02-20000-22

Original Effective Date: 10/15/02

Reviewed: 07/25/24

Revised: 08/15/24

Subject: Invasive Electrical Bone Growth Stimulator (EBGS)

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	<u>Definitions</u>	Related Guidelines
<u>Other</u>	References	<u>Updates</u>			

DESCRIPTION:

Invasive devices require surgical implantation of a current generator in an intramuscular or subcutaneous space, with an accompanying electrode implanted within the fragments of bone graft at the fusion site. The implantable device typically remains functional for 6 to 9 months after implantation. Although the current generator is removed in a second surgical procedure when stimulation is completed, the electrode may or may not be removed. Implantable electrodes provide constant stimulation at the nonunion or fracture site but carry increased risks associated with implantable leads.

Analysis and Summary of Evidence: The North American Spine Society Coverage Policy Recommendation titled "Electrical Stimulation for Bone Healing" (NASS, 2016) states the evidence is sufficient to support the use of electrical stimulation for augmentation of spinal fusion healing in any and all regions of the spine, including occipital-cervical, cervical, cervicothoracic, thoracic, thoracolumbar, lumbar and lumbosacral, in individuals at high-risk for the development of pseudarthrosis (ie, nonunion) who exhibit certain conditions and comorbidities. The NASS recommendations further state the evidence is insufficient to support the use of electrical stimulation as an adjunct for primary bone healing of a spinal fracture, or as a nonsurgical treatment of an established pseudarthrosis. The American Association of Neurological Surgeons/Congress of Neurological Surgeons Joint Section on Disorders of the Spine and Peripheral Nerves published a guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine that included review of use of bone growth stimulators as an adjunct for lumbar fusion (Kaiser et al, 2014). The practice guideline supports the use of direct current electrical bone growth stimulators as an adjunct to spinal fusion for some individuals (i.e., younger than age 60). A published Health Technology Assessment, "Bone Growth Stimulation" (Washington State Health Care Authority, 2009) and an AHRQ Evidence Report, "The Role of Bone Growth Stimulating Devices and Orthobiologics in Healing Nonunion

Fractures/Technology Assessment" (Schoelles et al, 2005) both support the use of direct electrical stimulation for healing of nonunion fractures. POSITION STATEMENT:

Invasive electrical bone growth stimulation **meets the definition of medical necessity** for the following indications:

- Fracture nonunions or congenital pseudoarthroses in the appendicular skeleton (includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities) when ALL of the following are met:
 - At least 3 months have passed since the date of fracture
 - Serial radiographs have confirmed that no progressive signs of healing have occurred
 - The fracture gap is 1 cm or less
 - The individual can be adequately immobilized
 - Is of an age likely to comply with non-weight bearing for fractures of the pelvis and lower extremities
- As an adjunct to spinal fusion surgery in individuals at high risk for fusion failure, defined as any one of the following:
 - One or more previous failed spinal fusion(s)
 - Grade III or worse spondylolisthesis
 - Fusion to be performed at more than one level
 - Current tobacco use
 - Diabetes
 - Renal disease
 - Alcoholism
 - Steroid use

BILLING/CODING INFORMATION:

CPT Coding:

20975	Electrical stimulation to aid bone healing; invasive (operative)
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HCPCS Coding:

E0749	Osteogenesis stimulator, electrical, surgically implanted
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ICD-10 Diagnosis Codes That Support Medical Necessity:

M43.00 – M43.09	Spondylosis
M43.10 – M43.19	Spondylolisthesis
M43.20 – M43.28	Fusion of spine
M53.9	Dorsopathy, unspecified

M8008XK, P	Age-related osteoporosis with current pathological fracture, vertebra(e),
	subsequent encounter for fracture with nonunion or malunion
M84.40XK, P	Pathological fracture, unspecified site, subsequent encounter for fracture
	with nonunion or malunion
M84.40XK, P	Pathological fracture, unspecified site, subsequent encounter for fracture
	with nonunion or malunion
M84.48XK, P	Pathological fracture, other site, subsequent encounter for fracture with
	nonunion or malunion
M84.68XK, P	Pathological fracture in other disease, other site, subsequent encounter for
	fracture with nonunion or malunion
M84.750G,K,P –	Atypical femoral fracture (delayed healing, nonunion, malunion)
M84.759G,K,P	
(G,K,P suffixes only)	
M96.0	Pseudarthrosis after fusion or arthrodesis
Q76.2	Congenital spondylolisthesis
S42.201G - S42.496G	Fracture of humerus, delayed healing (delayed healing, nonunion,
(G suffix only)	malunion)
S49.001G - S49.199G	Physeal fracture of humerus, delayed healing (delayed healing, nonunion,
(G suffix only)	malunion)
S52.001G,J;	Fracture of forearm, delayed healing (delayed healing, nonunion, malunion)
S52.002G,J;	
S52.009G,J;	
S52.011G,	
S52.012G,	
S52.019G,	
S52.021G,H,J;	
S52.022G,H,J;	
S52.023G,H,J;	
S52.024G,H,J;	
S52.025G,H,J;	
S52.026G,H,J;	
S52.031G,H,J;	
S52.032G,H,J;	
S52.033G,H,J;	
S52.034G,H,J;	
S52.035G,H,J;	
S52.036G,H,J;	
S52.041G,H,J;	
S52.042G,H,J;	
S52.043G,H,J;	
S52.044G,H,J;	
S52.045G,H,J;	
S52.046G,H,J;	
S52.091G,H,J;	

S52.092G,H,J;	
S52.099G,H,J;	
S52.101G,H,J;	
S52.102G,H,J;	
S52.109G,H,J;	
S52.111G,	
S52.112G,	
S52.119G,	
S52.121G,H,J;	
S52.122G,H,J;	
S52.123G,H,J;	
S52.124G,H,J;	
S52.125G,H,J;	
S52.126G,H,J;	
S52.131G,H,J;	
S52.132G,H,J;	
S52.133G,H,J;	
S52.134G,H,J;	
S52.135G,H,J;	
S52.136G,H,J;	
S52.181G,H,J;	
S52.182G,H,J;	
S52.189G,H,J;	
S52.201G,H,J;	
S52.202G,H,J;	
S52.209G,H,J;	
S52.211G,	
S52.212G,	
S52.219G,	
S52.221G,H,J;	
S52.222G,H,J;	
S52.223G,H,J;	
S52.224G,H,J;	
S52.225G,H,J;	
S52.226G,H,J;	
S52.231G,H,J;	
S52.232G,H,J;	
S52.233G,H,J;	
S52.234G,H,J;	
S52.235G,H,J;	
S52.236G,H,J;	
S52.241G,H,J;	
S52.242G,H,J;	
S52.243G,H,J;	

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S52.244G,H,J;	
S52.245G,H,J;	
S52.246G,H,J;	
S52.251G,H,J;	
S52.252G,H,J;	
S52.253G,H,J;	
S52.254G,H,J;	
S52.255G,H,J;	
S52.256G,H,J;	
S52.261G,H,J;	
S52.262G,H,J;	
S52.263G,H,J;	
S52.264G,H,J;	
S52.265G,H,J;	
S52.266G,H,J;	
S52.271G,H,J;	
S52.272G,H,J;	
S52.279G,H,J;	
S52.281G,H,J;	
S52.282G,H,J;	
S52.283G,H,J;	
S52.291G,H,J;	
S52.292G,H,J;	
S52.299G,H,J;	
S52.301G,H,J;	
S52.302G,H,J;	
S52.309G,H,J;	
S52.311G,	
S52.312G, S52.319G,	
S52.321G,H,J;	
S52.322G,H,J;	
S52.323G,H,J;	
S52.324G,H,J;	
S52.325G,H,J;	
S52.326G,H,J;	
S52.331G,H,J;	
S52.332G,H,J;	
S52.333G,H,J;	
S52.334G,H,J;	
S52.335G,H,J;	
S52.336G,H,J;	
S52.341G,H,J;	
S52.342G,H,J;	
332.3720,11,3,	

S52.343G,H,J;	
S52.344G,H,J;	
S52.345G,H,J;	
S52.346G,H,J;	
S52.351G,H,J;	
S52.352G,H,J;	
S52.353G,H,J;	
S52.354G,H,J;	
S52.355G,H,J;	
S52.356G,H,J;	
S52.361G,H,J;	
S52.362G,H,J;	
S52.363G,H,J;	
S52.364G,H,J;	
S52.365G,H,J;	
S52.366G,H,J;	
S52.371G,H,J;	
S52.372G,H,J;	
S52.379G,H,J;	
S52.381G,H,J;	
S52.382G,H,J;	
S52.389G,H,J;	
S52.391G,H,J;	
S52.392G,H,J;	
S52.399G,H,J;	
S52.501G,H,J;	
S52.502G,H,J;	
S52.509G,H,J;	
S52.511G,H,J;	
S52.512G,H,J;	
S52.513G,H,J;	
S52.514G,H,J;	
S52.515G,H,J;	
S52.516G,H,J;	
S52.521G,	
S52.522G,	
S52.529G,	
S52.531G,H,J;	
S52.532G,H,J;	
S52.539G,H,J;	
S52.541G,H,J;	
S52.542G,H,J;	
S52.549G,H,J;	
S52.551G,H,J;	

S52.552G,H,J;	
S52.559G,H,J;	
S52.561G,H,J; S52.562G,H,J;	
S52.569G,H,J;	
S52.571G,H,J;	
S52.572G,H,J;	
S52.579G,H,J;	
S52.591G,H,J;	
S52.592G,H,J;	
S52.599G,H,J;	
S52.601G,H,J;	
S52.602G,H,J;	
S52.609G,H,J;	
S52.611G,H,J;	
S52.612G,H,J;	
S52.613G,H,J;	
S52.614G,H,J;	
S52.615G,H,J;	
S52.616G,H,J;	
S52.621G	
S52.622G, S52.629G,	
S52.691G,H,J;	
S52.692G,H,J;	
S52.699G,H,J;	
S52.90XG,H,J;	
S52.91XG,H,J;	
S52.92XG,H,J	
S59.001G - S59.299G	Physeal fracture of radius, delayed healing (delayed healing, nonunion,
(G suffix only)	malunion)
S62.001G – S62.92xG	Fracture at wrist and hand level, delayed healing (delayed healing,
(G suffix only)	nonunion, malunion)
S72.001J;	Fracture of femur (delayed healing, nonunion, malunion)
S72.002G – S72.92XJ	
(G,H,J, suffixes only);	
S79.001G – S79.199G	Physeal fracture of femur, delayed healing (delayed healing, nonunion,
(G suffix only)	malunion)
S82.001G,H,J –	Fracture of lower leg, including ankle, delayed healing (delayed healing,
S82.92,G,H,J	nonunion, malunion)
(G, H, J suffixes only)	
S89.001G – S89.399G	Physeal fracture of fibula, delayed healing (delayed healing, nonunion,
(G suffix only)	malunion)
S92.001G – S92.919G	Fracture of foot and toe, except ankle, delayed healing (delayed healing,
(G suffix only)	nonunion, malunion)
(3 33 3)	1

S99.001G,K,P;	Calcaneus fracture (delayed healing, nonunion, malunion)
S99.002G,K,P;	(aca, ca, ca, ca, ca, ca, ca, ca, ca, ca,
S99.009G,K,P;	
S99.011G,K,P;	
S99.012G,K,P;	
S99.019G,K,P;	
S99.021G,K,P;	
S99.022G,K,P;	
S99.029G,K,P;	
S99.031G,K,P;	
S99.032G,K,P;	
S99.039G,K,P;	
S99.041G,K,P;	
S99.042G,K,P;	
S99.049G,K,P;	
S99.091G,K,P;	
S99.092G,K,P;	
S99.099G,K,P	
S99.101G,K,P,	Fracture of metatarsal (delayed healing, nonunion, malunion)
S99.102G,K,P,	, , , , , , , , , , , , , , , , , , , ,
S99.109G,K,P,	
S99.111G,K,P,	
S99.112G,K,P,	
S99.119G,K,P,	
S99.121G,K,P,	
S99.122G,K,P,	
S99.129G,K,P,	
S99.131G,K,P,	
S99.132G,K,P,	
S99.139G-K-P,	
S99.141G,K,P,	
S99.142G,K,P;	
S99.149G,K,P;	
S99.191G,K,P;	
S99.192G,K,P;	
S99.199G,K,P	
S99.201G,K,P;	Fracture of phalanx of toe (delayed healing, nonunion, malunion)
S99.202G,K,P;	
S99.209G,K,P;	
S99.211G,K,P;	
S99.212G,K,P;	
S99.219G,K,P;	
S99.221G,K,P;	
S99.229G,K,P;	

S99.231G,K,P;	
S99.232G,K,P;	
S99.239G,K,P;	
S99.241G,K,P;	
S99.242G,K,P;	
S99.249G,K,P;	
S99.291G,K,P;	
S99.292G,K,P;	
S99.299G,K,P	
Z98.1	Arthrodesis status

REIMBURSEMENT INFORMATION:

Refer to sections entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Osteogenic Stimulators (150.2) located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

Arthrodesis: surgical fixation of the joint by a procedure designed to cause fusion of the joint surfaces by promoting the generation of bone cells.

Delayed union: a fracture that fails to consolidate (unite) within normal limits, less than 9 months (i.e., healing has slowed with no indications that union will fail).

Nonunion: fracture site that shows no visibly progressive signs of healing after 3 months or more, as confirmed by serial radiographs (i.e., bone healing has ceased).

Pseudoarthrosis (pseudarthrosis): a pathologic entity characterized by the loss or reduction of mineral elements of a weight-bearing long bone, followed by bending and pathologic fracture, with inability to form normal callus, leading to the existence of the "false joint" that gives the condition its name.

Spondylolisthesis: forward displacement of one vertebra over another, usually of the fifth lumbar over the body of the sacrum, or of the fourth lumbar over the fifth, usually due to a developmental defect.

RELATED GUIDELINES:

Non-Invasive Electrical Bone Growth Stimulators (EBGS), 09-E0000-22

OTHER:

Index terms:

EBGS

Electric bone growth stimulator

Electric stimulation

Implanted electric bone growth stimulator

Invasive electric bone growth stimulator

Osteogenesis stimulator

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 07/25/24.

GUIDELINE UPDATE INFORMATION:

10/15/02	Medical Coverage Guideline Reformatted.
12/15/02	Medical Coverage Guideline re-numbered 09-E0000-27 to 02-20000-22 and moved to
	Musculoskeletal Surgery section of MCGs.
10/15/03	Annual review, references updated.
10/15/04	Review and revision of guideline; consisting of updated references, adding additional ICD-
	9 codes under Program Exceptions for Medicare and various formatting changes.
04/15/06	Review and revision of guideline consisting of updated references, added additional
	coverage criteria.
08/15/07	Review and revision of guideline consisting of updated references and reformatted
	guideline.
05/15/09	Scheduled review; add presence of other risk factors to the position statement. Update
	references.
10/15/10	Revision; related ICD-10 codes added.
03/15/11	Biennial review; position statement maintained and references updated.
05/11/14	Revision: Program Exceptions section updated.
05/15/15	Scheduled review. Position statement maintained. Reformatted guideline and updated
	references.
10/01/15	Revision; updated ICD10 coding section.
11/01/15	Revision: ICD-9 Codes deleted.

10/01/16	ICD-10 coding update: added codes M84.750G,K,P - M84.759G,K,P; S99.001G,K,P -
	S99.099G,K,P; S99.101G,K,P - S99.199G,K,P; and S99.201G,K,P - S99.299G,K,P.
10/15/19	Reformatted guideline.
11/15/19	Scheduled review. Revised description, maintained position statement, and updated
	references.
08/15/21	Scheduled review. Maintained position statement and updated references.
05/23/23	Update to Program Exceptions section.
08/15/23	Scheduled review. Revised description, maintained position statement, and updated
	references.
08/15/24	Scheduled review. Revised description, maintained position statement, and updated
	references.