5160-10-06 **DMEPOS: wearable cardioverter-defibrillators**.

(A) Prescribing provider. Only a physician experienced in the management of patients at risk for sudden cardiac death (SCD), such as a cardiologist, electrophysiologist, or cardiac surgeon, may prescribe a wearable cardioverter-defibrillator (WCD).

(B) Coverage.

- (1) Separate payment may be made for a WCD furnished to a resident of a long-term care facility (LTCF).
- (2) Payment may be made for a WCD on a rental basis only.
- (3) The default certificate of medical necessity (CMN) is form ODM XXXXX, "Certificate of Medical Necessity: Wearable Cardioverter-Defibrillators" (7/2021).
- (4) A completed CMN confirms that the following criteria are met:
 - (a) The individual is at high risk of SCD, established by the occurrence or presence of medically indicated factors including but not limited to the following examples:
 - (i) A documented episode of ventricular fibrillation or sustained ventricular tachyarrhythmia lasting at least thirty seconds, either spontaneous or induced during an electrophysiologic (EP) study but not attributable to a transient or reversible cause and not occurring within the first forty-eight hours after an acute myocardial infarction;
 - (ii) Familial or hereditary conditions with a high risk of life-threatening ventricular tachyarrhythmia, such as long QT syndrome or hypertrophic cardiomyopathy; or
 - (iii) <u>Recent myocardial infarction, dilated cardiomyopathy, newly</u> <u>diagnosed non-ischemic cardiomyopathy, coronary artery bypass</u> <u>graft (CABG), or percutaneous coronary intervention (PCI), with a</u> <u>left ventricular ejection fraction (measured during either the acute</u> <u>or post-acute phase) of not greater than thirty-five per cent; and</u>
 - (b) Treatment of the individual with an implantable cardioverter-defibrillator (ICD) is precluded by any of the following considerations:

(i) A currently implanted ICD needs to be explanted;

- (ii) An infection prevents initial implantation of an ICD; or
- (iii) <u>Some condition or circumstance, either temporary or permanent,</u> <u>contraindicates ICD implantation surgery.</u>
- (c) The individual is able to wear a properly fitted WCD at least ninety per cent of the time (an average total of at least twenty-one and a half hours per day).
- (5) A WCD is generally covered for a period of ninety days at a time. Additional ninety-day coverage periods may be authorized if the provider submits documentation, such as a detailed statement signed by the treating physician that the WCD continues to be medically necessity and the individual continues to use it correctly. Authorization may be given for indefinite (lifetime) coverage if the provider submits appropriate documentation, such as a detailed statement signed by the treating physician and a description of the circumstances that preclude future implantation of an ICD.
- (6) <u>Rental payment includes necessary replacement of batteries, electrodes, and the cover garment.</u>

Effective:

Five Year Review (FYR) Dates:

Certification

Date

Promulgated Under:	119.03
Statutory Authority:	5164.02
Rule Amplifies:	5164.02