Programming Considerations for Including Patients With Heart Failure Into Phase 2 Cardiac Rehabilitation

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More than 5.1 million Americans have clinically manifest heart failure (HF), with 650,000 new cases diagnosed annually. Approximately half the patients with clinical HF have a reduced left ventricular ejection fraction (LVEF), while the remainder has a preserved LVEF. HF accounts for over $30 billion in US healthcare costs annually, including more than 1 million hospitalizations. Patients with HF frequently have a significantly decreased health-related quality of life, which is a strong predictor of hospital readmission and mortality. Absolute mortality from HF has improved but still remains high at approximately 50% within 5 yr of diagnosis (9).

In 2009, the HF-ACTION (Heart Failure: A Controlled Trial Investigating Outcomes of Exercise TraiNing) investigators published data from the largest randomized clinical trial conducted examining the effects of exercise training versus usual care in the HF population. More than 2,300 patients were enrolled across 82 centers in the United States, Canada and France, with a median follow-up of 30 mo. HF-ACTION demonstrated that exercise training is associated with reductions in all-cause mortality and hospitalization as well as cardiovascular mortality or heart failure associated hospitalization. Exercise training was also shown to be safe (7). Lastly, HF-ACTION demonstrated a modest yet statistically significant improvement in self-reported health status in the exercise training group (6). With this study, the stage was set for the inclusion of HF into Phase 2 cardiac rehabilitation (CR).

On March 26, 2013, a multi-society request for reconsideration of national coverage determination (NCD) was submitted to the Centers for Medicare & Medicaid Services (CMS) by the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Failure Society of America (HFSA) for the inclusion of HF as an eligible diagnosis for CR (1). CMS responded in June 2013 with a request for public comments on a proposed new NCD supporting coverage of patients with HF for CR. More than 180 public comments were made in support of the proposed CMS decision memo by such organizations as AACVPR, ACC, AHA, the Clinical Exercise Physiology Association (CEPA), and by many individuals. In November 2013, CMS placed a proposal to expand coverage for CR services to include beneficiaries with chronic HF beginning at some point in 2014 (5).

This decision by CMS is to be applauded, as it will allow patients with HF to access CR services, which have been shown to reduce hospital readmissions and improve all-cause mortality while also improving functional capacity and quality of life. The introduction of this population into CR (a predicted 20% to 30% increase in referrals at Baystate Health System's CR program) will require some careful consideration on the part of clinical staff and CR program administrators. These considerations fall predominately into the following categories: referral and program entry, exercise testing and prescription, staffing, patient monitoring, and educational goals. The proposed CMS decision memo does not address these issues, thus leaving them to individual programs to determine how to best address. The following sections offer some considerations.

REFERRAL AND PROGRAM ENTRY

Before programs can begin to enroll patients with HF into CR, CMS will have to release final eligibility criteria for this population. The CMS decision memo cites eligibility criteria for CR as a LVEF ≤35%, a New York Heart Association Functional classification of II-IV, and being symptomatic after 6 wk of medical therapy but fails to address if there needs to be an index event (e.g., hospitalization) or if all patients with this

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chronic disease will be eligible for a new course of CR annually. There are no proposed parameters regarding an index event. Therefore, referral and CR enrollment are based on clinical judgment and medical necessity documentation. CR programs must have solid enough documentation to avoid a retroactive denial from the local Medicare contractor. Once the final eligibility criteria are determined, existing CR programs will need to educate physicians and other healthcare providers on the safety and efficacy of CR for the HF population as well as the eligibility criteria. If the requirement for patients to be symptomatic after 6 wk of medical therapy remains in the final eligibility criteria, programs should take care to ensure that this time period is clearly documented in the patient's medical record. Once appropriate patients have been identified, a referral process that allows patients to enter the program without undue delay would be beneficial. Long delays in program entry are associated with the decreased likelihood of attending CR (8).

EXERCISE TESTING AND PRESCRIPTION

All patients with HF meeting the eligibility criteria will be considered "high risk" due to the presence of HF and their LVEF being less than 40% according to AACVPR guidelines for risk stratification (2). The American College of Sports Medicine (ACSM) recommends a medical exam and a symptom-limited exercise test for patients with "known cardiac, pulmonary or metabolic disease" before moderate or vigorous exercise is initiated. However, ACSM also cites left ventricular dysfunction limited by shortness of breath and extreme deconditioning as reasons not to perform an exercise test prior to CR (4). Many CR programs no longer require such testing prior to program entry. Careful consideration should be given to continuing this policy in the HF population, especially those without implantable cardiac defibrillators (ICD). Perhaps one solution to resolving this apparent exercise testing paradox is to begin HF patients with low-intensity exercise and consider exercise testing when symptoms of HF are reduced or the patient is ready for moderate to vigorous exercise training.

Exercise prescription in this population is consistent with other patients with cardiovascular disease in that the goal is to gradually increase exercise duration, intensity, and frequency within patient tolerance limits (3). While the functional capacity of patients with HF can vary considerably, it is reasonable to expect that many of the patients referred to CR will be at the lower end functional capacity spectrum. Programs will need to assess if they have adequate availability of appropriate equipment modalities (e.g. NuStep recumbent steppers, recumbent cycles, or treadmills capable of low-speed [1.6 km/h or 1 mph] operation) to meet the needs of lower functional capacity patients.

STAFFING

As previously mentioned, the HF population in the United States is quite large, with many more patients diagnosed each year. This potentially large influx of patients into a traditionally underutilized service such as CR, while certainly welcome, may prove challenging for many CR programs. AACVPR recommends a patient/staff ratio of 5:1 for CR. Programs may need to reallocate staff from other areas or add personnel (ideally a clinical exercise physiologist) to meet this recommendation if referrals *and* participation rates in CR approach predicted levels. If existing Phase 2 classes are at or near this ratio, programs may need to consider adding additional class times.

PATIENT MONITORING

Most of the other covered indicators for CR, such as myocardial infarction and coronary revascularization procedures, are tied to a discrete event. HF is a chronic condition that unlike the other covered diagnoses may be prone to episodic exacerbation. At every visit to CR, patients with HF should be asked about medication compliance and assessed for signs of potential decompensation. Body weight should be assessed prior to each session while making every provision to ensure patient privacy. Weight gain of ≥1 kg (2 lb) in 2 d or 2 kg (5 lb) in 1 wk may be indicative of an exacerbation. Patients should also be queried regarding changes in sleep habits (e.g., inability to lay flat, needing additional pillows, sleeping in a chair, etc.), increasing shortness of breath, or fatigue. Programs should consider including auscultation of lung sounds and evaluating peripheral edema as part of annual staff competencies if they are not already. Also, it is important that clinicians have a quiet area in close proximity to the exercise space in which to assess lung sounds.

Continuous ECG telemetry monitoring is not required by CMS for reimbursement in CR, but it would be prudent for programs to ensure they have enough ECG transmitters available to meet the needs of patients in any given class. Programs should consider developing policies on which patients to monitor with ECG telemetry and when to monitor if this is not already in place. Some patients with HF may have a fluid restriction. CR programs should have a mechanism to quickly and easily identify these patients so the patient receives a consistent message regarding fluid intake from all the providers involved in his or her care.

Some CR programs may not have experience dealing with patients who have a ventricular assist device (VAD) implanted, but this therapy is not uncommon in the HF population. An in service from the hospital's VAD coordinator is recommended if feasible to familiarize the CR staff with the device. While patients with VADs receive extensive education regarding use and maintenance of the unit, CR staff will likely be more comfortable with these patients if they are given some guidelines regarding physical parameters (e.g., heart rate and blood pressure) and receive training on responding to device alarms and changing batteries and have a list of emergency contacts available. Because of the continuous flow of blood through the VAD (i.e., nonpulsatile flow), a Doppler ultrasound unit is often required to assess systolic blood pressure. Training and use of the Doppler should be part of annual staff competency tests.

EDUCATIONAL GOALS

Traditionally, CR programs have emphasized risk factor reduction and lifestyle modification in the educational component of the program. Patients with HF will also benefit from this educational component, but patients with HF (and those at risk for HF) will also benefit from education about symptom management skills to reduce the frequency and severity of exacerbations, with the overall goal being to reduce hospitalizations. Key areas to focus on in this regard are the importance of compliance with the prescribed medication, sodium restriction, regular physical activity, and early notification of their physicians when HF symptoms worsen. Every effort should be made to ensure that education provided in CR is consistent with education received from other providers, such as their primary care physician, cardiologist, or HF clinic. Incorporating a review of this education into the educational component of the patient's individualized treatment plan would ensure that the patient is receiving information specific to his or her diagnosis and would provide the clinician with an opportunity to reassess the ongoing educational needs of the patient.

CONCLUSION

In summary, the decision of CMS to expand the indications for CR allows many patients with HF to access services proven to be safe and effective for reducing mortality and hospitalization while improving quality of life. CR programs should be able to successfully integrate HF patients into existing classes with only minor changes to existing policies and procedures, provided adequate consideration is given to some of the unique needs of this population.

Keywords: cardiac rehabilitation, heart failure, programming

REFERENCES

1. American Association of Cardiovascular and Pulmonary Rehabilitation [Internet]. Chicago, IL: AACVPR Health Policy & Reimbursement Update: June 24, 2013: Why Heart Failure—Why Now? [cited January 12, 2014]. Available from: https://www.aacvpr.org/Portals/0/policy/Reimbursement%20Updates/June%2024,%202013.pdf
2. American Association of Cardiovascular and Pulmonary Rehabilitation. Guidelines for cardiac rehabilitation and secondary prevention programs. 5th ed. Champaign, IL: Human Kinetics; 2013; 81 p.
3. American College of Sports Medicine. Exercise management for persons with chronic diseases and disabilities. 3rd ed. Champaign, IL: Human Kinetics; 2009; 97 p.
4. American College of Sports Medicine. Guidelines for exercise testing and prescription. 8th ed. Baltimore: Lippincott Williams & Wilkins; 2010; 32, 219 p.
5. Centers for Medicare & Medicaid Services [Internet]. Washington, DC: Proposed decision memo for cardiac rehabilitation (CR) programs – chronic heart failure (CAG-00437N); [cited January 14, 2014]. Available from: http://www.cms.gov/medicare-coverage-database/details/nca-proposeddecision-memo.aspx?NCAId=270
6. Flynn KE, Pina IL, Whellan DJ, Lin L, et al. Effects of exercise training on health status in patients with chronic heart failure: HF-ACTION randomized controlled trial. JAMA. 2009; 301(14):1451-9.
7. O'Connor CM, Whellan DJ, Lee KL, Keteyian SJ, et al. Efficacy and safety of exercise training in patients with chronic heart failure: HF-ACTION randomized controlled trial. JAMA. 2009;301(14):1439-50.
8. Pack QR, Mansour M, Barboza JS, Hibner BA, et al. An early appointment to outpatient cardiac rehabilitation at hospital discharge improves attendance at orientation: a randomized, single-blind, controlled trial. Circulation. 2013;127:349-5.
9. Yancy CW, Jessup M, Bozkurt B, Butler J, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;128:e240-e327.