



**AUG 25 2017**

Patrick M. Tigue  
Medicaid Director  
Rhode Island Executive Office of Health & Human Services  
Hazard Building #74, 1st Floor, Rm #1-7  
74 West Road  
Cranston, RI 02920

Dear Mr. Tigue:

I am writing in response to the amendment request to launch a three-year pilot program that will evaluate the clinical and fiscal effectiveness of Cortical Integrative Therapy under the section 1115(a) demonstration entitled "Rhode Island Comprehensive Demonstration" (Project No. 11-W-00242/1). I appreciate your efforts to find alternative methods and approaches towards improved brain therapies that may result in positive outcomes for Medicaid beneficiaries. However, we are not able to approve your request.

The Centers for Medicare & Medicaid Services (CMS) received your amendment request on September 22, 2015, with a proposed effective date of January 23, 2016. Based on the information made available to CMS by the state, we understand that this is a proposal to permit section 1115(a) authority for a single Rhode Island chiropractor to provide a specific clinical treatment, termed "Cortical Integrative Therapy" (CIT), that would make available to Medicaid beneficiaries a multidisciplinary range of services for treatment of a variety of neurologic disorders and brain injuries.

As proposed, the CIT treatment is broadly described, with very few parameters for cost or quality control for the specific array of services billed, the intensity of the services, the length of therapy, or the clinical indications for each service. The state has not provided scientific evidence verifying the efficacy of CIT, nor any indication that CIT was subject to such evaluation. CMS does not grant authority, under a section 1115 demonstration, for clinical interventions that have not demonstrated clinical safety and efficacy through standard clinical evaluation processes, and ideally through a rigorous randomized controlled trial. These trials and similar demonstrations could more appropriately be covered through grants available from the National Institutes of Health or other private and public funders of clinical research. We recommend the state look in to these opportunities.

We appreciate the work that the state has put into developing this proposal. Although we are not able to approve this proposal, we look forward to working with the state on other approaches for Rhode Island's Medicaid population in 2017 and beyond.

Sincerely,

A large black rectangular redaction box covering the signature of Seema Verma.

Seema Verma