[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 **[name of patient]**. **[Name of patient]** has been under my care for **[his/her]** diagnosis of Dravet syndrome (DS). 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 (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 orphan product for DS. 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 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 **[physician's telephone number]** if you require additional information.

Sincerely,

[Physician's name], MD

Enclosures: **[Letter of Medical Necessity, 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