



June 22, 2015

The Honorable Orin Hatch
Chairman
Senate Committee on Finance
219 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Senate Committee on Finance
219 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Johnny Isakson
131 Senate Russell Office Building
Washington, DC 20510

The Honorable Mark Warner
475 Senate Russell Office Building
Washington, DC 20510

RE: Senate Finance Committee Chronic Care Working Group - Letter to Stakeholders

Dear Chairman Hatch, Ranking Member Wyden, Senator Isakson, and Senator Warner:

Avanir Pharmaceuticals, Inc. is pleased to take the opportunity to offer comment to the Committee's request for information regarding how to improve chronic care in new health care delivery and payment systems. Avanir believes that this is a unique opportunity to improve the lives of millions of Americans struggling with chronic conditions, while also finding and implementing efficiencies that will ensure the continued solvency of the Medicare program.

Founded in 1988, Avanir Pharmaceuticals, Inc. is a biopharmaceutical company focused on acquiring, developing, and commercializing novel therapeutic products for the treatment of central nervous system (CNS) disorders. Along with its currently approved product, Nuedexta, which treats a condition called Pseudobulbar Affect, or PBA, Avanir has invested in its pipeline in order to advance medicines that can substantially improve the lives of patients suffering from CNS conditions.

What is Pseudobulbar Affect (PBA)?

Pseudobulbar Affect (PBA) is a neurologic condition characterized by involuntary outbursts of laughing and/or crying that are incongruous or disproportionate to the patient's emotional stateⁱ. The condition is hypothesized to arise from disconnection of brainstem structures from cortical inhibition, and is associated with central nervous system disorders, including Alzheimer's disease (AD)ⁱⁱ, amyotrophic lateral sclerosis (ALS)^{iii,iv,v}, Parkinson's disease (PD)^{vi}, multiple sclerosis (MS)^{vii}, stroke^{viii}, and traumatic brain injury (TBI)^{ix}. PBA episodes may occur multiple times per day, and are associated with impaired social and occupational function^{x,x,xi,xii,xiii,xiv}, embarrassment, social phobia, withdrawal, and isolation for both patients and caregivers, which can result in increased disability in the patient^{xvi,xv}. Patients with PBA experience high rates of comorbidities, health care resource utilization, and institutionalization^{xvi}.

Quality Measure Utilization in Medicare Parts A and B

RE: #3. Reforms to Medicare's current fee-for-service program that incentivize providers to coordinate care for patients living with chronic conditions

Avanir applauds Congressional efforts to improve and standardize care through the passage of both the Medicare Post-Acute Care Transformations Act of 2014 (IMPACT) and the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Both pieces of legislation are monumental in improving and streamlining care for Medicare beneficiaries and reforming current volume incentives by shifting to new value and quality of care incentives. However, it is important that quality measures, which are key to assessing care in both laws, be meaningful and applicable for those with chronic conditions, especially chronic conditions that are associated with the deterioration of the body AND the mind, and for those conditions where a limited number of scientific biomarkers currently exist.

Because patients living with underlying chronic neurologic conditions that may trigger neuro-behavioral symptoms, including PBA, have a wide degree of inter- and intra-patient group variability and a lack of associated scientific bio markers, there exists a gap in outcome measures that are applicable to quality of life or functional status following treatment. With health care systems moving to apply quality systems as laid out in recent legislation, it is important that the outcome measures contained in new quality reporting systems be well rounded and address relative functional improvement, maintenance of function, and the prevention of functional deterioration rates through showing the practical value of measurable improvement, the ability of a patient to return to the community and its relative cost savings, or the prevention of social isolation.

Both IMPACT and MACRA specifically address functional outcomes and are currently being interpreted into regulations by the Centers for Medicare and Medicaid Services (CMS). Both attempt to make the development of functional measures a priority in new pay for performance health care delivery systems. However, only the IMPACT Act addresses the importance of developing measures for both the cognitive/behavioral aspects in addition to the physical aspects of function, although the development of these measures is still in its infancy.^{xvii} With a lack of measures applicable to cognitive/behavioral function, facilities and physicians will not be incentivized to treat, or will not be given credit for treating, functional impairment in these areas where improvement in quality of life are possible and medically necessary for the patient.

Currently, the functional **outcome** measures being considered for inclusion in the CY2016 Inpatient Rehabilitation Facility (IRF) prospective payment system (PPS) and the CY2016 Skilled Nursing Facility (SNF) PPS are physical in nature and include metrics addressing 30 day acute hospital readmissions, self-care and mobility, falls, and pressure ulcers.^{xviii} While ambulation is an important goal for many patients with neurologic conditions, cognitive and behavioral improvements are equally important and may be vital to improving quality of life and community engagement.

In sum, beneficiaries with chronic underlying neurologic conditions may experience cognitive and behavioral symptoms that inhibit social interaction and have a negative impact on daily activities. Those experiencing these symptoms may avoid community interaction, social activities, or group therapies which can be integral to gaining or maintaining both physical AND cognitive/behavioral function, which in turn, may promote quality chronic care management and favorable health outcomes. Thus, it is important for Congress to further define or brand the term function in a way that encompasses the breadth of challenges that most of these patients face, in order to remind regulators that diseases and injuries that are solely musculoskeletal or physical in nature are not the only symptoms of the chronic conditions treated in hospital settings or by individual physicians.

Avanir appreciates the opportunity to weigh in on this important issue and remains optimistic that policy change in the area of chronic disease management will continue to improve throughout this process. Please contact Crystal Vanuch, Head of Government Affairs, at (919) 538-1347 or cvanuch@avanir.com if you have any questions, or require additional information.

Sincerely,



Rohan Palekar, Executive Vice President and Chief Operating Officer (COO)
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ⁱ Dark FL, McGrath JJ, Ron MA. Pathological laughing and crying. *Aust N Z J Psychiatry*. 1996;30(4):472-479.

ⁱⁱ Starkstein SE, Migliorelli R, Tesón A, et al. Prevalence and clinical correlates of pathological affective display in Alzheimer's disease. *J Neurol Neurosurg Psychiatry*. 1995;59(1):55-60.

ⁱⁱⁱ Miller RG, Jackson CE, Kasarskis EJ, et al. Practice parameter update: The care of the patient with amyotrophic lateral sclerosis: multidisciplinary care, symptom management, and cognitive/behavioral impairment (an evidence-based review). *Neurology*. 2009;73(15):1227-1233.

^{iv} Miller RG, Rosenberg JA, Gelinas DF, et al. Practice parameter: The care of the patient with amyotrophic lateral sclerosis (An evidence-based review). *Muscle Nerve*. 1999;22(8):1104-1118.

^v Jackson CE, Bryan WW. Amyotrophic lateral sclerosis. *Semin Neurol*. 1998;18(1):27-39. doi:10.1055/s-2008-1040859.

^{vi} Strowd R, Cartwright M, Okun M, Haq Istsham, Siddiqui MS. Pseudobulbar affect: prevalence and quality of life impact in movement disorders. 2010. *Journal of Neurology*. 257(8):1382-7.

^{vii} Feinstein A, Feinstein K, Gray T, O'Connor P. Prevalence and neurobehavioral correlates of pathological laughing and crying in multiple sclerosis. *Arch Neurol*. 1997;54(9):1116-1121.

^{viii} House A, Dennis M, Molyneux A, Warlow C, Hawton K. Emotionalism after stroke. *BMJ*. 1989;298(6679):991-994.

^{ix} Brooks N. Personality change after severe head injury. *Acta Neurochir Suppl (Wien)*. 1988;44:59-64.

^x Work SS, Colamonico JA, Bradley WG, Kaye RE. Pseudobulbar affect: an under-recognized and under-treated neurological disorder. *Adv Ther*. 2011;28(7):586-601.

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- ^{xi} Schiffer R, Pope LE. Review of pseudobulbar affect including a novel and potential therapy. *J Neuropsychiatry Clin Neurosci*. 2005;17(4):447–54.
- ^{xii} Parvizi J, Arciniegas DB, Bernardini GL, et al. Diagnosis and management of pathological laughter and crying. *Mayo Clin Proc*. 2006;81(11):1482–6.
- ^{xiii} Phuong L, Garg S, Duda JE, Stern MB, Weintraub D. Involuntary emotional expression disorder (IEED) in Parkinson's disease. *Parkinsonism Relat Disord*. 2009;15(7):511–5.
- ^{xiv} Colamonic J, Formella A, Bradley W. Pseudobulbar affect: burden of illness in the USA. *Adv Ther*. 2012;29(9):775-798. doi:10.1007/s12325-012-0043-7.
- ^{xv} Ahmed A, Simmons Z. Pseudobulbar affect: prevalence and management. 2013. *Therapeutics and Clinical Risk Management* 9:483-489.
- ^{xvi} Fonda J, McGlinchey R, Milberg W, et al. Study of pseudobulbar affect symptoms in veterans with mild traumatic brain. *Neurology*. 2014;82(10).
- ^{xvii} H.R.4994, S. 2552, The Improving Medicare Post-Acute Care Transformations (IMPACT) Act of 2014, Signed into Law, October 6, 2014, Amended Title XVIII of the Social Security Act, Section 18999B(a)(E)(i)(1)
- ^{xviii} Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) for FY 2016, 80 FR 22043, pp 22043 -22086, 4.20.2015, <https://www.federalregister.gov/articles/2015/04/20/2015-08944/medicare-program-prospective-payment-system-and-consolidated-billing-for-skilled-nursing-facilities>; Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2016. 80 FR 23331, pp 23331 -23399, 4.27.2015, <https://www.federalregister.gov/articles/2015/04/27/2015-09617/medicare-program-inpatient-rehabilitation-facility-prospective-payment-system-for-federal-fiscal>