[Office letterhead]

[Date]

[Contact name of medical director or other payer representative]

[Contact title]

[Name of health insurance company]

[Mailing address]

Re:

Letter of Medical Necessity for J1823; UPLIZNA® (inebilizumab-cdon), injection, 1 mg

Patient: [Patient name]

Group/Policy Number: [Number]

Date(s) of Service: [Dates]

Diagnosis: G36.0, neuromyelitis optica [Devic]

Dear [Contact name or department],

I am writing on behalf of my patient, [Patient name], to document medical necessity for treatment with UPLIZNA® (inebilizumab-cdon). UPLIZNA is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. On behalf of [Patient name], I am requesting approval for use and subsequent payment for the treatments.

Medical History and Diagnosis

[Patient name] is [a/an] [age]-year-old [male/female] diagnosed with NMOSD. [Patient name] has been in my care since [DATE]. As a result of NMOSD, my patient [enter brief description of patient history]. Additionally, [Patient name] has tried [previous treatments] and [outcomes]. [If patient has been on UPLIZNA therapy, include outcomes experienced and consider including the effect of continuity of care.] The attached medical records document [Patient name]’s clinical condition and the medical necessity for treatments with UPLIZNA.

* [Diagnosis/ICD-10-CM code: Neuromyelitis optica [Devic]/G36.0]
* [Diagnosis of NMOSD confirmed by positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG) antibodies]
* [Documentation that UPLIZNA is prescribed by, or in consultation with, a neurologist]
* [Documentation of failure or of inadequate response to previous therapy (≥1 relapse in the past

12 months or ≥2 relapses in the past 24 months)]

* [Any relevant clinical/chart notes]

Based on the above facts, I have made the assessment that UPLIZNA is indicated and medically necessary for [Patient name]. The plan of treatment is to administer an initial dose of 300 mg of UPLIZNA via intravenous (IV) infusion on [date], followed [2 weeks later/on date] by a second 300-mg dose. Subsequent single 300-mg doses of UPLIZNA via IV infusion will follow every 6 months thereafter, starting 6 months from the date of the first infusion.

Please consider coverage of UPLIZNA for [Patient name] and approve use and subsequent payment for UPLIZNA as planned. Please refer to the enclosed Prescribing Information for UPLIZNA. If you have any further questions regarding this matter, please do not hesitate to call me at [physician telephone number]. Thank you for your prompt attention to this matter.

Sincerely,

[Physician’s name]

[Physician’s signature]

[Physician’s medical specialty]

[Physician’s NPI]

[Physician’s practice name]

[Phone #]

[Fax #]

Enclosures: [attach as appropriate]

[FDA approval letter (available at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)]

[Prescribing Information]

[Clinical notes and labs, such as patient relapse history, failure or inadequate response to previous therapy, discontinuation, documentation of AQP4-IgG antibody test results, and specialized test results (CSF examination, spinal taps, MRIs, or CT/CAT scans)]

CC: [Medical director, patient, specialty society, insurance]