Annual Notice to Providers

Dear Valued Client:

The Office of Inspector General has requested that all clinical laboratories annually provide their clients with the following information. Attached is the list of the 2017 American Medical Association (AMA) defined Organ/Disease Panels and their detailed test components. The enclosure is designed to assure that you are aware of and understand AMA defined Organ/Disease Panels and their applicable Medicare/Medicaid reimbursement rates, patient pricing, and currently used Current Procedural Terminology (CPT) codes.

Additionally, the Federal government has requested that all laboratories inform you of the following government policies that apply to physicians and other individuals authorized by law to order laboratory tests.

Medicare will only pay for tests that meet Medicare coverage criteria and are "reasonable and necessary to treat or diagnose and individual patient" section 1862 (a) (1) (A) of the Social Security Act. No payment may be made under Part A or Part B for tests or services which are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. Medicare may deny payment for a test the physician believes is appropriate, but which does not meet the Medicare coverage criteria (e.g. done for screening purposes).

To ensure testing of the utmost accuracy and efficiency valid test orders must include the below.

- Patient's full legal name
- Date of birth
- Medical necessity substantiation
- Physician Information
- Collection date
- Patient & Provider signature

When ordering tests for which Medicare or Medicaid reimbursement will be sought:

- Physicians and other authorized ordering parties should only order those tests they believe are medically necessary for their patients.
- The United States Department of Health and Human Services, the Office of Inspector General takes the position that the physician and other authorized ordering individuals, who order medically unnecessary tests, may be subject to civil monetary penalties.
- Physicians and other authorized ordering parties should only order AMA defined Organ/Disease Panels when all components are medically necessary. Payment for individual components of AMA defined Organ/Disease Panels will be rejected if not medically necessary.

- A list of AMA defined Organ/Disease Panels is attached for review.
- Physicians and other authorized ordering parties should order individual tests or a less inclusive profile when not all the tests are medically necessary for an individual patient
- Physicians utilizing customized profiles are advised: The Office of Inspector General takes the position that physicians or other individuals authorized by law to order laboratory tests, who knowingly cause a false claim to be submitted to any federally funded program, may be subject to sanctions or remedies available under civil, criminal and administrative law.
- The utilization of a customized profile may result in the ordering tests which are not covered, reasonable or necessary resulting in those tests not being billed, unless special circumstances exist.
- The Medicare reimbursement for each component of a customized profile can be found by CPT code at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-payment/ClinicalLabFeeSched/index.html
- Medicaid reimbursement is equal to or lower than the Medicare reimbursement.
- The Centers of Medicare and Medicaid Services has developed National Coverage Determinations (NCO). These guidelines give direction for medical necessity on selected tests; view all lab NCDs at: https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/LabNCDsICD10.html
- The Centers for Medicare and Medicaid Services has authorized Novitas Solutions, Inc. the Medicare Carrier for Texas, to develop Local Coverage Determinations (LCD). These guidelines may supplement or be in addition to the National Coverage Determinations and give direction for medical necessity on selected tests. Local Coverage Determinations may not contradict National Coverage Determinations; view the LCDs at: https://www.cms.gov/medicare-coverage-database/indexes/lcd-list.aspx?Cntrctr=332&ContrVer=1&CntrctrSelected=332*1&s=All&DocType=All&bc=AgAAAAAAAAAAAA%3D%3D&#ResultsAnchor
- Charges for screening, non-covered, medically unnecessary, experimental, research only and non-FDA approved tests will be the responsibility of the patient. A signed Advanced Beneficiary Notice of Non-Coverage (ABN) is required prior to delivery of the service. It is the responsibility of the physician and other authorized ordering party to obtain a properly completed ABN when the patient is serviced in their office.
- Section 4317 of the Balanced Budget act of 1997 requires the physician or authorized ordering party submit a diagnosis to the laboratory for submission of a Medicare claim. It is the responsibility of the physician or authorized party to document the diagnosis in the patient's medical record.

- The ordering individual is aware that the clinical laboratory may only bill Medicare and Medicaid for testing ordered by a licensed physician or other individuals authorized by law to order laboratory tests. If your license has been revoked or suspended, it is your responsibility to immediately notify the laboratory.
- The physician or authorized ordering party is aware that the clinical laboratory has the services of a client services representative available to ensure proper test ordering. A representative may be reached at (903)-805-9955.
- Federal law prohibits any payment or reward with anything of value to induce the ordering of tests covered by Medicare, Medicaid or any other federal healthcare program, A kickback, payment or reward of any type meant to induce the ordering of additional tests is strictly forbidden and should be reported to compliance@aalabs.com
- Advanta is cognizant that providing high quality patient care has a cost associated and that some patient may find this cost burdensome consequently denying certain medically necessary services. Advanta has designed a financial assistance program for such patients. This program works to ensure that patients of various socioeconomic statuses have access to Advanta’s high quality services at an affordable rate. Patients with financial need may be eligible for support, we urge these patients to call Advanta so that we can assess the level of financial support we can offer in accordance with federal guidelines.
- Advanta bills insured patients for all deductibles, co-insurance and co-payment in accordance with what is required by their insurance provider.

CMS National Coverage Policy

Title XVIII of the Social Security Act, Section 1862(a) (1) (A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

Title XVIII of the Social Security Act, Section 1833€ states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

Code of Federal Regulations (CFR) Title 42, Part 410.32 indicates that diagnostic tests may only be ordered by the treating physician (or other treating practitioner acting within the scope of his/her license and Medicare requirements) who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem.

Medicare regulations at 42 CFR 410.32(a) state in part, that " ... diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." This, except where other uses have been authorized by statute, Medicare does not cover diagnostic testing used for routine screening or surveillance.

Medicare 2017 Clinical Laboratory Fee Schedule (CLFS)

Reference Information and Websites

ICD-10 Resources

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/

Signature Requirements

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/

Medical Necessity Policies for Laboratory Tests

National Coverage Determinations:
https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/LabNCDsICD10.html

Advance Beneficiary Notices (ABN)
ABN Form CMS-R-131

https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html

42 U.S.C. §§1320a-7b (2006)

http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section1320a-7d&num=0&edition=prelim

Department of Health and Human Services Office of Inspector General
OIG Supplemental Compliance Guidance for Hospitals. 70 Fed. Reg. 4858, 4865 (Jan. 31, 2005).

https://oig.hhs.gov/fraud/docs/complianceguidance/012705hospsupplementalguidance.pdf

Department of Health and Human Services Office of Inspector General. Compliance Program Guidance for Clinical Laboratories
(63 Fed. Reg. 45076; August 24, 1 998)

https://oig.hhs.gov/authorities/docs/cpglab.pdf

Centers for Medicare & Medicaid Services
State Medicaid Director Letter. (April 19, 2016).

https://www.medicaid.gov/federal-policy-guidance/downloads/smd16005.pdf

Department of Health and Human Services Office of Inspector General
"The Effect of Exclusion from Participation in Federal Health Care Programs"
Special Advisory Bulletin (May 2013).

https://oig.hhs.gov/exclusions/advisories.asp

National Practitioner Data Bank (NPDB)

https://www.npdb.hrsa.gov/

CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 3619	**Date: October 7, 2016**
	Change Request 9790

SUBJECT: Table of Chemistry Panels

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to correct the Table of Chemistry Panels in Chapter 16, subsection 90.2 of Pub. 100-04, to clarify CPT 84075 (Alkaline phosphatase) should be listed under the 80053 (Comprehensive Metabolic panel)

EFFECTIVE DATE: January 10, 2017
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 10, 2017
Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	16/90.2/Organ or Disease Oriented Panels

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 3619	Date: October 7, 2016	Change Request: 9790

SUBJECT: Table of Chemistry Panels

EFFECTIVE DATE: January 10, 2017
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 10, 2017

I. GENERAL INFORMATION

A. Background: We are correcting the Table of Chemistry Panels in the Internet Only Manual (IOM) Publication 100-04, Chapter 16, section 90.2. CPT 84075 (Alkaline phosphatase) is removed from under 80048 (Basic Metabolic Panel) and listed under the 80053 (Comprehensive Metabolic panel).

B. Policy: Contractors shall be aware of the revisions to IOM Publication 100-04 - Claims Processing Manual, Chapter 16 - Laboratory Services, Section 90.2 Organ or Disease Oriented Panels.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9790.1	Contractors shall be aware of the correction to the table in IOM Publication 100-04 - Claims Processing Manual, Chapter 16 - Laboratory Services, section 90.2 - Organ and Disease Oriented Panels. CPT 84075 (Alkaline phosphatase) was removed from under 80048 (Basic Metabolic Panel) to under 80053 (Comprehensive Metabolic Panel).	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC		DME MAC		CEDI
		A	B	HHH		
	None					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A
"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Vickie Poff, 410-786-8036 or vickie.poff1@cms.hhs.gov, Eric Coulson, 410-786-3352 or Eric.Coulson@cms.hhs.gov.

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

90.2 - Organ or Disease Oriented Panels

(Rev.3619, Issued: 10-07-16, Effective: 01-10-17 Implementation: 01-10-17)

Organ or disease panels must be paid at the lower of the billed charge, the fee amount for the panel, or the sum of the fee amounts for all components. When panels contain one or more automated tests, the A/B MAC (A) or (B) determines the correct price for the panel by comparing the price for the automated profile laboratory tests with the sum of the fee amounts for individual tests. Payment for the total panel may not exceed the sum total of the fee amounts for individual covered tests. All Medicare coverage rules apply.

The Medicare shared systems must calculate the correct payment amount. The CMS furnishes fee prices for each code but the A/B MAC (A) or (B) system must compare individual codes billed with codes and prices for related individual tests. (With each HCPCS update, HCPCS codes are reviewed and the system is updated). Once the codes are identified, A/B MACs (A) and (B) publish panel codes to providers.

The only acceptable Medicare definition for the component tests included in the CPT codes for organ or disease oriented panels is the American Medical Association (AMA) definition of component tests. The CMS will not pay for the panel code unless all of the tests in the definition are performed. If the laboratory has a custom panel that includes other tests, in addition to those in the defined CPT or HCPCS panels, the additional tests, whether on the list of automated tests or not, are billed separately in addition to the CPT or HCPCS panel code.

NOTE: If a laboratory chooses, it can bill each of the component tests of these panels individually, but payment will be based upon the above rules.

TABLE OF CHEMISTRY PANELS

		Hepatic Function Panel 80076	**Basic Metabolic Panel** (Calcium, ionized) **80047**	**Basic Metabolic Panel** (Calcium, total) **80048**	**Comprehensive Metabolic Panel 80053**	**Renal Function Panel 80069**	**Lipid[1] Panel 80061**	**Electrolyte Panel 80051**
Chemistry	**CPT**							
Albumin	82040	X			X	X		
Alkaline phosphatase	84075	X			*X*			
ALT (SGPT)	84460	X			X			
AST (SGOT)	84450	X			X			
Bilirubin, total	82247	X			X			
Bilirubin, direct	82248	X						
Calcium	82310			X	X	X		
Calcium ionized	82330		X					
Chloride	82435		X	X	X	X		X
Cholesterol	82465						X	
CK, CPK	82550							
CO2 (bicarbonate)	82374		X	X	X	X		X
Creatinine	82565		X	X	X	X		
GGT	82977							
Glucose	82947		X	X	X	X		
LDH	83615							
Phosphorus	84100					X		
Potassium	84132		X	X	X	X		X
Protein	84155	X			X			
Sodium	84295		X	X	X	X		X
Triglycerides	84478						X	
Urea nitrogen (BUN)	84520		X	X	X	X		
Uric Acid	84550							

[1] CPT code 83718 is billed with Organ/Disease Panel 80061 but is not included in the AMCC bundling.