Re: Checklist to use for VIP

April 18, 2011

Dear Patient:

You are receiving this letter because your case has indicated the possibility that replacement dosing of vasoactive intestinal polypeptide (VIP) could be of benefit. We have seen significant improvement in quality of life and stabilization of inflammatory perimeters in nearly 400 patients who have used VIP since November 2008.

VIP is an "orphan drug," that has received an FDA designation for use in treatment of pulmonary hypertension. It is not on a list of drugs that are labeled by the FDA as "may not be compounded."

VIP is a naturally occurring human neuropeptide. This compound affects multiple pathways in the brain throughout the body. It raises intracellular levels of cyclic AMP; reduces pulmonary pressure in exercise; lowers C4a; and stabilizes TGF beta-1 to prevent production of pathogenic T-cells in tissue. It normalizes low VEGF; stabilizes aromatase and helps correct abnormal Vitamin D physiology.

One may say that VIP has the capability of being a "miracle drug."

We know that miracles don't happen often in medicine, however. VIP must be kept refrigerated and the vial of VIP that you use must be kept upright in the refrigerator as the aerosol adapter for the vial has (in some patients) not provided a 100% seal. VIP must be fresh; any peptide older than one month loses some of its efficacy.

In order to use VIP, there are three hurdles that each patient must pass. The first is the visual contrast sensitivity, either in a physician's office or on line @ <u>www.survivingmold.com</u>, must be normal. The Environmental Mold Index (ERMI) must be <2 if MSH is <35. Finally, a nasal culture performed at Cambridge Biomedical must show that there are no biofilm-forming coagulase negative staph present.

When all three of these criteria are met and patient has adequate understanding of what VIP can do, then the patient can begin treatment with one spray four times a day. It does not matter which side of the nose you use and it is not necessary to have the doses spread out exactly 6 hours apart. Typically patients will take a spray when they brush their teeth in the morning and at bedtime as well at lunch and supper. I suggest blowing your nose to remove any dust, debris and mucus before using the VIP.

We will need to monitor laboratory testing to show safety and efficacy. You will have to document that the levels of lipase remain normal after one month. We also will have follow up testing to show efficacy in treating biochemical abnormalities. If you do not have a requisition for these labs, please contact this office with adequate time so that 30 days after beginning VIP monitoring labs can be done.

Further titration of dosing either up or down is only done after consultation with me. Please send us a note in the mail if you have questions before starting VIP. Use of phone, fax or email has proved to be cumbersome, given the demand for this medication. Don't start VIP, however, until you are clear what the drug can do for you.

Sincerely,

Ritchie C. Shoemaker, M.D.