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WHO'S INCORPORATION OF ESSENTIAL MEDICATIONS FOR MULTIPLE SCLEROSIS

The World Health Organization (WHO) was founded in 1948 and serves as the United Nations agency that connects nations, partners, and people to promote global health.¹ The mission of the WHO is to ensure that globally everyone achieves the best health possible within the available resources. WHO publishes information as practical manuals, handbooks, training material, guidelines, analyses of health policies, and lists of medicines to best treat priority health core conditions.

Every two years, the World Health Organization (WHO) publishes the Model list of Essential Medicines (EML).² The purpose of the EML is to provide a list of medications to meet the needs of various nations within the context of their national priorities. Medications included on the list are of high priority and are considered as essential to provide evidence-based prescribing in a functioning health care system. For example, under the medicines for pain and palliative care section of the list - codeine, fentanyl, morphine and methadone are included as opioid analgesics. This list is beneficial as identifying a limited number of well-known and cost-effective medicines that can lead to better health care, improved medication supply, and lower costs. The first EML was published in 1977 and is revised

every two years by the Expert Committees which are made up of experts in the field of medicine, pharmacology, policy, regulation, and health organizations. The current EML, which was last updated in July of 2023, includes over 500 drugs and is organized by medication categories. The list presents the minimum medicine needs for a basic health-care system, including the most efficacious, safe, and cost-effective drugs for priority conditions. Priority conditions are chosen based on current and estimated future public health, and world-wide relevance.

Multiple Sclerosis (MS) is a chronic autoimmune disease in which the protective covering around nerves (myelin) in the brain and spinal cord are damaged. This disease affects approximately 2.3 million people worldwide. Demyelination of nerve cells results in the disruption of nerve signals which causes symptoms of the disease and disability. Symptoms commonly associated with MS include optic neuritis, vision loss, weakness or changes in sensation in the body, difficulty with balance, cognitive impairment, fatigue, issues with bladder control, and depression or anxiety. MS is the most common non-traumatic disabling disease to affect young adults.³ There is an increasing prevalence of MS in both developed and developing countries, the reason for which is not well understood. The exact cause of MS is unknown, however, risk factors for the disease include certain genetic factors, low vitamin D levels, Epstein-Barr virus infection. Women are about 3 times more likely to develop MS than men.

Diagnosis of MS is made typically by a neurologist based on a patient's symptoms, physical exam, and magnetic resonance imaging (MRI) findings. In some situations, a lumbar puncture (spinal tap) is performed to confirm an MS diagnosis. Both medication and non-medication interventions are used to treat MS. Health interventions other than



medications may include physical, occupational, and speech therapy and counseling services. Assistive devices such as braces and canes also may be helpful for patients with MS to help with balance and walking difficulties.

There are many classes of disease-modifying therapies for MS. These medications include interferons, glatiramer, teriflunomide, S1P receptor modulators, fumarates, cladribine, and several different monoclonal antibodies. Depending on the specific treatment, these medications can decrease the rate of MS relapses by up to ~70% and greatly increase a patient's quality of life. There is no cure for

MS, but these disease-modifying therapies can reduce relapses and disability progression in MS patients.

Prior to the most recent update to the EML, disease-modifying therapies for MS were not included on the list at all. This meant that there was unequal access to MS treatment. Through the effort of many MS advocacy groups and organizations, the three medications **cladribine**, **glatiramer acetate**, and **rituximab** were added to the WHO's 2023 update to the EML⁴. This decision was a crucial step in improving access to MS treatments for people living with MS, especially for those in low- and middle-income countries.

Table 1: Overview of Rituximab, Cladribine and Glatiramer acetate^{5,6}

	Rituximab	Cladribine	Glatiramer acetate
Class of medication	Anti CD20 mab B cell depleter	Purine antimetabolite	Amino acid polymer
Dosage form(s)	10 mg/ml 50 ml injection or 1.5 mg/ml in 0.9% sodium chloride bags	10 mg tablet	20 or 40 mg/ml injection
Route	Intravenous	Oral	Subcutaneous
Monitoring pre med	Complete Blood Cell Count with differential (CBC / diff), liver enzymes, Tuberculosis (TB) testing, Hepatitis B testing	CBC / diff with lymphocyte count, liver enzymes, TB testing, Human Immunodeficiency Virus (HIV), Hepatitis B & C, standard cancer screening. Exclude pregnancy in females	None
Monitoring post med	As ordered	CBC / diff 2, 6, 11 months after first cycle	None
Potential side effects	Infusion-related reactions, flu like symptoms, mucocutaneous reactions	Headaches, infections, risk of malignancy	Injection site reactions, vasodilation, rash, dyspnea, chest pain
Other	Refrigerate and stable up to 14 days in 10 mg/ml concentration or diluted 1.5 mg/ml with 0.9% sodium chloride injection bags	Store at controlled room temperature	Refrigerate but may be stored at room temp for up to 1 month



In conclusion, the addition of DMTs for MS in the EML was a momentous decision for people with MS and their caregivers, especially for those who live in countries with limited access to DMTs.⁷ This decision will assist with the availability and affordability of these medications which will in turn impact the health of people with MS all over the world. Cladribine, glatiramer acetate, and rituximab provide a baseline of care for MS, however there are other medications that are also effective and important in the treatment of MS. MS is now represented on the EML and has been recognized as a priority condition by the WHO. The decision to include these three medications underscores the importance of treating MS and ensuring better access to DMTs around the world.

References

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