Ohio Administrative Code

Rule 5160-10-28 DMEPOS: osteogenesis stimulators.

Effective: July 1, 2024

(A) Coverage.

(1) Payment may be made for the purchase only of a noninvasive osteogenesis stimulator.

(2) The default certificate of medical necessity (CMN) form is the ODM 07134, "Certificate of Medical Necessity: Osteogenesis Stimulators" (rev. 7/2024). The CMN includes an attestation that appropriate coverage criteria are met.

(3) Payment may be made for a spinal electrical osteogenesis stimulator only if at least one of the following criteria is met:

(a) The individual has undergone multilevel spinal fusion surgery;

(b) The individual has undergone spinal fusion surgery that has failed, and at least nine months have elapsed since the most recent operation; or

(c) The individual has undergone spinal fusion surgery, and previous attempts at spinal fusion at the same site have failed.

(4) Payment may be made for a non-spinal electrical osteogenesis stimulator only if at least one of the following criteria is met:

(a) The fracture is in a long bone and has failed to unite for at least three months, which the provider substantiates with the following documentation:

(i) At least two sets of images including multiple views of the fracture site, the first and last of which were taken at least ninety days apart; and

(ii) A written statement by a qualified interpreting practitioner that there has been no clinically significant evidence of fracture healing during the period when the images were taken.

(b) The individual has congenital pseudarthrosis; or

(c) The individual has undergone joint fusion surgery that has failed, and at least nine months have elapsed since the most recent operation.

(5) Payment may be made for an ultrasonic osteogenesis stimulator only if all of the following criteria are met:

(a) The fracture is in a bone other than the skull or a vertebra;

(b) The fracture is not tumor-related; and

(c) The fracture has failed to unite for at least three months, which the provider substantiates with the following documentation:

(i) At least two sets of images including multiple views of the fracture site, the first and last of which were taken at least ninety days apart; and

(ii) A written statement by a qualified interpreting practitioner that there has been no clinically significant evidence of fracture healing during the period when the images were taken.

(6) Payment may be made for either an electrical or an ultrasonic osteogenesis stimulator for an individual who is younger than twenty-one years of age only if all of the following additional criteria are also met:

(a) There is radiological documentation that skeletal maturity has been attained;

(b) The fracture gap is not greater than one half of the diameter of the bone to be treated; and

(c) The fracture does not involve a vertebra.

(B) Constraints and limitations.

(1) Possible contraindications to treatment include but are not limited to the following non-exhaustive list of examples:

(a) Fracture of a short bone, a flat bone, or an epiphysis;

(b) Fracture that results from cancer;

(c) Fracture that needs additional reduction or is comminuted;

(d) Fracture with post-reduction displacement of greater than fifty per cent;

(e) Fracture gap greater than one centimeter or greater than one half of the diameter of the bone;

(f) Avascularity, vascular insufficiency, or other vascular problems (e.g., thrombophlebitis);

(g) Severe osteoporosis;

(h) The taking of medication that may interfere with or alter bone metabolism and healing;

(i) Paget's disease, renal disease, or diabetes;

(j) Sensory paralysis; or

(k) Synovial pseudarthrosis.

(2) Payment will not knowingly be made for an electrical osteogenesis stimulator used in proximity to vital equipment, such as a pacemaker, that may be adversely affected by changes in electromagnetic fields.

(3) Separate payment will not be made for the concurrent use of more than one osteogenesis

stimulator on the same fracture site.