MSHP Pharmascript

Volume 45, Issue No. 2

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Deadlines for Pharmascript Submissions

Submit articles, including abstracts for the Resident Research Supplement, for publication in the Summer Edition of Pharmascript by July 1, 2021

Submit articles for publication in the Fall Edition of Pharmascript by September 1, 2021

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FDA Approves Fostemsavir for the Treatment of Multidrug-Resistant HIV-1 Infection

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The U.S. Food and Drug Administration (FDA) recently approved fostemsavir (Rukobia®) for heavily treatment-experienced adults with multidrug-resistant human immunodeficiency virus (HIV-1) failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.[1] Fostemsavir is the prodrug of temsavir, a glycoprotein 120 (gp120) inhibitor that prevents the attachment and entry of HIV into host CD4 cells.[1] The newly approved medication is the latest addition amongst drugs such as ibalizumab (Trogarzo®), maraviroc (Selzentry®), and enfuvirtide (Fuzeon®) in the entry inhibitor class, each with a different mechanism of action and target on either the viral envelope or host CD4 cell. The administration requirements (e.g., twice daily or subcutaneous injection) and prerequisite assay testing of drugs within this class are among the reasons that they have fallen out of favor as first-line therapies and thus reserved for patients who are treatment-experienced with limited treatment options available.[2] Fostemsavir is administered as one 600 mg oral tablet dosed twice daily.

The BRIGHTE Trial was a multicenter, international, phase three clinical trial that evaluated the safety and efficacy of fostemsavir in patients with multidrug-resistant HIV-1 infection.[3] The study consisted of two cohorts: a randomized cohort (n = 272) and a non-randomized cohort (n = 99). The randomized cohort included patients on a failing antiretroviral (ARV) regimen who had at least one fully active ARV in at least one, but no more than two antiretroviral drug classes. These patients were further randomized to receive either fostemsavir or placebo in a 3:1 ratio with their failing regimen from day 1 to day 8. Following day 8, fostemsavir was open-label in the randomized cohort. The non-randomized cohort consisted of patients who had no remaining fully active antiretroviral options. Patients in the non-randomized cohort received open-label fostemsavir plus optimized background therapy starting on day 1. The primary endpoint was the mean change in the HIV-1 RNA level in the randomized cohort from day 1 to day 8. Between the two arms in the randomized cohort, those receiving fostemsavir compared to those receiving placebo had a significant decrease in HIV-1 RNA (0.17 $\log_{10}$ copies/milliliter vs. 0.79 $\log_{10}$ copies/milliliter, $p<0.001$). At 48 weeks, 54% and 38% of patients in the randomized and non-randomized cohorts, achieved virologic response (defined as HIV-1 RNA <40 copies/milliliter). Diarrhea, nausea, and upper respiratory tract infection were the most common adverse events seen among patients in the study. Discontinuation of fostemsavir due to adverse events occurred in seven percent of patients.[3]

This study demonstrated the safety and efficacy of fostemsavir allowing approval and commercial use in patients who are heavily treatment-experienced with multidrug resistant HIV. The twice daily dosing of fostemsavir 600 mg tablets may present an adherence issue in a population of patients who have limited treatment options, therefore, its use should be reserved for patients who have one or less fully active antiretrovirals already optimized on a background regimen.

References

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3. Kozal M, Aberg J, Pialoux G, et al. Fostemsavir in Adults with Multidrug-Resistant HIV-1 Infection. N Engl J Med. 2020;382(13):1232-1243. doi:10.1056/NEJMoa1902493

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Clinical Technician Expansion at the Johns Hopkins Hospital

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Specialty pharmacy has revolutionized the way we practice in the outpatient pharmacy setting. Most notably, it has incorporated a level of clinical practice that was previously unseen in the community or outpatient/ambulatory setting. High-touch, high-cost medications require both pharmacist and technician support to ensure our patients are appropriately administering their medications, maintaining therapy without lapses, and connected to pharmacy resources for any questions or concerns. This practice model is especially important with regard to oral oncologic medications, as these agents can often be the difference between life and death.

At the Johns Hopkins Hospital, two outpatient pharmacies serve the oncology population, focusing on liquid (blood cancers) and solid tumors, respectively. Currently, we have seven ambulatory oncology clinical pharmacy specialists that serve areas from adult and pediatric neurologic, breast, and thoracic cancers to urologic and blood cancers requiring bone marrow transplant. Each of these areas has a multitude of oral oncologic options for their patients that must be chosen based on the characteristics of the cancer and the needs of the patient. Ensuring optimum therapy, with consistent administration and proper education for each patient, requires hours of coordination that are often burdensome for the pharmacist to handle alone. To help support the more technical aspects of patient coordination, the Outpatient Pharmacies at Johns Hopkins have implemented a Clinical Technician model that utilizes advanced-trained pharmacy technicians to assist with refill coordination, pharmacy program education, and insurance navigation.

In the last 18 months, the Outpatient Oncology Pharmacies have expanded their Clinical Technician pool from a single technician to three technicians to help support expanding agent approvals and the clinical needs of this population. The first new technician position was proposed and approved to share the total workload of the oral oncology population and help support vacation coverage. This role was filled in February 2020 and was accompanied by a workflow revamp with the installation of the EPIC Specialty Toolkit, a unique module within EPIC Hyperspace that allows for patient-specific task management. After a year of collaboration, the technician workforce has received consistent accolades for their ability to support the clinical pharmacy specialists and go above-and-beyond for our patients.
The latest Clinical Technician expansion will help support a unique clinical need within the Multiple Myeloma population, a subset of blood cancers that is treated with medications derived from thalidomide. These medications have a robust Risk Evaluation and Mitigation Strategies (REMS) program requiring thorough documentation for both the provider and dispensing pharmacy. To date, the heavy technical nature of prescribing and filling these medications has led to much turnover within the pharmacist role. This new clinical technician position will help to alleviate the burden of these tasks and allow the pharmacist to fulfill higher-level clinical needs of this population. At the time of this publication, the role is still in the recruitment phase. Our hope is that we will be able to utilize this technician creatively to meet the needs of the population while expanding the capabilities of the Clinical Pharmacist.

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Membership Committee Updates

Sujin Weinstein, PharmD, BCPS, Membership Committee Chair-Elect

This Spring, MSHP participated in a virtual fundraiser that allowed individuals to "shop" online for items to donate or to choose a general monetary donation. The initial fundraising goal was $1000, but due to the extreme generosity of our members, we surpassed this goal within 24 hours. We then increased the goal, which was also outmatched! MSHP members contributed a total of $3157 for the Maryland Food Bank. The generous donation will support food-insecure children and families in our community. Thank you for your generosity!

Interested in joining the Publications Committee?

Contact Michael Plazak (Michael.Plazak@umm.edu) or
Frances Aune (faune1@jhmi.edu) for more information.