**SAMPLE Letter of Medical Necessity**

This sample letter and related information is provided for informational purposes only. It provides an example of the types of information that may be provided when responding to a request from a patient’s health plan/insurer to provide a letter of medical necessity for Gliadel. Health plan requirements may vary, so the prescriber should refer to the prior authorization or coverage information specific to their patient’s health plan before completing a Letter of Medical Necessity. Use of the information in this letter does not guarantee coverage or that the health plan will provide reimbursement for Gliadel and is not intended to be a substitute for or to influence the independent medical judgment of the physician. It is the responsibility of the prescriber and/or their office staff, as appropriate, to determine the correct diagnosis, treatment protocol, and content of all such letters and related forms for each individual patient. The prescriber should refer to the Important Safety Information and the full Prescribing Information when determining whether the product is medically appropriate for a patient.

**SAMPLE Letter of Medical Necessity**

Patient: **[Patient Name]**

Group/policy Number: **[Number]**

Date(s) of service: **[Dates]**

Diagnosis: **[Code & Description]**

Dear **[Contact Name or Department]:**

I am writing on behalf of my patient, **[PATIENT NAME]**, to **[REQUEST PRIOR AUTHORZATION/DOCUMENT MEDICAL NECESSITY]** for treatment with **[Drug Name]**. **[Drug Name]** is indicated for treatment of **[Indication Statement]**. This letter serves to document that **[PATIENT NAME]** has a diagnosis of **[DIAGNOSIS] [Code]** and needs treatment with **[Drug Name]**, and that **[Drug Name]** is medically necessary for **[him/her]** as prescribed. On behalf of **[PATIENT NAME]**, I am requesting approval for use and subsequent payment for the treatment with **[Drug Name]**.

**Summary of Patient Medical History and Diagnosis**

**[PATIENT NAME]** is a **[AGE]**-year-old **[MALE/FEMALE]** diagnosed with **[DIAGNOSIS]**. **[NAME OF PATIENT]** has been in my care since **[DATE]**. As a result of **[DIAGNOSIS]**, my patient **[ENTER BRIEF DESCRIPTION OF PATIENT HISTORY and RECENT PRESENTATION]**. In my professional opinion, **[PATIENT NAME]**’s likely prognosis without treatment with **[Drug Name] [provide summary of medical opinion]**.

**Clinical Rationale for [Product]**

Given the **[PATIENT NAME]**’s history, condition, and the supporting clinical information **[attached supporting medical records, laboratory reports, etc.]**, I believe treatment of **[PATIENT NAME]** with **[Product]** is warranted, appropriate and medically necessary. **[Drug Name]** is indicated for **[Drug Indication]**. The accompanying prescribing information provides the approved clinical information for **[Drug Name]**. The plan of treatment is to start the patient on **[Drug Name]**, **[provide treatment course]**.

In summary, **[Drug Name]** is medically necessary and reasonable for **[PATIENT NAME]**’s medical condition and warrants coverage. Please contact me at **[PHYSICIAN TELEPHONE NUMBER]** if you require additional information about this case. Thank you for your prompt attention.

Sincerely,

**[PHYSICIAN NAME]**, **<DEGREE>**

**INDICATIONS**

GLIADEL Wafer is indicated for the treatment of patients with newly-diagnosed high-grade glioma as an adjunct to surgery and radiation.

GLIADEL Wafer is also indicated for the treatment of patients with recurrent glioblastoma as an adjunct to surgery.

**IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS**

**Seizures:** Seizures occurred in 37% of patients treated with GLIADEL Wafers for recurrent glioma in the recurrent high-grade glioma trial. New or worsening (treatment emergent) seizures occurred in 20% of patients; 54% of treatment emergent seizures occurred within the first 5 post-operative days. The median time to onset of the first new or worsened post-operative seizure was four days. Institute optimal anti-seizure therapy prior to surgery. Monitor patients for seizures postoperatively.

**Intracranial Hypertension:** Brain edema occurred in 23% of patients with newly diagnosed glioma treated with GLIADEL Wafers in the newly-diagnosed high-grade glioma trial. Additionally, one GLIADEL-treated patient experienced intracerebral mass effect unresponsive to corticosteroids which led to brain herniation. Monitor patients closely for intracranial hypertension related to brain edema, inflammation, or necrosis of the brain tissue surrounding the resection. In refractory cases, consider re-operation and removal of GLIADEL Wafers or Wafer remnants.

**Impaired Neurosurgical Wound Healing:** Impaired neurosurgical wound healing including wound dehiscence, delayed wound healing, and subdural, subgaleal, or wound effusions occur with GLIADEL Wafer treatment. In the newly-diagnosed high-grade glioma trial, 16% of GLIADEL Wafer-treated patients with newly diagnosed glioma experienced impaired intracranial wound healing and 5% had cerebrospinal fluid leaks. In the recurrent high-grade glioma trial, 14% of GLIADEL Wafer-treated patients with recurrent high-grade glioma experienced wound healing abnormalities. Monitor patients post-operatively for impaired neurosurgical wound healing.

**Meningitis:** Meningitis occurred in 4% of patients with recurrent glioma receiving GLIADEL Wafers in the recurrent high-grade glioma trial. Two cases of meningitis were bacterial; one patient required removal of the Wafers four days after implantation; the other developed meningitis following reoperation for recurrent tumor. One case was diagnosed as chemical meningitis and resolved following steroid treatment. In one case the cause was unspecified, but meningitis resolved following antibiotic treatment. Monitor postoperatively for signs of meningitis and central nervous system infection.

**Wafer Migration:** GLIADEL Wafer migration can occur. To reduce the risk of obstructive hydrocephalus due to wafer migration into the ventricular system, close any communication larger than the diameter of a Wafer between the surgical resection cavity and the ventricular system prior to Wafer implantation. Monitor patients for signs of obstructive hydrocephalus.

**Embryo-Fetal Toxicity:** GLIADEL Wafers can cause fetal harm when administered to a pregnant woman. Carmustine, the active component of GLIADEL Wafer, is embryotoxic and teratogenic in rats at exposures less than the exposure at the recommended human dose based on body surface area (BSA) and embryotoxic in rabbits at exposures similar to the exposure at the recommended human dose based on BSA. Advise patients of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception for 6 months after implantation of GLIADEL Wafer. Advise males with female partners of reproductive potential to use effective contraception for 3 months following implantation of Gliadel Wafers.

**ADVERSE REACTIONS**

The most common adverse reactions in newly-diagnosed high-grade glioma patients (incidence >10% and between arm difference ≥4%) are cerebral edema, asthenia, nausea, vomiting, constipation, wound healing abnormalities and depression.

The most common adverse reactions in recurrent high-grade glioma patients (incidence >10% and between arm difference ≥4%) are urinary tract infection, wound healing abnormalities and fever.

**The Important Safety Information does not include all the information needed to use GLIADEL safely and effectively. For additional safety information, please consult the full Prescribing Information for** [**GLIADEL**](https://gliadel.com/hcp/media/_pdfs/Gliadel-Prescribing-Information.pdf)**.**

**To report SUSPECTED ADVERSE REACTIONS, contact Azurity Pharmaceuticals, Inc. at 1-800-461-7449 or FDA at** [**www.fda.gov/medwatch**](https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program?utm_source=etechtrack&utm_medium=email&utm_campaign=etechtrack) **or call 1-800-FDA-1088.**

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