HAP CareSource™

REIMBURSEMENT POLICY STATEMENT
Michigan Marketplace

Policy Name & Number	Date Effective
CLIA-Waived Testing in Office Setting-MI MP-PY-1546	01/01/2025
Policy Type	
REIMBURSEMENT	

Reimbursement Policies prepared by CareSource and its affiliates are intended to provide a general reference regarding billing, coding and documentation guidelines. Coding methodology, regulatory requirements, industry-standard claims editing logic, benefits design and other factors are considered in developing Reimbursement Policies.

In addition to this Policy, Reimbursement of services is subject to member benefits and eligibility on the date of service, medical necessity, adherence to plan policies and procedures, claims editing logic, provider contractual agreement, and applicable referral, authorization, notification and utilization management guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any federal or state coverage mandate, Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

This Policy does not ensure an authorization or Reimbursement of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced herein. If there is a conflict between this Policy and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.
CareSource and its affiliates may use reasonable discretion in interpreting and applying this Policy to services provided in a particular case and may modify this Policy at any time.

According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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A. Subject
CLIA-Waived Testing in Office Setting

B. Background
During the course of an office visit with a physician or other qualified healthcare provider, the provider may determine that diagnostic laboratory testing is necessary to establish a diagnosis and/or determine treatment options to manage the member's current health issues. While most laboratory tests are best performed by an independent laboratory, in some instances, results from these laboratory tests are needed immediately to manage urgent medical conditions or medical emergencies and may be performed appropriately in the physician's office. Due to the complexity of laboratory tests and regulations around facilities that perform these tests, only laboratory procedures on the STAT lab list may be performed in the office, while all other tests should be referred to an independent, contracted lab provider.

C. Definitions
- **Clinical Laboratory Improvement Amendments (CLIA)** – The Centers for Medicare & Medicaid Services (CMS) regulates programs that test human specimens to ensure accurate, reliable, and timely patient test results, regardless of where a test is performed and including physician offices.
- **Independent Laboratory** – A laboratory certified to perform diagnostic and/or clinical tests independent of an institution or a provider's office.
- **Laboratory** – A facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.
- **Laboratory Procedures** – Defined in the Current Procedural Terminology (CPT) in the ranges 80300 through 89398 and panels 80047 through 80076.

D. Policy
I. CareSource will reimburse for laboratory procedures performed in the physician's office when **ALL** the following apply:
   A. The test results are needed immediately in order to manage urgent or emergent medical situations.
   B. The CPT code for the test is on the short turnaround time (STAT) code list. If a test has been developed and approved by the FDA as a CLIA-waived test since publication of this policy, the FDA list of CLIA-waived tests will rule.
   C. The physician billing for laboratory testing is in compliance with the final rules of CLIA 1988, which includes, at a minimum, a certificate of waiver for tests as

defined by the Centers for Medicare and Medicaid Services (CMS). For tests performed of moderate or higher complexity, the physician must meet the CLIA requirements for certification.

D. The place of service (POS) 11 is used.
E. Modifier QW is used to indicate the test is CLIA-waived.

II. All other laboratory procedures may not be performed in the office and should be referred to an independent, contracted laboratory provider. Claims submitted for all other laboratory procedures performed in office will be denied.

E. Conditions of Coverage

It is the responsibility of the submitting provider to submit the most accurate and appropriate CPT/HCPCS code(s) for the product or service that is being provided. The inclusion of a code in this policy does not imply any right to reimbursement or guarantee claims payment. Please refer to the individual fee schedule for appropriate codes.

Place of Service (POS) Code	Description
11 - Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis

CPT Modifier	Description
QW	CLIA waived test

STAT Code List

CPT / HCPCS	Description
0202U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected
0223U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected
0224U	Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), includes titer(s), when performed
0225U	Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
0226U	Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), ELISA, plasma, serum
80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; capable of being read by direct optical observation only (eg, utilizing immunoassay [eg, dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service
80306	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; read by instrument assisted direct optical observation (eg, utilizing immunoassay [eg, dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service
80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; by instrument chemistry analyzers (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS,

	RIA]), chromatography (eg, GC, HPLC), and mass spectrometry either with or without chromatography, (eg, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service
80324	Amphetamines; 1 or 2
80325	Amphetamines; 3 or 4
80326	Amphetamines; 5 or more
80327	Anabolic steroids; 1 or 2
80328	Anabolic steroids; 3 or more
80329	Analgesics, non-opioid; 1 or 2
80330	Analgesics, non-opioid; 3-5
80331	Analgesics, non-opioid; 6 or more
80332	Antidepressants, serotonergic class; 1 or 2
80333	Antidepressants, serotonergic class; 3-5
80334	Antidepressants, serotonergic class; 6 or more
80335	Antidepressants, tricyclic and other cyclicals; 1 or 2
80336	Antidepressants, tricyclic and other cyclicals; 3-5
80337	Antidepressants, tricyclic and other cyclicals; 6 or more
80338	Antidepressants, not otherwise specified
80339	Antiepileptics, not otherwise specified; 1-3
80340	Antiepileptics, not otherwise specified; 4-6
80341	Antiepileptics, not otherwise specified; 7 or more
80342	Antipsychotics, not otherwise specified; 1-3
80343	Antipsychotics, not otherwise specified; 4-6
80344	Antipsychotics, not otherwise specified; 7 or more
80345	Barbiturates
80346	Benzodiazepines; 1-12
80347	Benzodiazepines; 13 or more
80348	Buprenorphine
80349	Cannabinoids, natural
80350	Cannabinoids, synthetic; 1-3
80351	Cannabinoids, synthetic; 4-6
80352	Cannabinoids, synthetic; 7 or more
80353	Cocaine
80354	Fentanyl
80355	Gabapentin, non-blood
80356	Heroin metabolite
80357	Ketamine and norketamine
80358	Methadone
80359	Methylenedioxyamphetamines (MDA, MDEA, MDMA)
80360	Methylphenidate
80361	Opiates, 1 or more
80362	Opioids and opiate analogs; 1 or 2
80363	Opioids and opiate analogs; 3 or 4
80364	Opioids and opiate analogs; 5 or more
80365	Oxycodone
80366	Pregabalin
80367	Propoxyphene

The REIMBURSEMENT Policy Statement detailed above has received due consideration as defined in the REIMBURSEMENT Policy Statement Policy and is approved.

80368	Sedative hypnotics (non-benzodiazepines)
80369	Skeletal muscle relaxants; 1 or 2
80370	Skeletal muscle relaxants; 3 or more
80371	Stimulants, synthetic
80372	Tapentadol
80373	Tramadol
80374	Stereoisomer (enantiomer) analysis, single drug class
80375	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 1-3
80376	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 4-6
80377	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 7 or more
83992	Phencyclidine (PCP)
81000	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, with microscopy
81001	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, with microscopy
81002	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, without microscopy
81003	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, without microscopy
81005	Urinalysis; qualitative or semiquantitative, except immunoassays
81015	Urinalysis; microscopic only
81025	Urine pregnancy test, by visual color comparison methods
82043	Albumin; urine (eg, microalbumin), quantitative
82044	Albumin; urine (eg, microalbumin), semiquantitative (eg, reagent strip assay)
82247	Bilirubin; total
82270	Blood, occult, by peroxidase activity (eg, guaiac), qualitative; feces, consecutive collected specimens with single determination, for colorectal neoplasm screening (ie, patient was provided 3 cards or single triple card for consecutive collection)
82271	Blood, occult, by peroxidase activity (eg, guaiac), qualitative; other sources
82272	Blood, occult, by peroxidase activity (eg, guaiac), qualitative, feces, 1-3 simultaneous determinations, performed for other than colorectal neoplasm screening
82465	Cholesterol, serum or whole blood, total
82565	Creatinine; blood
82731	Fetal fibronectin, cervicovaginal secretions, semi-quantitative
82947	Glucose; quantitative, blood (except reagent strip)
82948	Glucose; blood, reagent strip
82950	Glucose; post glucose dose (includes glucose)
82951	Glucose; tolerance test (GTT), 3 specimens (includes glucose)
82952	Glucose; tolerance test, each additional beyond 3 specimens (List separately in addition to code for primary procedure)
82962	Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use
83036	Hemoglobin; glycosylated (A1C)
83037	Hemoglobin; glycosylated (A1C) by device cleared by FDA for home use
83655	Lead
83861	Microfluidic analysis utilizing an integrated collection and analysis device, tear osmolarity
83986	pH; body fluid, not otherwise specified

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84132	Potassium; serum, plasma or whole blood
84703	Gonadotropin, chorionic (hCG); qualitative
85013	Blood count; spun microhematocrit
85014	Blood count; hematocrit (Hct)
85018	Blood count; hemoglobin (Hgb)
85025	Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count) and automated differential WBC count
85027	Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count)
85049	Blood count; platelet, automated
85610	Prothrombin time;
85651	Sedimentation rate, erythrocyte; non-automated
86308	Heterophile antibodies; screening
86318	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single-step method (eg, reagent strip);
86328	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])
86408	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]); screen
86409	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]); titer
86580	Skin test; tuberculosis, intradermal
86756	Antibody; respiratory syncytial virus
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])
87070	Culture, bacterial; any other source except urine, blood or stool, aerobic, with isolation and presumptive identification of isolates
87172	Pinworm exam (eg, cellophane tape prep)
87205	Smear, primary source with interpretation; Gram or Giemsa stain for bacteria, fungi, or cell types
87210	Smear, primary source with interpretation; wet mount for infectious agents (eg, saline, India ink, KOH preps)
87220	Tissue examination by KOH slide of samples from skin, hair, or nails for fungi or ectoparasite ova or mites (eg, scabies)
87270	Infectious agent antigen detection by immunofluorescent technique; Chlamydia trachomatis
87301	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; adenovirus enteric types 40/41
87400	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; Influenza, A or B, each
87426	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19])
87428	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19]) and influenza virus types A and B
87430	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; Streptococcus, group A
87490	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, direct probe technique

The REIMBURSEMENT Policy Statement detailed above has received due consideration as defined in the REIMBURSEMENT Policy Statement Policy and is approved.

87491	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, amplified probe technique
87492	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, quantification
87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), amplified probe technique
87800	Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; direct probe(s) technique
87802	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Streptococcus, group B
87803	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Clostridium difficile toxin A
87804	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Influenza
87806	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies
87807	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; respiratory syncytial virus
87808	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Trichomonas vaginalis
87811	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])
87880	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Streptococcus, group A
87905	Infectious agent enzymatic activity other than virus (eg, sialidase activity in vaginal fluid)
C9803	Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), any specimen source
G0480	Drug test(s), definitive, utilizing (1) 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 (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (eg, to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (eg, to control for instrument variations and mass spectral drift); 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 (1) 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 (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (eg, to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (eg, to control for instrument variations and mass spectral drift); 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 (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, 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 specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes
G2023	Specimen collection for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source
G2024	Specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source

The REIMBURSEMENT Policy Statement detailed above has received due consideration as defined in the REIMBURSEMENT Policy Statement Policy and is approved.

Q0111	Wet mounts, including preparations of vaginal, cervical or skin specimens
Q0112	All potassium hydroxide (KOH) preparations
U0001	CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel
U0002	2019-nCoV coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC
U0003	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R
U0004	2019-nCoV coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R

F. Related Policies/Rules

NA

G. Review/Revision History

	DATE	ACTION
Date Issued	09/25/2024	New policy, approved at Committee.
Date Revised		
Date Effective	01/01/2025	
Date Archived		

H. References

1. CLIA-Clinical Laboratory Improvement Amendments – Currently Waived Analytes. U.S. Food and Drug Administration. Updated August 12, 2024. Accessed August 14, 2024. www.accessdata.fda.gov
2. CPT Code Detail. Optum Encoder Pro; 2023. Accessed September 6, 2023. www.encoderprofp.com
3. Diagnostic X-Ray Tests, Diagnostic Laboratory Tests, and Other Diagnostic Tests: Conditions, 42 U.S.C. § 410.32 (2023).
4. HCPCS Code Detail. Optum Encoder Pro; 2023. Accessed September 6, 2023. www.encoderprofp.com
5. Laboratory Requirements, 42 U.S.C. §§ 493 (2023).
6. Laboratory Services, 42 U.S.C. § 441.17 (2023).
7. Other Laboratory and X-Ray Services, 42 U.S.C § 440.30 (2023).
8. *Place of Service Code Set.* Centers for Medicare and Medicaid Services; 2024. Accessed September 6, 2024. www.cms.gov