

Introduction

Use of the ICD-10 diagnosis code sets for most healthcare claims is required, effective October 1, 2015. This document is a guide for healthcare professionals on the aspects of the transition to ICD-10 that impact the documentation of medical necessity of the use of Zimmer Biomet's electrical bone growth stimulation (EBGS) devices.

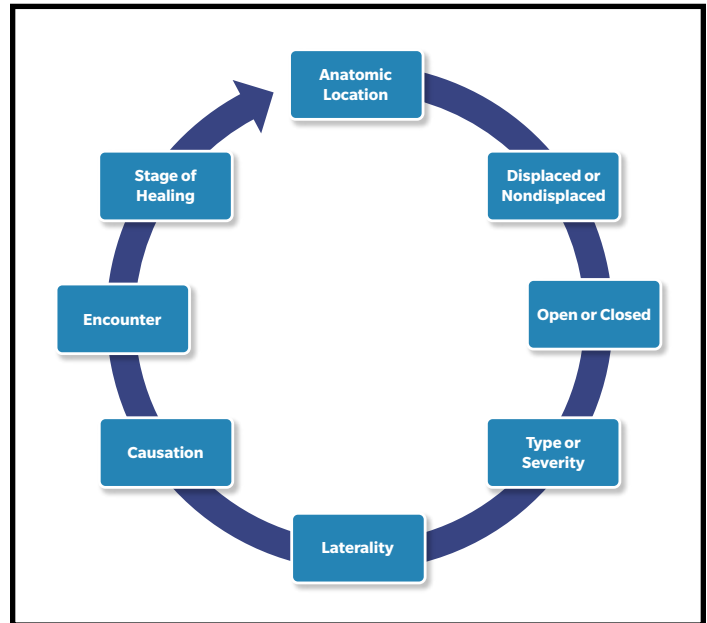
There are three main categories of changes between ICD-9 and ICD-10:

- Definition Changes
- Terminology differences
- Increased specificity

The most significant change in ICD-10 that impacts documentation of medical necessity for a medical device is the focus on specificity. There is new information that must be obtained in order to determine the correct code. For example, nearly a third of the changes can be attributed to identification of laterality. There are also modifications in the reporting of 'external causes' and fracture healing status.

While there are no changes to how payers cover EBGS devices as a result of the transition to ICD-10, the increased specificity of the diagnosis codes could impact whether or not a given prescription of an EBGS device for a patient will be approved or denied for coverage by a patient's insurance carrier.

It is important for healthcare professionals and their staff to understand these nuances and clearly document the medical necessity of a prescribed EBGS device in the patient's medical record, including accurate assignment of diagnosis codes for the condition that the device is intended to treat.



The Importance of 7th Character Codes

The 7th alphabetic character in an ICD-10 code details a high level of specificity by conveying three pieces of information:

- Encounter
- Type of fracture
- Healing status

Key Point: Be aware that payer coverage policies on EBGs devices frequently provide specific definitions and associated limitations related to the type of healing, or status, of a fracture.

Definitions

Digit	Description
A	initial encounter for closed fracture
B	initial encounter for open fracture type I or II initial encounter for open fracture NOS
C	initial encounter for open fracture type IIIA, IIIB, or IIIC
D	subsequent encounter for closed fracture with routine healing
E	subsequent encounter for open fracture type I or II with routine healing
F	subsequent encounter for open fracture type IIIA, IIIB, or IIIC with routine healing
G	subsequent encounter for closed fracture with delayed healing
H	subsequent encounter for open fracture type I or II with delayed healing
J	subsequent encounter for open fracture type IIIA, IIIB, or IIIC with delayed healing
K	subsequent encounter for closed fracture with nonunion
M	subsequent encounter for open fracture type I or II with nonunion
N	subsequent encounter for open fracture type IIIA, IIIB, or IIIC with nonunion
P	subsequent encounter for closed fracture with malunion
Q	subsequent encounter for open fracture type I or II with malunion
R	subsequent encounter for open fracture type IIIA, IIIB, or IIIC with malunion
S	sequela

Clinical Example: On October 31st, patient was seen in the ER for shoulder pain and x-rays indicated there was a fracture of the right clavicle, shaft Patient returned three months later with complaints of continuing pain. X-rays indicated a nonunion. The second encounter for the right clavicle fracture is coded as 542.021k, displaced fracture of the shaft of right clavicle, subsequent for fracture with nonunion.

Zimmer Biomet Bone Healing Technologies

399 Jefferson Road
 Parsippany, NJ 07054
 Telephone: 1.800.526.2579
 Fax: 1.888.299.9022



Indications

The Biomet® EBI Bone Healing System is indicated for the treatment of fracture **nonunions, failed fusions, and congenital pseudarthrosis** in the appendicular system.

The Biomet® OrthoPak® Non-invasive Bone Growth Stimulation System is indicated for the treatment of an established **nonunion** acquired secondary to trauma, excluding vertebrae and all flat bones, where the width of the nonunion defect is less than one-half the width of the bone to be treated.

Nonunions and Documenting Medical Necessity

In rare cases, fractures that do not heal can result in a nonunion. Making the determination that the healing status of the patient is a **nonunion** can be challenging. The FDA defines a nonunion as follows:

A nonunion is considered to be established when the fracture site shows no visible progressive signs of healing.

As noted previously, ICD-10 has expanded the level of specificity of diagnosis codes significantly. The quality of documentation, which supports correct coding, has a direct impact on patient’s coverage for services and access to care. The specificity designating healing status is of particular importance as it relates to patients who are candidates for bone growth stimulation. The 7th character codes D through R (as noted on the previous table) specify the healing status of fractures as follows:

D – F: Routine Healing	H – N: Nonunion
G – J: Delayed Healing	P – R: Malunion

Symptoms of a nonunion may include, but are not limited to¹:

- Persistent pain at the fracture site
- A persistent gap with no bone spanning the fracture site
- No progress in bone healing when repeated imaging studies are compared over several months
- Inadequate healing in a time period that is usually enough for normal healing

In addition, there are a number of comorbidities which influence fracture and or fusion healing, they include but are not limited to²:

- Smoking or tobacco use
- Obesity
- Age
- Use of anti-inflammatories
- Diabetes
- Hypothyroidism

Key Point: While these comorbidities are not identified within on ICD-10 diagnosis code, if they are present they should be clearly documented in the patient’s medical record.

¹ American Academy of Orthopedic Surgeons <http://orthoinfo.aaos.org/topic.cfm?topic=A00374>
² American Academy of Orthopedic Surgeons <http://orthoinfo.aaos.org/topic.cfm?topic=A00374>

Coverage Guidelines for Bone Growth Stimulators

The majority of payer coverage guidelines that address EBGs devices (including Medicare) reflect the FDA labeling for the devices. The medical necessity of the bone growth stimulator must be clearly reflected in the patient's medical record. It is essential for providers to define and accurately document the patient's medical condition(s), including comorbidities and any health factors negatively impacting the patient's ability to consolidate their fracture or fusion. Furthermore, when there are no visibly progressive signs of healing, the status of the fracture or fusion must be explicit, and well-documented within the patient's medical record so that the 7th character code may be appropriately assigned.

Key Point: Appropriate assignment of the 7th character codes K, M or N Indicating a healing status of nonunion requires clear documentation and explicit notation of nonunion. In order for providers, coders or billing staff to assign the appropriate ICD-10 coding characters, the medical record must be thorough, complete and explicit.

Sources

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