Patient Name:

DOB:

To whom it may concern,

I am writing in response to your denial of coverage for my patient, (patient name) for treatment with responsive neurostimulation delivered by the RNS System for medically uncontrolled focal (partial) onset seizures. The reason for denial was (insert reason). I am writing to formally appeal this decision.

The RNS System has become the standard of care for individuals over the age of 18 with medically refractory focal onset seizures with a well localized seizure focus and has become an increasingly utilized treatment in refractory epilepsy in the pediatric population. It has been approved for over a decade for adults, and the evidence is very strong to support safety, effectiveness and medical necessity. The evidence has been published, was used by the FDA to approve the device for commercialization and has been sufficient to result in over 66 payers adopting a positive coverage policy on the RNS System including large national payers like Aetna, Anthem, Cigna, Humana and United Healthcare. In addition, the BCBS Association has a formal, positive reference policy that can be adopted by its member plans of which over 30 regional plans have done so.

The RNS System has Class I evidence for safety and efficacy in patients with medically intractable focal seizures. The RNS System pivotal trial[[1]](#footnote-1),[[2]](#footnote-2) , and results of the 7-year long-term follow-up trial[[3]](#footnote-3) have demonstrated clinically meaningful and sustained results supporting the medical necessity of treatment in patients with medically uncontrolled focal onset seizures. In addition, there is a peer reviewed article[[4]](#footnote-4) describing sustained improvements in quality of life in patients treated with the RNS System in the randomized controlled trial and another on neuropsychological outcomes following responsive neurostimulation for focal onset epilepsy.[[5]](#footnote-5)

Responsive neurostimulation (RNS) is an important treatment for pediatric patients with drug-resistant epilepsy for whom resective surgery is not an option. Over 100 patients under the age of 18 years have had RNS devices implanted and publications have shown the safety of the device in the pediatric age group[[6]](#footnote-6). In a case series and review of the literature, Curtis, K., et al performed a retrospective chart review to identify patients implanted with RNS devices for the treatment of drug-resistant epilepsy at their institution between 2020 and 2022. The authors identified 20 pediatric patients ranging in age from 8 to 21 years (mean 15 [SD 4] years), who underwent RNS implantation. There were no acute complications of RNS implantation (hemorrhage or stroke) or device malfunctions. The authors report comparable rates of serious adverse events to current RNS literature in pediatric and adult populations. This case series supports current literature suggesting that RNS is a safe and effective surgical intervention for pediatric patients with drug-resistant epilepsy. 7 Similar results have been noted in retrospective studies of pediatric RNS patients at Cincinnati Children’s Hospital Medical Center 8, and in a large multi-center retrospective study where data suggest that RNS is well tolerated and an effective off-label surgical treatment of drug-resistant epilepsy in pediatric patients as young as 3 years of age. 9

Efficacy of the RNS device in the pediatric population has been shown in recent publications. In a retrospective chart review of 22 patients who underwent RNS implantation at Phoenix Children’s Hospital, all patients had positive responses with reduction in seizure frequency and/or intensity10. Overall, seizure frequency reduction of >50% was seen in 86% of patients10. In 16 patients at UCLA Mattel Children’s Hospital there were 62% of patients with >50% reduction11. Finally in a study of RNS system implantation in pediatric patients at Children’s National Hospital all patients experienced a decrease in seizure frequency >50% from baseline preoperative seizure frequency11.

Cumulative positive long-term effects of the RNS device have been demonstrated in adults as reported in a multicenter clinical study[[7]](#footnote-7) of the RNS System published in *Epilepsia*. The retrospective study of 150 patients across eight epilepsy centers showed that patients who received the RNS System achieved a one-year median seizure frequency reduction of 67% and a two-year reduction of 75%. At three or more years, patients experienced an unprecedented 82% median reduction in seizure frequency—the highest reported for any neuromodulation system. In addition, recent long-term studies have shown that the cumulative seizure reduction effects of the RNS device decreases the risk of sudden unexpected death in epilepsy (SUDEP) 12. In order to provide pediatric patients with the maximum benefit from RNS and decrease their risk of SUDEP, early use of this device is paramount.

The safety data demonstrate that the risks of implantation are low, and that treatment is well-tolerated and safe over time. Adverse events were consistent with the known risks of stereotactic surgery and implantation of DBS systems for Parkinson’s Disease and Essential Tremor and of epilepsy surgery.

My patient is an ideal candidate for the RNS System for the reasons stated below:

* He/she has medically refractory focal onset epilepsy (DESCRIBE TYPE AND SEVERITY OF SEIZURES): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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* He/She has failed at least \_\_\_\_\_\_\_\_\_\_\_\_ different AEDs
* He/ She has undergone comprehensive diagnostic testing, including: (LIST ALL TESTS. DESCRIBE RESULTS AND WHY HE/SHE IS NOT A CANDIDATE FOR SURGERY.)

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(HIS/HER) care has been managed by (HIS/ HER) board-certified epileptologist and neurosurgeon. The details of the case, including all diagnostic tests and their results, have been presented before a multi-disciplinary case conference. After reviewing all the data and considering the risks and benefits of all available therapeutic modalities, the decision of the multidisciplinary group was to recommend RNS.

Given my patient’s clinical condition, treatments tried and failed, and the evidence supporting the safety and efficacy of the therapy, I believe responsive stimulation is the most appropriate treatment for my patient at this time and ask that you reverse the denial of coverage.

Please feel free to contact me directly at (enter phone number) if you have any questions or need additional information to approve coverage.

Sincerely,

(Insert attending epileptologist/neurosurgeon), MD/DO, PhD.

1. Morrell et al, Responsive cortical stimulation for the treatment of medically intractable partial epilepsy. Neurology 2011; 77: 1295-1304. [↑](#footnote-ref-1)
2. Heck et al., Two year seizure reduction in adults with medically intractable partial onset epilepsy treated with responsive neurostimulation: Final results of the RNS System Pivotal trial. Epilepsia 2014; 55: 432-44. [↑](#footnote-ref-2)
3. Nair et al., Nine-year prospective efficacy and safety of brain-responsive neurostimulation for focal epilepsy. Neurology. 2020; 95: e1244-e1256. [↑](#footnote-ref-3)
4. Meador et al., Quality of life and mood in patients with medically intractable epilepsy treated with targeted responsive neurostimulation. Epilepsy and Behavior 2015; Apr;45:242-7. [↑](#footnote-ref-4)
5. Loring et al. Differential Neuropsychological Outcomes Following Responsive Targeted Neurostimulation for Partial Onset Epilepsy. Epilepsia. 2015 Nov;56(11):1836-44.

6 Panov F, et al Safety of responsive neurostimulation in pediatric patients with medically refractory epilepsy. J NeurosurgPediatr 26:525–532, 2020

7 Curtis et al. Responsive neurostimulation for pediatric patients with drug-resistant epilepsy: a case series and review of the literature. Neurosurgical Focus, 2022;53(4):E10

 8Hartnett et al. Responsive neurostimulation device therapy in pediatric patients with complex medically refractory epilepsy. J Neurosurg Pediatr. 2022;1-8.

9 Nagahama et al. Real-World Preliminary Experience with Responsive Neurostimulation in Pediatric Epilepsy: A Multicenter Retrospective Observational Study. Neurosurgery. 2021;89(6):997-1004. [↑](#footnote-ref-5)
6. 10 Falls, et al. Responsive neurostimulation in pediatric patients with drug-resistant epilepsy. Nuerosurg Focus. 2022:53(4):E9

12 Mortazavi et al. Responsive neurostimulation for the treatment of medically refractory epilepsy in pediatric patients: strategies, outcomes, and technical considerations. J Neurosurg Pediatr. 2021:1-8.

11 Ahn et al. Bilateral centromedian nucleus of thalamus responsive neurostimulation for pediatric-onset drug-resistant epilepsy. Epilepsia. 2024; Aug;65(8):e131-e140. [↑](#footnote-ref-6)
7. 12Devinsky O, et al. Sudden unexpected death in epilepsy in patients treated with brain-responsive neurostimulation. Epilepsia. 2018 Mar;59(3):555-561.. [↑](#footnote-ref-7)