



## **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)”**

MLN Matters Number: MM12049

Related Change Request (CR) Number:  
12049

Related CR Release Date: November 20, 2020

Effective Date: Claims received on or after  
February 1, 2021

Related CR Transmittal Number: R104700TN

Implementation Date: February 22, 2021

### **PROVIDER TYPES AFFECTED**

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

### **PROVIDER ACTION NEEDED**

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This article informs you about two newly created condition codes:

- “90” – To allow providers to report when the service is provided as part of an Expanded Access approval
- “91” – To allow providers to report when the service is provided as part of an Emergency Use Authorization (EUA)

Please make sure your billing staffs are aware of these updates. These codes are effective for claims received on or after February 1, 2021.

### **BACKGROUND**

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Since the 1970s, the United States Food & Drug Administration (FDA) has made investigational drugs available to patients with serious diseases or conditions when there is no comparable satisfactory alternative therapy to diagnose, monitor, or treat that patient’s disease or condition. The FDA formalized this Expanded Access (EA) process in 1987 for drugs and biologics through [21 Code of Federal Regulations \(CFR\) 312 Section I](#). In 1996, the FDA formalized the process for devices via [21 CFR Part 812](#). EA was further codified in law in 1997. The 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.

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 for use outside of clinical trial settings per the Food and Drug Administration Modernization Act of 1997 (FDAMA).

In this context, “approved” or “approval” refers to the following:

- Approval for a drug or device
- Licensing for a biologic
- Marketing authorization for a medical device via the premarket approval, 510(k) or De Novo classification pathway
- For a medical device that is exempt from premarket notification to be marketed in the United States.

Providers shall append the newly created condition code 90 to claims with Expanded Access (EA) services.

The EUA authority allows the FDA to help strengthen the nation’s public health protections against Chemical, Biological, Radiological, and Nuclear (CBRN) threats by making available the use of Medical Countermeasures (MCMs) needed during Public Health Emergencies (PHEs).

Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) permits the FDA Commissioner to 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 21<sup>st</sup> Century Cures Act of 2016, and Public Law 115-92 of 2017.

A determination under Section 319 of the Public Health Service Act that a PHE 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 FD&C Act to enable the FDA to issue EUAs, provided other statutory criteria are met.

Providers shall append the newly created condition code 91 to claims with Emergency Use Authorization (EUA) services.

CR 12049 does not implement any new policy. Usage of condition codes 90 or 91 do not affect coverage of services. Providers shall continue to follow Medicare billing and coverage guidelines for services billed to the Medicare program.

## ADDITIONAL INFORMATION

The official instruction, CR 12049, issued to your MAC regarding this change is available at <https://www.cms.gov/files/document/r10470otn.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
November 20, 2020	Initial article released.

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