March 26, 2013

Louis Jacques, MD

Director, Coverage and Analysis Group

Centers for Medicare and Medicaid Services

7500 Security Blvd.

Mailstop S3-02-01

Baltimore, MD 21244

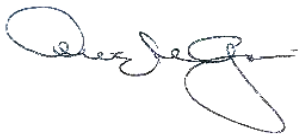
Dear Dr. Jacques:

Attached is a formal request for NCD Reconsideration. Specifically, this request is for the inclusion of chronic heart failure patients as an eligible population to receive cardiac rehabilitation. This is submitted by the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), American College of Cardiology (ACC), American Heart Association (AHA), and Heart Failure Society of America (HFSA).

Also attached to this email are specific references cited in the request that were not included with references provided on 2-15-13 via email to Michelle Issa.

Please feel free to contact Karen Lui, at Karen@GRQconsulting.com or 770-531-9298 if you need any additional information.

Sincerely,



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FORMAL REQUEST FOR NCD RECONSIDERATION

March 26, 2013

Request for NCD Reconsideration

Benefit Category

Section 1861(eee) of the Social Security Act defines Cardiac Rehabilitation (CR) as a physician-supervised program that furnishes physician prescribed exercise, cardiac risk factor modification, psychosocial assessment, and outcomes assessment. Further, Section 1861(eee)(3)(E) provides the Secretary discretionary authority to adjust the benefit and to ensure that the services provided are reasonable and necessary and are expected to improve or maintain the individual's condition and functional level.

Current qualifying diagnoses do not include chronic heart failure (CHF). This NCD reconsideration request addresses that gap by providing comprehensive information from recent peer reviewed literature that validates the benefits of CR services for selected CHF patients. These Medicare beneficiaries will receive the services provided under the current legislative and regulatory framework authorized by Section 1861(eee).

Submitted by

- American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR)
- American College of Cardiology (ACC)
- American Heart Association (AHA)
- Heart Failure Society of America (HFSA)

Description of Service

Cardiac rehabilitation (CR) represents a physician-supervised program that furnishes physician-prescribed exercise, cardiovascular risk factor modification, disease management-related counseling (including education on medications and disease processes), psychosocial

assessment, and outcomes assessment. CR services are recognized as a significant component in the continuum of care for persons with cardiovascular disease. CR is a Class I guideline therapy for many cardiovascular disorders, including stable CHF (Hunt 2005).

We are not requesting a new service. This request is for the inclusion of the qualifying diagnosis for selected Medicare beneficiaries with a CHF diagnosis within the Medicare provision, 42 CFR § 410.49: *Cardiac rehabilitation program and intensive cardiac rehabilitation program: Conditions of coverage*.

Description of Proposed Use of Service for Identified Medical Conditions in Target Medicare Population and Medical Conditions for Which It Can Be Used

Within the 4 staged (A through D) ACC/AHA classification system for CHF (Hunt 2009), patients with Stage C stable CHF (patients with past or current symptoms of CHF associated with underlying structural heart disease) with New York Heart Association (NYHA) Class II or III symptoms are most likely to benefit from participating in a CR program. Therefore, based on the following review of scientific evidence, the target CHF Medicare population that would receive the greatest benefit from participation in CR are:

Indications

- Heart failure hospital admission ($\geq$ 30days < 12 months) with CHF as primary discharge diagnosis (reduced or preserved ejection fraction) and confirmed stable Class II or III symptoms on evidence-based therapies at $\geq$ 30 days.

OR

- In the absence of a recent hospital admission (as defined above), CR is indicated for individuals with Class C heart failure with reduced or preserved ejection fraction with continued significant symptoms (dyspnea and fatigue, NYHA II or III) despite optimal medical and device therapy.

Contraindications

Cardiac rehabilitation should generally be withheld in patients with any of the following:

- Stage D heart failure and NYHA class IV symptoms
- Uncontrolled metabolic disorders (e.g., diabetes)
- Uncontrolled hypertension
- Atrial fibrillation with a poorly controlled or uncontrolled ventricular response
- Complex arrhythmia at rest
- Moderate to severe aortic stenosis
- Hypertrophic *obstructive* cardiomyopathy
- Significant ischemia at < 2 metabolic equivalents (METs) of work
- A pre-existing co-morbidity that prevents exercise participation
- Signs of acute cardiac decompensation such as a > 1.8 kg increase in body mass or worsening dyspnea over the previous 3 days
- Acute myocarditis or other acute cardiomyopathy unless stabilized with ongoing left ventricular dysfunction and stable CHF (NYHA class II or III) at 90 days

Recommendation for a Clinically-Beneficial Application of CR for Target Medicare Population

Given that prompt post-hospital follow-up care is important in the care coordination and outcomes of HF patients (Hernandez 2010), enrollment in CR shortly after hospital discharge would appear warranted, even though it is generally recognized from published research that exercise training should not be started until the patient's HF is stable (i.e., at least 30 days post-hospitalization). Early enrollment soon after hospital discharge could allow for patient assessment and management adjustments, as well as provide important educational and counseling CR sessions for 1-2 weeks prior to initiating exercise training. These non-exercise (non-monitored) sessions would provide educational and counseling sessions geared toward important self-monitoring and treatment adherence skills which are important contributors to optimal patient outcomes.

Compilation of Supporting Medical and Scientific Evidence for Medical Benefits

Cardiac rehabilitation confers significant clinical benefits to the Medicare population that meets the above CHF criteria. Benefits include increased exercise capacity, reduced morbidity and mortality, and enhanced quality of life, as systematic reviews and meta-analyses of CR exercise

training have demonstrated. The cardinal symptom of CHF is exercise intolerance and CR exercise training unequivocally improves exercise intolerance (Downing 2011).

CHF is a syndrome that represents the 'final common pathway' of a multitude of cardiovascular disorders. Because systole and diastole are inextricably coupled, patients with CHF often have abnormalities of both systolic and diastolic function that can be detected using sophisticated imaging techniques. Nonetheless, it is conventional to refer to heart failure patients with a LV ejection fraction (LVEF) of less than 40-45% as having heart failure with reduced ejection fraction (HFREF), and those having heart failure with an LVEF of greater than 40-45% as having heart failure with preserved ejection fraction (HFPEF) (Hunt 2005). It is important to note that there is little correlation between LVEF and symptom severity, exercise intolerance, or hospitalization rates (Kitzman 2002). Thus, the beneficial effects of exercise, patient education, and associated disease management administered under the auspices of structured CR programs are generally similar in patients with either form of heart failure.

Increased Exercise Capacity

In patients with CHF, exercise training can positively affect peak oxygen uptake (VO_2), central hemodynamic function, autonomic nervous system function, peripheral vascular and muscle function, and most importantly from a clinical perspective, exercise capacity. The characteristics of exercise intolerance or loss of functional capacity that accompany CHF are often quantified by either the six-minute walk test (6MWT) or peak VO_2. The mechanism(s) responsible for the often substantial loss in exercise tolerance are many and include abnormalities in cardiac, respiratory, vascular endothelial and skeletal muscle function. Compared to normal controls or age- and gender-matched predicted values, patients with CHF have 30% to 70% reductions in peak VO_2; similarly observed in patients with HFREF or HFPEF (Kitzman 2002). This significant reduction in functional capacity underlies the declines seen in physical activity, mobility, and ability to perform activities of daily living.

Exercise training improves exercise tolerance (i.e., peak VO_2) in patients with reduced or preserved ejection fraction (Kitzman 2010). A meta-analysis of 57 studies that directly measured peak VO_2, (a more robust measure compared to estimates derived from peak exercise work rate) reported an average 17% improvement in peak VO_2 (Smart 2004). While most studies of

exercise training for CHF have focused on patients with reduced cardiac systolic function (measured by left ventricular ejection fraction), CHF with a preserved ejection fraction is just as common in the clinical realm. Clinical trials have shown that physical training is a safe and effective intervention to improve symptoms, increase aerobic capacity and endurance, and improve self-reported quality of life in patients with HFPEF and HFREF.

Morbidity, Mortality, and Hospitalization Rates

Although the number of available treatments for CHF has increased over the past three decades, the impact of the disease on mortality, disability and functional status remains burdensome. Prognosis for patients with CHF remains poor. One study that analyzed Medicare data for over 600,000 beneficiaries found that nearly 30% died within 1 year of incident diagnosis and more than 60% died within 5 years (Curtis 2008).

The ExTraMATCH meta-analysis of 9 datasets that included 801 heart failure patients demonstrated a significant reduction in mortality in those patients who underwent exercise training compared to non-exercising controls during a mean follow-up of 705 days (HR 0.65; 95% CI 0.46-0.92) (Piepoli 2004). A more recent Cochrane Review of 19 trials (3647 participants) showed a non-significant trend to lower mortality among those trials with follow-up of > 1year, and no difference in pooled mortality at < 1 year follow-up (Davies 2010). A significant 28% reduction in hospitalization rate at 1 year was demonstrated with exercise programs in this latter analysis, which in the clinical arena would have a favorable impact on medical costs.

A large administrative database of Medicare beneficiaries yielded an analysis in over 600,000 patients which addressed the effects of exercise -based CR on morbidity and mortality. Subgroup analyses of patients with CHF provides evidence of a survival benefit for these patients with a 15% lower mortality rate in CHF patients who underwent CR compared to matched CHF patients who did not participate in CR (Suaya 2009). High CR users (25+ sessions vs. 1-24 sessions) had a greater mortality reduction than low CR users; thus there was a dose effect of CR. This is comparable to the strong dose-response relationship that exists between the number of CR sessions and long-term outcomes for patients with coronary heart disease who are

currently eligible for CR (e.g., myocardial infarction, coronary revascularization) (Hammill 2010).

The largest multi-center randomized trial of exercise training in CHF, HF-ACTION (Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training), (O'Connor 2009) showed an approximate 10% decrease (HR: 0.89; 95% CI: 0.81-0.99) in adjusted risk among patients undergoing exercise training (versus control) for the combined end point of total mortality and hospitalizations, similarly, an approximate 15% reduction (HR: 0.85; 95% CI: 0.74-0.99) in adjusted risk was observed for the disease specific combined end point of cardiovascular mortality and CHF hospitalizations. In a subsequent analysis that investigated the relationship between the volume of exercise completed and subsequent clinical events in the HF-ACTION trial, Keteyian et al observed that among patients who exercised as prescribed, the risk for mortality or hospitalization was each reduced by more than 30% (Keteyian 2012). This is highly relevant to Medicare because outlays would occur only when beneficiaries actually attend sessions. This analysis also demonstrated the significant independent relationship between exercise volume and clinical outcomes.

Enhanced quality of life

Quality of life, subjective symptoms, and functional class measures clearly improve after exercise training in CHF (Flynn 2009*)*. Using the Kansas City Cardiomyopathy Questionnaire (KCCQ) the HF-ACTION trial showed that 3 months of exercise training led to a greater improvement in the KCCQ total score vs. controls ($p<0.001$), a differential increase that was maintained throughout a 30 month follow-up period (Flynn 2009).

Similarly, a 2010 Cochrane Review of 6 exercise training studies (700 patients) that utilized the Minnesota Living with Heart Failure (MLWHF) questionnaire showed that exercise training induced a favorable reduction of more than 10 units in this scale (Davies 2010); a magnitude of improvement that was quite similar to the change reported previously in the 2006 meta-analysis by van Tol et al (van Tol 2006). Thus, exercise training unequivocally improves quality of life in CHF.

Relevance and Rationale of Evidence Selected to Demonstrate Medical Benefits

Evidence demonstrates benefits of CR for this population relating to:

- Improved mortality and morbidity
- Increased exercise capacity
- Fewer clinical symptoms
- Enhanced quality of life

Magnitude of Medical Benefit for Target Medicare Population

Due in part to the aging of the population and to improved outcomes for acute cardiac disease, the prevalence of CHF is increasing both in the U.S. and around the world (Roger 2012). Decompensated CHF is the single most common admitting diagnosis in older Americans, resulting in 1,094,000 hospitalizations in 2008, of which 930,000 were discharged alive (Roger 2012). Patients with CHF account for more than 12 million office visits and 6.5 million hospital days each year and 25% of patients are readmitted in 30 days and 66% are re-admitted within 1 year after a CHF hospitalization (Curtis 2008). The number of new cases of CHF annually in the U.S. is 670,000 whereas the overall prevalence was 6.6 million in 2010 (Roger 2012). Due to the aging of the American population, and the powerful effect of age on incidence of CHF, its prevalence is expected to increase by 45% to 9.6 million by 2030.

Reasoning for How Coverage of CR Will Help Improve Medical Benefit to Target Population

Medicare beneficiaries with CHF currently do not receive the physician service of CR unless other co-morbid qualifying conditions are met. Thus, the segment of the CHF population would unequivocally benefit from this recommendation i.e. to revise the eligibility criteria for CR. Specifically, the research clearly shows an improved quality of life, improved clinical outcomes, including exercise tolerance, as well as morbidity, mortality, and hospitalization rates.

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