**Galzin® (zinc acetate) capsules**

 **Insurance Appeal and/or Medical Necessity Template**

[Date]

[Insurance Company]

RE: Coverage for Galzin (zinc acetate) capsules

[Member ID]

[Patient Name]

[DOB]

[Address] [City, State, Zip]

[Medical Condition: E83.01: Wilson Disease]

Group Number: {Insert here]

Policy Number: {Insert here]

To Whom It May Concern:

I am writing to document [Patient Name] need for Galzin (zinc acetate) capsules, which is medically necessary to treat Wilson disease, a rare autosomal recessive disorder of the *ATP7B* gene, which causes an abnormal accumulation of copper is key organs, especially the brain and liver

Galzin is not being prescribed as a mineral supplement. In contrast, Galzin is an FDA-approved formulation of zinc acetate with precise bioavailability and drug delivery to enhance the production of a protein, metallothionein, which binds free copper from foods, preventing absorption. The ramifications of not receiving Galzin would be increased absorption of copper that would be accumulated in the liver and brain. The increased copper would then cause more serious consequences. For example, if the hepatotoxicity gets bad enough, then the only available treatment would be a liver transplant, which has its own issues.

Galzin was studied in careful clinical trials.  Galzin is the only formulation of zinc approved by the FDA under the Orphan Drug Act for the treatment of Wilson's disease. In contrast, dietary supplement zinc preparations have not been studied to demonstrate safety or efficacy in patients with Wilson disease.   Moreover, the manufacturing of dietary supplement zinc preparations is not regulated by the FDA to ensure tight pill-to-pill regularity, bioavailability, or absence of toxins.

As stated in the AASLD Guidelines for the Diagnosis and Treatment of Wilson Disease, it is recommended that full-dose zinc, 150 mg/day divided into three doses, be used is asymptomatic patients or maintenance therapy (Schilsky et al., *Hepatology* DOI: 10.1002/hep.32801). Additionally, the guidelines state that it is important that Wilson disease patients to remain on Galzin to stay asymptomatic.

In closing, it is medically necessary for [Patient name] to be on Galzin to treat Wilson disease. There are no other FDA-approved zinc preparations for the treatment of Wilson disease. Additionally, dietary supplements are not a viable option because they have not been studied for their safety or efficacy in this vulnerable population.

We do appreciate your consideration of this request. If you have further questions, please do not hesitate to call [Phone Number].

Sincerely,

Dr. XXXXXXXX

[Phone #]

[Email Address]

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