

THE LOUISIANA HEALTH-SYSTEM PHARMACIST

Newsletter of LSHP || December 2023
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A MESSAGE FROM THE PRESIDENT

As the holiday season approaches, I would like to take a moment to express my deepest appreciation to our members for their hard work, dedication, and unwavering commitment to health and well-being of the patients in Louisiana.

The LSHP board completed strategic planning in July of 2023, focusing on initiatives to improve technician growth and engagement, clinical support for our pharmacists, and public policy initiatives to change our way of practice. We look forward to presenting the committee work to you at the 2024 LSHP annual meeting.

Each member has been a beacon of support as LSHP has worked to better serve you. This year, we aimed to grasp member's awareness and understanding of diversity, equity, and inclusion (DE&I) concepts by conducting an online survey. From this survey, LSHP's DE&I task force has been working on your behalf to offer on-going education and awareness through the 2024 year.

May your holidays be filled with joy, warmth, and moments of relaxation. Thank you for all that you do, and we look forward to another year of working together to make a positive difference for the pharmacists and pharmacy technicians of LSHP.

Sincerely,

Neil Hunter, PharmD, MBA, BCSCP
LSHP President.

THE LOUISIANA HEALTH- SYSTEM PHARMACIST

Useful Resources

- Comprehensive, updated medication shortage information from ASHP

- <https://www.ashp.org/Drug-Shortages>

- ASHP Covid-19 resource center (includes a regularly updated evidence summary table for available treatments, testing and vaccine information, and tools for hospitals)

- <https://www.ashp.org/COVID-19>

- Louisiana Department of Health Coronavirus resource center

(includes vaccine information/eligibility and links to many other state-specific resources):

- <https://ldh.la.gov/coronavirus/>

- Infectious disease information, links to resources, and articles with a little dose of fun

- <http://www.idstewardship.com>

SUNLENCA[®] (LENACAPAVIR, ORAL AND SUBCUTANEOUS INJECTION) FOR TREATMENT OF MULTI-DRUG RESISTANT HIV-1 INFECTION

Brooke Habetz, PharmD Candidate 2024;
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Human Immunodeficiency Virus (HIV) is a virus that targets and weakens the immune system, which makes the individual who acquired it more susceptible to viral, bacterial, or fungal infections. In 2020, there were 30,635 people who were newly diagnosed with HIV in the United States.¹ The virus is spread through contact with bodily fluids, which may include unprotected sex or sharing of needles. Treatment of HIV relies on suppressing HIV ribonucleic acid (RNA) amounts, which is also known as a viral load. Treatments also attempt to increase the CD4+ T-cell count, which is a marker of immune function. A viral load of <200 copies/mL is considered sufficient viral suppression and is a primary goal of therapy in all HIV patients. Once the viral load is considered undetectable through lab work, patients are no longer at risk of transmitting the virus to their HIV-negative partners through unprotected sex.²

In order to meet this low viral load goal, patients are initiated on antiretroviral therapy (ART). This therapy can include many medications that target different pathways of the retrovirus. Current therapies include nucleotide reverse transcriptase inhibitors (NRTI), non-nucleotide reverse transcriptase inhibitors (NNRTI), integrase strand transfer inhibitors (INSTI), and protease inhibitors (PI). Traditional therapy includes two to three of these medications, with an NRTI as a backbone combined with one to two of the other medication classes.³

Many patients are infected with a multi-drug resistant (MDR) variant of HIV-1, meaning the virus is not appropriately responding to one or more of the medications currently being used to target it. When this occurs, the ART for the patient must be reconsidered. Often, HIV drug resistance testing must occur in order to identify which medication classes are likely to be effective.

In December of 2022, the FDA approved a new medication called lenacapavir (Sunlenca[®]), for the treatment of MDR HIV-1 in patients who are heavily treatment-experienced.^{4,5} Lenacapavir is the first agent in a new class of antiretrovirals called capsid-inhibitors. Capsid inhibitors work by directly binding to capsid protein (p24) subunits.⁵ This prevents the nuclear uptake of the virus by inhibiting import proteins which normally bind the viral capsid in order to transport it into the nucleus. Lenacapavir also inhibits virion assembly and release and produces a malformed capsid in any newly synthesized viruses. Through these mechanisms, replication is impacted at early and late stages of the virus life cycle.^{5,6}

The safety and efficacy of this new class of medication was established through a phase III, multicenter, cohort clinical trial entitled “Capsid Inhibition with Lenacapavir in Multidrug-Resistant HIV-1 Infection.” The CAPELLA study enrolled 76 patients from 11 different countries who had documented resistance to at least two antiviral medications from different classes of the four previously mentioned. As both monotherapy and in combination with optimized background therapy, lenacapavir showed a clinically meaningful increase in CD4+ count along with a significant decrease in viral load.⁶

The most common side effects seen with lenacapavir are upset stomach, increased serum creatinine, and injection site reactions. The injection site reactions may include erythema, swelling, pruritis, induration or nodule. There is a warning for the potential of immune reconstitution syndrome during initial treatment. This medication has not been studied in renally impaired patients or patients currently on hemodialysis (HD), although the medication is not expected to be removed by HD as it is highly protein bound. Use of lenacapavir along with cytochrome P450 3A inducers is contraindicated. Its use is not recommended in pregnant patients or patients trying to conceive. If discontinuing from the subcutaneous injection, residual amounts may remain in the body for up to 12 months.⁵

Lenacapavir is available in 300 mg oral tablets and 463.5 mg/ 1.5 mL subcutaneous injections. Initiation dosing is required when starting this medication and has two different dosing regimens available, including a 2-day and a 15-day initiation period (Table 1).⁵ The 2-day initiation provides a more uniform medication concentration as the patient is starting their subcutaneous dosing earlier than in the 15-day initiation period, which only contains oral administration during that time. The 15-day regimen provides a higher medication concentration earlier than the 2-day regimen. The type of initiation used for each patient is decided upon by their physician. After the initiation period is completed, subcutaneous dosing is only required once every 6 months. With this low frequency dosing, pill burden for the patient will not increase, and the variability of medication concentrations that may accompany lack of adherence will not occur.

Table 1.

Treatment time	Lenacapavir dosage	
Initiation dosing	2-day initiation	15-day initiation
Day 1	Oral: 600 mg once and SUBQ: 927 mg once	Oral: 600 mg once
Day 2	Oral: 600 mg once	Oral: 600 mg once
Day 8		Oral: 300 mg once
Day 15		SUBQ: 927 mg once
Maintenance dosing	SUBQ: 927 mg every 6 months (26 weeks) from the date of last injection \pm 2 weeks	

In summary, lenacapavir is the first FDA-approved medication of the capsid inhibitor class. It can be used to treat MDR HIV-1 infections in treatment experienced patients in addition to other HIV medications. It has been proven safe and effective through clinical trials and has minimal side effects. Future pathways for lenacapavir includes using this medication for treatment-naïve HIV-1 patients and as preexposure prophylaxis in patients at high risk for HIV-1 infection. Studies are currently underway to assess the efficacy and safety of lenacapavir in these patient populations.⁵

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INPEFA™ (SOTAGLIFLOZIN): NEW FDA-APPROVED DRUG FOR HEART FAILURE

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Heart failure (HF) affects approximately 6.7 million individuals in the United States.¹ It is a serious condition in which the heart exhibits diastolic and/or systolic dysfunction and, therefore, cannot supply enough blood and oxygen to fulfill the demands of the body. The risk of developing HF is increased in persons with coronary artery disease, diabetes, history of myocardial infarction, hypertension, obesity, and valvular heart disease.² The severity of heart failure is outlined using a numeric classification by the New York Heart Association and an alphabetical stage by the American College of Cardiology (ACC) and American Heart Association (AHA): classification ranges from 1-4 to describe the impact of symptoms on an individual's daily life, and stage ranges from A-D to clarify presence of symptoms and progression of the disease. Individuals with current or previous symptoms of HF are assigned to ACC/AHA Stage C. Symptoms of HF include dyspnea, edema, fatigue, jugular venous distension, orthopnea, and wheezing.³ In 2019, there were over 1.5 million emergency department visits and 1.3 million hospitalizations for HF.¹ The increasing rate of HF-related cardiovascular death is a growing concern.

Heart failure is treated using guideline-directed medical therapy. Several classes of medications are used to treat symptomatic HF, including angiotensin receptor-neprilysin inhibitors, angiotensin-converting enzyme inhibitors, beta blockers, diuretics, and sodium-glucose cotransporter 2 inhibitors (SGLT2i).³ Drugs within the SGLT2i class are commonly used for the treatment of type 2 diabetes mellitus (T2DM) due to their glucose-lowering effects in the kidney. The benefit seen with SGLT2i in HF is not completely understood, but a few mechanisms have been suggested. These drugs promote diuresis, which can reduce preload, and may increase vasodilation to reduce afterload. SGLT2 inhibitors may also boost cardiac efficiency through improved myocardial metabolism and reduced cardiac fibrosis.⁴ Empagliflozin and dapagliflozin, SGLT2 inhibitors, have been shown to decrease hospitalizations for HF and cardiovascular (CV) mortality in individuals with a reduced ejection fraction (EF) of <40%, validating their place in therapy.^{5,6} Another study examining empagliflozin in individuals with a preserved EF of >50% led to a lower risk of hospitalization for HF.⁷ The most recent guidelines issued for treatment of HF contain a strong recommendation for the use of SGLT2i in HF patients with a reduced EF and a moderate recommendation for use in patients with a mildly reduced (41-49%) or preserved EF.³

On May 27, 2023, the United States Food and Drug Administration (FDA) approved Inpefa™ (sotagliflozin) for use in adults with heart failure or T2DM, chronic kidney disease (CKD), and other cardiovascular risk factors to reduce the risk of cardiovascular death, hospitalization for HF, and urgent HF visit. Other cardiovascular risk factors are defined as dyslipidemia, hypertension, elevated cardiac or inflammatory biomarkers, and obesity. Inpefa™ is the first dual SGLT1 and SGLT2 inhibitor in its class. The addition of SGLT1 inhibition further lowers glucose levels by delaying glucose absorption via SGLT1 in the intestines.⁸

Approval of Inpefa™ was based on the combined outcomes of the SCORED and SOLOIST clinical studies. The SCORED trial was a phase 3, randomized, double-blind, placebo-controlled, parallel-group, multicenter study that evaluated the effects of Inpefa™ on total number of deaths from CV events, hospitalizations for HF, and urgent visits for HF in 10,584 enrolled patients. Patients included in the study were at least 18 years old with T2DM, CKD, and other CV risk factors such as obesity, hypertension, and dyslipidemia. Patients in the treatment group received sotagliflozin 200 mg once daily, with an increase to 400 mg daily if tolerated. Compared to placebo, Inpefa™ was superior in reducing the risk of the primary composite endpoint ($p < 0.001$).⁹

The SOLOIST trial was a phase 3, randomized, double-blind, placebo-controlled, multicenter study that assessed the efficacy of Inpefa™ in patients with T2DM and worsening HF. To be included in the trial, patients were required to be between 18-85 years of age, diagnosed with T2DM, and hospitalized due to HF. Patients with end-stage heart failure were excluded. Seventy-nine percent of patients included had a left ventricular ejection fraction less than 50%. Subjects in the treatment group received sotagliflozin 200 mg once daily beginning before hospital discharge or within 3 days of discharge, with potential titration to 400 mg once daily depending on tolerability. The primary endpoints were the total number of deaths from CV causes, hospitalizations for HF, and urgent visits for HF. In relation to the placebo group, Inpefa™ therapy resulted in significantly lower primary endpoint events ($p < 0.001$).¹⁰

Common adverse events with Inpefa™ include urinary tract infection, diarrhea, and hypovolemia. Inpefa™ increases the risk of diabetic ketoacidosis in patients with type 1 diabetes mellitus and is not indicated for glycemic control at this time. Due to a drug interaction that increases the exposure of digoxin, patients taking Inpefa™ with digoxin should be monitored and may require a reduction in dose. Conversely, SGLT2 inhibitors may decrease serum lithium concentrations. Inpefa™ is not recommended in patients who are pregnant, planning to become pregnant, or breastfeeding during treatment. No dose adjustment is necessary for patients of older age. There are no current recommendations for dose adjustments based on renal function as Inpefa™ studies excluded patients with an eGFR < 25 mL/min. Inpefa™ is not recommended in patients with moderate to severe hepatic impairment.⁸

Inpefa™ is available in 200 and 400 mg oral tablets. The recommended starting dose is 200 mg once daily within one hour before breakfast. Titration to 400 mg once daily is recommended as tolerated after 2 weeks of initial treatment.⁸

A 30-day supply of Inpefa™ can cost more than \$1,200, depending on the prescribed dosage. All patients, regardless of insurance coverage status, are currently eligible for a first 30-day trial at no cost. Following the free trial, commercially insured patients may be eligible to pay as little as \$10 per month through the Inpefa Together™ Copay Program. Uninsured patients may qualify for a Patient Assistance Program.¹¹

In summary, Inpefa™ is the first dual SGLT1 and SGLT2 inhibitor approved with a proven mortality benefit and reduction in hospitalizations and urgent visits related to heart failure. At this time, no studies comparing Inpefa™ to other SGLT2i for the treatment of HF have been conducted. Current guidelines for the management of HF have not been updated to include sotagliflozin at this time, but its clinical use may increase once more providers are familiar with the evidence behind its approval.

References

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There are many ways to get involved with LSHP, whether it's a one-time volunteer opportunity, attending a meeting, participating in a committee, or becoming a local or state officer. Please join us at any of the upcoming events and/or reach out to your local chapter or the LSHP office for more information on getting involved in areas that interest you!

UPCOMING EVENTS

LSHP 2023-2024

Thursday, May 23 - Saturday, May 25, 2024

2024 LSHP Annual Meeting at the Hyatt

Regency New Orleans



*Please contact the LSHP Office
(office@lsph.org) for more information on any of
these events.*

Newsletter Submission Information & Guidelines

Please submit newsletter-related comments, questions, and potential publishable content to LSHPnewsletter@outlook.com. Thank you!

Please reference the checklist and article submission guidelines to help us standardize the submission process for the newsletter. To avoid duplication of work, please contact us prior to starting work on an article to ensure that there are no other pending articles with duplicate information.

LSHP Newsletter - Content Submission Checklist

Title/Cover Page:

- .. Name of all authors with professional degrees, job title, and contact information (e-mail)
- .. For student pharmacists and student technicians, please include year of graduation, school, and name of reviewing pharmacist or pharmacy technician.
- .. Disclosure of any conflicts of interest
- .. Title of article clearly reflects / relates to the content within
- .. All text uses Times New Roman, size 12 font

Article Text:

- .. All text is Times New Roman, size 12 font
- .. All abbreviations are clearly defined
- .. Descriptive headings are used to identify major sections

Photos & Figures (if applicable):

- .. Photos / figures are submitted in high resolution .jpeg or .png format
- .. Source of photo / figure is referenced appropriately

Consent:

- .. Consent given for any name(s), other than authors, that is included in the article
- .. Consent received from individuals appearing in any photos
- .. Received written permission to use copyrighted material from publisher/organization or individual who holds copyright

References:

- .. References are placed under a bolded heading "References"
- .. References are formatted in American Medical Association style
- .. References within text, figures, or tables are noted with superscript Arabic numbers

LSHP Newsletter - Content Submission & Approval Process (General Outline)

I. Student Pharmacists (PharmD Candidates)

LSHP welcomes the submission of new-literature review articles, original research, practice or medication updates, and other relevant content from student pharmacists in Louisiana to be featured in our periodical newsletter. A general guideline of the content submission process is outlined below. Questions and content can be directed to LSHPnewsletter@outlook.com

- a. Student pharmacists wishing to submit content for consideration for publication in the LSHP newsletter should be currently enrolled in a school of pharmacy located within Louisiana.
- b. Student pharmacists must choose at least one advisor/preceptor who is a registered pharmacist in Louisiana to act as sponsor and co-author as the student develops their content.
- c. The sponsoring pharmacist(s) should be involved with all phases of content development - selecting the subject, reviewing quality of any literature to be discussed, outlining the discussion, ensuring adequacy of references and evidence, and producing preliminary and final drafts.
- d. All e-mail communications between the student pharmacist author(s) and the LSHP newsletter staff should copy ("cc") the sponsoring pharmacist(s) to maintain their involvement.
- e. When the student pharmacist author(s) and sponsoring pharmacist(s) have selected a subject for potential publication in the LSHP newsletter, they should submit their topic (along with attachment of any relevant literature or source material) to the LSHP newsletter editors/LSHP office for initial review.
- f. LSHP newsletter staff will judge the appropriateness of the topic based on its relevance to the LSHP member audience, application to health-system pharmacy, relative impact of findings, and avoidance of duplication of recent newsletter content. LSHP newsletter will then notify the student pharmacist(s) if the submitted topic is approved based on the considerations listed above.
- g. As the student pharmacist(s) work with sponsoring pharmacist(s) to develop their content for submission to the LSHP newsletter, they may submit an initial draft to the LSHP office. LSHP newsletter staff will review the draft and note any requests for revisions (for appropriate grammar, length, level of discussion, references, etc.) within a goal timeframe of 2-3 weeks.

- h. The student pharmacist(s) should work with their sponsors to make all necessary revisions and refinements, and submit a subsequent draft to the LSHP office within a goal of 2-3 weeks.
- i. LSHP newsletter staff will reply with any final requests for adjustments and revisions as well as give notice as to which newsletter edition in which the content may appear. All listed authors of content will also need to sign, complete, and submit a Disclosure Notice before publication.

II. Post-Graduate Pharmacists (Residents, Fellows, MBA / MHA / MS / PhD Candidates)

LSHP welcomes the submission of new-literature review articles, original research, practice or medication updates, and other relevant content from post-graduate pharmacists in Louisiana to be featured in our periodical newsletter. A general guideline of the content submission process is outlined below. Questions and content can be directed to LSHPnewsletter@outlook.com

- a. Post-graduate pharmacists wishing to submit content for consideration for publication in the LSHP newsletter should be currently training in a program located in the state of Louisiana.
- b. Post-graduate pharmacists should inform their residency program director / faculty advisor / research sponsor of their decision to submit content for publication in the LSHP newsletter. The post-graduate pharmacist should include any documentation of approval of their intent and topic.
- c. For new-literature review articles, practice or medication updates, and other non-original research topics, a sponsoring pharmacist or co-author is not required (only require approval by a program leader to submit content to LSHP newsletter). However, for submissions of original research proceeding under the direct supervision of one or more faculty advisors or sponsors, the directly supervising program leader should be involved with all phases of content submission by the post-graduate pharmacist – such as outlining the research project, ensuring adequacy of methods, analyzing and discussing the findings, and producing preliminary and final drafts.
- d. When the post-graduate pharmacists have selected a subject with director / advisor / sponsor approval for potential publication in the LSHP newsletter, they should submit their topic (along with attachment of relevant literature or source material) to the LSHP newsletter editors/LSHP office for initial review.

e. LSHP newsletter staff will judge the appropriateness of the topic based on its relevance to the LSHP member audience, application to health-system pharmacy, relative impact of findings, and avoidance of duplication of recent newsletter content. LSHP newsletter will then notify the post-graduate pharmacist if the submitted topic is approved based on the considerations listed above.

f. As the post-graduate pharmacists develop their content for submission to the LSHP newsletter, they may submit an initial draft to the LSHP office. LSHP newsletter staff will review the draft and note any requests for revisions within a goal timeframe of 2-3 weeks.

g. The post-graduate pharmacists should make all necessary revisions and refinements and submit a subsequent draft to the LSHP office within a goal timeline of 2-3 weeks.

h. LSHP newsletter staff will reply with any final requests for adjustments and revisions, as well as give notice as to which newsletter edition in which the content may appear. All listed authors of content will also need to sign, complete, and submit a Disclosure Notice before publication.

III. Practicing Pharmacists & Pharmacy Technicians (“Practitioners”)

LSHP welcomes the submission of new-literature review articles, original research, practice or medication updates, and other relevant content from practicing pharmacists and pharmacy technicians (“practitioners”) in Louisiana to be featured in our periodical newsletter. A general guideline of the content submission process is outlined below. Questions and content can be directed to LSHPnewsletter@outlook.com

a. Practitioners wishing to submit content for consideration for publication in the LSHP newsletter should be currently licensed and practicing pharmacy in the state of Louisiana. Consideration can be given for out-of-state practitioners if the content is of particular merit.

b. For new-literature review articles, practice or medication updates, and other non-original research topics, a sponsoring pharmacist or co-author is not required (only require approval by a program leader to submit content to LSHP newsletter). However, for submissions of original research, any co-investigators involved in the research process should be noted as co-authors, and ideally should be involved with the steps of the content submission process.

c. When practitioners have selected a subject for potential publication in the LSHP newsletter, they should submit their topic (along with attachment of relevant literature or source material) to the LSHP office for initial review.

d. LSHP newsletter staff will judge the appropriateness of the topic based on its relevance to the LSHP member audience, application to health-system pharmacy, relative impact of findings, and avoidance of duplication of recent newsletter content. LSHP newsletter will then notify the practitioner if the submitted topic is approved based on the considerations listed above.

e. As the practitioners develop their content for submission to the LSHP newsletter, they may submit an initial draft to the LSHP office. LSHP newsletter staff will review the draft and note any requests for revisions within a goal timeframe of 2-3 weeks.

f. The practitioners should make all necessary revisions and refinements and submit a subsequent draft to the LSHP office within a goal timeline of 2-3 weeks.

g. LSHP newsletter staff will reply with any final requests for adjustments and revisions, as well as give notice as to which newsletter edition in which the content may appear. All listed authors of content will also need to sign, complete, and submit a Disclosure Notice before publication.