CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-20 One-Time Notification	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 10470	**Date: November 20, 2020**
	Change Request 12049

SUBJECT: Implementation of Two (2) New NUBC Condition Codes. Condition Code "90", "Service provided as Part of an Expanded Access Approval (EA)" and Condition Code "91", "Service Provided as Part of an Emergency Use Authorization (EUA)"

I. SUMMARY OF CHANGES: This Change Requests implements the newly created condition code "90" in order to allow providers to report when the service is provided as part of an Expanded Access approval and condition code "91" in order to allow providers to report when the service is provided as part of an Emergency Use Authorization.

EFFECTIVE DATE: February 1, 2021 - for claims received on or after 02/01/2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: February 22, 2021 - (MACs); January 4, 2021 - (FISS – for documentation updates, Using April hours)

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
N/A	N/A

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:

One Time Notification

Attachment - One-Time Notification

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I. GENERAL INFORMATION

A. Background: Since the 1970s, the U.S. Food and Drug Administration (FDA) has facilitated making investigational drugs available to patients with serious diseases or conditions when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the patient's disease or condition. The FDA's Expanded Access (EA) process was formalized through regulation in 1987 (drugs and biologics) - 1 and 1996 (devices) - 2, and EA was further codified in law in 1997 - 3. The EA program provides a process for patients to obtain authorization to use an investigational medical product for treatment use that has not been FDA approved - 4 for use outside of a clinical trial setting - 5.

1 Per 21 CFR 312 section I
2 Per 21 CFR part 812
3 FDA's EA program is sometimes referred to as the "compassionate use" program. "Expanded access" involves use of an investigational medical product outside of a clinical trial.
4 "Approved" or "Approval" is used in this report to refer to the following: approval for a drug or device, licensing for a biologic, and marketing authorization for a medical device via the premarket approval, 510(k) or De Novo classification pathway and for a medical device that is exempt from premarket notification to be marketed in the US.
5 Food and Drug Administration Modernization Act of 1997 (FDAMA).

The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against CBRN threats by facilitating the availability and use of MCMs needed during public health emergencies.

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.

Section 564 of the FD&C Act was amended by the Project Bioshield Act of 2004 and was further amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA), the 21st Century Cures Act of 2016, and Public Law 115-92 of 2017.

Please note: a determination under section 319 of the Public Health Service Act that a public health emergency exists, such as the one issued on January 31, 2020, does not enable FDA to issue EUAs. A separate determination and declaration are needed under section 564 of the Federal Food, Drug and Cosmetic Act to enable FDA to issue EUAs, provided other statutory criteria are met.

B. Policy: No new policy is being implemented.

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	
12049.1	Medicare contractors shall accept the new Condition Codes “90” and “91” effective with claim receipt dates of 02/01/2021 and after. “**90**” Service provided as part of an Expanded Access approval. Code is for Inpatient and Outpatient claims that have reported Expanded Access services. “**91**” Service provided as part of an Emergency Use Authorization. Code is for Inpatient and Outpatient claims that have reported Emergency Use Authorization.	X				X				BCRC, HIGLAS, IDR

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12049.2	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 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.	X				

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): Fred Rooke, fred.rooke@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: 0