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Coverage for CRT-D

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Medicare Coverage for CRT-D

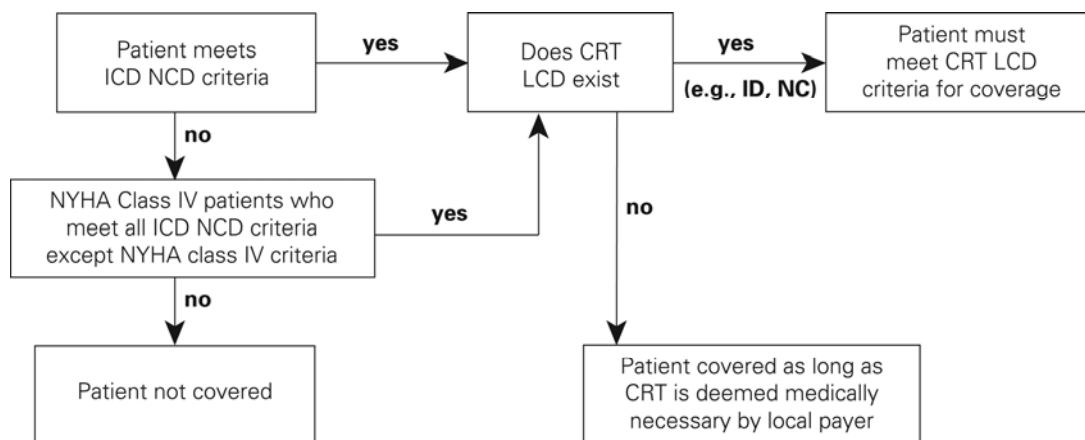
Cardiac resynchronization therapy defibrillator (CRT-D) is composed of two main functions: cardiac resynchronization therapy (CRT) and defibrillation (D). While a Medicare National Coverage Determination (NCD) for Implantable Cardioverter Defibrillators (ICDs) currently exists, there is no NCD for CRT. There is also no indication that Medicare is considering an NCD for CRT at this time.

As a result, the coverage criteria for CRT-D therapy must satisfy both:

- The NCD for ICDs¹; **and**
- Local Coverage Determinations (LCDs) for CRT, if one exists.

Note: Currently only Idaho and North Carolina have LCDs for CRT (See Table 1 for LCD details). In the absence of an LCD for CRT, the criteria under the ICD NCD should be sufficient for coverage, provided the CRT functionality is deemed reasonable and medically necessary.

A patient must meet the medical necessity requirements for the above therapies to receive benefits under the Medicare program. Also note, Medicare does not preauthorize medical procedures.



¹Centers for Medicare and Medicaid Services. National Coverage Determination for Implantable Automatic Defibrillators (20.4). In: Medicare Coverage Database. Effective January 27, 2005. Available at: <http://www.cms.hhs.gov/mcd/viewncd.asp>. Accessed September 1, 2009.



Table 1. Medicare Local Coverage Decisions

Medicare Contractor	CRT-D
NATIONAL MEDICARE COVERAGE DETERMINATIONS (LCD)	
No NCD's- Local Contractor Discretion	
MEDICARE ADMINISTRATIVE CONTRACTORS (MAC)	
Jurisdiction 1 (CA, HI, NV) Palmetto GBA	No Published LCD
Jurisdiction 3 (AK, OR, WA) Noridian	No Published LCD
Jurisdiction 4 (CO, NM, OK, TX) Trailblazers	No Published LCD
Jurisdiction 5 (IA, KS, MO, NE) Wisconsin Physician Services (WPS)	No Published LCD
Jurisdiction 9 (FL, PR, VI) First Coast Service Options (FCSO)	No Published LCD
Jurisdiction 12 (DC, DE, MD, NJ, PA) Highmark	No Published LCD
Jurisdiction 13 (CT, NY) National Government Services (NGS)	No Published LCD
Medicare Part B Carriers	
Cigna Government Services (ID, NC)	Resynchronization Therapy for Congestive Heart Failure (Bi-Ventricular Pacing) LCD² Policy #:L11585

² Centers for Medicare and Medicaid Services. LCD for Resynchronization Therapy for Congestive Heart Failure (Biventricular Pacing) (L12193). Effective May 1, 2007. Available at: http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=12193&lcd_version=18&show=all. Accessed September 1, 2009.



Medicare Contractor	CRT-D
	<p>Effective Date: 5/1/07 Updated Date: 9/23/08</p> <p>Indications and Limitations of Coverage and/or Medical Necessity Biventricular pacing or resynchronization therapy is a non-pharmacological treatment modality for patients with advanced heart failure. Its rationale is based on the observation that intraventricular conduction defects (IVCD) are associated with dysynchronization between the left and the right ventricle resulting in decreased cardiac performance. In biventricular pacing, the right and left ventricle are activated simultaneously. In addition to the right atrial and right ventricular leads, a dedicated lead is required to pace the left ventricle. The latter is positioned via the coronary sinus.</p> <p>Resynchronization therapy will be considered as medically reasonable and necessary if:</p> <ul style="list-style-type: none"> • The patient is symptomatic despite optimal medical therapy with ACE (angiotensin converting enzyme) inhibitors and beta blockers as well as other appropriate pharmacologic measures; and • The patient has symptoms of moderate to severe congestive heart failure (NYHA Functional Class III or IV); and • The patient has a left ventricular ejection fraction of <35%; and • The QRS duration is ≥ 130 milliseconds. <p>All four provisions must be met and documented. Although patients with a left ventricular end diastolic diameter (LVEDD) of 55 mm or greater are the group for which data suggests optimum clinical improvement, this will not be used as an exclusionary criterion when all the other requirements have been satisfied. As long as documented in the medical record, a patient's intolerance or inability to take ACE inhibitors or beta blockers does not disqualify her/him for resynchronization therapy.</p> <p>For the initial implantation, a dedicated system must be used that is Food and Drug Administration (FDA) approved for this particular indication. Based on the individual patient situation, this carrier will consider the upgrade of previously implanted devices, as long as they are FDA approved.</p> <p>For the implantation of a biventricular pacing implantable cardiac defibrillator (ICD), all coverage criteria for the implantation of the ICD must be met first (CMS Manual System, Pub. 100-3, National Coverage Decisions, Ch. 1, section 20.4), in addition to all of the requirements for synchronized biventricular pacing. Documentation supporting this must be recorded in the medical record and available upon request.</p> <p>Resynchronization therapy is denied as not reasonable and necessary if these coverage criteria are not met.</p>
Cahaba GBA (AL, GA, MS, TN)	No Published LCD
National Government Services (IN)	No Published LCD



Medicare Contractor	CRT-D
NHIC (MA, ME, NH, RI, VT)	No Published LCD
Noridian (AZ, MT, ND, SD, UT, WY)	No Published LCD
Palmetto GBA (OH, SC, WV)	No Published LCD
Pinnacle (AR, LA)	No Published LCD
Wisconsin Phys Svcs (Part B: IL, MI, WI, MN)	No Published LCD



Private Payer Coverage for CRT-D

Coverage for CRT-D therapy will vary by non-Medicare private payer. As such, it is best to determine the coverage for each patient prior to rendering medical services. The most effective way to determine whether coverage for a non-Medicare patient is available for the hospital and physician costs is for the provider to research the patient's coverage by contacting the payer regarding whether or not there is a coverage policy for CRT-D. Table 2 lists the coverage criteria for many of the top insurers in the United States for CRT-D therapy.

In many cases, providers may be required to submit a formal request for preauthorization of benefits prior to scheduling procedures. Preauthorization helps to clarify benefits and payment rates in advance, allowing both the provider and patient to make informed decisions about their care. The one exception to this general rule is Medicare. Medicare does not preauthorize medical procedures.

Table 2. Private Payer Policies

Private Payers	
UnitedHealth Group, Inc.	<p>No Published LCD</p> <p>Total Plan Enrollment: 32,702,445</p>
WellPoint, Inc. (licensed subsidiaries: CO, CT, GA, IN, KY, ME, MI, NV, NH, OH, VI, WI)	<p>Cardiac Resynchronization Therapy (CRT) with or without an Implantable Cardioverter Defibrillator (CRT/ICD) for the Treatment of Heart Failure³</p> <p>Total Plan Enrollment: 30,622,381</p> <p>Policy #: SURG.00064 Current Effective Date: 4/22/09 Last Review Date: 2/26/09</p> <p>Wellpoint Anthem considers FDA-approved biventricular pacemakers for cardiac resynchronization therapy (CRT) medically necessary for individuals who meet all of the following criteria:</p> <ul style="list-style-type: none"> • NYHA functional Class III or ambulatory Class IV symptoms, secondary to heart failure who remain symptomatic despite recommended, optimal medical therapy;* and • Who have cardiac dyssynchrony, (which is currently defined as a QRS duration > 120 ms); and • Left ventricular ejection fraction (LVEF) less than or equal to 35%; and • Are in sinus rhythm. <p>The use of an FDA- approved ICD, in combination with cardiac resynchronization therapy (CRT/ICD), is considered medically necessary when the criteria listed above for CRT therapy AND the criteria within SURG.00033 Implantable Cardioverter Defibrillators (ICD) are met.</p>

³ Anthem. Medical Policy: Cardiac Resynchronization Therapy (CRT) with or without an Implantable Cardioverter Defibrillator (CRT/ICD) for the Treatment of Heart Failure. Effective April 22, 2009. Available at: http://www.anthem.com/medicalpolicies/policies/mp_pw_a053365.htm. Accessed September 1, 2009.



	<p>Implantable Cardioverter-Defibrillator (ICD)⁴</p> <p>Policy #: SURG.00033 Current Effective Date: 1/14/09 Last Review Date: 11/20/08</p> <p>Wellpoint Anthem considers implantable cardioverter-defibrillator (ICD) therapy medically necessary for the treatment of ventricular tachyarrhythmias and for the prevention of sudden cardiac death (SCD) in patients who are receiving optimal medical therapy and have a reasonable expectation of survival with a good functional status for more than 1 year when one of the following indications is present:</p> <ul style="list-style-type: none"> • After evaluation to define the cause of the event and to exclude any completely reversible causes in survivors of cardiac arrest due to ventricular fibrillation (VF) or hemodynamically unstable sustained ventricular tachycardia (VT); or • Those with structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable; or • Those with syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or VF induced at electrophysiological study; or • Those with left ventricular ejection fraction (LVEF) less than 35% due to prior myocardial infarction (MI) who are at least 40 days post-MI and are in New York Heart Association (NYHA) functional Class II or III; or • Those with nonischemic dilated cardiomyopathy (DCM) who have an LVEF less than or equal to 35% and who are in NYHA functional Class II or III; or • Those with left ventricular (LV) dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF less than 30%, and are in NYHA functional Class I; or • Those with nonsustained VT due to prior MI, LVEF less than 40% , and inducible VF or sustained VT at electrophysiological study; or • Those with long-QT syndrome who are experiencing syncope or VT while receiving beta blockers.
<p>Aetna</p>	<p>Biventricular Pacing (Cardiac Resynchronization Therapy)/ Combination Resynchronization- Defibrillation Devices for Congestive Heart Failure⁵</p> <p>Total Plan Enrollment: 16,318,625</p> <p>Policy #: 0610 Last Review: 11/11/2008 Effective Date: 4/30/02 Next Review: 9/10/09</p> <p>Aetna considers FDA-approved biventricular pacemakers (cardiac resynchronization therapy) medically necessary for the treatment of members with congestive heart failure (CHF) when all of the following criteria are met:</p>

⁴ Anthem. Medical Policy: Implantable Cardioverter-Defibrillator (ICD). Effective January 14, 2009. Available at: http://www.anthem.com/medicalpolicies/policies/mp_pw_a053321.htm. Accessed September 1, 2009.

⁵ Athena. Clinical Policy Bulletin: Biventricular Pacing (Cardiac Resynchronization Therapy)/Combination Resynchronization-Defibrillation Devices for Congestive Heart Failure (0610). Effective April 30, 2002. Available at: http://www.aetna.com/cpb/medical/data/600_699/0610.html. Accessed August 21, 2009.



	<ul style="list-style-type: none"> • New York Heart Association (NYHA) classification of heart failure III or IV; and • Left ventricular ejection fraction less than or equal to 35%; and • QRS duration greater than or equal to 120 msec; and • Member is on a stable pharmacologic regimen before implantation, which may include any of the following, unless contraindicated; <ul style="list-style-type: none"> ○ Angiotensin-converting enzyme inhibitor; or ○ Angiotensin receptor blocker; or ○ Beta blocker; or ○ Digoxin; or ○ Diuretics <p>Aetna considers biventricular pacemakers experimental and investigational for all other indications (e.g., atrial fibrillation, mild heart failure, and antibradycardia pacing).</p> <p>Aetna considers FDA-approved combination resynchronization-defibrillator devices medically necessary for members who are at high risk for sudden cardiac death when the afore-mentioned criteria are fulfilled and any of the criteria listed below is met:</p> <ul style="list-style-type: none"> • Members have at least one episode of cardiac arrest as a result of ventricular tachyarrhythmias; or • Members have recurring, poorly tolerated sustained ventricular tachycardia; or • Members have a prior heart attack and a documented episode of non-sustained ventricular tachycardia, with an inducible ventricular tachyarrhythmia; or • Members have a prior heart attack and a left ventricular ejection fraction of less than or equal to 30%. <p>Aetna considers combination resynchronization-defibrillator devices experimental and investigational for all other indications.</p>
<p>BCBS of Illinois, New Mexico, Oklahoma, & Texas</p>	<p>Biventricular Pacing⁶ Total Plan Enrollment: 12,218,623</p> <p>Policy #: MED202.054 Effective Date: 5/1/09</p> <p>Biventricular pacing with biventricular pacemakers with or without an accompanying implantable cardiac defibrillator (ID) (i.e., a combined biventricular pacemaker and ICD) may be considered medically necessary as a treatment of CHF (congestive heart failure) in patients who meet all the following requirement:</p> <ul style="list-style-type: none"> • New York Heart Association (NYHA) Class III or IV; and • Left ventricular ejection fraction <= (less than or equal to) 35%; and • QRS duration of >= (greater than or equal to) 120-130 msec; and • Under treatment with a stable pharmacological medical regime prior to implant that includes appropriate combinations of Angiotensin-converting Enzyme (ACE inhibitor), an Angiotensin Receptor Blocker (ARB), beta

⁶ BlueCross BlueShield of Texas. Medical Policies – Medicine: Biventricular Pacing (MED202.054). Effective May 1, 2009. Available at: <http://medicalpolicy.hcsc.net/medicalpolicy/home?corpEntCd=IL1&path=/templatedata/m>. Accessed September 1, 2009.



	<p>blocker, digoxin, and diuretics.</p> <p>Inclusion of an intrathoracic fluid monitoring sensor as a component of an implanted biventricular pacemaker is considered experimental, investigational and unproven.</p>
CIGNA Healthcare	<p>Biventricular Pacing/Cardiac Resynchronization Therapy⁷ Total Plan Enrollment: 9,922,135</p> <p>Policy #: 0174 Effective Date: 12/15/08 Next Review Date: 8/15/09</p> <p>CIGNA covers the use of biventricular pacemakers alone or combined with a defibrillator for cardiac resynchronization therapy (CRT) as medically necessary for the treatment of individuals with congestive heart failure (CHF) when ALL of the following criteria are met:</p> <ul style="list-style-type: none"> • New York Heart Association (NYHA) classification of heart failure III or IV • Left ventricular ejection fraction (LVEF) is less than or equal to 35% • QRS duration is greater than or equal to 120 milliseconds (ms) • Sinus rhythm or chronic atrial fibrillation (AF) • Individual on an optimal pharmacologic regimen before implantation, which may include the following, unless contraindicated: <ul style="list-style-type: none"> ○ Aldosterone antagonists ○ Angiotensin-converting enzyme (ACE) inhibitor ○ Angiotensin receptor blocker (ARB) ○ Beta blocker ○ Digoxin ○ Diuretics
Humana	<p>Cardiac Resynchronization Therapy⁸</p> <p>AN AICD or a unit that includes a cardiac resynchronization therapy pacer with a defibrillator (CRT-D) MAY be considered medically necessary when ALL of the following requirements are met:</p> <ul style="list-style-type: none"> • NYHA classification of heart failure III or IV; and • Left ventricular ejection fraction (LVEF) < 35%; and • Atrial fibrillation is not the baseline rhythm; and • QRS duration greater than or equal to 130 milliseconds. • <p>All indications listed above must also meet the following criteria:</p> <ul style="list-style-type: none"> • Patients must not have irreversible brain damage from preexisting cerebral disease; or • MIs 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; * <p>Indications (primary prevention of sudden cardiac death) must also meet the following</p>

⁷ Cigna. Cigna Medical Coverage Policy: Biventricular Pacing/Cardiac Resynchronization Therapy (CRT). Effective December 15, 2008. Available at: http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0174_coveragepositioncriteria_biventricular_pacing_crt_for_chf.pdf. Accessed September 1, 2009.

⁸ Humana. Cardioverter Defibrillators Medical Coverage Policy. Effective December 9, 2005. Available at: http://apps.humana.com/tad/tad_new/returnContent.asp?mime=application/pdf&id=6477&issue=773. Accessed September 1, 2009.



	<p>criteria:</p> <ul style="list-style-type: none"> • Patients must be able to give informed consent; and • Patients must NOT have: <ul style="list-style-type: none"> ○ Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; or ○ CABG or PTCA within the past 3 months; or ○ Acute MI within the past 40 days; or ○ Clinical symptoms or findings that would make them a candidate for coronary revascularization; or ○ Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year; and ○ Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography; and ○ Must be able to justify the medical necessity of devices other than single lead devices. This justification should be available in the patient's medical record. <p>Note: This criteria as listed above for an AICD or a unit that includes a cardiac resynchronization therapy pacemaker with a defibrillator (CRT-D) is not consistent with the Medicare National Coverage Policy, and therefore may not be applicable to Medicare members. Refer to the CMS web site at: http://www.cms.hhs.gov for additional information.</p>
<p>Health Net</p>	<p>Biventricular Pacemakers/Combination Resynchronization-Defibrillation Devices for the Treatment of Congestive Heart Failure⁹ Total Medical Enrollment: 6,180,395</p> <p>Policy #: NMP334 Effective Date: 4/2007 Updated: 4/2009</p> <p>Health Net, Inc. considers FDA-approved biventricular pacemakers (e.g., InSync Biventricular Pacing System) medically necessary for cardiac resynchronization therapy (CRT) when all of the following are met:</p> <ul style="list-style-type: none"> • Patient is diagnosed with New York Heart Association (NYHA) Class III or IV heart failure; and • Patient has a left ventricular ejection fraction (LVEF) is less than or equal to 35%; and • Left Ventricular (LV) end-diastolic diameter is greater than or equal to 55 mm; and • Patient has electrical dyssynchrony as evidenced by a major intraventricular conduction delay (predominately left bundle branch block), a prolonged QRS duration of greater than or equal to 130 milliseconds and/or a narrow QRS where significant dyssynchrony is documented by echo; and • CHF is stable, but patient continues to have advanced symptoms despite maximal medical therapy, which includes three or more of the following, unless not tolerated or contraindicated:

⁹ HealthNet. National Medical Policy: Biventricular Pacemakers/Combination Resynchronization-Defibrillation Devices for the Treatment of Congestive Heart Failure. Effective April 2007. Available at: https://www.healthnet.com/static/general/unprotected/pdfs/national/policies/biventricular_pacemaker_apr_07.pdf. Accessed September 1, 2009.



- Angiotensin-converting enzyme (ACE) inhibitor; **or**
- Angiotensin receptor blocker (ARB); **or**
- Aldosterone antagonists; **or**
- Beta blocker (carvedilol, bisoprolol, metoprolol); **or**
- Hydralazine in combination with nitrates
- Digoxin; **or**
- Diuretics.

Health Net considers biventricular pacing **medically necessary** for patients who are at high risk for sudden cardiac death when the afore-mentioned criteria for biventricular pacemakers are fulfilled **and any** of the following is met:

- History of life-threatening clinical event(s) associated with spontaneous, sustained ventricular tachyarrhythmia which is not due to reversible or transient causes; **or**
- Patient has recurring, poorly tolerated sustained ventricular tachycardia with or without structural heart disease, that is not amenable to other treatments; **or**
- Syncope of undetermined origin with clinically relevant, hemodynamically significant, sustained VT or VF induced at electrophysiological study when drug therapy is ineffective or not tolerated; **or**
- Familial or inherited conditions with a high risk for life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy; **or**
- Patient is at least 1 month post myocardial infarction (MI) or 3 months post coronary artery revascularization surgery, left ventricular ejection fraction (LVEF) less than or equal to 35%; **or**
- Ischemic dilated cardiomyopathy (IDCM) with NYHA Class II or III heart failure, at least 30 days post MI, and measured LVEF is less than or equal to 35%; **or**
- Non-ischemic dilated cardiomyopathy (NIDCM) of > 9 months duration, NYHA Class II or III heart failure, and measured LVEF is less than or equal to 35%.
- Patient has a prior heart attack and a LVEF of less than or equal to 30%.

FDA-approved combination resynchronization-defibrillator devices (e.g., Guidant CONTAK CD CRT-D System, Medtronic InSynch ICD Model 7272, St Jude Medical Epic and Atlas Systems).

Health Net does **not** consider **any** of the following **medically necessary** because they are either investigational in nature or are contraindications:

- Asymptomatic dilated cardiomyopathy
- Class I CH which is not an indication for ICD
- Symptomatic dilated cardiomyopathy when patients are rendered asymptomatic by drug therapy
- Symptomatic ischemic cardiomyopathy when the ischemia is amenable to intervention
- Asynchronous pacing in the presence (or likelihood) of competitive paced and intrinsic rhythms; **or**
- Chronic atrial arrhythmias, except for patients with atrial fibrillation and low ejection fraction (<35%).
- Unipolar pacing in individuals with an implanted defibrillator or cardioverer-



	<p>defibrillator (ICD) because it may cause unwanted delivery or inhibition of defibrillator or ICD therapy; or</p> <ul style="list-style-type: none"> • Prior pacing systems or indications or contraindications for pacing. • Unstable angina, myocardial infarction of prior coronary artery revascularization or coronary angioplasty within the past 3 months • Existing implantable cardioverter defibrillator (ICD) or indications for an ICD • For individuals whose heart failures or ventricular arrhythmias are reversible or temporary • An intrathoracic fluid monitoring sensor as a component of a biventricular pacemaker
<p>Highmark</p>	<p>Biventricular Pacemakers for the Treatment of Congestive Heart Failure¹⁰ Total Medical Enrollment: 5,182,186</p> <p>Policy #: S-153 Effective Date: 1/19/09 Issued Date: 1/19/09</p> <p>This policy on Biventricular Pacemakers for the Treatment of Congestive Heart Failure has been archived as of January 19, 2009 and is no longer in effect. For services rendered prior to the archived date of this policy, please refer to the prior versions of the policy as follows:</p> <p>Effective Date: 1/1/08 Issued Date: 12/31/07</p> <p>Insertion of the biventricular pacemaker may be considered medically necessary as a treatment of congestive heart failure in patients who meet all of the following criteria:</p> <ul style="list-style-type: none"> • New York Heart Association Class III or IV • Left ventricular ejection fraction < 35% • QRS duration of greater than or equal to 120 msec • Patients treated with a stable pharmacological medical regimen prior to implant, including an ACE inhibitor (or an angiotensin receptor blocker) and a beta blocker (or angiotensin receptor blocker), digoxin, and diuretics <p>If the insertion of a biventricular pacemaker for congestive heart failure is reported for any indication other than those listed, it should be denied as not medically necessary and, therefore, not covered. A participating, preferred, or network provider cannot bill the member for the denied service.</p>

¹⁰ Highmark. Highmark Medical Policy: Biventricular Pacemakers for the Treatment of Congestive Heart Failure. Effective January 1, 2008. Available at: <https://secure.highmark.com/ldap/medicalpolicy/wpa-highmark/S-153-008.html>. Accessed September 1, 2009.



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