## Letter to the Editor: Insurance Should Cover Vancomycin for Primary Sclerosing Cholangitis

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**Conflict of Interest:** Ryan Fisher advises and is on the speakers' bureau for Mirum Pharmaceuticals. He is on the speakers' bureau for Albireo Pharma, Inc. Shamita Shah is on the speakers' bureau for Abbvie and Janssen. She advises Pfizer.



## Dear Editors,

Healthcare insurers should cover costs of oral vancomycin (OV) for treatment of primary sclerosing cholangitis (PSC). AASLD's 2022 PSC Practice Guidance ("Guidance") combined with the AASLD separate "Support Statement" are helpful.

While the Guidance doesn't recommend OV for PSC [1], AASLD published a separate "Support Statement" stating: "The Guidance notes the insufficiency of the evidence and accordingly does not make a recommendation for or against the use of OV for the treatment of PSC. In the absence of a definitive clinical trial, the decision to use an off-label medication should remain between the doctor and the patient. Larger clinical trials or studies are needed to conclusively assess the efficacy and safety of vancomycin in PSC. Although there is not sufficient evidence to make a formal recommendation regarding the use of OV for PSC, it should not be used as justification to restrict coverage of this treatment if a physician feels it is the right course of action."[2]

Although large, controlled trials are not yet completed, two small, controlled trials and evidence from multiple cohort studies are summarized in a systematic review and meta-analysis demonstrating OV has beneficial effects on liver functions in PSC patients. These robust findings are further supported by a recent pediatric/adult cohort study where OV showed benefits in lowering cholestatic enzymes and improving MRCP findings of bile duct dilatation and stenoses[3,4]. This might translate to fewer liver transplants, fewer hospitalizations for acute cholangitis, and other expensive consequences of not treating this devastating disease.

Additionally, OV has beneficial effects on PSC associated colitis with improvement of the diarrhea and other symptoms.[3,4] The medical community desires better treatments at lower costs. For responsive PSC/inflammatory bowel disease (IBD) patients, insurers stand to benefit financially by allowing OV to be substituted for biologic drugs. The beneficial effects of OV on colitis are its most reliable effects. Biologics typically cost 5 times more than OV, and the gain over placebo is small. Some surgeries might also be avoided; our patients have avoided colectomies with OV.

While OV does not work for all PSC patients, no other treatment (besides liver transplantation) has proven effective in even a subgroup of PSC patients. Medical and financial reasons for insurers to cover OV for PSC are compelling as long as the physician and patient can demonstrate that OV benefits the patient.

## **References:**

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