Respiratory Treatment for Patients with Neuromuscular Weakness
Clinical Protocol Demonstration
September 18, 2016

Background

Patients with neuromuscular disease or other chronic debilitating disorders can experience muscle weakening that can result in the need for intubation and (unless treated in the manner we propose) eventually a tracheotomy. The use of invasive, tracheostomy mechanical ventilation (TMV) mandates ongoing around-the-clock nursing care, often initially in a long-term care acute hospital facility (LTAC), but ultimately in skilled care nursing facilities or at home with 16-24 hours per day of nursing care. New Jersey's University Hospital Department of Physical Medicine and Rehabilitation uses a cost effective clinical protocol that provides an alternative, extubation to continuous noninvasive ventilatory support (CNVS) and long-term noninvasive management that eliminates the need for surgical tracheotomies and in most cases, need for long-term nursing care.

Many individuals with these diseases are not initially eligible for NJ Medicaid and receive services through commercial insurers. However, once there is need for institutional care, in most cases, the individuals will qualify for Medicaid. Therefore, the broader statewide use of this protocol has the potential to very significantly lower costs for NJ Medicaid.

Proposal

As part of a 3-year demonstration project, the state will require the MCOs under contract with Medicaid to conduct an e-consult with University Hospital Department of Physical Medicine and Rehabilitation to determine if CNVS is a viable alternative for patients with neuromuscular weakness who are intubated and can not be weaned from respiratory support to be successfully extubated without resort to tracheotomy and TMV.

Initially, the program will be limited to disorders that do not require need for in-person evaluation for candidature for the program. All cognitively intact OR patients with sufficient cognition to follow directions and with adequate family support for home management with the following disorders are eligible:

- All muscular dystrophies including congenital and Duchenne muscular dystrophies
- All spinal muscular atrophies (SMAs) including SMA type 1
- All congenital myopathies
- Neuromuscular conditions without severe central nervous system or upper motor neuron pathology in acute crises such as of myasthenia gravis and Guillain-Barre' syndrome
- Ventilator "unweanable" patients with critical care neuromyopathies without multi-organ failure

Benefits – Quality and Costs

The quality of life benefits resulting from the use of this protocol are hard to overstate. Patients fortunate enough to take advantage of this option return directly home from critical care and avoid the trauma of a tracheotomy, invasive mechanical ventilation, and potentially avoid a lifetime of institutionalization/nursing care.

On the cost side, per patient savings from adopting CNVS instead of a TMV via tracheostomy tubes are substantial (American Journal of Physical Medicine and Rehabilitation Vol 94, No 6, June 2015). Based on the research done at University Hospital, on average, Medicaid would experience an immediate cost savings by avoiding the costs of surgical tracheotomies and institutionalization in ventilator units (from $280,000 for skilled care units to over $300,000 for home nursing) per year per case. While the number of cases may be relatively small initially at approximately 150, annual savings to Medicaid would approximate $15M (75 x $200,000), assuming only 50% of the cases were able to avoid tracheotomy and subsequent invasive mechanical ventilation even though our success rates for over 250 cases is over 98% (Bach JR, Gonçalves MR, Hamdani I, Winck JC. Extubation of unweanable patients with neuromuscular weakness: a new management paradigm. Chest 2010;137(5):1033-1039; Bach JR, Sinquee D, Saporito LR, Botticello AL. Efficacy of mechanical insufflation-exsufflation in extubating unweanable subjects with restrictive pulmonary disorders. Respir Care 2015;60(4):477–483).

Implementation

The NJ Medicaid MCO contract will include the requirement that the HMOs, upon notice of admission for selected DRGs, will require the treating physician to first obtain an e-consult with the Rutgers Department of Physical Medicine and Rehabilitation for intubated patients with the noted diagnoses before requesting consent for a tracheotomy. The Rutgers Department of Physical Medicine and Rehabilitation will either attempt to talk the patient's intensivists through extubation to CNVS (since a primary goal is to disseminate the knowledge of how to accomplish this) or facilitate transferring the patient to University Hospital ICUs for extubation to CNVS. Initial consultation by telephone is available 24/7 by cell phone 1-973-7143662.

Research Component and Proof of Efficacy

The following data will be gathered on the percentage of patients who avoid tracheotomy in every diagnostic category:

- Diagnosis and demographics (age, gender),
- Pulmonary function (including vital capacity, cough peak flows, CO2, and ambient air oxyhemoglobin saturation upon arrival at University Hospital),
- Co-morbidities,
- To where the patient was projected to have been discharged had they not benefitted from the noninvasive protocol (from the referring hospital's social worker) and the anticipated costs,
- Perspective cost-savings as a result of discharge to the community including annual respiratory equipment rentals will be determined.

Potential Program Expansion

After the first year, with the accord of Medicaid, candidature for noninvasive management will be expanded to patients with chronic obstructive pulmonary disease and more broadly to ventiltator "unweanable" patients with critical care neuromyopathies (deconditioning) who will require on-site evaluation for candidature for transfer to University Hospital by Dr. Bach or his appointee. This may greatly increase the population requiring transfer and would require the establishment of a separate ventilator management unit.