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Independent Laboratory Billing of Laboratory Tests for End-Stage Renal Disease (ESRD) Beneficiaries and the Sunset of the CB Modifier

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Related Change Request (CR) Number: 11061
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Implementation Date: July 1, 2019

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for ESRD services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 11061 sunsets the requirement for Independent Laboratories to use the CB modifier to bill separately for renal dialysis laboratory tests. Make sure your billing staff is aware of these changes.

BACKGROUND

The Skilled Nursing Facility (SNF) Consolidated Billing (CB) provision requires a SNF to include on its Part A bill almost all of the services that its residents receive during the course of a Part A covered stay. There are several categories of services that the Social Security Act ((Section 1888(e)(2)(A)(ii) (https://www.ssa.gov/OP_Home/ssact/title18/1888.htm) specifically excludes from this provision. These excluded services remain separately billable under Part B by the outside provider or supplier that furnishes them.

One of the excluded categories encompasses those items and services that fall within the scope of the Part B benefit that covers chronic dialysis for beneficiaries with ESRD (see the Social Security Act (Section 1861(s)(2)(F)) at https://www.ssa.gov/OP_Home/ssact/title18/1861.htm).

Prior to January 1, 2011

Prior to January 1, 2011, Medicare paid independent laboratories directly for furnishing diagnostic tests that were ESRD dialysis-related. For purposes of the SNF CB, ESRD dialysis-related was defined as:

1. The beneficiary must be an ESRD beneficiary.
2. The test must have been ordered by an ESRD facility.
3. The test must relate directly to the dialysis treatment of the beneficiary's ESRD.

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Therefore, an independent laboratory could be paid separately (outside of the SNF CB) for an ESRD dialysis-related diagnostic test furnished to a SNF Part A resident, provided the test was outside the ESRD facility's composite rate when the diagnostic test was billed with the CB modifier – services ordered by a dialysis facility physician as part of the ESRD beneficiary's dialysis benefit, is not part of the composite rate, and is separately reimbursable.

Note: CR 2475 established the CB modifier, and CR 2906 revised the criteria for using the CB modifier.

January 1, 2011, ESRD Prospective Payment System (PPS)

The Medicare Improvements for Patients and Providers Act (MIPPA; Section 153(b)) required the implementation of the ESRD PPS effective January 1, 2011.

The ESRD PPS replaced the basic case-mix adjusted composite payment system and the methods for the reimbursement of separately billable outpatient ESRD related items and services. The ESRD PPS provides a single payment to ESRD facilities (that is, hospital-based providers of services and renal dialysis facilities) that pays for all the resources used in providing an outpatient dialysis treatment, including supplies and equipment used to administer dialysis in the ESRD facility or at a patient's home, drugs, biologicals, laboratory tests, training, and support services.

The ESRD PPS includes CB requirements for limited Part B services included in the ESRD facility's bundled payment. The Centers for Medicare & Medicaid Services (CMS) periodically updates the lists of items and services that are subject to Part B CB and are, therefore, no longer separately payable when provided to ESRD beneficiaries by providers other than ESRD facilities.

CR 7064 (also see MLN Matters Article MM7064)established the ESRD PPS CB requirements, which are discussed on the CMS website located at this link: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html.

Since the implementation of the ESRD PPS, independent laboratories are no longer able to bill Medicare directly for any diagnostic test that is related to the treatment of ESRD as payment for the test is already included in the ESRD PPS base rate paid to the ESRD facility. CMS inadvertently did not eliminate the use of the CB modifier in the ESRD PPS.

CR 11061 July 1, 2019, Sunset of CB Modifier

Therefore, CR 11061 sunsets the requirement for independent laboratories to use the "CB" HCPCS modifier to bill separately for renal dialysis laboratory tests.

Effective January 1, 2011, independent laboratories are no longer allowed to report the CB modifier. All laboratory tests determined to be furnished for the treatment of ESRD are paid in the ESRD facility bundled payment and therefore, may only be reported by the ESRD facility.

Therefore, effective with dates of service on or after July 1, 2019, the CB modifier, which is a payment mechanism for independent laboratories to report when requesting separate payment outside the SNF CB for ESRD dialysis-related services, will not be available.

Effective with dates of service on or after July 1, 2019, claims with the CB modifier will be returned to the provider (RTP) with the following codes:

- Reason code 31164 - Invalid line item modifier or line item date of service is not within or equal to modifier effective and termination date
- CARC Code 182 - "Procedure modifier was invalid on the date of service."
- Group Code CO - Contractual Obligation.

With the January 1, 2011, implementation of the ESRD PPS and effective for date of service on or after July 1, 2019, Exhibit 1 (see "Medicare Claims Processing Manual" Chapter 16) is no longer recognized as the list of separately billable ESRD dialysis-related services. Instead, a list of the recognized renal dialysis laboratory tests that are subject to Part B ESRD PPS CB requirements, are considered routinely performed for the treatment of ESRD, and are not separately paid when provided to ESRD beneficiaries by providers or suppliers other than the ESRD facility, is located on the CMS website: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html.

The list of renal dialysis laboratory tests provided in the Part B ESRD PPS CB requirements is not an all-inclusive list. For laboratory tests not included in this list, the distinction of what is considered to be a renal dialysis laboratory test is a clinical decision determined by the ESRD beneficiary's ordering practitioner. If the practitioner orders such a laboratory test for the treatment of ESRD, then the laboratory test is considered to be included in the ESRD PPS, is the responsibility of the ESRD facility and is excluded from the SNF PPS. More information regarding renal dialysis services payable under the ESRD PPS is available in the "Medicare Benefit Policy Manual", Chapter 11.

Beneficiaries in a SNF Part A stay are eligible for a broad range of diagnostic services as part of the SNF Part A benefit. Physicians ordering medically necessary diagnostic tests that are not directly related to the beneficiary's ESRD are subject to the SNF CB requirements. Physicians may bill the A/B MAC (B) for the professional component of these diagnostic tests. In most cases, however, the technical component of diagnostic tests is included in the SNF PPS rate and is not separately billable to the A/B MAC (B). Physicians should coordinate with the SNF in ordering such tests since the SNF will be responsible for bearing the cost of the technical component.

Note: A patient's physician or practitioner may order a laboratory test that is included on the list of items and services subject to CB edits for reasons other than for the treatment of ESRD. When this occurs, the SNF CB applies.

ADDITIONAL INFORMATION

The official instruction, CR11061, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4227CP.pdf.

If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

DOCUMENT HISTORY

Date of Change	Description
February 1, 2019	Initial article released.