MVP HEALTH CARE

MEMORANDUM

TO: Senate Health and Welfare Committee
FROM: Susan Gretkowski, MVP Health Care
DATE: March 7, 2013
RE: S.44 Comments

Thank you for allowing us to submit these written comments on S.44. We will testify on this bill Wednesday, March 13, 2013.

MVP's overall comment is that this bill is not necessary, that virtually all what is in it is already required by law or is in place.

Section 1: This contains definitions of urgent health service and adverse determination. These are already defined in and required by DFR Rule H-2009-03. Relevant sections attached.

Section 2: This requires insurers to list the services requiring prior authorization and the clinical criteria on its website. MVP already does this.

It then goes on to require insurers to put on their website data regarding the number and frequency of prior authorization requests, average time to make a determination, number of denials and summary of reasons for the denials. Act 171 passed last session set the time period within which an insurer must make a prior authorization decision: 48 hours for urgent requests and 120 hours for non-urgent. As for the posting of the other data elements, we are not sure what this would accomplish. Services requiring prior authorization change all the time as our medical directors look at utilization patterns and make adjustments. Some prior authorization requirements last only a few months and then are removed if utilization shows it is not necessary. As new services or drugs come on line, prior authorization may be implemented until utilization trends are known and we can evaluate whether we need to continue prior authorization. There would be no way to do any kind of apples to apples comparisons from one time period to the next or between insurers.

Subsection (e) lists the criteria insurers must use to make prior authorization determinations. Again, this is already defined in and required by Rule H-2009-03, which is attached. Also attached is a sample of one of our benefit interpretation policies showing the criteria MVP relies on to make this benefit determination.

Subsection (f) requires adverse determinations to be made by a physician. Again, this is already required by H-2009-03, which is attached.

Subsection (h)(5) would require an insurer to assign a unique electronic identification number to each request so the provider can track the request. MVP already has in place a mechanism for providers to track requests on the provider section of our website.

It may be helpful to understand when prior authorization is required and why it is used. Prior authorization is not required for all services. It is reserved for a relative small set of services under certain circumstances. For example, the place of service – is the requested location the most cost-effective? Sleep studies is an example. Sleep studies can be performed in the home or in the hospital setting. Providers and patients prefer them to be done in the home, however, some patients have co-conditions that require them to be in the hospital. Studies done in the home cost significantly less than those done in the hospital. Therefore, MVP requires prior authorization only for hospital sleep studies.

Another criteria for applying prior authorization associated with place of service is for highly technical or rare services, such as bariatric surgery. There are stringent requirements around where and how bariatric surgery is done, and we require that it only be done in facilities that do a large volume and are high quality. This is for the protection of the patient.

Prior authorization is also used when an out-of-network provider's services are requested, or for very high cost services, or to determine if the service is in fact a covered service. An example is the so-called tummy tuck. This is normally a non-covered service as it is cosmetic. However, there are a few situations where it would be medically necessary and would be covered. This amounts to a protection for our members – they will know before having the service whether it will be covered. The alternative is for there to be no prior authorization and then have the claim denied and the members having to pay the full bill.

Prior authorization is not required for a primary care physician to refer a patient to a specialist, except to an out-of-network specialist.

For these reasons we do not see the need for the bill as it will add nothing to what is already in place.

STATE OF VERMONT
Department of Banking, Insurance, Securities
And Health Care Administration

Division of Health Care Administration

Rule H-2009-03

Consumer Protection and Quality Requirements for Managed Care Organizations

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under contract with managed care organizations, when they issue and/or participate in administering comprehensive major medical health benefit plans and products subject to the Department's jurisdiction that:

1. Use utilization management mechanisms and financial incentives for members to use certain providers; and

2. Have 10,000 or more covered lives.

The Department in its sole discretion may choose to waive parts of the requirements in Part 6 for these managed care organizations and mental health review agents.

(F) Each managed care organization, including a mental health review agent and any delegate subject to this rule, in whole or in part, is accountable for ensuring that it operates in compliance with all applicable requirements of 18 V.S.A. § 9414 and 8 V.S.A. §§4089a, 4089b, and 4724, this rule, and any other applicable laws and rules, regardless of whether it is functioning as a delegate or the delegating entity. If a managed care organization delegates any activities or functions to other persons or entities, the managed care organization may not delegate its responsibility for the activities or functions, is accountable for ensuring that its delegates operate in compliance with all applicable requirements and shall maintain effective oversight of those activities, which shall include:

1. A written description of the delegate's activities and responsibilities, including reporting requirements;

2. Evidence of formal approval of the delegate's program by the managed care organization; and

3. A process by which the managed care organization at least annually evaluates the performance of the delegate and any sub-delegates, including but not limited to a process by which the managed care organization documents, tracks, addresses and resolves complaints from members and providers regarding the delegate's conduct and/or the conduct of any other managed care organization that performs any activities on its behalf.

1.4 Definitions.

(A) "Adverse benefit determination" means a denial, reduction, modification or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit, including but not limited to:

1. a denial, reduction, termination or failure to provide or make payment that is based on a determination of a participant's or beneficiary's eligibility to participate in a health benefit plan;

2. a denial, reduction, modification or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit resulting from the application of any utilization review; and

3. a failure to cover an item or service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate.

(B) "Blueprint for Health" means the state's plan for chronic care infrastructure, prevention of chronic conditions, and chronic care management program, and includes an integrated approach to patient self-management, community development, health care system and professional practice change, and information technology initiatives.

(C) "Case management" means a coordinated set of activities conducted to support the member and his/her health care provider in managing serious, complicated, protracted or other health conditions.

(D) "Chronic care" means health services provided by a health care professional for an established clinical condition that is expected to last a year or more and that requires ongoing clinical management attempting to restore the individual to highest function, minimize the negative effects of the condition, and prevent complications related to chronic conditions. Examples of conditions that are or may be considered chronic include diabetes, hypertension, cardiovascular disease, cancer, asthma, pulmonary disease, substance abuse, mental illness, spinal cord injury, and hyperlipidemia.

(E) "Chronic care management" means a system of coordinated health care interventions and communications for individuals with chronic conditions, including significant patient self-care efforts; systemic supports for the physician and patient relationship; and a plan of care emphasizing prevention of complications utilizing evidence-based practice guidelines, patient empowerment strategies, and evaluation of clinical, humanistic, and economic outcomes on an ongoing basis with the goal of improving overall health.

(F) "Clinical peer" means a health care provider in a specialty that typically provides the procedure or treatment, or diagnoses or manages the medical condition under review and who holds a non-restricted license in a state of the United States.

(G) "Clinical review criteria" means the written screening procedures, clinical protocols, practice guidelines and utilization management and review guidelines used by the managed care organization to determine the necessity and appropriateness of health care services.

(H) "Commissioner" means the commissioner of the Vermont Department of Banking, Insurance, Securities and Health Care Administration or his or her designee.

(I) "Concurrent review" means utilization review conducted during a member's stay in a hospital or other facility, or other ongoing course of treatment.

medical probability, that no material deterioration of the condition is likely to result from discharge or to occur during transfer.

(HHH) "Step therapy" means a type of protocol that specifies the sequence in which different prescription drugs are to be tried for treating a specified medical condition.

(III) "Urgently-needed care" or "urgent care" means those health care services that are necessary to treat a condition or illness of an individual that if not provided promptly (within twenty-four hours or a time frame consistent with the medical exigencies of the case) presents a serious risk of harm.

(JJJ) "Utilization management" means the set of organizational functions and related policies, procedures, criteria, standards, protocols and measures used by a managed care organization or pharmaceutical benefit management program to ensure that it is appropriately managing access to and the quality and cost of health care services, including prescription drug benefits, provided to its members.

(KKK) "Utilization review" means a set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings, including prescription drugs.

(LLL) "Utilization review guidelines" mean the normative standards and clinical review criteria for resource utilization for various clinical conditions and medical services that are used by managed care organizations in deciding whether to approve or deny health care services.

1.5 Confidentiality of Quality Management and Peer Review Information.

(A) Except as otherwise required by 18 V.S.A. § 9414, each managed care organization shall take the appropriate steps necessary to ensure that information gathered by it in its peer review and quality management activities, including those conducted in relation to credentialing, recredentialing and associated monitoring, shall be maintained as confidential and privileged.

(B) Peer review, quality management and other similar information made available to the Department or other designated organizations under 18 V.S.A. § 9414(f)(2) shall be furnished in a manner that does not disclose the identity of individual patients, health care providers or other individuals, unless otherwise specified by the Department.

(C) The minutes or records of the peer review or quality management committee formed under Parts 5 or 6 of this rule are confidential and privileged under 26 V.S.A. § 1443, except as otherwise provided in 18 V.S.A. § 9414(f)(2) and this rule.

(D) The Department's confidentiality code shall apply to the collection and review of information by the Department or its designated organization under 18 V.S.A. § 9414 and this rule.

utilization management activities and reports to the managed care organization's governing body; and

10. The staff position functionally responsible for the day-to-day management of the utilization management function.

(C) Each managed care organization's utilization management program shall use documented utilization review guidelines that are informed by generally accepted medical and scientific evidence and consistent with clinical practice parameters as recognized by health care professions in the same specialties as typically provide the procedure or treatment, or diagnose or manage the medical condition. The managed care organization shall demonstrate to the satisfaction of the Commissioner that the utilization review guidelines have been periodically reviewed and updated, taking into account input from practicing physicians and other health care providers, including providers under contract with the managed care organization, if any. Relevant utilization review guidelines shall be made available to all providers under contract with the managed care organization, if any, and shall be made available to members and any of their treating providers upon request. With respect to utilization review guidelines for services related to mental health and/or substance abuse conditions and disorders, the Commissioner may consult with the Vermont Department of Health, the Vermont Department of Mental Health and/or other clinical experts in mental health and substance abuse conditions and disorders in assessing compliance with this subsection. This subsection shall not be construed to require managed care organizations to make modifications to nationally-recognized guidelines based on input from their contracted providers.

(D) Utilization management mechanisms shall:

1. not deter timely access to or compromise the effectiveness of medically necessary care for any condition;

2. not result in any compromise to a member's safety;

3. be of a nature, frequency and periodicity that is clinically reasonable in view of the diagnosis or condition generally, the nature of the service(s) under review and, with respect to concurrent review or other review during an ongoing course of treatment, that takes into account the member's past history, current condition and progress during the course of treatment; and

4. take into account and make reasonable accommodations when a member's condition impacts the member's ability to follow utilization management procedures.

(E) In addition to the other requirements in this part, utilization management mechanisms applied to mental health and/or substance abuse benefits shall:

2. All determinations to deny, limit, reduce, terminate or modify an admission, service, procedure or extension of stay are rendered by a physician under the direction of the medical director responsible for medical services provided to the managed care organization's members, except when the denial is based on eligibility for coverage or is a denial of a service that is clearly excluded from coverage and that could not in any way be considered an appealable decision pursuant to 8 VSA §4089f or any other Vermont laws or rules regarding independent external review.

3. If services that require prior authorization have been authorized and the services are either currently being provided to a member in a health care facility or are another type of ongoing course of treatment and the treating provider has determined that it is medically necessary for the ongoing course of treatment to continue without disruption or delay, the services shall continue to be covered until:

   a. the exhaustion of all internal expedited grievances, if requested within twenty-four (24) hours of receipt of the denial(s); or until the independent external review decision is issued, if expedited independent external review is requested within twenty-four (24) hours of the receipt of the final grievance decision and notice of appeal rights by the member and is conducted in accordance with the time frames specified by law; and

   b. the managed care organization has authorized coverage for a medically safe and appropriate discharge or transition plan developed after consultation with the member's treating health care provider or the treating health care provider's designee. For purposes of this subsection, a treating health care provider may select a hospital discharge planner as his or her designee.

4. If the denial is upheld by an independent external review conducted pursuant to Vermont law, the managed care organization is not responsible for payment for the services that were the subject to the independent external review beyond the date the independent external review decision is issued. If the member nonetheless elects to continue the current level of treatment, the managed care organization may require that the member or treating provider contact the managed care organization in advance of discharge for the purpose of initiating utilization management regarding the discharge plan described in Subsection 3.b. above.

5. Except in cases where there was material misrepresentation or fraud, the managed care organization shall not retroactively deny or limit reimbursement for the services described below. Nothing in this subsection prohibits managed care organizations from requiring utilization management mechanisms permitted by law or from communicating those requirements to members.

MVP HEALTH CARE

MVP Health Care Medical Policy

Implantable Cardioverter Defibrillators, Implantable Dual Chamber Automatic Defibrillators, Cardiac Resynchronization Devices

Type of Policy:	Surgical
Prior Approval Date:	03/14/2011
Approval Date:	04/09/2012
Effective Date:	06/01/2012
Related Polices:	Cardiac Output Monitoring by Thoracic Electrical Bioimpedance

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes: 33216, 33217, 33225, 33230, 33231, 33240, 33249

HCPCS Codes: G0448

Codes Subject to Retrospective Review

CPT Codes: N/A

Experimental/Investigational

Experimental codes are not covered.

N/A

Common Diagnosis Codes

ICD-9 Diagnosis Codes: 425.1, 426.2, 426.3, 426.4, 426.50, 426.51, 426.52, 426.53, 427.1, 427.41, 427.42, 427.5, 427.31, 428.0, 428.1, 428.9, V12.50

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Implantable cardioverter defibrillator (ICD) is an electronic device designed to detect and treat life-threatening

tachyarrhythmia. The device consists of a pulse generator and electrodes for sensing dual chamber or single chamber and defibrillator. ICDs are indicated to prevent "r;sudden death" in patients who have experienced life-threatening ventricular arrhythmias such as sustained ventricular tachycardia (VT) and ventricular fibrillation (VF). Recently, there have been large randomized studies that have established a significant reduction in mortality in those patients with CAD (Coronary Artery Disease) and/or prior myocardial infarction who have poor ventricular function as evidenced by an ejection fraction of 30% or less. Careful screening of candidates is necessary; the ideal candidate is one that is at high-risk of death from an arrhythmia but not death from other causes.

Biventricular pacing or Cardiac Resynchronization Therapy (CRT), using three leads (one in the right atrium and one in each ventricle), has been shown to improve hemodynamic status in patients with Congestive Heart Failure (CHF). It has been studied in patients with New York Heart Association (NYHA) Class III or IV that have intraventricular conduction disorders resulting in a discoordinated contraction pattern and a wide QRS interval on the electrocardiogram. It is estimated that 20-30% of patients with advanced heart failure may have a condition in which the ventricles are not beating in a synchronized fashion. This condition, ventricular dysynchrony, may worsen heart failure symptoms. Currently, there is no drug therapy available to correct ventricular dysynchrony. There are times when a combination CRT/ICD system is used when the member has ventricular dysfunction that may also have indications for an ICD.

Indications/Criteria

Documentation Requirements

- Medical necessity must be documented in the medical record and available upon request, including a functional classification of the member's heart failure as well as diagnostic studies (EP Studies). Myocardial infarction should be documented by elevated cardiac enzymes or Q-waves on EKG and ejection fraction should be measured by angiography, radionuclide scanning or echocardiography.
- For CRT, the treating physician must submit documentation that all medical therapies have been tried and exhausted.

Policy Criteria

Indications for Implantable Cardioverter Defibrillator (ICD) [19]

- Documented episode of cardiac arrest due to ventricular fibrillation (VF) not due to transient reversible cause (e.g., drug toxicity, electrolyte imbalance, ischemia). [22]
- Documented sustained one or more episodes of ventricular tachycardia (VT), either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (MI) and not due to transient or reversible cause. [23]
- Documented familial or inherited conditions with a high-risk of life-threatening VT, such as long QT syndrome or Brugada syndromes, hypertrophic cardiomyopathy, catecholaminergic polymorphic ventricular tachycardia and arrhythmogenic right ventricular dysplasia.
- CAD with documented prior MI, a measured left ventricular ejection fraction $\leq$ 35% and inducible, sustained VT or VF at EP study. (The MI must have occurred forty days prior to defibrillator insertion. The EP study must be done more than four weeks after qualifying MI).
- For primary prevention, Implantable Cardiac Defibrillators (ICDs) are indicated for the following:
  - members with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction, New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular

ejection fraction (LVEF) ≤ 35%;

- members with non-ischemic dilated cardiomyopathy (NIDCM), NYHA Class II and III heart failure, measured LVEF ≤ 35%, and experienced continued symptoms after maximal medical treatment including ace inhibitors and beta blockers; [21]
- members who meet all current coverage requirements for a cardiac resynchronization therapy (CRT) device and have Class IV heart failure; or
- members with documented prior MI with LVEF ≤ 30% without NYHA Class IV heart failure.

- Hypertropic cardiomyopathy with prior documentation of cardiac arrest, ventricular fibrillation, or hemodynamically significant ventricular tachycardia (VT)
- For each of the above mentioned primary prevention conditions, the following additional criteria must be met:
  - members must be able to give informed consent; and
  - members must not have:
    - cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
    - had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within the last three (3) months;
    - had an acute MI within the past 40 days;
    - clinical symptoms or findings that would make them a candidate for coronary revascularization;
    - irreversible brain damage from pre-existing cerebral disease; or
    - any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than one year;
  - ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography; or
  - myocardial infarctions must be documented and defined according to the consensus document of the Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction.

Indication for dual chamber ICD [3]

- Must meet the listed indications for ICD (noted above).
- Evidence of SA and AV nodal dysfunction, including, but not limited to, bradyarrythmia, supraventricular tachycardia (i.e., atrial fibrillation, atrial flutter, atrioventricular nodal re-entry tachycardia), bundle branch block, or long PR interval.

Biventricular pacing, resynchronization therapy are medically indicated when all criteria are met: [13]

- member has moderate to severe heart failure defined as NYHA Class III and IV; and
- left ventricular ejection fraction of < 35%; and
- electrocardiogram QRS duration >120 msec; and
- member remains symptomatic despite optimized medical therapy, includes use of an ACE inhibitor or angiontensin receptor blocker, beta-blocker, digoxin and diuretics for at least one month or more.

The use of biventricular pacemaker cardioverter is considered medically indicated when the member meets criteria for biventricular pacing as well as one of the indications for ICD implantation. [16]

Interrogation device evaluation (in person and remote) is indicated for device evaluation, pacing and sensing

thresholds, lead wire function, battery level, and recorded episodes of arrhythmia detection and device activation. [26]

Exclusions

Implantable cardioverter-defibrillators are not medically indicated when:

- other disease processes are present that clearly limit the member's life expectancy;
- member has asymptomatic VT or symptomatic VT/VF associated with acute myocardial infarction within two days, controlled by appropriate drug therapy and amenable to a definitive therapy (e.g., ablative procedure);
- clinical symptoms or findings that would make the member a candidate for revascularization;
- all members being considered for implantation of ICD must not have irreversible brain damage, disease or dysfunction that would preclude the ability to give informed consent;
- cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
- ICDs in the treatment of only chronic atrial fibrillation; or
- implantable hemodynamic cardiovascular monitoring devices (e.g., Chronicle IHM System) are considered experimental/investigational. The evidence in the medical literature does not support that these devices improve health outcomes. [18]
- interrogation device evaluation (in person and remote) for cardiac hemodynamic monitoring and thoracic bioimpedence are considered not medically necessary. Refer to the MVP Cardiac Output Monitoring by Thoracic Electrical Bioimpedance medical policy.

Medicare Variation

Implantable Cardioverter Defibrillator [7]

Members receiving the defribrillator implantation for primary prevention of sudden cardiac death conditions must be enrolled in either an FDA-approved category B investigational device exemption (IDE) clinical trial, a trial under the CMS Clinical Trial Policy, or a qualifying data collection system including approved clinical trials and registries, and must meet the additional criteria (listed above) for primary prevention conditions.

Primary prevention of sudden cardiac death conditions:

- documented familial or inherited conditions with a high-risk of life-threatening VT, such as long QT syndrome, hypertrophic cardiomyopathy;
- CAD with documented prior MI, a measured left ventricular ejection fraction < 35% and inducible, sustained VT or VF at EP study. (The MI must have occurred forty days prior to defibrillator insertion. The EP study must be done more than four weeks after qualifying MI);
- members with documented prior MI with LVEF ≤ 30% without NYHA Class IV heart failure;
- members with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction, New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular ejection fraction (LVEF) ≤ 35%;
- members with non-ischemic dilated cardiomyopathy (NIDCM) >3 months, NYHA Class II and III heart failure, and measured LVEF ≤ 35%; or
- members who meet all current coverage requirements for a cardiac resynchronization therapy (CRT) device and have Class IV heart failure.

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Member Product	Medical Management Requirements*
New York Products	