Automatic External Defibrillators

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury, or improve the functioning of a malformed body member
3. Meet all other applicable The Health Plan statutory and regulatory requirements

For the items addressed in this medical policy, the criteria for "reasonable and necessary" is defined by the following indications and limitations of coverage and/or medical necessity. *Please refer to individual product lines, and certificates of coverage for possible exclusions of benefits.*

Suppliers are to follow The Health Plan requirements for precertification, as applicable.

Automatic external defibrillators require precertification and physician face-to-face.

National Coverage Determination Policy	None
Local Coverage Determination Policy	**J-B/C**
Effective Date	**For services performed on or after 01/01/11**
Review/Revision Date	**01/2019, 10/2018, 5/2018, 04/2017 , 02/16/2016, 05/01/2014**
The Health Plan	Plans will follow Coverage Determination posted on the CGS website unless otherwise indicated in sections of this policy, contractual agreements, or benefit plan documents. **West Virginia Medicaid:** See The Health Plan Compensation Guide for possible non-covered item E0617

DESCRIPTION

An automatic external defibrillator or AED is an electronic apparatus used to counteract atrial or ventricular fibrillation by application of a brief electric shock to the heart. This policy refers a portable defibrillator (wearable or nonwearable) designed to be automated such that it can be used by persons without substantial medical training who are responding to a cardiac emergency.

COVERAGE GUIDELINES

Automatic external defibrillators are covered for members at high-risk for sudden cardiac death (SCD) due to one of the conditions described under I or II below. It is expected the ordering physician be experienced in the management of patients at risk for SCD.

I. A wearable defibrillator (K0606) is covered for patients if they meet one of the criteria 1-4 and criterion 5 as described below:
   1. A documented episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia. These dysrhythmias may be either spontaneous or induced during an electrophysiologic (EP) study, but may not be due to a transient or reversible cause and not occur during the first 48 hours of an acute myocardial infarction or
   2. Familial or inherited conditions with high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy; or
   3. Either documented prior myocardial infarction, or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 0.35; or
   4. A previously implanted defibrillator now requires explanation
   5. Member had a face-to-face that meets the Affordable Care Act guidelines.

II. A nonwearable automatic defibrillator (E0617) is covered for members in two circumstances. They meet either criteria A and B or, criteria C below:
   A. The member has one of the following conditions (1-8):
      1. A documented episode of cardiac arrest due to ventricular fibrillation, not due to a transient or reversible cause
      2. A sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia, either spontaneous or induced during an electrophysiologic (EP) study, not associated with acute myocardial infarction and not due to a transient or reversible cause
      3. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrythmias such as long QT syndrome or hypertrophic cardiomyopathy.
      4. Coronary artery disease with documented prior myocardial infarction with measured left ventricular ejection fraction less than or equal to 0.35, and inducible, sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) during an EP study. To meet this criterion:
         a. The myocardial infarction must have occurred more than four weeks prior to the external defibrillator prescription; and
         b. The EP test must have been performed more than four weeks after the qualifying myocardial infarction.
      5. Documented prior myocardial infarction and a measured left ventricular ejection fraction less than or equal to 0.30.

         Members must not have:
         a. Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; or
         b. Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within the past three months; or
         c. Had an enzyme-positive MI within the past month; or

   d. Clinical symptoms or findings that would make them a candidate for coronary revascularization; or
   e. Irreversible brain damage from preexisting cerebral disease; or
   f. Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than one year.
6. Members with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI), New York Heart Association (NYHA) Class II and III heart failure and measured left ventricular ejection fraction (LVEF) ≤ 35 percent.
7. Members with nonischemic dilated cardiomyopathy (NIDCM) > three months, NYHA Class II and III heart failure, and measured LVEF ≤ 35 percent.
8. Members who meet one of the previous 1-7 criteria and have NYHA Class IV heart failure.

B. Implantation surgery is contraindicated.
C. A previously implanted defibrillator now requires explanation.

Claims for defibrillators for any other indications will be denied.

NONCOVERAGE STATEMENT

AED will not be covered for failure to meet guidelines above**.**

E0617-External Defribrillator with integrated electrocardiogram analysis is not covered under West Virginia Medicaid Plans.

REPAIR, REPLACEMENT, AND REASONABLE USEFUL LIFETIME

Supplies are not separately payable during rental period.

Repair and replacement is the responsibility of the provider during the rental period**.**

A wearable automatic defibrillator is usually required for 3-4 months. Need after 6 months will need specific well documented information as to why an implantable defibrillator is contraindicated.

CODING INFORMATION

CPT/HCPCS codes: The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS

EY	**NO PHYSICIAN OR OTHER HEALTH CARE PROVIDER ORDER FOR THIS ITEM OR SERVICE**

GA	WAIVER OF LIABILITY STATEMENT ISSUED AS REQUIRED BY PAYOR POLICY, INDIVIDUAL CASE
GZ	ITEM OR SERVICE EXPECTED TO BE DENIED AS NOT REASONABLE AND NECESSARY
KF	ITEM DESIGNATED BY FDA AS CLASS III DEVICE
KX	REQUIREMENTS SPECIFIED IN THE MEDICAL POLICY HAVE BEEN MET

HCPCS CODES

A9999	MISCELLANEOUS DME SUPPLY OR ACCESSORY, NOT OTHERWISE SPECIFIED
E0617	EXTERNAL DEFIBRILLATOR W/INTEGRATED ELECTROCARDIOGRAM ANALYSIS
K0606	AUTOMATIC EXTERNAL DEFIBRILLATOR W/INTEGRATED ELECTROCARDIOGRAM ANALYSIS, GARMENT TYPE
K0607	REPLACEMENT BATTERY FOR AUTOMATED EXTERNAL DEFIBRILLATOR, GARMENT TYPE ONLY, EACH
K0608	REPLACEMENT GARMENT FOR USE WITH AUTOMATED EXTERNAL DEFIBRILLATOR, EACH
K0609	REPLACEMENT ELECTRODES FOR USE WITH AUTOMATED EXTERNAL DEFIBRILLATOR, GARMENT TYPE ONLY, EACH

The presence of an ICD-10 code listed in the following section is not sufficient by itself to assure coverage. Refer to the coverage guidelines and documentation requirements section for other coverage criteria.

ICD-10 CODES FOR E0617

I21.01-I21.4	ST ELEVATIONS (STEMI) MYOCARDIAL INFARCTION AND NON-ST ELEVATION (NSTEMI)MYOCARDIAL INFARCTION
I22.0-I22.9	SUBSEQUENT ST(STEMI) AND NON-ST ELEVATION(NSTEMI) MYOCARDIAL INFARCTION
I25.2	OLD MYOCARDIAL INFARCTION
I42.1-I42.2	HYPERTROPHIC CARDIOMYOPATHY OBSTRUCTIVE OR OTHER
I45.81	LONG QT SYNDROME
I46.2-I46.9	CARDIAC ARRESTS
I47.0	RE-ENTRY VENTRICULAR RYTHYM

I47.2	VENTRICULAR TACHYCARDIA
I49.01	VENTRICULAR FIBRILLATION
I49.02	VENTRICULAR FLUTTER
T82.110A-T82.199A	MECHANICAL COMPLICATIONS OF AUTOMATIC IMPLANTABLE CARDIAC DEFIBRILLATOR THRU OTHER MECHANICAL COMPLICATION OF UNSPECIFIED CARDIAC DEVICE,INITIAL ENCOUNTER
T82.6XXA-T82.7XXA	INFECTION AND INFLAMMATORY REACTION DUE TO CARDIAC VALVE PROSTHESIS THRU IMPLANTS AND GRAFTS, INITIAL ENCOUNTER

ICD-10 CODES FOR K0606 - K0609

A18.84	Tuberculosis of heart
I21.01	ST elevation (STEMI) myocardial infarction involving left main coronary artery
I21.02	ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery
I21.09	ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall
I21.11	ST elevation (STEMI) myocardial infarction involving right coronary artery
I21.19	ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall
I21.21	ST elevation (STEMI) myocardial infarction involving left circumflex coronary artery
I21.29	ST elevation (STEMI) myocardial infarction involving other sites
I21.3	ST elevation (STEMI) myocardial infarction of unspecified site
I21.4	Non-ST elevation (NSTEMI) myocardial infarction
I22.0	Subsequent ST elevation (STEMI) myocardial infarction of anterior wall
I22.1	Subsequent ST elevation (STEMI) myocardial infarction of inferior wall
I22.2	Subsequent non-ST elevation (NSTEMI) myocardial infarction
I22.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites
I22.9	Subsequent ST elevation (STEMI) myocardial infarction of unspecified site
I25.2	Old myocardial infarction

I42.0	Dilated cardiomyopathy
I42.1	Obstructive hypertrophic cardiomyopathy
I42.2	Other hypertrophic cardiomyopathy
I42.3	Endomyocardial (eosinophilic) disease
I42.4	Endocardial fibroelastosis
I42.5	Other restrictive cardiomyopathy
I42.6	Alcoholic cardiomyopathy
I42.7	Cardiomyopathy due to drug and external agent
I42.8	Other cardiomyopathies
I42.9	Cardiomyopathy, unspecified
I43	Cardiomyopathy in diseases classified elsewhere
I45.81	Long QT syndrome
I46.2	Cardiac arrest due to underlying cardiac condition
I46.8	Cardiac arrest due to other underlying condition
I46.9	Cardiac arrest, cause unspecified
I47.0	Re-entry ventricular arrhythmia
I47.2	Ventricular tachycardia
I49.01	Ventricular fibrillation
I49.02	Ventricular flutter
T82.110A	Breakdown (mechanical) of cardiac electrode, initial encounter
T82.111A	Breakdown (mechanical) of cardiac pulse generator (battery), initial encounter
T82.118A	Breakdown (mechanical) of other cardiac electronic device, initial encounter
T82.119A	Breakdown (mechanical) of unspecified cardiac electronic device, initial encounter
T82.120A	Displacement of cardiac electrode, initial encounter
T82.121A	Displacement of cardiac pulse generator (battery), initial encounter
T82.128A	Displacement of other cardiac electronic device, initial encounter
T82.129A	Displacement of unspecified cardiac electronic device, initial encounter

T82.190A	**Other mechanical complication of cardiac electrode, initial encounter**
T82.191A	**Other mechanical complication of cardiac pulse generator (battery), initial encounter**
T82.198A	**Other mechanical complication of other cardiac electronic device, initial encounter**
T82.199A	**Other mechanical complication of unspecified cardiac device, initial encounter**
T82.6XXA	**Infection and inflammatory reaction due to cardiac valve prosthesis, initial encounter**
T82.7XXA	**Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, initial encounter**

Diagnoses and ICD-10 codes that either support or do not support medical necessity are listed above.
NOTE: The ICD-10 code that justifies the need for these items must be included on the claim.

DOCUMENTATION REQUIREMENTS

For the purposes of this policy, it is expected that the medical record will support the need for the care provided. It is generally understood that the medical record includes the physician's office records, hospital records, nursing home records, home health agency records, records from other health care professionals and test reports.

This documentation must be available with precertification.

Medicare has made changes to its requirements for dispensing orders, detailed written orders, and proof of delivery. The Health Plan will require the following:

1. Physician detailed written order. Order must include the following:
    a. Member's name
    b. Date of order and date of face-to-face
    c. Description of item. The medical record must contain the information that supports the request for each item and must be submitted with the precertification if the item requires precertification, or with the claim, if no precertification was required
    d. Order must include diagnosis code
    e. Physician signature with date. Date stamps are not appropriate
    f. Quantity of items required and duration. A new order is required if there is an increase in the quantity of the supply used per month and/or the type of supply used.
    The supplier is to contact The Health Plan in this instance to update referral.

2. There must be documentation in the supplier's records to support the medical necessity of that item. This information must be available upon request usually with precertification per The Health Plan policy.
3. Proof of delivery to be kept on file by the provider of the item.

    Note: If templates or forms are submitted, (i.e., a Medicare Certificate of Medical Necessity, and/or a provider created form), The Health Plan reserves the right to request the medical record, that may include, but not limited to, the physician office notes, hospital and nursing

facility records, and home health records.

Note: Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician.

Precertification is required when supplies used are greater than the usual maximum quantity listed in above. There must be adequate, clear documentation in the medical record corroborating the medical necessity of this amount. This documentation is to be submitted with precertification.

AED PROVIDED WHILE MEMBER IN PART A FACILITY

Reimbursement for a wearable AED provided to a member while the member is covered in a Part A facility is based on specific contract information with the individual facility, and whether or not the device is intended for use while the member is in the facility.

An AED should not be billed under DME benefit while in an acute hospital stay.

EQUIPMENT RETAINED FROM A PRIOR PAYOR:

The Health Plan will not pay in excess of the contracted purchase price for any item in this policy. If the provider is seeking payment from The Health Plan, the item must be precerted and The Health Plan will pay the remaining rental months up to purchase price- if member meets guidelines above.

DISPENSING SUPPLIES

The Health Plan is following Medicare guidelines for supplies provided on reoccurring basis:

Providers are required to contact members prior to dispensing supplies and/or medications and not automatically ship supplies. Contact with member must not take place prior to 14 calendar days of delivery and delivery is to be no sooner than 10 calendar days of end of usage.

KX, GA, and GZ MODIFIERS

Suppliers may submit a claim with a KX modifier only if all the criteria for that item is met.

If coverage criteria are not met, the GA or GZ modifier must be used. When there is an expectation of a medical denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier, if they have not obtained a valid ABN.

ADVANCED BENEFICIARY STATEMENT

The Health Plan expects providers to follow the Medicare policy on ABN across all Medicare, Medicaid, and Commercial plans.

NOTE: Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or ABN to The Health Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN are not acceptable.

PRICING, DATA ANALYSIS, AND CODING (PDAC)

The Health Plan has implemented use of Medicare's PDAC contractor for review of authorizations. Suppliers should contact the PDAC contractor for guidance on the correct coding of these items. dmepdac.com/

MEDICARE DEFINITIONS AND DESCRIPTION OF CODES

Myocardial infarctions are defined by elevated cardiac enzymes or Q-waves on an electrocardiogram.

Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography.

Transient or reversible causes include conditions such as drug toxicity, severe hypoxia, acidosis, hypokalemia, hypercalcemia, hyperkalemia, systemic infections, and myocarditis (not all-inclusive).

Automatic defibrillators are devices that are capable of monitoring cardiac rhythms, detecting dysrhythmias, and delivering a defibrillation shock to the heart ,when appropriate, without any user decision making.

Nonwearable, automatic external defibrillators with integrated electrocardiogram capability are coded using HCPCS code E0617.

Wearable, automatic, external defibrillators with integrated electrocardiogram analysis are coded using HCPCS code K0606.

Other types of defibrillators are coded as A9270. No separate payment is made for carrying cases or mounting hardware.

Replacement supplies and accessories for use with K0606 are coded using K0607–K0609, as appropriate.

Replacement supplies and accessories for use with K0617 are coded using A9999.

The KF modifier is to be added to claim lines for codes K0606 and E0617, only if the device is classified by the Food and Drug Administration (FDA) as a Class III device.

AMA CPT/ADA CDT COPYRIGHT STATEMENT

INTERNET LINKS AND SOURCES

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