

APPENDIX F

MATRIX LEVEL III — V REQUIREMENTS IN PRE-AMENDMENT SETTLEMENT AGREEMENT WHICH ARE MODIFIED UNDER THE SEVENTH AMENDMENT¹		
PRE-AMENDMENT SETTLEMENT AGREEMENT		SEVENTH AMENDMENT MODIFICATIONS
L E V E L I I I	Severe Mitral or Aortic Regurgitation <u>and</u> ACC/AHA Class I indications for surgery to repair or replace the involved valve(s) <u>and</u> surgery not performed and a statement from the attending Cardiologist or Cardiothoracic Surgeon, supported by medical records, regarding the recommendations made to the patient regarding valve surgery and the reason why surgery was not performed.	Class Member has to have actual surgery performed. Valve surgery that is medically recommended, but not performed, whether because of medical contraindications or because of patient choice, will not qualify for Level III Matrix Compensation Benefits.
	Moderate or Severe Mitral Regurgitation and a stroke, as a consequence of chronic atrial fibrillation with left atrial enlargement, that results in a permanent condition that meets the criteria of AHA Stroke Outcome Classification Functional Level II, as determined six months after the stroke.	Basic criteria for a stroke-based claim are the same as under existing Settlement Agreement, <u>but</u> Seventh Amendment, in addition, requires a statement under penalty of perjury from an examining physician, along with supporting contemporaneous medical records, establishing that the claimant had chronic atrial fibrillation with left atrial enlargement as a direct consequence of moderate or severe mitral regurgitation.
L E V E L I V	Moderate or Severe Mitral Regurgitation and a stroke, as a consequence of chronic atrial fibrillation with left atrial enlargement, that results in a permanent condition that meets the criteria of AHA Stroke Outcome Classification Functional Level III, as determined six months after the stroke.	Basic criteria for a stroke-based claim are the same as under existing Settlement Agreement, <u>but</u> Seventh Amendment, in addition, requires a statement under penalty of perjury from an examining physician, along with supporting contemporaneous medical records, establishing that the claimant had chronic atrial fibrillation with left atrial enlargement as a direct consequence of moderate or severe mitral regurgitation.
	Mild, Moderate or Severe Aortic Regurgitation or Moderate or Severe Mitral Regurgitation, in addition to a peripheral embolus due to either (i) bacterial endocarditis contracted after use of Pondimin [®] and/or Redux [™] , or to (ii) atrial fibrillation with left atrial enlargement, that results in severe permanent impairment to the kidneys, abdominal organs, or extremities.	Basic criteria are the same as under existing Settlement Agreement <u>but</u> , in the case of a peripheral embolus caused by atrial fibrillation with left atrial enlargement, Seventh Amendment also requires a statement under penalty of perjury from an examining physician, along with supporting contemporaneous medical records, establishing that the claimant had chronic atrial fibrillation with left atrial enlargement as a direct consequence of moderate or severe mitral regurgitation.
	Mild, Moderate or Severe Mitral or Aortic Regurgitation and (i) New York Heart Association Functional Class I or Class II Symptoms, <u>and</u> (ii) either (a) valvular repair or replacement surgery on the valve or valves with the required level of regurgitation or (b) ineligibility for such surgery due to documented medical reasons and (iii) significant damage to the heart muscle, defined as (a) an ejection fraction <30% with aortic regurgitation or <35% with mitral regurgitation in individuals who have <u>not</u> had valve surgery or (b) an ejection fraction of <40% six months after valvular repair or replacement surgery.	Basic criteria are the same as under existing Settlement Agreement, <u>but</u> in the case of ineligibility for surgery due to medical reasons, the individual must have ACC/AHA Class I indications for surgery and the medical reasons that make him or her eligible for surgery have to be documented contemporaneously in the Diet Drug Recipient’s medical records by the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist and certified to under penalty of perjury by an Examining Physician, and such medical reasons have to be more than acute conditions requiring a postponement of surgery.

¹ Modifications apply only to Category One and Category Two persons.

	Moderate or Severe Mitral Regurgitation and a stroke, as a consequence of chronic atrial fibrillation with left atrial enlargement, that results in a permanent condition that meets the criteria of AHA Stroke Outcome Classification Functional Level IV or V, as determined six months after the stroke.	Basic criteria for a stroke-based claim are the same as under existing Settlement Agreement, <u>but</u> Seventh Amendment, in addition, requires a statement under penalty of perjury from an examining physician, along with supporting contemporaneous medical records, establishing that the claimant had chronic atrial fibrillation with left atrial enlargement as a direct consequence of moderate or severe mitral regurgitation.
L E V E	Mild, Moderate or Severe Mitral or Aortic Regurgitation and (i) New York Heart Association Functional Class III or Class IV Symptoms, and (ii) either (a) valvular repair or replacement surgery on the valve or valves with the required level of regurgitation or (b) ineligibility for such surgery due to documented medical reasons and (iii) significant damage to the heart muscle, defined as (a) an ejection fraction <30% with aortic regurgitation or <35% with mitral regurgitation in individuals who have <u>not</u> had valve surgery or (b) an ejection fraction of <40% six months after valvular repair or replacement surgery.	Basic criteria are the same as under existing Settlement Agreement, <u>but</u> in the case of ineligibility for surgery due to medical reasons, the individual must have ACC/AHA Class I indications for surgery and the medical reasons that make him or her ineligible for surgery have to be documented contemporaneously in the Diet Drug Recipient's medical records by the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist and certified to under penalty of perjury by an Examining Physician, and such medical reasons have to be more than acute conditions requiring a postponement of surgery.
L V	Death resulting from a condition caused by valvular heart disease or valvular repair or replacement surgery that occurred after the use of Pondimin [®] and/or Redux [™] , supported by a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist, supported by medical records.	Basic criteria are the same as under existing Settlement Agreement, <u>but</u> Seventh Amendment requires prior or simultaneous eligibility for benefits under Matrix Levels I or II, as defined in the existing Settlement Agreement, or prior or simultaneous eligibility for benefits based upon High Matrix Level Qualifying Factors, as defined in the Seventh Amendment.
	Mild, Moderate or Severe Valvular regurgitation, and qualification for benefits under Matrix Levels II, III or IV, as defined in the Settlement Agreement, and ventricular fibrillation or sustained ventricular tachycardia, which results in hemodynamic compromise.	Basic criteria are the same as under existing Settlement Agreement, <u>but</u> in the case of a supporting Matrix Level claim based upon ineligibility for surgery due to medical reasons, the individual must have ACC/AHA Class I indications for surgery and the medical reasons that make him or her ineligible for surgery have to be documented contemporaneously in the Diet Drug Recipient's medical records by the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist and certified to under penalty of perjury by an Examining Physician, and such medical reasons have to be more than acute conditions requiring a postponement of surgery.