

CellCept® Covered by Medicare part d

R People who have systemic sclerosis (SSc) find out quickly that there are no medications approved by the U.S. Food and Drug Administration (FDA) specifically for the treatment of their disease. They also know that the Scleroderma Foundation works every day to raise money to fund research to discover the cause of scleroderma, to understand the disease mechanism, and to overcome its symptoms. What people might not know is that we don't stop there.

There are many drugs on the market that doctors prescribe that are not approved by the FDA specifically for the particular illness the doctor is using it to treat. Prescribing drugs in this manner is called "off-label," and doctors have the authority to use drugs this way. Drug companies, however, are not allowed to market their drug for any use other than what is approved by the FDA.

Insurance companies don't necessarily pay for off-label prescriptions. Medicare Part D (prescription coverage) is specifically prohibited from covering off-label drugs unless they appear on an approved list referred to as "the compendia." Drugs are only listed on the compendia if there is sufficient scientific data to prove that they are safe and effective for a particular illness. That means that someone has to pick up the ball and run with it to collect the data and present it to the compendia for their review, and to follow up to make sure it's been addressed.

That's where the Scleroderma Foundation comes in, specifically **Jessica Farrell**, Pharm.D., a member of the Foundation's **Medical & Scientific Advisory Board** (MSAB), Clinical Pharmacist at The Center for Rheumatology, and Associate Professor at Albany College of Pharmacy and Health Sciences.

It is well known among physicians that **CellCept®** (*mycophenolate mofetil*) has been shown in multiple studies to lower measures of

skin thickening and a stabilizing effect on lung involvement in patients with SSc. Because it is not FDA-approved for use in SSc, CellCept often requires a lengthy and often unsuccessful prior authorization process before the insurance company will approve coverage. For patients with Medicare Part D, CellCept is never approved due to strict laws regarding off-label use.

Because the MSAB includes physicians who treat patients in addition to carrying out research, they are well aware of the challenge of prescribing CellCept as an off-label medication. They are equally aware of its benefit for individuals with systemic sclerosis.

Dr. Farrell became a member of the MSAB over the past year, and was asked to use her professional knowledge and experience to help make the case for CellCept. With the help of her pharmacy students, she compiled the necessary data and determined the required procedures for submitting the application.

"With rare conditions like SSc, every aspect of medical care can be met with a road block, especially when it comes to insurance coverage for medication," said Farrell. "We (healthcare providers, supporters, and patients) have no choice but to advocate for this condition and fight to pave new paths to accomplish even small feats."

Thanks to Dr. Farrell, CellCept is now listed in the Medicare drug database for off-label use in scleroderma.

"We had a patient who was denied the week before I found the indication was listed in Micromedex. The cost to her would have been extraordinary," said Farrell. "We resubmitted stating SSc was an off-label use referenced in the compendia and a day later got the approval response! Now the medication will cost the patient \$19.34/month." 