

CONFER Cases Round 11

Description

Case 1

Case Title	Effectiveness and Safety of Ozanimod and Natalizumab in Patients with Coexisting Inflammatory Bowel Disease and Multiple Sclerosis
Principal Investigator	Marie Truyens
Case Manager	Mette Julsgaard
Case Description	Patients with both inflammatory bowel disease (IBD) and multiple sclerosis (MS) present unique therapeutic challenges due to overlapping immune mechanisms and the complex safety profiles of immunomodulatory treatments. While both ozanimod and natalizumab, selective immunomodulators, have demonstrated efficacy in managing IBD and MS individually, their effectiveness in patients with concurrent IBD and MS has yet to be comprehensively evaluated. Natalizumab, a monoclonal antibody that targets the a4-subunit of both a4 β 1 and a4 β 7 integrins has proven effectiveness in
	reducing MS relapse rates (1) as well as inducing remission in Crohn's disease (CD) (2, 3). However, its association with progressive multifocal leukoencephalopathy (PML) and the availability of alternative agents that are not associated with PML have limited the use of natalizumab for CD.
	Currently, in Europe, natalizumab is only approved for MS (3). Ozanimod, an oral sphingosine 1-phosphate receptor modulator (S1PR), has demonstrated promising results in managing moderate-to-severe ulcerative colitis (UC) (4) and relapsing-remitting MS (5), and is approved in Europe for bothconditions.
Main Clinical Question	This CONFER case aims to evaluate the effectiveness and safety profiles of ozanimod and natalizumab in patients with concurrent IBD and MS. The study will focus on disease activity, relapse rates, and adverse events of both diseases under treatment with one of these molecules. By examining real-world data across multiple centers, this study seeks to provide valuable insights into the optimal management of this complex patient population, guiding therapeutic decisions.
Literature on the topic	Several studies have confirmed the effectiveness of ozanimod and natalizumab for both IBD as well as MS (1, 3-6), but to our knowledge, no studies have specifically assessed outcomes in patients with concurrent IBD and MS. References:
	 Brandstadter R, Katz Sand I. The use of natalizumab for multiple sclerosis. Neuropsychiatric Disease and Treatment. 2017;13(null):1691-702. Pagnini C, Arseneau KO, Cominelli F. Natalizumab in the treatment of Crohn's disease patients. Expert Opinion on Biological Therapy. 2017;17(11):1433-8. Nelson SML, Nguyen TM, McDonald JWD, MacDonald JK. Natalizumab for induction of remission in Crohn's disease. Cochrane Database of Systematic Reviews. 2018(8). Sandborn WJ, Feagan BG, D'Haens G, Wolf DC, Jovanovic I, Hanauer SB, et al. Ozanimod as Induction and Maintenance Therapy for Ulcerative Colitis. New England Journal of Medicine. 2021;385(14):1280-91. Lassiter G, Melancon C, Rooney T, Murat A-M, Kaye JS, Kaye AM, et al. Ozanimod to Treat Relapsing Forms of Multiple



- Sclerosis: A Comprehensive Review of Disease, Drug Efficacy and Side Effects. Neurology International. 2020;12(3):89-108.

 6. Rubin DT, Cree BAC, Wolf DC, Alekseeva O, Charles L, Petersen A, et al. S911 Long-Term Safety of Ozanimod in Moderately to Severely Active Ulcerative Colitis and Relapsing Multiple Sclerosis. Official journal of the American College of Gastroenterology | ACG. 2023;118(10S):S680