



## Change in ACEI for LVSD measures (HF-3, AMI-3): Incorporation of ARBs November 15, 2004

### Clinical Rationale

Excessive activation of the renin-angiotensin hormone system is a hallmark of heart failure (HF) and is an important mediator of adverse clinical outcomes in patients with HF and left ventricular systolic dysfunction (LVSD). Both angiotensin converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) act to decrease the activity of the renin-angiotensin system and have been studied in clinical HF trials. Randomized trials, studying a wide range of patients with HF and LVSD, have demonstrated the efficacy of ACEIs compared to placebo in reducing mortality and morbidity from HF.<sup>i, ii</sup> Thus, ACEIs have long been considered the cornerstone of therapy for all patients with HF and LVSD unless contraindicated or not tolerated.

Subsequent HF trials assessed ARBs as alternatives to ACEIs or have compared ARBs with placebo in patients who are intolerant of ACEIs. Early studies failed to demonstrate the equivalence of ARBs to ACEIs.<sup>iii, iv</sup> However, more recent trials demonstrate that ARBs have an important role in HF treatment. The CHARM Alternative trial compared ARBs with placebo in patients with heart failure and a history of prior intolerance of ACEIs.<sup>v</sup> In this trial, the ARB candesartan was well tolerated and reduced mortality and hospitalization.

The VALIANT trial directly compared an ACEI with an ARB (as well as the combination of the two) in patients with signs and symptoms of heart failure or LVSD after acute myocardial infarction.<sup>vi</sup> In this trial, the ARB was statistically “non-inferior” to ACEIs in this patient population. This study was the first to demonstrate the equivalence of ARBs, albeit in a circumscribed patient population (i.e., those after myocardial infarction).

For both HF and AMI, the ACEI quality measures have evolved to acknowledge the changing evidence. Although many questions remain unanswered, and although many experts believe that ACEIs should remain the first-line method of renin-angiotensin blockade in patients with HF, the accumulating evidence has provided the impetus to include ARBs as acceptable alternatives to ACE inhibitors. Guideline committees have also supported the inclusion of ARBs in performance measures for AMI<sup>vii</sup> and for heart failure<sup>viii</sup>. This measure is based on the premise that all patients with HF and LVSD, including those post-MI, should be treated with either an ACEI or an ARB unless there is documentation of a specific absolute contraindication or drug intolerance to both ACEIs and ARBs. Because it is known that many patients with HF still do not receive either an ACEI or ARB,<sup>ix</sup> improvement of care as assessed by this measure is expected to have an important impact on patient outcomes.



## **Implementation**

CMS/JCAHO Technical Measures Workgroup has approved a two-step plan of implementation:

### 1. Short Term – Effective January 1, 2005+ discharges

The short-term steps will address the inclusion of ARBs through re-labeling of data element and measure names, and rewording of ACEI data element definitions. Programming changes are not warranted, ensuring expeditious inclusion of ARBs.

- Change current data element names from 'ACEI Prescribed at Discharge' to 'ACEI or ARB Prescribed at Discharge' and 'Contraindication to ACEI at Discharge' to 'Contraindication to Both ACEI and ARB at Discharge'. Notes for abstraction, inclusion/exclusion lists, etc. within the definitions will be revised and reworded accordingly.
- Revise AMI/HF measure names: "ACEI or ARB for LVSD".
- Reflect data element and measure name changes in all CMS-JCAHO manual documentation (e.g., Data Element Lists, Data Dictionary, Measure Information Forms, Algorithms, Verification section, CART related sections).
- Add new medication table in Appendix C containing the list of ARBs.

### 2. Long Term – Effective October 1, 2005+ discharges

The long-term plan will allow differentiating between ACEI and ARBs through the addition of new ARB data elements. These changes will require programming changes.

- Two new data elements will be added, 'ARB Prescribed at Discharge' and 'Contraindication to ARB at Discharge'.
- The two original ACEI data elements, 'ACEI Prescribed at Discharge' and 'Contraindication to ACEI at Discharge', will be restored, to enable separation of patients who received ACEI from those who received ARBs.
- CART tool will be reprogrammed accordingly.



## Questions and Answers

#	Question	Answer
1.	<b>How will these changes be disseminated?</b>	Today, November 15, 2004, JCAHO announced the ACEI measure changes via a list serve message to hospitals and vendors, and the National Heart Care QIOSC sent news via the inpatient Community of Practice network. On November 16, 2004, CMS will post updates to the CMS-JCAHO Specifications Manual on the Quality Net Exchange web site ( <a href="http://www.qnetexchange.org/public/hdc/docs/nhqm_manual">http://www.qnetexchange.org/public/hdc/docs/nhqm_manual</a> ) and JCAHO will update their website. The Heart Care QIOSC plans to send out an SDPS memo notification to the QIOs during the week of November 15, 2004.
2.	<b>What about the fact that the original measures were included as a formal part of the requirements under the Medicare Modernization Act?</b>	The Centers for Medicare & Medicaid Services Office of General Counsel has approved the update of both the AMI and HF ACEI measures to include ARBs on November 12, 2004. OGC ruled that changing these measures based on updated findings to the evidence base on which these measures are constructed is entirely consistent with the intent of the Medicare Modernization Act.
3.	<b>What implications does this change have for QIOs?</b>	QIOs are strongly encouraged to work with their providers to ensure all hospitals are adequately informed of these changes and are prepared to begin adjusting their abstraction as of January 1, 2005 discharges.
4.	<b>What implication does this have for providers?</b>	Providers are strongly encouraged to ensure all affected staff are adequately informed of these changes and are trained and prepared to begin adjusting their abstraction as of January 1, 2005 discharges.
5.	<b>Does this change affect QIO evaluation?</b>	No. The QIO 7 SoW evaluation period will have ended prior to the 1.1.05 implementation of this update.
6.	<b>How will this affect public reporting on voluntary initiative?</b>	CMS is currently working with the principal partners in the Hospital Quality Alliance to accept the changes to these measures for public reporting.....



## References

- <sup>i</sup> Garg R, Yusuf S. Overview of randomized trials of angiotensin-converting enzyme inhibitors on mortality and morbidity in patients with heart failure. Collaborative Group on ACE Inhibitor Trials. *JAMA*. 1995;273:1450-1456.
- <sup>ii</sup> Flather MD, Yusuf S, Kober L et al. Long-term ACE-inhibitor therapy in patients with heart failure or left-ventricular dysfunction: a systematic overview of data from individual patients. ACE-Inhibitor Myocardial Infarction Collaborative Group. *Lancet*. 2000;355:1575-1581.
- <sup>iii</sup> Pitt B, Poole-Wilson PA, Segal R et al. Effect of losartan compared with captopril on mortality in patients with symptomatic heart failure: randomised trial--the Losartan Heart Failure Survival Study ELITE II. *Lancet*. 2000;355:1582-1587.
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- <sup>v</sup> Granger CB, McMurray JJ, Yusuf S et al. Effects of candesartan in patients with chronic heart failure and reduced left-ventricular systolic function intolerant to angiotensin-converting-enzyme inhibitors: the CHARM-Alternative trial. *Lancet*. 2003;362:772-776.
- <sup>vi</sup> Pfeffer MA, McMurray JJ, Velazquez EJ et al. Valsartan, captopril, or both in myocardial infarction complicated by heart failure, left ventricular dysfunction, or both. *N Engl J Med*. 2003;349:1893-1906.
- <sup>vii</sup> Antman EM, Anbe DT, Armstrong PW, Bates ER, Green LA, Hand M, Hochman JS, Krumholz HM, Kushner FG, Lamas GA, Mullany CJ, Ornato JP, Pearle DL, Sloan MA, Smith SC Jr; American College of Cardiology; American Heart Association; Canadian Cardiovascular Society. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction--executive summary. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to revise the 1999 guidelines for the management of patients with acute myocardial infarction). *J Am Coll Cardiol*. 2004 Aug 4;44(3):671-719.
- <sup>viii</sup> Executive Council of the Heart Failure Society of America. Implications of recent clinical trials for heart failure performance measures. HFSA Position Statement. *J Card Fail*. 2004;10:4-5.
- <sup>ix</sup> Masoudi FA, Rathore SS, Wang Y et al. National patterns of use and effectiveness of angiotensin-converting enzyme inhibitors in older patients with heart failure and left ventricular systolic dysfunction. *Circulation*. 2004;110:724-731.