CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-02 Medicare Benefit Policy	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 244	**Date: July 20, 2018**
	Change Request 10809

SUBJECT: Internet Only Manual (IOM) Update to Publication 100-02, Chapter 11 - End Stage Renal Disease (ESRD), Section 100

I. SUMMARY OF CHANGES: This Change Request (CR) will update the Benefit Policy manual, chapter 11, section 100 related to acute kidney injury.

EFFECTIVE DATE: October 23, 2018
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 23, 2018

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	11/100.6/Applicability of Specific ESRD PPS Policies to AKI Dialysis

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. 100-02	Transmittal: 244	Date: July 20, 2018	Change Request: 10809

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I. GENERAL INFORMATION

A. Background: On June 29, 2015, the Trade Preferences Extension Act of 2015 was enacted in which section 808 amended Section 1861(s)(2)(F) of the Social Security Act (42 U.S.C. 1395x(s)(2)(F)) by extending renal dialysis services paid under section 1881(b)(14) to beneficiaries with acute kidney injury, effective January 1, 2017.

B. Policy: This CR contains no policy changes. Contractors shall note the updates to the manual section.

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	
10809.1	Contractors shall be in compliance with the updates to CMS IOM publication 100-02, chapter 11-End Stage Renal Disease (ESRD), section 100.	X								
10809.2	Contractors shall continue to follow instructions provided in change requests 9598, 9987 and others until manual instructions are implemented.	X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
10809.3	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or	X				

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.					

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): Janae James, janae.james@cms.hhs.gov.

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
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ATTACHMENTS: 1

100.6 Applicability of Specific ESRD PPS Policies to AKI Dialysis

(Rev.244, Issued: 07-20-18, Effective: 10-23-18, Implementation: 10-23- 18)

A. Dialysis Modality

Beneficiaries with AKI can receive their dialysis via the most clinically appropriate in-facility modality.

B. Uncompleted Dialysis Treatment

Generally, CMS only pays for one treatment per day across all settings. However, similar to the policy applied under the ESRD PPS for treatments for patients with ESRD, in the interest of fairness and in accordance with Chapter 8, section 10.2 of the Medicare Claims Processing Manual, if a dialysis treatment is started, that is, a patient is connected to the machine and a dialyzer and blood lines are used, but the treatment is not completed for some unforeseen, but valid reason, for example, a medical emergency when the patient must be rushed to an emergency room, both the ESRD facility and the hospital would be paid. This is considered to be a rare occurrence that must be fully documented to the A/B MAC's satisfaction.

C. Home and Self-Dialysis

Due to the nature of AKI, dialysis treatments at home or self-dialysis in the dialysis facility are not permitted. Specifically, these patients require supervision by qualified staff during their dialysis and close monitoring through laboratory tests to ensure that they are receiving the necessary care to improve their condition and get off of dialysis. Therefore, the home dialysis benefit does not extend to beneficiaries with AKI.

D. Vaccines and Their Administration

Section 1881(b)(14)(B) of the Act specifically excludes vaccines covered under section 1861(s)(10) of the Act from the ESRD PPS. However, ESRD facilities are identified as an entity that can bill Medicare for vaccines and their administration. Therefore, ESRD facilities may furnish vaccines to beneficiaries with AKI and bill Medicare in accordance with billing requirements in the Medicare Claims Processing Manual (Pub. 100-04, Chapter 18 Preventive and Screening Services, section 10.2). The staff time associated with vaccine administration is covered in the AKI dialysis payment rate.

E. Telehealth

Since telehealth dialysis services are limited to renal dialysis services for home dialysis patients telehealth related to renal dialysis services is not available for beneficiaries with AKI.

F. ESRD Conditions for Coverage (CfCs)

The ESRD CfCs at 42 CFR part 494 are health and safety standards that all Medicare participating dialysis facilities must meet. These standards set baseline requirements for patient safety, infection control, care planning, staff qualifications, record keeping, and other matters to ensure that all patients, including ESRD and AKI patients, receive safe and appropriate care.

G. Payment for Erythropoietin Stimulating Agents (ESAs) and the ESA Monitoring Policy for AKI Patients

ESAs are included in the bundled payment amount for treatments administered to patients with AKI. The Non-ESRD HCPCS codes should be used (J0881, *J0883*, J0885, J088*8*, *Q0138*) *and* reported using revenue code 0636.

The ESA monitoring policy has not yet been extended to AKI patients receiving treatment in an ESRD facility. Since this policy is not applicable to these treatments, the value codes used to report hemoglobin and hematocrit levels are not required when billing for ESAs.