

## FDA-Approved Oral Disease-Modifying Therapies for MS and the Recommended Laboratory Tests for Pretreatment Testing and Treatment Monitoring

Detailed prescribing information can be found on the FDA's website at: [accessdata.fda.gov/scripts/cder/daf/index.cfm](https://accessdata.fda.gov/scripts/cder/daf/index.cfm).

Medication	Pretreatment Testing	Recommended Laboratory Monitoring
Aubagio (teriflunomide)	CBC (within 6 mos) hCG (if pregnancy is possible) Liver function tests (within 6 mos) Tuberculosis screening	CBC (every 6 mos) Liver function tests (at least monthly for 6 mos after initiating treatment, then every 6 mos while receiving treatment)
Bafiertam (monomethyl fumarate)	CBC with ALC Liver function tests	CBC with ALC (after 6 mos and every 6-12 mos thereafter) Liver function tests (every 6 mos)
Dimethyl fumarate	CBC with ALC Liver function tests	CBC with ALC (after 6 mos and every 6-12 mos thereafter) Liver function tests (every 6 mos)
Gilenya (fingolimod)	CBC with ALC (within 6 mos or after discontinuation of previous therapy) IgG antibodies to VZV <sup>a</sup> Liver function tests	CBC with ALC (every 6 mos) Liver function tests (every 6 mos)
Mavenclad (cladribine)	CBC with differential (before each course) HBsAg and HBcAb (before each course) hCG if pregnancy is possible (before each course) HCV antibody (before each course) HIV screening <sup>b</sup> (before each course) IgG antibodies to VZV <sup>a</sup> Liver function tests (before each course) Tuberculosis screening (before each course)	CBC with differential <sup>c</sup> (at 2 and 6 mos after the start of each treatment course, then every 6 mos)
Mayzent (siponimod)	CBC with ALC (within 6 mos or after discontinuation of previous therapy) CYP2C9 genotyping IgG antibodies to VZV <sup>a</sup> Liver function tests (within 6 mos)	CBC with ALC (periodically) Liver function tests (as clinically indicated)
Ponvory (ponesimod)	CBC with ALC (within 6 mos or after discontinuation of previous therapy) IgG antibodies to VZV <sup>a</sup> Liver function tests (within 6 mos)	CBC with ALC (periodically) Liver function tests (as clinically indicated)
Tecfidera (dimethyl fumarate)	CBC with ALC Liver function tests	CBC with ALC (after 6 mos, then every 6-12 mos (if clinically indicated)) Liver function tests (if clinically indicated)
Vumerity (diroximel fumarate)	CBC with ALC Liver function tests	CBC with ALC (after 6 mos, then every 6-12 mos as clinically indicated) Liver function tests (if clinically indicated)
Zeposia (ozanimod)	CBC with ALC (within 6 mos or after discontinuation of previous therapy) IgG antibodies to VZV <sup>a</sup> Liver function tests (within 6 mos)	CBC with ALC (periodically) Liver function tests (if clinically indicated)

<sup>a</sup>Testing for VZV is not required in cases with a professionally confirmed history of chickenpox or documentation of a full course of VZV vaccination.

<sup>b</sup>Detailed information about the recommended tests for HIV screening can be found in the ARUP Consult Human Immunodeficiency Virus topic.

<sup>c</sup>CBC should be monitored monthly until month 6 if lymphocyte count at month 2 is <200 cells/ $\mu$ L.

ALC, absolute lymphocyte count; FDA, U.S. Food and Drug Administration; HBcAb, hepatitis B core antibody; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; hCG, human chorionic gonadotropin; HCV, hepatitis C virus; IgG, immunoglobulin G; MS, multiple sclerosis; VZV, varicella-zoster virus

Source: U.S. Department of Health and Human Services, U.S. Food and Drug Administration. Drugs@FDA: FDA-approved drugs. [Updated: Mar 2018; Accessed: Dec 2022]