For the benefit of patients for whom you prescribe DIACOMIT, we are providing this sample letter of appeal, which can be customized by your office and submitted to insurers as part of the prior authorization, medical exception, or pre-determination process. This sample includes general information on Dravet Syndrome and DIACOMIT. You may use this to supplement your patient-specific assessment, clinical judgement and rationale for the medical necessity of DIACOMIT. Please fax this letter to US Bioservices at 833-871-4137 and send a copy to the patient.

If you would like more information on how to utilize this template letter, please contact the Support Center by calling toll-free at 833-248-0467, Monday through Friday, 8 AM to 8 PM ET.

**\*\*\*Remove this section prior to sending this letter\*\*\***



**[Practice Letterhead]**

**[Date]**

**[Name of Medical Director] [Title] [Name of Insurer]**

**[Address of Insurer]**

**[City, State, Zip Code]**

**Re: [Patient Name]**

**[Patient ID Number]
[Diagnosis Code(s) and Description(s)]**

This letter serves as a request for reconsideration for payment of a denied **[prior authorization request, formulary exception, claim]** for DIACOMIT® (stiripentol) for **[patient’s full name]**. **[Name of patient]** has been under my care for **[his/her/their]** treatment of seizures associated with Dravet syndrome (DS) for **[number of years]**. You have indicated that access to DIACOMIT is prevented by **[insurance company name]** because of **[reason for denial]**.

**[Provide a brief overview of the patient’s clinical course of the disease which may include: working diagnosis prior to DS confirmation, diagnosis prior to confirmation of any gene mutations, response to any antiepileptic drugs taken (such as clobazam [CLP] or valproic acid [VPA]), occurrence of myoclonic seizures and ataxia, occurrence of developmental delay, mental retardation, psychiatric and behavior problems, orthopedic and movement issues, and sleep disorders.]**

DIACOMIT is an FDA-approved medication for the treatment of seizures associated with DS in children aged 2 years and up. DIACOMIT comes in capsules and fruit-flavored powder packets so that caregivers have options for giving the treatment to their child. DIACOMIT offers clinically meaningful reduction in seizure frequency and duration, in frequency of emergency room/hospital visits, and in frequency of rescue medication use. Finally, DIACOMIT fills an unmet need in this rare and potentially catastrophic epilepsy.

DIACOMIT is a medically necessary part of **[name of patient]**’s treatment. I respectfully request that a specialist at your **[insurance company name]** who is familiar with this therapeutic area review this appeal letter with the additional documentation provided. I am confident that your reconsideration of this appeal would help facilitate access to DIACOMIT for **[name of patient]**. Please contact me at **[(XXX) XXX-XXXX]** if you require additional information.

Sincerely,
**[Physician’s name and title]**

Enclosures: **[Please list and include any additional clinic notes, prescribing Information, FDA approval letter, other supportive medical literature]**

**INDICATION**

DIACOMIT (stiripentol) capsules for oral use or powder for oral suspension are indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older taking clobazam. There are no clinical data to support the use of DIACOMIT as monotherapy in Dravet syndrome.

**IMPORTANT SAFETY INFORMATION CONTRAINDICATIONS**

No contraindications are listed.

**WARNINGS & PRECAUTIONS**

**Somnolence**

DIACOMIT can cause somnolence. Monitor patients for somnolence, particularly when DIACOMIT is used concomitantly with other CNS depressants or clobazam, which is also known to cause somnolence.

**Decreased Appetite and Decreased Weight**

DIACOMIT can cause decreases in appetite and weight. The growth and weight of pediatric patients treated with DIACOMIT should be carefully monitored.

**Neutropenia and Thrombocytopenia**

DIACOMIT can cause significant declines in neutrophil and platelet counts. Hematologic testing should be obtained prior to starting treatment with DIACOMIT and then every 6 months.

**Withdrawal Symptoms**

As with most antiepileptic drugs (AEDs), DIACOMIT should be gradually withdrawn to minimize the risk of increased seizure frequency and status epilepticus.

**Risks in Patients with Phenylketonuria (PKU)**

DIACOMIT powder for suspension contains phenylalanine, which can be harmful to patients with PKU. Before prescribing DIACOMIT powder for suspension to a patient with PKU, consider the total daily intake of phenylalanine from all sources, including DIACOMIT powder for suspension. DIACOMIT capsules do not contain phenylalanine.

**Suicidal Behavior and Ideation**

AEDs, including DIACOMIT, increase the risk of suicidal thoughts or behavior. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

**ADVERSE REACTIONS**

The most common adverse reactions that occurred in at least 10% of DIACOMIT-treated patients and more frequently than on placebo were somnolence, decreased appetite, agitation, ataxia, decreased weight, hypotonia, nausea, tremor, dysarthria, and insomnia.

**PREGNANCY**

There are no adequate data on the developmental risks associated with the use of DIACOMIT in pregnant women. Based on animal data, DIACOMIT may cause fetal harm.

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to AEDs, such as DIACOMIT, during pregnancy. Physicians are advised to recommend that pregnant patients taking DIACOMIT enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry (information at http://www.aedpregnancyregistry.org). This can be done by calling the toll-free number 1-888-233-2334, and must be done by patients themselves or their caregiver.

To report suspected adverse reactions, contact BIOCODEX at 1-866-330-3050 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.