Living with MS

Tecfidera generic approved by FDA

On August 17, 2020, the United States Food and Drug Administration (FDA) awarded approval of Mylan's generic version of Tecfidera® (dimethyl fumarate), an oral medication approved in 2013 for relapsing forms of MS in adults. This is the first generic of any MS oral treatment available to individuals in the United States.



Generic treatments have the same active ingredients and carry the same benefits and risks of the brand-name medication. Inactive ingredients can differ with generic medications, and generic treatments are not required to conduct the same degree of rigorous clinical trials prior to approval. As a result, generic medications are normally offered at a lower cost to the patient. While having more affordable medications is important, the cost of generics may still be a lot for patients to pay out of pocket and generic medications do not come with the high level of patient support provided by the manufacturer of the brand-name medication.

Biogen launched Vumerity

In October 2019, the FDA also approved Vumerity (diroximel fumarate) for people with relapsing forms of MS, including clinically isolated syndrome, relapsing-remitting MS and active secondary progressive MS.

Vumerity is similar to Tecfidera but has a different chemical structure. Once in the body Vumerity is modified to become the same active ingredient as Tecfidera. Because of the similarity to Tecfidera, Vumerity was not required to undergo the extensive clinical trials that other disease modifying treatments do. Vumerity only had to approve bioequivalence to Tecfidera. If two products are said to be bioequivalent then they are determined to be the same. Biogen announced the results of their study that compared side effects of Tecfidera vs Vumerity. Vumerity was better tolerated and had significantly fewer reported gastrointestinal symptoms compared to Tecfidera. The most common adverse events for both treatment groups were flushing, diarrhea and nausea. Rates of these events were significantly lower for the Vumerity group though.



While the active ingredient is the same, the initial molecule is different for Vumerity. Because of this, Vumerity requires two pills twice a day instead of the one pill twice a day needed for Tecfidera.

How this might affect you

Sometimes when your provider writes a prescription for a brand-name medication, the pharmacy changes it to the generic. Please speak with someone at our office before you agree to switch to the generic to ensure there are no problems. Since there is no patient support for generic medications your provider may discuss switching to Vumerity from Tecfidera depending on insurance coverage as well as if you are experiencing side effects. Please talk with your provider if you have any questions regarding Tecifera, its generic or Vumerity.







Unfortunately, Abby Chase will be leaving our office next month. Her last day will be November 17th. We wish her all the best in her future endeavors.

Aaron Bartek, APRN has been hired as our new MS provider. Aaron has worked as a nurse practitioner in the Emergency Department at Saunders Medical Center for the past two years. Aaron will be joining us as soon as his replacement is hired and trained. You may see him along with Melissa Fulton as he learns about MS. Please join us in welcoming Aaron to our office.

Until Aaron is trained and ready to see patients on his own, all patients will see Melissa Fulton. She is still taking time off for surgery and during that time Abby has agreed to help out by taking calls and answering messages. So, you may hear from her at that time.



Upcoming Events:

- Unfortunately, we have had to cancel this year's Night of Lights due to COVID-19
- Melissa Fulton will be out of the office for surgery December 23, 2020 January 14, 2021. You will not be able to have an appointment during this time but phone calls



2021 is coming

Please notify Patti or Katherine of any insurance changes. You should also notify the manufacturer of your medicine as that can change your financial aid or patient support. A change to Medicare can make you ineligible for manufacturer assistance and you would need to apply for charitable funding. If you have Medicare or Medicare Advantage and are on free drug you need to contact the pharmaceutical company to be rescreened for assistance. Also, charitable funding can go fast so it is best to apply at the beginning of the year. On the SMC website under MS Clinic and MS News you will find a list of some of the assistance options that are out there under the October 2018 newsletter.



- Please refrain from calling or texting Melissa or Abby on their personal cell phones. If you have an emergency after hours please contact our nurse line at 402-443-4191 and ask for the hospital nurses.
- Due to our increasing patient load, we need to start charging patients who cancel their appointment less than 24 hours in advance.
- Please arrive a half hour before your appointment to ensure there is adequate time for the check in process and our providers do not get behind for other patients.
- To schedule appointments please call registration at 402-443-4191. Our nurse is unable to schedule appointments and will have to transfer you.
- If you have questions regarding the newsletter, please email Sam <u>sjack@smcne.com</u>.



