec. 1905(a)(3) (1935). Social Security Administration, <u>https://www.ssa.gov/OP Home/ssact/title19/1905.htm</u>.

"Definitions." Social Security Act, Sec. 1905(r)(1)(B)(iv) (1935). Social Security Administration, <u>https://www.ssa.gov/OP Home/ssact/title19/1905.htm</u>.

Laboratory Services, 42 C.F.R. Sec. 441.17 (1998). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol4/pdf/CFR-2019-title42-vol4-sec441-17.pdf</u>.

Other Laboratory and X-ray Services, 42 C.F.R. Sec. 440.30 (1992). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol4/pdf/CFR-2019-title42-vol4-sec440-30.pdf</u>.

The Patient Protection and Affordable Care Act. H.R. 3590 (2010). Government Printing Office,

https://www.gpo.gov/fdsys/pkg/BILLS-111hr3590enr/pdf/BILLS-111hr3590enr.pdf.

### 4.1.3. Idaho Medicaid Publications

"Attention Laboratories: Tests for Non-Medical Physicals." *MedicAide Newsletter,* May 2018,

https://www.idmedicaid.com/MedicAide%20Newsletters/May%202018%20MedicAide.pd f.

"Idaho Medicaid Covers Screening Services per the Affordable Care Act and USPSTF Recommendations." *MedicAide Newsletter*, October 2018,

https://www.idmedicaid.com/MedicAide%20Newsletters/October%202018%20MedicAid e.pdf.

"Physician Supervision of Medical and Surgical Services, Levels of Supervision per the Centers for Medicare & Medicaid Services." *MedicAide Newsletter*, January 2019, <u>https://www.idmedicaid.com/MedicAide%20Newsletters/January%202019%20MedicAide.pdf</u>.

"Screening Services Not Mandated are Statutorily Excluded from Reimbursement." MedicAide Newsletter, March 2018, https://www.idmedicaid.com/MedicAide%20Newsletters/March%202018%20MedicAide. pdf.

#### 4.1.4. State Regulations

"Laboratory Services." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 653.01. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature, https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255.

"Medical Necessity (Medically Necessary)." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 011.10. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

### 4.2. Abortions

See the Abortions section of the <u>Medical Services</u>, Idaho Medicaid Provider Handbook for coverage and codes triggering the requirement for claims to be submitted with documentation.

# 4.3. Cervical Cancer Screening

See the Medical Services, Idaho Medicaid Provider Handbook for coverage.

### 4.4. Controlled Substance and Drug Testing

Drug testing is an important part of treatment for substance use disorder (SUD) and chronic pain. Drug testing can be used to assess for adherence, persistent substance use, and diversion. However, its effectiveness and impact on patient-important outcomes such as addiction, overdose, and death have not been delineated. Although the ideal frequency of drug testing in situations of chronic pain and SUD treatment is unclear, different guidelines suggest at least eight times per year for SUD treatment (with more frequent testing being typical) and at least baseline and as needed testing for chronic pain treatment.

This controlled substance and drug testing section applies to urine drug testing, drug testing of oral fluids or hair, testing for substance use disorder treatment or monitoring of chronic pain management, whether billed through Idaho Medicaid fee-for-service programs or the Idaho Behavioral Health Plan administered by <u>Magellan Healthcare, Inc</u>. It does not apply to breathalyzer testing for alcohol.

Idaho Medicaid reimburses presumptive and confirmatory drug testing when medically necessary (such as in the determination of altered mental status or possible overdose, substance use treatment, and chronic pain treatment). Drug testing is not covered as part of routine physicals or for participation in sports, legal, criminal justice, employment, or administrative purposes. However, tests that meet the coverage requirements of this policy may be used additionally for other purposes. Blanket orders and orders specifying that both presumptive and confirmatory testing will be performed simultaneously are not allowed. A blanket order is considered any order that is not specific to the participant, such as orders a provider establishes for all patients under their care. Drug testing is also subject to the following limitations:

- Tests for specimen validity are included in the reimbursement for the test.
- To be reimbursable, drug tests must be ordered by a licensed or certified healthcare professional who:
  - Has performed a face-to-face evaluation of the participant (this may include telehealth if the requirements of the telehealth policy are met);
  - Is treating the participant for the condition the test is being ordered for; and
  - Is enrolled with Idaho Medicaid and/or the IBHP.
- Claims for tests ordered by non-enrolled persons or entities (e.g., non-enrolled recovery support staff, law enforcement personnel, probation, and parole officers, etc.) will be denied and/or are subject to recoupment action. Tests ordered by a healthcare professional on behalf of law enforcement personnel, probation, and parole officers, etc. are also not covered.

Presumptive (or qualitative) testing is immunoassay-based and is the most inexpensive form of drug testing. This type of testing can be performed in a laboratory or via a point-of-care test in the office. Immunoassays have a significant false positive rate, especially for certain substances; however, they are typically sufficient for routine drug testing. Idaho Medicaid will reimburse up to 24 presumptive (qualitative) drug tests per calendar year without a prior authorization when they meet the requirements of this section.

Confirmatory (or quantitative) tests, analyzed via liquid chromatography tandem mass spectrometry (LCMS/MS) or gas chromatography mass spectrometry (GC-MS), are significantly more expensive. These tests should be reserved for situations when the result of a presumptive test is disputed by the participant or the drug of concern cannot be tested for via immunoassay. The majority of drug tests conducted should be presumptive, with only a fraction of those being confirmatory tests. Idaho Medicaid will reimburse up to 12 confirmatory drug tests per calendar year without a prior authorization. Claims for confirmatory testing

performed in the absence of a positive result on a presumptive test or documented need for testing beyond what a presumptive test can provide, will be denied and/or subject to recoupment. Coverage of confirmatory tests only includes panels up to a maximum of 14 classes at a time or unique tests for specific substances; whether a panel or an individual test, each test would count toward the cap of 12 confirmatory tests per calendar year. Testing for more than 14 classes at a time is not considered medically necessary and is not reimbursable.

The testing limits for presumptive and confirmatory tests are inclusive of tests ordered through the IBHP (e.g., point-of-care, in-office, CLIA-waived, presumptive tests done in the behavioral health provider's office) or fee-for-service Medicaid claims reimbursed through Gainwell Technologies. The IBHP and Medicaid will both have separate system limits. Providers should be aware that although they can theoretically bill the maximum limitation for each test in each system (i.e., IBHP and fee-for-service Medicaid), this would be a violation of coverage requirements and could be subject to recoupment action and investigation by the Medicaid Program Integrity Unit.

Providers can apply for additional drug tests if medically necessary (beyond the pre-approved 24 qualitative tests and 12 quantitative tests) using the prior authorization process. Prior authorizations should be requested from Magellan Healthcare, Inc. or the Medical Care Unit as appropriate, but not both. An example of an appropriate prior authorization request, would be for a participant experiencing multiple relapses in a calendar year requiring multiple episodes of restarting treatment. An example of inappropriate requests for prior authorization, would be additional testing being required by probation and parole requirements. The prior authorization process may include a retroactive review of drug testing services provided to the participant to ensure services were medically necessary before authorizing additional units. Paid claims failing to meet the criteria for coverage will be recouped. Blanket prior authorization requests will be denied.

Idaho Medicaid uses coding for drug testing that reports the number of drug classes tested. CPT<sup>®</sup> or HCPCS codes representing individual drug tests are not covered by Idaho Medicaid. Services should be billed using the correlating code below that best matches the testing performed. Only one quantitative code and one qualitative code may be billed per date of service. Only the codes listed below are eligible for reimbursement:

Presumptive (qualitative) test codes (reimbursed by fee-for-service Medicaid and Magellan Healthcare, Inc.):

- CPT 80305: Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation only (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service.
- CPT 80306: Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) read by instrument-assisted direct optical observation (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service.
- CPT 80307: Drug test(s), presumptive, any number of drug c lasses, any number of devices or procedures; by instrument chemistry analyzers (e.g., utilizing immunoassay [e.g., EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (e.g., GC, HPLC), and mass spectrometry either with or without chromatography, (e.g., DART, DESI, GCMS, GC-MS/MS, LC-MS, LC-MS/MS, LDT D, MALDI, T OF) includes sample validation when performed, per date of service.

Confirmatory (quantitative) test codes (reimbursed by fee-for-service Medicaid):

- G0480: Drug test (s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources, includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed.
- G0481: Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources, includes specimen validity testing, per day, 8-14 drug class(es), including metabolite(s) if performed.
- G0659: Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimer; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes.

#### 4.4.1. References: Controlled Substance and Drug Testing

# (a) CMS Guidance

"Chapter 10 – Pathology/Laboratory Services CPT Codes 80000 - 89999." National Correct Coding Initiative Policy Manual for Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, <u>https://www.cms.gov/medicare/coding-billing/ncci-medicaid/medicaid-ncci-policy-manual</u>.

Local Coverage Determination (LCD): Urine Drug Testing (L36707). Centers for Medicare and Medicaid Services, Department of Health and Human Services. <u>https://www.cms.gov/medicare-coverage-</u> <u>database/view/lcd.aspx?lcdid=36707&ver=39&</u>.

"Proper Coding for Specimen Validity Testing Billed in Combination with Drug Testing." *MLN Matters SE18001, March 2018,* Centers for Medicare and Medicaid Services, Department of Health and Human Services, <u>https://www.cms.gov/Outreach-and-</u><u>Education/Medicare-Learning-Network-</u><u>MLN/MLNMattersArticles/Downloads/SE18001.pdf</u>.

# (b) Federal Regulations

Enrollment and Screening of Providers, 42 CFR 455.410 (2023). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/CFR-2023-title42-vol4/pdf/CFR-2023-title42-vol4-sec455-410.pdf</u>.

Medication Assisted Treatment for Opioid Use Disorders, 42 CFR 8 (2016). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol1/pdf/CFR-2019-title42-vol1/pdf/CFR-2019-title42-vol1-part8.pdf</u>.

#### (c) Idaho Medicaid Publications

"Changes for 2015 Laboratory Codes 80300 – 80377." MedicAide Newsletter, March 2015,

https://www.idmedicaid.com/MedicAide%20Newsletters/March%202015%20MedicAide. pdf.

"Clarifications on Drug Testing Laboratory and Pathology Coverage." MedicAide Newsletter, April 2020,

https://www.idmedicaid.com/MedicAide%20Newsletters/April%202020%20MedicAide.p df.

"Coverage for Drug Testing Laboratory and Pathology." MedicAide Newsletter, March 2020,

https://www.idmedicaid.com/MedicAide%20Newsletters/March%202020%20MedicAide. pdf.

"Covered Indications for Urine Drug Tests." MedicAide Newsletter, August 2018, <u>https://www.idmedicaid.com/MedicAide%20Newsletters/August%202018%20MedicAide</u>.<u>.pdf</u>.

"Drug Testing and Specimen Validity Testing Billed in Combination: Medicare Correct Coding, Diagnostic, Clinical Guidelines and Limits Apply to Medicaid. As of July 1, 2018, G0659 is Covered by Idaho Medicaid." MedicAide Newsletter, June 2018, <u>https://www.idmedicaid.com/MedicAide%20Newsletters/June%202018%20MedicAide.p</u> <u>df</u>.

"Drug Testing CPT/HCPCS and NCCI Limitations for CPTs 80000-89999 at Medicaid.gov." MedicAide Newsletter, June 2018, <u>https://www.idmedicaid.com/MedicAide%20Newsletters/June%202018%20MedicAide.p</u> <u>df</u>.

Drug Testing Policy, *Information Release MA20-43* (9/29/2020). Division of Medicaid, Department of Health and Welfare, State of Idaho, <u>https://publicdocuments.dhw.idaho.gov/WebLink/DocView.aspx?id=4983&dbid=0&repo</u> <u>=PUBLIC-DOCUMENTS&cr=1</u>.

Handbooks and Forms, Magellan Healthcare of Idaho. <u>https://www.magellanhealthcare.com/magellan-of-idaho-2-2/for-providers/handbooks-forms/</u>

"Laboratory Tests: Controlled Substances/Drug Testing and Non-Covered Testing for Legal Purposes." *MedicAide Newsletter*, November 2017, <u>https://www.idmedicaid.com/MedicAide%20Newsletters/November%202017%20MedicAide.pdf</u>.

**"Medicaid Program Integrity:** Correct Billing for Drug Screening with Multiplex Drug Test Kit." MedicAide Newsletter, September 2013,

https://www.idmedicaid.com/MedicAide%20Newsletters/September%202013%20Medic Aide.pdf.

# (d) Scholarly Works

"CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016." Morbidity and Mortality Weekly Report: Recommendations and Reports, March 2016; Vol. 65, No. 1, pages 1-49; Deborah Dowell, Tamara M. Haegerich, Roger Chou, https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf

Pensa, M., Wu, C., & Harrod, C. (2016). Urine drug testing for patients prescribed chronic opioids or with substance use disorder. Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University, <u>https://www.medclearinghouse.org</u>.

Substance Abuse and Mental Health Services Administration (2021). TIP 63: Medications for Opioid Use Disorder - Full Document. Rockville, MD: Substance Abuse and Mental Health Services Administration, <u>https://store.samhsa.gov/product/TIP-63-</u><u>Medications-for-Opioid-Use-Disorder-Full-Document/PEP20-02-01-006</u>.

# (e) State Regulations

"Laboratory and Radiology Services: Quality Assurance." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 656. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"Laboratory Services." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 653.01. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature, <u>https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255</u>.

"Medical Necessity (Medically Necessary)." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 011.10. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"Quality Control." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 650.04. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

# 4.4.2. Drug Testing for 15 or More Classes

Drug testing for more than 14 classes, including HCPCS G0482 and G0483, are non-covered. If 15 or more classes are tested, then the provider may bill the code that represents the number that is medically necessary and compliant with this policy. For example, if a provider is testing 18 drug classes, and 14 drug classes are medical necessary and meet the other requirements for coverage, then the provider can bill G0481 for testing the 14 classes. Providers should ensure if they opt for this option that they don't engage in balance billing of the covered services to the participant. Providers should also not bill another entity that traditionally would not be liable for services after Medicaid provided reimbursement, which would result in the provider receiving double payment from various State of Idaho agencies.

The Department understands that there may be rare individual circumstances that this policy cannot predict. If 15 or more classes are medically necessary for testing, then the provider may submit a claim for denial and follow the process detailed in the Claim Reconsideration and Appeals section of the <u>General Billing Instructions</u>, Idaho Medicaid Provider Handbook. Providers must attach clinical documentation to their request showing why the number of drug classes was necessary. Additionally, a letter of medical necessity addressing why each tested class is necessary is suggested, but not required. The exceptions process does not allow for coverage of testing in situations prohibited by this policy. For example, the exceptions process will not approve reimbursement for testing provided for criminal justice purposes. It will only allow coverage for those situations that are medically warranted and would affect treatment decisions.

# (a) References: Drug Testing for 15 or More Classes

#### (i) CMS Guidance

Local Coverage Determination (LCD): Urine Drug Testing (L36707). Centers for Medicare and Medicaid Services, Department of Health and Human Services. <u>https://www.cms.gov/medicare-coverage-</u> <u>database/view/lcd.aspx?lcdid=36707&ver=39&</u>.

#### (ii) Idaho Medicaid Publications

"Changes for 2015 Laboratory Codes 80300 – 80377." MedicAide Newsletter, March 2015,

https://www.idmedicaid.com/MedicAide%20Newsletters/March%202015%20MedicAide. pdf.

"Clarifications on Drug Testing Laboratory and Pathology Coverage." MedicAide Newsletter, April 2020,

https://www.idmedicaid.com/MedicAide%20Newsletters/April%202020%20MedicAide.p df.

"Coverage for Drug Testing Laboratory and Pathology." MedicAide Newsletter, March 2020,

https://www.idmedicaid.com/MedicAide%20Newsletters/March%202020%20MedicAide. pdf.

"Covered Indications for Urine Drug Tests." MedicAide Newsletter, August 2018, <u>https://www.idmedicaid.com/MedicAide%20Newsletters/August%202018%20MedicAide</u>.<u>pdf</u>.

"Drug Testing and Specimen Validity Testing Billed in Combination: Medicare Correct Coding, Diagnostic, Clinical Guidelines and Limits Apply to Medicaid. As of July 1, 2018, G0659 is Covered by Idaho Medicaid." MedicAide Newsletter, June 2018, <u>https://www.idmedicaid.com/MedicAide%20Newsletters/June%202018%20MedicAide.p</u> <u>df</u>.

"Drug Testing CPT/HCPCS and NCCI Limitations for CPTs 80000-89999 at Medicaid.gov." MedicAide Newsletter, June 2018, <u>https://www.idmedicaid.com/MedicAide%20Newsletters/June%202018%20MedicAide.p</u> <u>df</u>. Drug Testing Policy, *Information Release MA20-43* (9/29/2020). Division of Medicaid, Department of Health and Welfare, State of Idaho, <u>https://publicdocuments.dhw.idaho.gov/WebLink/DocView.aspx?id=4983&dbid=0&repo=PUBLIC-DOCUMENTS&cr=1</u>.

#### (iii) Scholarly Works

"CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016." Morbidity and Mortality Weekly Report: Recommendations and Reports, March 2016; Vol. 65, No. 1, pages 1-49; Deborah Dowell, Tamara M. Haegerich, Roger Chou, https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf

Pensa, M., Wu, C., & Harrod, C. (2016). Urine drug testing for patients prescribed chronic opioids or with substance use disorder. Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University, <u>https://www.medclearinghouse.org</u>.

Substance Abuse and Mental Health Services Administration (2020). TIP 63: Medications for Opioid Use Disorder - Full Document. Rockville, MD: Substance Abuse and Mental Health Services Administration, <u>https://store.samhsa.gov/product/TIP-63-</u><u>Medications-for-Opioid-Use-Disorder-Full-Document/PEP20-02-01-006</u>.

#### (iv) State Regulations

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature,

https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255.

"Medical Necessity (Medically Necessary)." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 011.10. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

### 4.5. COVID-19 Testing

Idaho Medicaid covers all medically necessary and Centers for Disease Control & Prevention (CDC) recommended testing for SARS-CoV-2, the virus that causes COVID-19. Covered services for testing for SARS-CoV-2 includes molecular, rapid antigen and serologic (antibody) tests. An individualized test result for either diagnostic and/or screening services must be obtained to support a claim for reimbursement. Providers should educate participants on symptoms and prevention of COVID-19 when ordering testing. At a minimum, prevention education should include a discussion of the importance and correct use of masks or face coverings, social distancing, hand washing, quarantine and isolation, and the benefits of immunizations for the prevention of COVID-19.

Per the Public Readiness and Emergency Preparedness Act (PREP Act), pharmacists can order and administer tests for SARS-CoV-2. If a pharmacist collects a specimen and sends it to a laboratory or other healthcare entity for processing, the receiving laboratory or healthcare entity must be enrolled in Idaho Medicaid and must bill the service directly.

### 4.5.1. References: COVID-19 Testing

# (a) Idaho Medicaid Publications

"COVID-19 Testing." MedicAide Newsletter, May 2023, https://www.idmedicaid.com/MedicAide%20Newsletters/May%202023%20MedicAide.pd f.

# (b) State Regulations

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature,

https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255.

"Medical Necessity (Medically Necessary)." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 011.10. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

### 4.5.2. Molecular Testing for SARS-CoV-2

Molecular testing demonstrating the presence of viral RNA is the only way to definitively diagnose an active infection with SARS-CoV-2. These tests may detect the virus 1–2 days before symptoms occur and for a short period after symptoms cease. If clinical suspicion for COVID-19 remains high, self-isolation should be recommended regardless of test result. Molecular testing cannot determine if a person has recovered from a previous infection with the virus. Molecular tests available on the market include:

- Rapid molecular testing at the point of care for results within minutes (up to 4-5 per hour);
- High-throughput platforms that process large numbers of tests within hours (up to 2,000 per day);
- Out-of-state laboratories with capabilities similar to high-throughput platforms with turnarounds in 2–4 days.

Molecular tests for SARS-CoV2 are limited to a total of four (4) tests per participant per month. If additional tests are needed, providers can submit a prior authorization request form to Telligen's provider portal at <u>https://idmedicaid.telligen.com</u>.

#### **References: Molecular Testing for SARS-CoV-2 (a)**

#### (i) Idaho Medicaid Publications

"COVID-19 Testing," MedicAide Newsletter, May 2023, https://www.idmedicaid.com/MedicAide%20Newsletters/May%202023%20MedicAide.pd f.

#### *(ii)* State Regulations

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature, https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255.

"Medical Necessity (Medically Necessary)." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 011.10. Department of Administration, State of Idaho, https://adminrules.idaho.gov/rules/current/16/160309.pdf.

#### **Rapid Antigen Testing for SARS-CoV-2** 4.5.3.

Rapid antigen testing is less complex than molecular testing methods and can generally provide results in fifteen to thirty minutes. Rapid antigen tests are available as selfadministered at home tests and can be great tools for determining if a mild symptom such as congestion is likely to be COVID-19 before an individual goes to a space where they may be in contact with others (e.g. school, work, or a family gathering). However, these tests are less sensitive than molecular tests and require much more virus in the sample to be detected. These tests may not be effective five days after the onset of symptoms or for those that are asymptomatic. It is recommended that those with a negative result and a high degree of suspicion for infection be tested a second time with a molecular test and be told to isolate while awaiting the results of the follow-up test.

At home rapid antigen tests require a prescription from a physician, nurse practitioner, physician assistant, or pharmacist and should be billed to Idaho Medicaid at the pharmacy at the point-of-sale.

Rapid Antigen tests for SARS-CoV2 are limited to a total of four (4) tests per participant per month. If additional tests are needed, providers can submit a prior authorization request form to Telligen's provider portal at https://idmedicaid.telligen.com.

#### **(a) References: Rapid Antigen Testing for SARS-CoV-2**

#### (i) Idaho Medicaid Publications

"COVID-19 Testing." MedicAide Newsletter, May 2023, https://www.idmedicaid.com/MedicAide%20Newsletters/May%202023%20MedicAide.pd f.

#### State Regulations *(ii)*

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature,

https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255.

"Medical Necessity (Medically Necessary)." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 011.10. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

#### 4.5.4. Coverage of Serologic Testing for SARS-CoV-2

Serologic testing looks for previous infection with the virus, by detecting the presence of antibodies that bind to viral proteins. The extent to which antibodies to SARS-CoV2 confer immunity to reinfection is unclear. Given the high risk of false positive COVID-19 antibody tests, a second test should be performed to confirm the positive result in addition to assessment of other relevant information, such as clinical history or diagnostic test results. Serologic tests should not be used for diagnosing acute infection, for determining the need for quarantine after exposure or for assessing immunity following COVID-19 vaccination. Serologic testing has limited clinical applicability and is not recommended by the CDC or by the State of Idaho's Testing Task Force for use in directing patient care.

Serologic testing is limited to twice (2) per year without a prior authorization. Claims for serologic testing must have the <u>Serologic Testing for SARS-CoV-2 Documentation Form</u> attached. If additional tests are needed, providers can submit a prior authorization request form to Telligen's provider portal at <u>https://idmedicaid.telligen.com</u>.

	Codes Requiring Documentation with the Claim
CPT®	Description
86328	Test for detection of severe acute respiratory syndrome coronavirus 2 (Covid- 19) antibody, qualitative or semiquantitative
86413	Quantitative measurement of severe acute respiratory syndrome coronavirus 2 (COVID-19] antibody
86769	Measure of severe acute respiratory syndrome coronavirus 2 (Covid-19) antibody

#### (a) References: Coverage of Serologic Testing for SARS-CoV-2

#### (i) Idaho Medicaid Publications

"COVID-19 Testing." *MedicAide Newsletter*, May 2023, <u>https://www.idmedicaid.com/MedicAide%20Newsletters/May%202023%20MedicAide.pd</u> <u>f</u>.

#### (ii) State Regulations

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature,

https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255.

"Medical Necessity (Medically Necessary)." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 011.10. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

### 4.6. Fertility Testing

Laboratory services for the testing of infertility or fertility are non-covered. This includes services related to surrogate motherhood.

# 4.6.1. References: Fertility Testing

# (a) State Regulations

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature, https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255.

"Medical Necessity (Medically Necessary)." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 011.10. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"Service Categories Not Covered." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 390.01.e. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

### 4.7. General Health Panel

Idaho Medicaid considers CPT<sup>®</sup> 80050 (General Health Panel) to not be medically necessary. This service is non-covered. Providers may still bill individual tests with medical necessity established for each.

# 4.7.1. References: General Health Panel

# (a) Idaho Medicaid Publications

"CPT<sup>©</sup> 80050: General Health Panel." MedicAide Newsletter, September 2018, <u>https://www.idmedicaid.com/MedicAide%20Newsletters/September%202018%20MedicAide.pdf</u>.

# (b) State Regulations

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature, https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255.

"Medical Necessity (Medically Necessary)." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 011.10. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

# 4.8. Genetic Testing

This section applies to all genetic testing coverage including those otherwise specified in this handbook. Genetic testing is a covered benefit under Idaho Medicaid when it meets the criteria of this section and any test specific criteria established by the Department or Telligen. Tests must at a minimum meet the following criteria to be covered:

- Tests must be ordered by a physician or non-physician practitioner;
- Be used to diagnose a clinical symptom displayed by the participant, which is indicative of a genetic condition, or provide a differential diagnosis when one of the possible diagnoses is genetic in nature;
- The results of the test will affect changes to health monitoring, or the treatment provided. If potential treatments that would be applicable to the results of the testing are non-covered, then so is the testing;
- The test utilized must be considered scientifically valid for the identification of a specific genetically linked inheritable disease to the condition being tested for as evidenced by peer-reviewed literature;
- The chance of the genetic abnormality being tested for must be greater than 10% for coverage; and
- <u>Genetic counseling</u> must be provided to the participant before and after testing.

Providers must consult with the participant to determine if they have been previously tested. Genetic tests should not be duplicated unless there is uncertainty about the validity of the existing test result, such as the participant's clinical presentation is inconsistent with the previous test results or the test methodologies have changed and may yield different results that could affect care management.

The following types of genetic testing are not covered by Idaho Medicaid:

- Tests performed for screening purposes only, in the absence of signs, symptoms, or personal history of disease or injury;
- Tests that are done solely to diagnose a patient, and will not impact medical decisionmaking for the patient or the patient's treatment plan;
- Tests for conditions and diseases which are symptomatically treated;
- Tests done to confirm a diagnosis;
- Tests done for informational purposes only;
- Tests on people other than the participant;
- Tests for paternity;
- Tests for legal reasons; or
- Tests performed for the purposes of genetic counseling or family planning.

# **4.8.1. References: Genetic Testing**

### (a) Idaho Medicaid Publications

"Genetic Testing." MedicAide Newsletter, June 2021, https://www.idmedicaid.com/MedicAide%20Newsletters/June%202021%20MedicAide.p df.

"Screening Services Not Mandated are Statutorily Excluded from Reimbursement." MedicAide Newsletter, March 2018,

https://www.idmedicaid.com/MedicAide%20Newsletters/March%202018%20MedicAide. pdf. "Types of Non-Covered Genetic Laboratory Tests." MedicAide Newsletter, October 2018, <u>https://www.idmedicaid.com/MedicAide%20Newsletters/October%202018%20MedicAide.pdf</u>.

# (b) Professional Organizations

5 Questions to Ask Your Doctor Before You Get Any Test, Treatment, or Procedure. Choosing Wisely. American College of Medical Genetics and Genomics. <u>https://choosingwisely.org/files/5-Questions\_ENG</u>.

# (c) State Regulations

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature,

https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255.

"Medical Necessity (Medically Necessary)." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 011.10. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

## 4.8.2. Genetic Counseling

Genetic counseling provides participants with the ability to make informed decisions about their healthcare. Participants should be made aware of the benefits, risks, limitations, and potential consequences of genetic testing. This also involves:

- A review of individual and family medical histories to determine genetic risk for medical conditions and diseases;
- Discussion of the features, means of diagnosis, genetic and environmental factors, and management of risk for genetic medical conditions and diseases;
- Communicating test results and the risk of a genetic condition or disease in the context of personal and family medical histories; and
- The clinical implications of conducting a test.

Genetic counseling must be provided by one of the following:

- A genetic counselor with a master's degree specifically in genetic counseling or related field, who is certified by the American Board of Genetic Counseling (ABGC) or American Board of Medical Genetics (ABMG).
- A physician, nurse practitioner or physician assistant with the appropriate expertise and training about inherited conditions, risks for disease, testing implications for health management, and interpreting findings of genetic tests.
- A pharmacist with ASHP pharmacogenetic certification.

If provided by the laboratory or hospital, genetic counseling and the genetic counselor's fees are bundled for reimbursement in the cost of the laboratory test. Qualifying physicians, physician assistants, nurse practitioners, and pharmacists may bill CPT<sup>®</sup> 96041 for their services or the services of a genetic counselor employee. Genetic counseling is limited to four (4) units per month without a prior authorization.

# (a) References: Genetic Counseling

#### (i) Idaho Medicaid Publications

"Genetic Testing." MedicAide Newsletter, June 2021, https://www.idmedicaid.com/MedicAide%20Newsletters/June%202021%20MedicAide.p df.

### (ii) State Regulations

Genetic Counselors – Exemptions for Licensure, Idaho Code 54-5604 (2015). Idaho State Legislature,

https://legislature.idaho.gov/statutesrules/idstat/Title54/T54CH56/SECT54-5604.

Genetic Counselors – Scope of Practice, Idaho Code 54-5603 (2015). Idaho State Legislature, <u>https://legislature.idaho.gov/statutesrules/idstat/title54/t54ch56/sect54-5603</u>.

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature, https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255.

## **4.8.3.** Genetic Testing for Alzheimer Disease

Testing for apolipoprotein E (APOE) (CPT<sup>®</sup> 81401) to determine the risk of Alzheimer Disease is non-covered. The presence of the allele is not alone enough to determine the risk of the disease and has poor predictive value and limited clinical use.

# (a) References: Genetic Testing for Alzheimer Disease

#### (i) Idaho Medicaid Publications

"Genetic Testing." MedicAide Newsletter, June 2021, https://www.idmedicaid.com/MedicAide%20Newsletters/June%202021%20MedicAide.p df.

#### (ii) Professional Organizations

5 Questions to Ask Your Doctor Before You Get Any Test, Treatment, or Procedure. Choosing Wisely. American College of Medical Genetics and Genomics. <u>https://choosingwisely.org/files/5-Questions\_ENG</u>.

#### (iii) State Regulations

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature, https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255.

#### **Genetic Testing for Pharmacogenetics** 4.8.4.

Pharmacogenomics is genetic testing that identifies variations in an individual's genetic makeup to determine if a drug is suitable for a participant, and what dose would be safe and effective. The drug must be covered for the participant for the pharmacogenetic testing to be a covered service, and, in addition the general genetic testing requirements, one of the following conditions must be met:

- Testing is required or recommended by the drug prescribing information; or
- A drug trial would be contra-indicated without genetic testing results known ahead of time.

Tests for the selection of medications or determination of dosage to treat mental health disorders such as depression are non-covered due to being experimental/investigational unless required by the prescribing information for a covered drug.

Codes Requiring a Prior Authorization from Telligen			
CPT®	Description		
81225	CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (e.g., drug metabolism), gene analysis, common variants (e.g., *2, *3, *4, *8, *17)		
81226	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism), gene analysis, common variants (e.g., *2, *3, *4, *5, *6, *9, *10, *17, *19, *29, *35, *41, *1XN, *2XN, *4XN)		
81227	CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (e.g., drug metabolism), gene analysis, common variants (e.g., *2, *3, *5, *6)		
81291	MTHFR (5,10-methylenetetrahydrofolate reductase) (e.g., hereditary hypercoagulability) gene analysis, common variants (e.g., 677T, 1298C)		
81355	VKORC1 (vitamin K epoxide reductase complex, subunit 1) (e.g., warfarin metabolism), gene analysis, common variant(s) (e.g., -1639G>A, c.173+1000C>T)		
81401	Molecular pathology procedure, Level 2		
81479	Unlisted molecular pathology procedure		

#### **References:** Genetic Testing for (a) **Pharmacogenetics**

### (i) Idaho Medicaid Publications

"Genetic Testing." MedicAide Newsletter, June 2021, https://www.idmedicaid.com/MedicAide%20Newsletters/June%202021%20MedicAide.p df.

#### *(ii)* State Regulations

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature,

https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255.

# 4.8.5. Genetic Testing for Hemochromatosis

In addition to Telligen's criteria for testing hereditary hemochromatosis using the HFE gene (CPT<sup>®</sup> 81256), tests should only be performed on participants with iron overload (e.g., elevated fasting transferrin saturation >45%) or participants with a family history of HFE-associated hereditary hemochromatosis.

# (a) References: Genetic Testing for Hemochromatosis

#### (i) Idaho Medicaid Publications

"Genetic Testing." MedicAide Newsletter, June 2021, https://www.idmedicaid.com/MedicAide%20Newsletters/June%202021%20MedicAide.p df.

#### (ii) Professional Organizations

5 Questions to Ask Your Doctor Before You Get Any Test, Treatment, or Procedure. Choosing Wisely. American College of Medical Genetics and Genomics. <u>https://choosingwisely.org/files/5-Questions\_ENG</u>.

#### (iii) State Regulations

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature,

https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255.

### 4.8.6. Genetic Testing for Hyperbilirubinemia

Idaho Medicaid considers genotyping of SLCO1B1 and UGT1A1 experimental and investigational for assessing risk of neonatal hyperbilirubinemia.

Non-covered Codes for Hyperbilirubinemia				
CPT®	Description			
81328	SLCO1B1 (solute carrier organic anion transporter family, member 1B1) (e.g., adverse drug reaction), gene analysis, common variant(s) (e.g., *5)			
81350	UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (e.g., drug metabolism, hereditary unconjugated hyperbilirubinemia [Gilbert syndrome]) gene analysis, common variants (e.g., *28, *36, *37)			

# (a) References: Genetic Testing for Hyperbilirubinemia

#### (i) Idaho Medicaid Publications

"Genetic Testing." MedicAide Newsletter, June 2021, https://www.idmedicaid.com/MedicAide%20Newsletters/June%202021%20MedicAide.p df.

#### (ii) State Regulations

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature,

https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255.

# **4.8.7.** Genetic Testing for Mental Health Disorders

Genetic Testing for mental health disorder is considered experimental and investigational, such as Genecept Assay, STA<sup>2</sup>R, the GeneSight Psychotropic panel, the Proove Opioid Risk assay and the Mental Health DNA Insight panel. Testing is non-covered for all situations including, but not limited to:

- Confirming diagnosis of a mental health disorder;
- Predicting risk of future development of a mental health disorder; or
- Selecting or determining the dosage of medications to treat mental health disorders.

### (a) References: Genetic Testing for Mental Health Disorders

#### (i) Idaho Medicaid Publications

"Genetic Testing." MedicAide Newsletter, June 2021, https://www.idmedicaid.com/MedicAide%20Newsletters/June%202021%20MedicAide.p df.

### (ii) State Regulations

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature, https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255.

# 4.8.8. Genetic Testing for Thrombophilia

In addition to Telligen's criteria for testing for methylenetetrahydrofolate reductase (MTHFR) (CPT<sup>®</sup> 81291), testing to determine the risk of thromboembolism is non-covered. The gene variants are common in the general population and meta-analyses have disproven any association.

# (a) References: Genetic Testing for Thrombophilia

### (i) Idaho Medicaid Publications

"Genetic Testing." MedicAide Newsletter, June 2021, https://www.idmedicaid.com/MedicAide%20Newsletters/June%202021%20MedicAide.p df.

### (ii) Professional Organizations

5 Questions to Ask Your Doctor Before You Get Any Test, Treatment, or Procedure. Choosing Wisely. American College of Medical Genetics and Genomics. <u>https://choosingwisely.org/files/5-Questions\_ENG</u>.

#### (iii) State Regulations

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature, https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255.

### **4.8.9.** Molecular Pathology for Infants

CPT<sup>®</sup> codes 81329, 81403, 81406 and 81479 are allowed without a prior authorization for newborns from birth to 120 days of life when billed with the EP modifier.

# (a) References: Molecular Pathology for Infants

#### (i) Idaho Medicaid Publications

"Molecular Pathology for Infants." MedicAide Newsletter, June 2023, https://www.idmedicaid.com/MedicAide%20Newsletters/June%202023%20MedicAide.p df.

# 4.9. Home Monitoring of Anticoagulant Therapy

Home International Normalization Ratio (INR) monitoring may be covered for participants taking oral anticoagulants if the following criteria is met:

- The participant has either mechanical heart valves, chronic atrial fibrillation or venous thromboembolism;
- The participant has been anticoagulated before beginning home monitoring for at least three months;
- The participant received face-to-face education from their treating provider on anticoagulation management and was able to demonstrate proper use of the device;
- The participant will only be self-testing once a week, unless they live in an area where it would be unreasonable to obtain testing in the office more frequently.

The treating physician or non-physician practitioner must also order the home monitoring supplies for these conditions. When providing test materials and equipment under CPT<sup>®</sup> 93792, providers should bill HCPCS G0249 instead of 99070. Idaho Medicaid will not provide reimbursement for 99070 under these circumstances.

### 4.9.1. References: Home Monitoring of Anticoagulant Therapy

# (a) Idaho Medicaid Publications

"International Normalized Ratio (INR) Monitoring Services: Billing Guidance." MedicAide Newsletter, February 2018,

https://www.idmedicaid.com/MedicAide%20Newsletters/February%202018%20MedicAide.pdf

# (b) State Regulations

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature,

https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255.

### 4.10. Lead Screening

The Department of Health and Welfare (DHW) reimburses providers for lead testing (CPT<sup>®</sup> 83655) performed by a venous blood draw or by capillary test (CPT<sup>®</sup> 36416). Screening for lead poisoning is a required component of an Early and Periodic Screening, Diagnosis, and Treatment screening. All Medicaid eligible children are required to be screened at 12 months and 24 months of age. Children between the ages of 24 months and 21 years of age, should receive a screening blood lead test if there is no record of a previous test. Coverage is also available for children requiring lead screening to enter the head start program.

Providers are required to report lead poisoning to the Department of Health and Welfare, Office of Epidemiology and Food Protection or local health district within three (3) working days. Lead poisoning may be diagnosed by symptoms, or a blood level of:

- Ten (10) micrograms or more per deciliter (10 ug/dL) in adults eighteen (18) years and older; or
- Five (5) micrograms or more per deciliter (5 ug/dL) in children under eighteen (18) years of age.

Elevated blood lead levels have been linked to developmental disabilities and other serious conditions in children including reduced IQ, hyperactivity, nervous system, and kidney damage. Providers diagnosing lead poisoning, in addition to their reporting requirement, should:

- Educate the participant, their parent or guardian, as applicable, about the hazards of lead poisoning;
- Evaluate the participant for complications from lead poisoning;
- Perform follow-up blood lead analyses everyone to two-month intervals until the blood lead level remains below the threshold for lead poisoning for at least six months and the source of the lead has been removed. Then continue analyses at three-month intervals until the participant is 36 months of age. If the participant receives additional lead-hazard exposure, then monitoring should return to a monthly or bi-monthly frequency;
- Refer the family to the local health district for more information; and
- Perform chelation therapy, if appropriate.

Claims should be submitted with a diagnosis reflecting a wellness visit. DHW will provide a Lead Care Analyzer machine to providers at no cost. This machine tests for lead by a simple capillary test (finger prick). The results are available immediately. Machines may be requested by completing the <u>"Lead Care Analyzer Provider Agreement"</u> form and submitting it by mail, fax or e-mail to:

Lead Screening Program Division of Medicaid PO Box 83720 Boise, ID 83720-0036 Fax: (208) 332-7280 MedicalCareUnit@dhw.idaho.gov

Please contact the Medical Care Unit at 1 (208) 364-1835 or visit the website <u>Idaho's Medicaid</u> <u>Lead Program</u>, for more information on lead screening.

# 4.10.1. References: Blood Lead Screening

# (a) Idaho Medicaid Publications

"Blood Lead Reporting Levels." *MedicAide Newsletter*, September 2015. <u>https://www.idmedicaid.com/MedicAide%20Newsletters/September%202015%20MedicAide.pdf</u>.

"New Recommendations to Define Elevated Blood Lead Levels." MedicAide Newsletter, November 2012.

https://www.idmedicaid.com/MedicAide%20Newsletters/November%202012%20MedicAide.pdf.

# (b) State Regulations

"Lead Poisoning." IDAPA 16.02.10, "Idaho Reportable Diseases," Sec. 380. Department of Administration, State of Idaho, https://adminrules.idaho.gov/rules/current/16/160210.pdf.

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature, <u>https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255</u>.

"Medical Necessity (Medically Necessary)." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 011.10. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

### 4.11. Newborn Screening

Newborn screening kits are a covered benefit of the Idaho Medicaid Program. Newborn screening is required by law to consist of two screening tests. Preferably the tests should be done once within 24-48 hours of birth and again at 10 to 14-days of age. Idaho Medicaid provides coverage for the screening under HCPCS S3620 (Newborn metabolic screening panel, includes test kit, postage and the laboratory tests specified by the state for inclusion). Follow-up testing for participants diagnosed with one of the 50 screened conditions can be done in a laboratory.

Providers, who performed the initial test after birth that will not be performing the additional tests in the kit at a later date, must give the additional tests to the participant's parent or guardian for their use with another provider. Idaho Medicaid does not reimburse for the cost of tests when the provider:

- Loses or misplaces the test;
- Contaminates or damages the test; or
- Neglects to give the second test to the family.

S3620 represents kits with 2-3 tests. S3620 can be billed with modifier UC for a single-test kits are appropriate when:

- The initially performing provider will not perform the additional tests in the kit and neglected to give them to the family for their follow-up appointment;
- The provider didn't perform the first test, is performing the second test, and the participant does not have access to the second test strip; or
- A two-test kit was used initially, but the infant later transferred to the NICU.

Providers shall only bill one unit per test kit per newborn. The collection of blood for the first and second part of the screening is reimbursable under the appropriate venipuncture CPT<sup>®</sup> code. Idaho Medicaid will reimburse these tests at cost to providers.

Test kits are ordered through the Newborn Screening for Providers Program <u>website</u> and must be purchased in advance from this program provider:

Idaho Newborn Screening Program 450 West State Street, 4<sup>th</sup> floor PO Box 83720 Boise, ID 83720-0036 1 (208) 334-5962 https://id.accessgov.com/nbsk/Forms/Page/nbsk/nbsk/0

### 4.11.1. References: Newborn Screening

### (a) Idaho Medicaid Publications

"Attn Hospitals: Newborn Metabolic Screening Test Kits." MedicAide Newsletter, October 2023.

https://www.idmedicaid.com/MedicAide%20Newsletters/October%202023%20MedicAid e.pdf.

"Clarification for Newborn Screening." *MedicAide Newsletter*, November 2019. <u>https://www.idmedicaid.com/MedicAide%20Newsletters/November%202019%20MedicAide.pdf</u>. Newborn Care Providers, *Information Release MA02-21* (2002). Division of Medicaid, Department of Health and Welfare, State of Idaho.

"Reimbursement for Newborn Screening." *MedicAide Newsletter*, August 2019. <u>https://www.idmedicaid.com/MedicAide%20Newsletters/August%202019%20MedicAide</u>.<u>pdf</u>.

# (b) State Regulations

Dried Blood Specimen Collection, Idaho Code 39-906 (2025). Idaho State Legislature, <u>https://legislature.idaho.gov/statutesrules/idstat/Title39/T39CH9/SECT39-906</u>.

IDAPA 16.02.12, "*Newborn Screening."* Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160212.pdf</u>.

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature, https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255.

"Medical Necessity (Medically Necessary)." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 011.10. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

Required Tests, Idaho Code 39-905 (2025). Idaho State Legislature, <u>https://legislature.idaho.gov/statutesrules/idstat/Title39/T39CH9/SECT39-905</u>.

# 4.12. Non-Invasive Prenatal Testing

Based on recommendations from the Society for Maternal Fetal Medicine (SMFM) to decrease the need for multiple visits/tests during the COVID-19 public health emergency, Idaho Medicaid is implementing temporary coverage of noninvasive prenatal testing (NIPT) for fetal aneuploidy screening, effective 5/01/2020.

Covered Non-Invasive Prenatal Testing				
CPT®	Procedure Code Description			
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			
81420	Fetal chromosomal aneuploidy (e.g., trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood			

# 4.12.1. References: Non-Invasive Prenatal Testing

# (a) Idaho Medicaid Publications

"Coverage of Non-invasive Prenatal Testing." *MedicAide Newsletter*, May 2020. <u>https://www.idmedicaid.com/MedicAide%20Newsletters/May%202020%20MedicAide.pd</u> <u>f</u>.

# (b) State Regulations

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature, https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255.

# 4.13. Papanicolaou Testing

The Papanicolaou test or pap smear is a covered benefit of Idaho Medicaid. See the Cervical Cancer Screening section of the <u>Medical Services</u>, Idaho Medicaid Provider Handbook for criteria and coverage requirements.

# 4.14. Pregnancy Testing

Pregnancy testing (CPT<sup>®</sup> 81025) is a covered benefit of Idaho Medicaid. Testing is covered at a maximum of twice per month when medically necessary without a prior authorization. Testing is only covered if the woman suspects they are pregnant, or the test would have an impact on the participant's treatment.

# 4.14.1. References: Pregnancy Testing

# (a) Idaho Medicaid Publications

"Pregnancy Testing." MedicAide Newsletter, June 2021, https://www.idmedicaid.com/MedicAide%20Newsletters/June%202021%20MedicAide.p df.

# 4.15. Proprietary Laboratory Analyses

Services represented by Proprietary Laboratory Analyses (PLA) codes do not usually meet the requirement of medical necessity for standard of care or are considered experimental/investigational. PLA codes are for used for laboratory tests provided by a single source or licensed to other laboratories for processing. Unless specifically stated in the CPT<sup>®</sup> manual PLA codes do not meet the standards for Category I codes. They are only required to be commercially available in the United States for use on human specimens and be requested by the laboratory or manufacturer. Laboratory tests represented by a PLA that do not meet the requirements to be a Category I CPT code are not covered and cannot be billed with an unspecified code.

### 4.15.1. References: Proprietary Laboratory Analyses

# (a) Idaho Medicaid Publications

"Proprietary Laboratory Analyses." MedicAide Newsletter, June 2021, <u>https://www.idmedicaid.com/MedicAide%20Newsletters/June%202021%20MedicAide.p</u> <u>df</u>.

# (b) State Regulations

"Experimental Treatments or Procedures." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 390.03. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

Medical Assistance Program – Services to be Provided, Idaho Code 56-255(5)(a)(iv) (2018). Idaho State Legislature, <u>https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-255</u>.

# 4.16. Refugee Screening

Tests performed as a result of examinations for refugee immigration are covered when medically necessary. The Department considers tests recommended by the <u>Centers for</u> <u>Disease Control and Prevention (CDC)</u> to be medically necessary. Tests meeting these criteria should be billed with diagnosis Z02.89 (Encounter for other administrative examinations) and modifier U7.

## 4.16.1. References: Refugee Screening

# (a) Federal Regulations

Refugee Medical Assistance – Medical Screening, 45 C.F.R. Sec. 400.107 (1989). Government Printing Office, <u>https://www.ecfr.gov/cgi-bin/text-</u> <u>idx?SID=0a34f4d3cf26941ec1bdafbbe551e398&mc=true&node=se45.2.400 1107&rgn=</u> <u>div8</u>.

# (b) Idaho Medicaid Publications

"Wellness Examinations for Refugee Screening." MedicAide Newsletter, July 2019, <u>https://www.idmedicaid.com/MedicAide%20Newsletters/July%202019%20MedicAide.pdf</u>.

# (c) Professional Organizations

Immigrant and Refugee Health. Centers for Disease Control and Prevention, Department of Health and Human Services. <u>https://www.cdc.gov/immigrant-refugee-health/index.html</u>.

# (d) State Regulations

Refugee Medical Assistance, IDAPA 16.03.06, "Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160306.pdf</u>.

# 4.17. Specimen Collection and Handling

Collection for specimens drawn by venipuncture or catheterization are payable only to the physician, non-physician practitioner or laboratory who draws the specimen. If done during an office visit on the same day the service is ordered, specimen collection may be reimbursed even if prior authorization of a test requiring one is not approved.

An office visit cannot be billed when a participant comes in for a blood draw by a lab technician and does not see the physician or non-physician practitioner. The lab technician's cost is included in the lab procedure payment.

Covered Specimen Collection and Handling Codes				
CPT®	Description			
36400	Venipuncture, younger than age 3 years, necessitating the skill of a physician or other qualified health care professional, not to be used for routine venipuncture; femoral or jugular vein			
36405	Venipuncture, younger than age 3 years, necessitating the skill of a physician or other qualified health care professional, not to be used for routine venipuncture; scalp vein			
36406	Venipuncture, younger than age 3 years, necessitating the skill of a physician or other qualified health care professional, not to be used for routine venipuncture; other vein			
36410	Venipuncture, age 3 years or older, necessitating the skill of a physician or other qualified health care professional (separate procedure), for diagnostic or therapeutic purposes (not to be used for routine venipuncture)			
36415	Collection of venous blood by venipuncture			
36416	Collection of capillary blood specimen (e.g., finger, heel, ear stick)			
36420	Venipuncture, cutdown; younger than age 1 year			
36425	Venipuncture, cutdown; age 1 or over			
36591	Collection of blood specimen from a completely implantable venous access device			
36592	Collection of blood specimen using established central or peripheral catheter, venous, not otherwise specified			
99001	Handling and/or conveyance of specimen for transfer from the patient in other than an office to a laboratory (distance may be indicated)			
P9612	Catheterization for collection of specimen, single patient, all places of service			

The Department does not recognize or reimburse for S9529 or G0471. These services are best represented by other codes. In the event that multiple venipuncture types occur on the same day by the same provider, reimbursement for CPT<sup>®</sup> 36416 is bundled into 36415, and CPT<sup>®</sup> 36591 is bundled into 36592.

Handling and conveyance of specimens for transfer to a laboratory from place of service 12 (Home), 25 (Birthing Center) or 32 (Nursing Facility) are covered by Medicaid when billed with CPT<sup>®</sup> 99001. All other handling and conveyance charges such as 99000 are bundled into reimbursement for the care and management of the participant.

# 4.17.1. References: Specimen Collection

# (a) State Regulations

"Specimen Collection Fee." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 655.02. Department of Administration, State of Idaho, https://adminrules.idaho.gov/rules/current/16/160309.pdf.

# **5. Quality Assurance**

Laboratories, as a condition of payment, must maintain a quality-control program, including proficiency testing consistent with federal requirements. Quality control must include a day-to-day analysis of reference materials to ensure reproducibility and accuracy of laboratory results, and includes an acceptable system to assure proper functioning of instruments, equipment, and reagents. Personnel carrying out testing must have the appropriate qualifications and supervision as established by the Secretary for Health and Human Services. Proficiency testing must include an evaluation of a laboratory's ability to perform laboratory procedures within acceptable limits of accuracy through analysis of unknown specimens distributed at periodic intervals. The laboratory must provide the results of proficiency testing to the Department or Telligen upon request.

### 5.1. References: Quality Assurance

## **5.1.1.Federal Regulations**

"Standards." P.L. 100-578, "*Clinical Laboratory Improvement Amendments of 1988*," Sec. 353(2)(D)(f). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/STATUTE-102/pdf/STATUTE-102-Pg2903.pdf</u>.

### 5.1.2. State Regulations

"Laboratory and Radiology Services: Quality Assurance." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 656. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"Proficiency Testing." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 650.03. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"Quality-Control." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 650.04. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

# **6. Prior Authorization**

See the <u>General Billing Instructions</u>, Idaho Medicaid Provider Handbook for more information on prior authorizations.

# 7. Documentation

The laboratory is required to obtain all medical necessity documentation prior to billing for services. All providers are required to generate records at the time the service is delivered and to maintain documentation to support reimbursement for services. Individual services may have additional documentation requirements. General documentation requirements are also required and found in the <u>General Information and Requirements for Providers</u>, Idaho Medicaid Provider Handbook, including standard retention requirements. If a clinical diagnostic test order does not require a signature, there must be signed medical documentation such as a progress note by the treating physician or non-physician practitioner.

In addition to standard documentation requirements and <u>quality assurance</u> requirements, laboratories must maintain documentation of:

- Physician or non-physician practitioner's order;
- Documentation supporting medical necessity;
- Identification number of the specimen;
- Means of identifying who the specimen belongs to;
- Name of the ordering physician or non-physician practitioner;
- Date specimen was collected;
- Date specimen was received;
- Test performed;
- Date test was performed;
- Results of test;
- Name and address of laboratory specimen was referred to, if applicable; and
- The referring laboratory that submitted the specimen, if applicable.

Documentation must be made available immediately upon request by Department personnel acting in their official capacity. Services delivered without adequate documentation are not eligible for reimbursement. Providers should only submit records for utilization management when requested by the Department. Documentation sent unsolicited, or not for a service requiring prior authorization, may not be reviewed by the Department. Unreviewed documentation does not constitute approval or authorization of a service.

### 7.1. **References: Documentation Requirements**

### 7.1.1.CMS Guidance

"Medical Documentation Signature Requirements." *Noridian Healthcare Solutions*, 27 July 2018, <u>https://med.noridianmedicare.com/web/jfb/cert-reviews/signature-requirements</u>.

### 7.1.2. State Regulations

"Review of Records." *IDAPA 16.03.09*, "*Medicaid Basic Plan Benefits*," Sec. 230.07. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

# 8. Reimbursement

Providers must be enrolled to receive reimbursement from Idaho Medicaid. Reimbursement can only be made to the provider of the service. Pass through billing is not permitted except as noted below:

- An independent laboratory can bill for the services of a reference laboratory;
- A hospital providing inpatient services can bill for the services of an external laboratory within their health system;
- A transplant facility can bill for histocompatibility testing for a transplant; and
- Healthcare professionals acting within their licensure and scope of practice to comply with IDAPA 16.02.12, "Newborn Screening."

The date of service on claims for laboratory services is the date the specimen is obtained except when a specimen is collected over multiple days, or the specimen is older than 30 days. Specimens collected over multiple days are billed with the date the collection ended. Tests performed on specimens in storage for over 30 days are billed with the date the test is performed.

Idaho Medicaid reimburses most laboratory services on a fee-for-service basis except when bundled into a prospective payment system for an encounter in an Indian Health Services (IHS) clinic, Federally Qualified Health Center (FQHC) or Rural Health Clinics (RHC), or diagnosis-related group (DRG) for institutional reimbursement. Usual and customary fees are paid up to the Medicaid maximum allowance listed in the current <u>Numerical Fee Schedule</u>. The Medicaid maximum allowance for clinical diagnostic laboratory tests cannot exceed the Medicare reimbursement rate. The Medicaid maximum allowance for other tests, and clinical diagnostic laboratory tests performed by a hospital laboratory for an inpatient participant, will be established by the Department. When available, services are reimbursed at 90% of the Medicare fee schedule. Rates are set when the code becomes covered by Idaho Medicaid, if available. Rate updates require legislative approval.

Procedure codes which appear on the Medicaid Numerical Fee Schedule with a reimbursement amount of \$0.00 must have the appropriate documentation for the code to be priced correctly. If the code is prior authorized by the Medical Care Unit, the documentation must be sent with the prior authorization request. If the code is not prior authorized or is prior authorized by Telligen, then the documentation must be attached to the claim. Services on claims or authorization requests without the required attachments will be denied. Documentation must be legible and not handwritten. Amounts invoiced directly to the Department must be at the provider's usual and customary rate, which is the amount the provider charges to Medicare beneficiaries and other patients liable for such charges, as supported by the provider's records. This amount must be adjusted to reflect the provider's billing policies so that the amount reflects what the provider actually receives through reasonable collection efforts. Laboratory tests will be priced by the Medical Care Unit based off the submitted documentation. Acceptable documentation for these services includes an invoice on letterhead with:

- The Department as the entity being invoiced;
- The Idaho Medicaid provider as the invoicing entity;
- A date of invoice (Dates after the date of service are acceptable);
- The date the specimen was obtained, or the test was ordered; and
- The service provided and corresponding procedure code.

Reimbursement for the professional component of a test for participants receiving hospice care is included in the payment to the hospice. The professional component is not separately

billable unless it is provided by a physician not employed by the hospice and is not related to the hospice diagnosis.

In-house laboratory services provided by Indian Health Services (IHS), Federally Qualified Health Clinic (FQHC), or Rural Health Clinics (RHC) are part of the encounter rate if the participant saw a qualifying provider type on the day the specimen was collected. If the participant did not see a qualifying provider on the day the specimen was collected, the test may be billed under fee-for-service. See the <u>IHS, FQHC and RHC Services</u>, Idaho Medicaid Provider Handbook for more information.

See the <u>General Billing Instructions</u>, Idaho Medicaid Provider Handbook regarding policy on billing, prior authorization, and requirements for billing all other third party resources before submitting claims to Medicaid.

See the <u>General Information and Requirements for Providers</u>, Idaho Medicaid Provider Handbook for information on when billing a participant is allowable including co-payment.

## 8.1. References: Reimbursement

## 8.1.1. Federal Regulations

Laboratory Date of Service for Clinical Laboratory and Pathology Specimens, 42 CFR 414.510 (2017). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/CFR-2018-title42-vol3/pdf/CFR-2018-title42-vol3-sec414-510.pdf</u>.

Prohibition Against Reassignment of Provider Claims, 42 CFR 447.10 (2014). Government Printing Office, <u>https://www.govinfo.gov/content/pkg/CFR-2018-title42-vol4/pdf/CFR-2018-title42-vol4-sec447-10.pdf</u>.

"State Plans for Medical Assistance." Social Security Act, Sec. 1902(a)(32) (1935). Social Security Administration, <u>https://www.ssa.gov/OP Home/ssact/title19/1902.htm</u>.

# 8.1.2. Idaho Medicaid Publications

"Documentation for Manually Priced Goods and Services." *MedicAide Newsletter, August 2019*,

https://www.idmedicaid.com/MedicAide%20Newsletters/August%202019%20MedicAide .pdf.

House Bill 260 Budget Reductions – Provider Payments, Information Release MA11-19 (05/26/2011). Division of Medicaid, Department of Health and Welfare, State of Idaho.

### 8.1.3. State Regulations

"Customary Charges." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 010.10. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"General Payment Procedures: Review of Records." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 230.07.a.iii. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"Hospice Employed Physician Direct Patient Service." IDAPA 16.03.10, "Medicaid Enhanced Plan Benefits," Sec. 458.01. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160310.pdf</u>.

"Laboratory and Radiology Services: Provider Reimbursement." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 655. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"Organ Transplants: Provider Reimbursement." IDAPA 16.03.10, "Medicaid Enhanced Plan Benefits," Sec. 096. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160310.pdf</u>.

"Outpatient Hospital." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 415.01.a. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"Newborn Screening", IDAPA 16.02.12. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160212.pdf</u>.

Provider Payment, Idaho Code 56-265 (2020). Idaho State Legislature, <a href="https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-265">https://legislature.idaho.gov/statutesrules/idstat/Title56/T56CH2/SECT56-265</a>.

"Provider Reimbursement." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 230.02. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

"Provider Services." IDAPA 16.03.09, "Medicaid Basic Plan Benefits," Sec. 230.01.b. Department of Administration, State of Idaho, <u>https://adminrules.idaho.gov/rules/current/16/160309.pdf</u>.

# 8.2. Laboratory Modifiers

### 8.2.1. Modifier 90

The Department recognizes modifier 90 as only for use by a reference laboratory's services for an independent laboratory. Physicians are not eligible to bill Modifier 90.

### (a) References: Modifier 90

#### (i) Idaho Medicaid Publications

"Medicaid Program Integrity Unit: Laboratory Tests Performed by Independent Laboratories." *MedicAide Newsletter,* January 2013, <u>https://www.idmedicaid.com/MedicAide%20Newsletters/January%202013%20MedicAid</u> <u>e.pdf</u>.

#### (ii) Professional Organizations

American Medical Association (2019). Appendix A – Modifiers. CPT<sup>®</sup> 2020: Professional Edition (pp. 811). Chicago, Ill.: American Medical Association.

### 8.2.2. Modifier 91

Modifier 91 is for use on clinical diagnostic laboratory tests when a test is necessary a second time for a participant on the same day. This modifier should not be used in conjunction with codes that represent a series of tests or that include all tests on a given day. Tests that are ran a second time to confirm the initial results are non-covered and should not be billed with this modifier. Tests ran again due to an error, issues with equipment or specimens are also non-covered and ineligible to be billed with this modifier.

# (a) References: Modifier 91

#### (i) Professional Organizations

American Medical Association (2019). Appendix A – Modifiers. CPT<sup>®</sup> 2020: Professional Edition (pp. 811). Chicago, Ill.: American Medical Association.

### (ii) Modifier QW

Modifier QW is required to identify a Clinical Laboratory Improvement Amendments (CLIA) waived test unless the service is excluded from CLIA edits.

### 8.2.3. Professional and Technical Components

Some laboratory codes are global procedures that include both a professional and technical component. These codes can only be billed without a 26 or TC modifier when all parts of the service are completed by the same provider. Providers only completing the professional portion of the code must append modifier 26 to the claim line. While providers only completing the technical portion of the code must append the TC modifier to the claim line.

If a pathologist has their own office and equipment, they may bill and be paid for the complete test including those that cannot be broken out into the professional and technical components.

# Appendix A. Laboratory, Provider Handbook Modifications

The table below contains modifications to this handbook for three years preceding the most recent publication.

Laboratory, Provider Handbook Modifications				
Version	Section/	Modification Description	Date	SME
	Column			
11.0	All	Published version	05/13/2025	TQD
10.4	8. Reimbursement	Added exception for billing within the same healthcare system. Added information about reimbursement for encounters and rate setting.	05/09/2025	W Deseron G Bosnjak
10.3	4.2. Abortions	New section.	05/09/2025	W Deseron G Bosnjak
10.2	1.4. Medicaid	Removed section.	05/09/2025	W Deseron G Bosnjak
10.1	Laboratory Services	Added provision on scope.	05/09/2025	W Deseron G Bosnjak
10.0	All	Published version	07/01/2024	TQD
9.4	7. Documentation Requirements	Updated to standard language.	06/27/2024	W Deseron M Hanifen
9.3	4.3. Controlled Substance and Drug Testing	Changed Optum to Magellan.	06/27/2024	W Deseron M Hanifen
9.2	1.3. Magellan Healthcare, Inc.	New section.	06/27/2024	W Deseron M Hanifen
9.1	Laboratory Services	Requesting older citations.	06/27/2024	W Deseron M Hanifen
9.0	All	Published version	03/05/2024	TQD
8.11	8. Reimbursement	Non-substantive language changes.	03/01/2024	W Deseron G Bosnjak
8.10	6. Prior Authorizations	Deleted text and subsections. Point to General Billing Instructions.	03/01/2024	W Deseron G Bosnjak
8.9	4.10. Newborn Screening	Non-substantive changes.	03/01/2024	W Deseron G Bosnjak
8.8	4.7.2. Genetic Counseling	Clarify billing for counseling.	03/01/2024	W Deseron G Bosnjak
8.7	4.4.4. Coverage of Serologic Testing for SARS-CoV-2	Clarify form requirement.	03/01/2024	W Deseron G Bosnjak
8.6	4.4.3. Rapid Antigen Testing for SARS-CoV-2	Clarified use of provider portal.	03/01/2024	W Deseron G Bosnjak
8.5	4.4.2. Molecular Testing for SARS- CoV-2	Clarified use of provider portal.	03/01/2024	W Deseron G Bosnjak
8.4	4. Covered Services and Limitations	Non-substantive language changes.	03/01/2024	W Deseron G Bosnjak
8.3	3. Eligible Participants	Updated DXC to Gainwell.	03/01/2024	W Deseron G Bosnjak

Laboratory, Provider Handbook Modifications				
Version	Section/	Modification Description	Date	SME
	Column			
8.2	1.3. Medicaid	Added language around trading partner account.	03/01/2024	W Deseron G Bosnjak
8.1	Laboratory Services	Added disclaimer regarding regulations and handbook.	03/01/2024	W Deseron G Bosnjak
8.0	All	Published version	08/16/2023	TQD
7.12	6. Prior Authorizations	Update process.	08/02/2023	E Garibovic W Deseron
7.11	6.3. Telligen, Inc.	Update process.	08/02/2023	E Garibovic W Deseron
7.10	4.7.9.(a) References: Molecular Pathology for Infants	New section.	08/02/2023	E Garibovic W Deseron
7.9	4.7.9. Molecular Pathology for Infants	New section.	08/02/2023	E Garibovic W Deseron
7.8	4.7.2. Genetic Counseling	Made allowance for NP and pharmacist to provide counseling.	08/02/2023	E Garibovic W Deseron
7.7	4.7. Genetic Testing	Removed prohibition on pharmacist ordering.	08/02/2023	E Garibovic W Deseron
7.6	4.4.4. References: COVID-19 Testing	Deleted section. References sourced to appropriate sections.	08/02/2023	E Garibovic W Deseron
7.5	4.4.4.(a) References: Coverage of Serologic Testing for SARS-CoV-2	New section.	08/02/2023	E Garibovic W Deseron
7.4	4.4.3.(a) References: Rapid Antigen Testing for SARS-CoV-2	New section.	08/02/2023	E Garibovic W Deseron
7.3	4.4.2. (a) References: Molecular Testing for SARS-CoV-2	New section.	08/02/2023	E Garibovic W Deseron
7.2	4.4.1. References: COVID-19 Testing	New section.	08/02/2023	E Garibovic W Deseron
7.1	1.4. Telligen, Inc.	Update pa requirements and remove fax number.	08/02/2023	E Garibovic W Deseron
7.0	All	Published version	06/02/2023	TQD
6.6	4.4.4. References: COVID-19 Testing	New section.	05/26/2023	W Deseron K Duke
6.5	4.4.3. Coverage of Serologic Testing for SARS-CoV-2	New section. Incorporate newsletter article.	05/26/2023	W Deseron K Duke
6.4	4.4.2. Rapid Antigen Testing for SARS-CoV-2	New section. Incorporate newsletter article.	05/26/2023	W Deseron K Duke

Laboratory, Provider Handbook Modifications					
Version	Section/	Modification Description	Date	SME	
	Column				
6.3	4.4.1. Molecular Testing for SARS- CoV-2	New section. Incorporate newsletter article.	05/26/2023	W Deseron K Duke	
6.2	4.4. COVID-19 Testing	New section. Incorporate newsletter article.	05/26/2023	W Deseron K Duke	
6.1	3.2. Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Services	Clarification that periodicity schedule testing does not require PA.	05/26/2023	W Deseron K Duke	
6.0	All	Published version	11/18/2022	TQD	
5.1	1.2 Provider Relations Consultants	Updated contact phone numbers for PRCs	11/18/2022	R Lynch M Payne J Kennedy-King	