To whom it may concern:

I am writing this letter on behalf of my patient,      , to provide justification for the necessity of topical sirolimus (rapamycin) for medical treatment of his/her facial angiofibromas.       has a diagnosis of tuberous sclerosis complex (TSC), a genetic disorder that causes non-malignant tumors to form in many different organs, primarily in the brain, eyes, heart, kidney, skin and lungs. Most people with TSC have changes in their skin due to uncontrolled cell proliferation resulting from a genetic mutation in the TSC1 or TSC2 tumor-suppressor gene. Angiofibroma is a skin growth which initially may appear in early childhood as flat red “spots” on the face, or a diffuse redness of the cheeks. The redness is due to increased blood vessels in the skin. The lesions tend to be progressive and become nodular in adolescence due to increased amounts of fibrous tissue and may spontaneously bleed as well as multiply in numbers if not removed. They are usually, but not always, distributed over the centrofacial areas, particularly near the nasolabial folds, onto the cheeks in a butterfly pattern, and on the chin. They are sometimes seen on the forehead, scalp region, or even laterally on the face. Facial angiofibroma is a well-recognized cause of morbidity for patients with TSC, which can have significant psychological impact as well.

In the past, dermabrasion and surgical removal were the only options for removal of facial angiofibromas. The use of CO2 and pulse dye lasers to treat facial angiofibromas are now widely accepted and are proving to be more effective, less painful, and less likely to leave scars than older treatments. However, general anesthesia is often necessary depending on the individual’s ability to cope with the procedure, especially for those individuals with severe developmental disabilities. The results of laser treatment are usually short-lived and reoccurrence is common. As a result, laser surgery may need to be repeated with or without general anesthesia over the course of an individual’s lifetime. The TSC Dermatology and Dentistry Subcommittee of the 2012 International TSC Clinical Consensus Conference considered these factors in providing treatment recommendations for tuberous sclerosis, and included the use of topical sirolimus in their consensus statement15.

The introduction of mTOR inhibitors for the treatment of TSC has led to the use of topical sirolimus (rapamycin) for facial angiofibromas in a number of case studies and several large clinical trials1-14. Cream or ointment preparations are custom compounded by specialty pharmacies in strengths ranging from 0.1% to 1.0% per the prescribing doctor. Topical treatment appears to be well-tolerated with no evident local or systemic adverse effects and results in dramatic improvement of the skin lesions1-14. It also is a cost-effective option for management of facial angiofibromas compared to most of the surgical interventions that require general anesthesia.

I am prescribing topical sirolimus for       with the expectation that the cost will be covered. Please contact me if you have any questions.

Sincerely,

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