



April 11, 2022

[Clinic Address]

Re: [Patient Name] [Patient DOB]

[Patient ID] [Case Number]

Dear Appeals Department:

I am writing on behalf of my patient, [Patient Name], to document an appeal for Cabenuva 600/900mg dosed every 2 months for Human Immunodeficiency Virus-1 infection. He cannot use any other oral antiretroviral formulary alternatives since they are not effective or well absorbed due to his post-bariatric surgery. He has several documented medical conditions and adverse drug reactions that also prevent him from being successfully treated with these alternatives. Biktarvy and Genvoya have the potential to worsen his obesity. His GERD precludes other formulary alternatives like Symtuza, and Odefsey. Texas law SB680 prohibits any further step therapy requirements for [Patient Name]. Other formulary alternatives will cause a significant barrier to his adherence or compliance to his plan of care. They are also expected to be ineffective based on the known clinical characteristics of him and known characteristics of the drug regimen

[Patient Name] has been in continuous care regarding his health and is currently taking Triumeq. His previous antiretroviral regimens were, Truvada, Prezcobix, Norvir, Prezista, Complera, and Atripla (EFV/FTC/TDF). He has developed several intolerances to oral medications. His irritable bowel syndrome, ulcers, and gastrointestinal issues also create pill aversion issues. In addition, he has ongoing vomiting post bariatric surgery. This makes it difficult to adhere to his daily oral Triumeq doses, which may also be elevating his weight, glucose, and triglycerides. He discontinued Prezcobix due to increased insomnia, fatigue, depression, anxiety, and anger. He experienced diarrhea with Truvada, Norvir, and Prezista. The combination of these health problems makes [Patient Name] an ideal candidate for Cabenuva injections, and he has been looking forward to the freedom of receiving treatments every other month.

With Cabenuva, there is no daily pill aversion or pill fatigue to hinder compliance. [Patient Name] history has proven that he is dependable and will not miss injection appointments. Our current Cabenuva patients report fewer depressive symptoms and a freedom from the painful daily reminder of their HIV status as well as freedom from the anxiety associated with not being able to remember if they took their pill. Failure to treat [Patient Name] with Cabenuva will require him to continue daily oral treatment. This would be unfavorable and his continued success at maintaining viral suppression would be placed into question. As you know, failure to



maintain viral suppression can have dire consequences for [Patient Name] health as well as the health of his current intimate partner.

Several of our patients struggle with daily HIV medication adherence for many reasons well documented in HIV Standards of Care. For example, we know young women trying to adhere to birth control have added success when switching to a long-term injectable. Switching patients to Cabenuva helps those young populations, those who live chaotic lifestyles, individuals struggling with addiction, or patients who simply cannot prioritize a daily pill regimen. Data has shown that 66% of patients who cannot tolerate oral medication can reach the goal of undetectable with long acting injectables. Being undetectable is life-changing and important for public health and reducing transmission. Our current patients on Cabenuva prove that this regimen does solve adherence issues. Knowing these benefits, I am requesting [Patient's Plan Name] to approve Cabenuva as it has become a great adherence tool. [Patient's Plan Name] needs to be on the right side of public health, and the right side on the history to end HIV.

People living with HIV face challenges with daily therapies and are interested in alternative dosing options. Research shows nine out of every ten trial participants preferred long-acting Cabenuva injections dosed every two months compared to daily oral Vocabria and Edurant taken as the oral lead-in. This preference data highlights the meaningful impact long-acting regimens can have on the treatment experience for the HIV community.

[Patient Name] laboratory results meet the clinical diagnosis criteria for HIV disease. He was diagnosed with HIV-1 infection in 2011 and has been a patient with our practice since 2016. With dosing six times a year, this makes Cabenuva the least expensive antiretroviral medication available. This will be a continuation of treatment as he will be starting the oral lead-in regimen Vocabria and Edurant. [Patient Name] requires enhanced treatment support, and I am requesting approval for use of Cabenuva 600/900mg and subsequent payment for treatments through [Patient's Plan Name].

We believe that Cabenuva is indicated for the treatment of HIV-1 infection in the case of [Patient Name], and this is supported by the FDA approved package insert, the International AIDS Society USA guidelines, as well as the Department of Health and Human Services Guidelines Regarding the Treatment of HIV-1 Infection in Adults and Adolescents. Please reconsider approval and coverage of Cabenuva on his behalf. If you have any further questions, please do not hesitate to contact me.



Thank you for your prompt attention to this matter,

[Provider Name and Credentials]

[Provider NPI]

[Provider Phone and Fax]

CC: A copy of this letter will be placed in the patient's permanent medical record.