Ohio Administrative Code

Rule 5160-11-11 Laboratory services.

Effective: January 1, 2021

(A) Definitions and explanations that apply to this chapter of the Administrative Code.

(1) "Clinical consultation" is the formal evaluation by a physician or other qualified healthcare professional, performed on the written order of a treating practitioner, of test results that appear to be abnormal. Payment for the clinical consultation is based on the physician fee schedule relative value file published by the centers for medicare and medicaid services (CMS). (The procedure code used for clinical consultation is different and separate from the procedure code for the test whose results are being evaluated.)

(2) "Clinical pathology interpretation" is the interpretation, performed on the written order of a treating practitioner by another practitioner, of the results of any of a certain group of clinical diagnostic procedures that are distinguished by three shared traits:

(a) Separate payment may be made for interpretation;

(b) Payment for the clinical diagnostic procedures themselves is based on the clinical laboratory fee schedule published by CMS; and

(c) Payment for the clinical pathology interpretation is based on the physician fee schedule relative value file published by CMS. (The procedure code for the clinical pathology interpretation consists of a professional component modifier appended to the relevant clinical diagnostic procedure code.)

(3) "Eligible provider" has the same meaning as in rule 5160-1-17 of the Administrative Code.

(4) "Global procedure" or "total procedure" is a procedure, in its entirety, that comprises both a technical component (the part of a laboratory procedure that relies on the technical skill of a trained individual to secure a specimen and prepare it for analysis) and a professional component (the part of a laboratory procedure that relies on the professional skill or training of a physician or other qualified

healthcare professional to analyze the results produced by the technical component and to provide a written report of findings).

(5) "Independent" means separate from an attending or consulting practitioner's office or group practice, an ambulatory surgery center, a hospital, or a nursing facility. A laboratory facility under the ownership and direction of an individual practitioner or group practice is considered to be independent if it is represented to other practitioners that both the owners and directors and the facility itself are available for the performance of procedures.

(6) "Routine procedure" is a procedure for which no separate payment is made for either of two reasons:

(a) It is very common and is performed only in connection with another procedure (e.g., the collection of a clean-catch urine sample or a throat swab); or

(b) It is included in a treatment protocol for which a composite payment amount has been established (e.g., a specific laboratory test performed for an individual receiving dialysis, the reading by automated glucose monitor of blood samples taken from nursing facility residents who have diabetes).

(7) For purposes of medicaid, most covered laboratory procedures fall into two main categories.

(a) For the performance of clinical diagnostic procedures, no highly specialized skill is needed (such as the knowledge and training of a physician or other qualified healthcare professional).

(i) Clinical diagnostic procedures have no separate professional and technical components.

(ii) Performance of these procedures is generally predicated on certification of the laboratory provider under the "Clinical Laboratory Improvement Amendments of 1988" (CLIA, Pub. L. No. 100-578, 42 U.S.C. 263a as in effect on January 1, 2021).

(iii) Payment for these procedures is based on the clinical laboratory fee schedule published by CMS.

(b) The performance of professional procedures relies on the skill and training of a physician or other qualified healthcare professional, usually a pathologist or a hematologist.

(i) Pathology procedures have both a professional component and a technical component. In most instances, these components are distinguished on claims by the inclusion of a modifier along with the procedure code. (The professional and technical components of a few procedures may be represented by separate procedure codes.) The professional component of a pathology procedure represents the professional services a practitioner renders in the performance of the procedure. It does not represent the simple reading of test results, which is included in the associated originating service (e.g., office visit or surgery).

(ii) Some procedures are exclusively professional in nature and have no technical component.

(iii) Only an eligible practitioner or an independent laboratory submitting claims on behalf of its eligible practitioners may receive payment for a professional procedure (or a professional component of a procedure).

(iv) Payment for pathology procedures and for other professional procedures or components of procedures is based on the physician fee schedule relative value file published by CMS. (There are a very few exclusively technical procedures for which payment is also based on the physician fee schedule relative value file.)

(B) Providers.

(1) Providers. An entity may enroll in medicaid as a laboratory provider only if the following conditions are satisfied:

(a) The entity holds appropriate certification under CLIA; and

(b) The laboratory procedures it performs are within its usual scope.

(2) A facility that only collects or prepares specimens or that functions only as a mailing service and does not perform testing is not considered to be a laboratory.

(C) Coverage.

(1) Payment is made in accordance with Chapter 5160-2 of the Administrative Code for the following services, which in a hospital setting are treated not as laboratory services but rather as hospital services:

(a) A clinical diagnostic procedure performed for a hospital inpatient; and

(b) The technical component of a pathology procedure performed for a hospital inpatient.

(2) Payment can be made only for a laboratory service or procedure that, in accordance with Chapter 5160-1 of the Administrative Code, is medically necessary or is medically indicated when performed in conjunction with a covered preventive health service.

(3) A laboratory provider obtains and maintains appropriate documentation.

(a) A laboratory service may be rendered on the verbal order of a physician or other qualified healthcare professional. Unless an exception is stated in this rule, the laboratory provider may submit a claim only after it has obtained a written order. A written order may consist of an entry in a person's medical records (e.g., in an individual practitioner's office, a group practice, or a hospital). A written order includes the following information:

(i) The name of the medicaid-eligible individual;

(ii) Contact information for the practitioner ordering the service;

(iii) Specification of the service (e.g., procedure code, description, number of units);

(iv) At least one appropriate diagnosis code;

(v) The date of the order;

(vi) The names of the relevant persons or entities involved in providing the service (e.g., referring laboratory, reference laboratory, interpreting practitioner, radiographer); and

(vii) Any additional information necessary to ensure accurate and timely testing or reporting (e.g., for a Pap test, the beginning date of the individual's last menstrual period, the individual's age or date of birth, an indication of previous abnormal results and subsequent actions).

(b) A written order may be given in any industry-recognized format, such as handwriting, typed text, or electronic transmission.

(c) No separate written order is needed for a medically necessary follow-up procedure (e.g., a quantitative test performed in response to a positive qualitative test result) so long as the procedure is performed in accordance with appropriate standard practices and is included in the laboratory provider's written protocols. A written order is needed for any additional procedure that is based solely on a laboratory provider's internal protocols.

(d) A laboratory provider is to keep the following records for the period of time specified in rule 5160-1-17.2 of the Administrative Code:

(i) A copy of each written order for a procedure or service (clinical diagnostic procedure, pathology procedure, consultation, or interpretation);

(ii) A copy of any clinical diagnostic procedure result for which consultation or interpretation was ordered; and

(iii) A copy of any written narrative report prepared by the consulting or interpreting practitioner.

(4) Payment may be made to a physician or other qualified healthcare professional (such as a pathologist or a hematologist) for the following professional laboratory services:

(a) The professional component of a pathology procedure;

(b) A global pathology procedure that was performed in the practitioner's own full-service, in-office

laboratory (certified for the performance of the technical component) on a specimen obtained from an individual who was not a hospital patient;

(c) A clinical pathology consultative service; or

(d) The professional administration of a testing device, isotope, or other material.

(5) Specific coverage provisions apply to certain groups of services and procedures.

(a) Referred procedures.

(i) In general, payment for a clinical diagnostic procedure may be made only to the laboratory provider that actually performs the procedure. Payment may be made to a referring provider for a clinical diagnostic procedure performed by a reference laboratory only if all of the following conditions are satisfied:

(a) The reference laboratory has the appropriate CLIA certification to perform the procedure;

(b) One of the following two sets of criteria is met:

(i) Either the referring provider is a FQHC or RHC or the reference laboratory is a hospital, and the referring provider and the reference laboratory are related in one of three ways:

(A) The referring provider is wholly owned by the reference laboratory;

(B) The reference laboratory is wholly owned by the referring provider; or

(C) Both of them are wholly owned by a third entity.

(ii) The referring laboratory is a hospital that performs clinical diagnostic procedures, the procedure is performed for a hospital outpatient or hospital emergency department patient, and the referring laboratory provider and the reference laboratory provider have a written agreement that specifies which provider is exclusively permitted to submit claims to the department for clinical diagnostic

procedures.

(c) At the request of the department, the referring provider discloses to the department in writing the following information and any changes made to it:

(i) The name, address, and CLIA number of the reference laboratory;

(ii) A delineation of the relationship between the referring provider and the reference laboratory; and

(iii) A list of all the clinical diagnostic procedures it routinely refers to the reference laboratory.

(ii) In the event that the department issues payment to both a referring provider and a reference laboratory for the same clinical diagnostic procedure, the expenditure subject to recovery is assumed to be the payment issued to the reference laboratory.

(b) Procedures bundled into a panel.

(i) Altered descriptions of a particular panel are not to be used in place of the official description established by a national authority such as the American medical association or the centers for medicare and medicaid services.

(ii) When a provider performs all of the constituent procedures of a covered panel (and all of the constituent procedures are medically necessary or medically indicated), the entire panel is reported on a claim rather than the separate constituent procedures.

(iii) When a provider performs some but not all of the constituent procedures of a panel, the separate constituent procedures are reported on a claim.

(iv) When a provider performs more procedures than are included in a panel, both the panel and the additional procedures are reported on a claim.

(c) Specimen collection.

(i) Specimen collection performed in a nursing facility, skilled nursing facility, or intermediate care facility for individuals with intellectual disabilities is not a laboratory service.

(ii) Payment as laboratory services may be made only for the following specimen collection procedures:

(a) Collection of a blood specimen by venipuncture;

(b) Collection of a blood specimen by capillary puncture that has the same diagnostic value as a specimen collected by venipuncture;

(c) Collection of a blood specimen from a completely implantable venous access device; and

(d) Collection of a blood specimen from an established central or peripheral venous catheter.

(iii) The collection of multiple specimens is considered to be a single procedure in either of the following circumstances:

(a) The specimens are collected in a single encounter from a single body site; or

(b) The specimens are needed for a single test (e.g., a glucose tolerance test).

(iv) Only the eligible provider that performs a specimen collection may receive payment for it.

(v) Payment for specimen collection includes costs for handling and shipping.

(vi) Payment for specimen collection is independent of payment for the laboratory procedure performed on the specimen.

(vii) No payment is made for the following specimen collection services:

(a) Collection of a blood specimen by capillary puncture when the collection is part of a test procedure (e.g., bleeding time);

(b) Collection of a specimen for a Papanicolaou test (Pap test, Pap smear) or of a tissue specimen for which there is no discrete procedure code; and

(c) Travel associated with the collection of specimens.

(d) Evocation/suppression testing.

(i) Only the laboratory provider performing the technical evocation/suppression test (the actual measurement of the chemical constituents) may receive payment for it.

(ii) Separate payment may be made to a physician or other qualified healthcare professional for identifiable evaluation and management services rendered on the same date of service as an evocation/suppression test. Such services include supervision and monitoring of the individual during testing, intermittent or continual attendance during the administration of the evocation/suppression agent, and interpretation of the test results in relation to the individual's condition.

(iii) Separate payment may be made in accordance with Chapter 5160-4 of the Administrative Code for an evocation/suppression testing agent administered to an individual who is not a hospital patient. Such payment includes costs for the agent itself and for administration of the agent, which may be intradermal, subcutaneous, intramuscular, intraarterial, or intravenous (injection by syringe, intravenous push injection, or intravenous infusion of short duration).

(iv) Separate payment may be made to a physician or other qualified healthcare professional for prolonged infusion services rendered for an individual who is not a hospital patient. Such payment includes costs for additional supplies used in the prolonged administration of the evocation/suppression testing agent.

(e) Neonatal diagnostic screening. Payment for neonatal diagnostic screening may be made to a physician laboratory provider, a professional medical group laboratory provider, a hospital laboratory provider, or a clinic laboratory provider if both of the following conditions are satisfied:

(i) The procedure was performed with a prefabricated laboratory kit purchased from the Ohio department of health (ODH) laboratory and used for screening a newborn infant for genetic, endocrine, or metabolic disorders listed in Chapter 3701-55 of the Administrative Code; and

(ii) The kit was used for an initial screening, a repeat screening, or a follow-up screening in accordance with Chapter 3701-55 of the Administrative Code.

(f) Urine drug screening.

(i) The performance of drug screening by urinalysis is subject to the following frequency limits, which may be exceeded with prior authorization:

(a) For presumptive screens, thirty dates of service per benefit year; and

(b) For definitive tests, twelve dates of service per benefit year.

(ii) Prior authorization is needed for a definitive drug test involving twenty-two or more drug classes on a single date of service.

(6) Non-covered laboratory services.

(a) No payment is made for the following services:

(i) Laboratory services exceeding the provisions set forth in this chapter for which no prior authorization has been given;

(ii) Routine laboratory or screening procedures;

(iii) Laboratory services for which a laboratory provider is not appropriately certified under CLIA;

(iv) Laboratory services rendered in conjunction with those non-covered services that are delineated in rule 5160-1-61 of the Administrative Code; and

(v) Laboratory services rendered for forensic investigation, autopsy, or paternity testing.

(b) Although certain provisions in Chapter 5160-1 of the Administrative Code allow an eligible provider to seek payment directly from a medicaid-eligible individual for services that are not covered by the medicaid program, no laboratory provider may seek payment for any laboratory service for which it lacks the necessary CLIA certification.

(D) Claim payment.

(1) When submitting a claim to the department, a laboratory provider is to use the code that describes the procedure in the most detail.

(a) Analytic procedures can be listed by analyte (the substance or material being measured), by method, by both analyte and method, or by specimen type (e.g., urine, blood). Many laboratory procedures, especially drug tests, have synonyms. Care therefore needs to be taken in the selection of the most appropriate procedure code.

(b) A "not otherwise specified," "miscellaneous," or "unlisted" procedure code in the appropriate area of specialty may be used only if no other code accurately corresponds to a procedure. For such a service, the laboratory provider submits a claim "by report" in accordance with rule 5160-1-60.4 of the Administrative Code and notes the analyte, the specimen type, and the method in the claim. The department may deny a claim that omits necessary information or that includes a "not otherwise specified," "miscellaneous," or "unlisted" procedure code when an appropriate procedure-specific code is available.

(2) When a laboratory provider uses the Ohio department of health (ODH) laboratory to perform a covered laboratory procedure for a medicaid-eligible individual, the laboratory provider prepares specimens and completes necessary paperwork in accordance with all applicable ODH rules and practices. The laboratory provider is exempt from paying the ODH laboratory for the service; instead, the department will pay the ODH laboratory. Claims for such procedures are not to be submitted to the department.

(3) For a covered laboratory service represented by a new healthcare common procedure coding

system (HCPCS) procedure code, the initial maximum payment amount is established in accordance with rule 5160-1-60 of the Administrative Code.

(4) For any other covered laboratory service (global procedure, professional component, or technical component), the initial payment amount is the lesser of the submitted charge or the applicable medicaid maximum from the following list:

(a) For a service that is payable under the clinical laboratory fee schedule published by CMS, seventy-five per cent of the Ohio-specific medicare allowed amount for that service; or

(b) For a service that is payable under the medicare physician fee schedule, seventy-five per cent of the Ohio-specific medicare allowed amount for that service.

(5) If the medicare amount for a service becomes less than the current medicaid maximum payment amount, then the medicaid maximum payment amount for that service is reestablished on the basis of the new medicare amount:

(a) For a service that is payable under the clinical laboratory fee schedule published by CMS, it is seventy-five per cent of the Ohio-specific medicare allowed amount for that service; or

(b) For a service that is payable under the medicare physician fee schedule, it is seventy-five per cent of the Ohio-specific medicare allowed amount for that service.

(6) Both the medicare physician fee schedule and the clinical laboratory fee schedule are available from CMS, http://www.cms.gov.

(7) For convenience, a list of medicaid maximum payment amounts and additional claim-related information for clinical diagnostic procedures, molecular pathology procedures, and pathology procedures is available on the department's 'Fee Schedule and Rates' web page, which may be accessed through the department's main web page (http://medicaid.ohio.gov).