Clinical Practice Guideline: **In-Office Clinical Laboratory Services**

Date of Implementation: **April 19, 2012**

Product: **Specialty**

GUIDELINES

American Specialty Health – Specialty (ASH) considers clinical laboratory services performed by a qualified healthcare professional as medically necessary when meeting all of the following criteria:

- The history and physical exam findings substantiate the working diagnosis and the need for further evaluation through laboratory testing;
- The clinical laboratory procedure is known to be reliable and reproducible; and
- The procedure is CLIA (Clinical Laboratory Improvement Amendments) waived.

DESCRIPTION/BACKGROUND

A variety of clinical laboratory services are performed by practitioners in the office. Dipstick urinalysis, for example, utilizes a dipstick or tablet reagent to test for a variety of constituents including ketones and leukocytes. This procedure may be done manually or via automation and microscopic review may (CPT® codes 81000 and 81001) or may not (CPT® code 81002) be included.

Venipuncture and finger sticks are other examples of clinical laboratory services, which provide blood samples for analyses such as prothrombin time, glucose, or lipid levels.

All laboratory services should be supported by the appropriate ICD codes at the primary and secondary level. The diagnosis must be documented for the procedure to be considered for reimbursement. In addition, the procedure must be reasonable and necessary for that diagnosis. Documentation within the medical record must support the necessity for the test(s) performed for each date of service.

Handling or conveying laboratory specimens is an adjunct to basic services provided. Handling and/or conveyance of a specimen for transfer may be from the physician's office to a laboratory (CPT® code 99000). Alternatively, the specimen may be processed for transfer from the patient in a location other than the physician's office to a laboratory (CPT® code 99001).

ASH expects all practitioners that perform laboratory services to follow Clinical Laboratory Improvement Amendments (CLIA) requirements.

The following table lists CPT® codes that may be medically necessary upon meeting the criteria listed above.

CPT® Codes and Descriptions

CPT® Code	CPT® Code Description
36415	Collection of venous blood by venipuncture
36416	Collection of capillary blood specimen (e.g., finger, heel, ear stick)
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
81020	Urinalysis, 2 or 3 glass test
81025	Urine pregnancy test, by visual color comparison methods
82465	Cholesterol, serum or whole blood, total
82947	Glucose; quantitative, blood (except reagent strip)
82962	Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use
84550	Uric acid; blood
85013	Blood count; spun microhematocrit
85014	Blood count; hematocrit (Hct)
85018	Blood count; hemoglobin (Hgb)
85060	Blood smear, peripheral, interpretation by physician with written report
85610	Prothrombin time

CPT® Code	CPT® Code Description
87426	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV, SARS-CoV-2 [COVID-19])
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
99000	Handling and/or conveyance of specimen for transfer from the office to a laboratory
99001	Handling and/or conveyance of specimen for transfer from the patient in other than an office to a laboratory (distance may be indicated)

DOCUMENTATION REQUIREMENTS TO SUBSTANTIATE MEDICAL NECESSITY

'Medically necessary' or 'medical necessity' shall mean health care services that a Healthcare Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of evaluating, diagnosing, or treating an illness, injury, disease or its symptoms, and that are (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and considered effective for the patient's illness, injury, or disease; and (c) not primarily for the convenience of the patient or healthcare provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury, or disease.

The patient's medical records should document the practitioner's clinical rationale for performing/ordering the specific laboratory procedures, as well as their impact on the treatment plan for the patient. In addition, copies of all laboratory reports must be included in the patient's medical records.

PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education training, and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine if they have the knowledge and skills necessary to perform such services and whether the services are within their scope of practice.

It is best practice for the practitioner to appropriately render services to a patient only if they are trained to competency, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and training, it would be best practice to refer the patient to the more expert practitioner.

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

Depending on the practitioner's scope of practice, training, and experience, a patient's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is essential for the practitioner to refer the patient for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* clinical practice guideline for information.

References

American Medical Association. (current year). *Current Procedural Terminology (CPT) Current year* (rev. ed.). Chicago: AMA

Centers for Disease Control and Prevention (CDC). (2024) About CLIA. Retrieved July 18, 2024 from https://www.cdc.gov/clia/

Joint Commission International. (2020). Joint Commission International Accreditation Standards for Hospitals (7th ed.): Joint Commission Resources