



Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**

09 March 2022

**DEPARTMENT CIRCULAR**

No. 2022 - 0164

**FOR: ALL CENTERS FOR HEALTH DEVELOPMENT, NATIONAL DRUG POLICY COMPLIANCE OFFICES, LEAGUES OF CITIES, PROVINCES AND MUNICIPALITIES, PROFESSIONAL HEALTH SOCIETIES, DIRECTORS OF BUREAUS AND REGIONAL OFFICES, BARMM MINISTER OF HEALTH, CHIEFS OF MEDICAL CENTERS AND SANITARIA, AND OTHER CONCERNED**

**SUBJECT: Health Technology Assessment Council (HTAC) Recommendation for Reinclusion of Vasopressin 20 IU/mL (IM/IV) in the Philippine National Formulary**

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By virtue of Republic Act 11223, otherwise known as the Universal Health Care (UHC) Act, health technology assessment (HTA) shall be institutionalized as a fair and transparent priority-setting mechanism to provide financing and coverage recommendations on health technologies to be funded by the Department of Health (DOH) and the Philippine Health Insurance Corporation (PhilHealth).

As such, please be informed that the Secretary of Health has approved the HTAC recommendation for the reinclusion of vasopressin 20 IU/mL (IM/IV) in the PNF on the basis of the following:

- Vasopressin was previously listed in the PNF; however, it was automatically delisted in 2017 since the drug was no longer registered in the Philippine Food and Drug Administration (FDA) as stated in Department Memorandum No. 2017-0202 with the subject "*List of medicines and medicine dosage form, strength, volume, and net content officially deleted from the Philippine National Formulary (PNF)*".
- The Philippine FDA issued a Certificate of Product Registration (CPR) for vasopressin valid until 31 August 2024. The issuance of a CPR as shown in *Annex A* establishes the efficacy and safety of the product. The FDA-approved indications for vasopressin are as follows:
  - To increase blood pressure in adults with vasodilatory shock (e.g., postcardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines
  - Treatment of diabetes insipidus (excluding nephrogenic diabetes insipidus)
  - Control of bleeding esophageal varices
- Vasopressin is a standard of care for the management of sepsis. In addition, this drug is also recommended for the management of septic shock among severe/critical COVID-19 patients. The summary of Clinical Practice Guidelines (CPG) recommending the use of vasopressin is shown in *Annex B*.


- Since vasopressin is the standard drug for the management of sepsis in COVID-19 and non-COVID-19 patients, there is no additional cost to the health system of using the drug on top of the current cost of the medication per patient per regimen that ranges from Php 10,434.00 to Php 73,038.00. The details of the costing analysis are shown in *Annex C*.

The HTAC guidance is made available through the HTA Philippines website for more details:

<https://hta.doh.gov.ph/2022/03/09/htac-recommendation-on-the-re-inclusion-of-vasopressin-in-the-pnf/>

For your information and guidance.

By Authority of the Secretary of Health:

  
ATTY. CHARADE MERCADO-GRANDE  
Undersecretary of Health  
Health Regulation Team

## Annex A. Vasopressin - Certificate of Product Registration



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**  
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City



### CERTIFICATE OF PRODUCT REGISTRATION

Pursuant to the provisions of Republic Act (R.A.) No. 3720 as amended, known as the Foods, Drugs, Devices and Cosmetics Act, and consistent with R.A. No. 6675, known as the Generics Act of 1988, and R.A. No. 9711, otherwise known as the Food and Drug Administration Act of 2009, the product described hereunder has been found to conform with the requirements and standards for marketing authorization of pharmaceutical products per existing regulations in force as of date hereof.


Registration Number	: DRP-10143
Generic Name	: Vasopressin (as Argipressin)
Brand Name	: Presson
Dosage Strength & Form	: 20 I.U./mL Solution for Injection (I.V./I.M./S.C.)
Pharmacologic Category	: Posterior Pituitary Lobe Hormone (Vasopressin/Vasopressin Analogue)
Classification	: Prescription (Rx) Drug
Approved Shelf-life	: 24 months
Storage Condition	: Store at 2°C to 8°C. Protect from light. Do not freeze.
Packaging	: 1 mL (net content) Type I clear and colorless glass ampoule (box of 10 ampoules)
Manufacturer	: Joint Stock Company (JSC) Farmak 74 Kyrilivska Str., Kyiv, 04080, Ukraine
Importer/Distributor	: Phileare Pharma, Inc No. 3 Mahogany St., Agapito Subdivision, Santolan, Pasig City

The marketing authorization shall be valid until 31 August 2024 subject to the conditions listed on the reverse side. No change in the formulation, labelling and commercial presentation of this product shall be made at any time during the effectivity of this registration without prior written approval of this Office.

This marketing authorization is subject to suspension, cancellation or recall should any violation of R.A. No. 3720, R.A. No. 6675 and R.A. No. 9711 and/or regulations issued thereunder involving the product be committed.

Witness My Hand and Seal of this Office, this 31 August 2021

By Authority of the Director-General  
Per FDA Order No. 2016-005

  
**JESUSA JOYCE N. CIRUNAY, RPh**  
Director IV  
Center for Drug Regulation and Research

# Annex B. Clinical Practice Guidelines (CPG) Recommendations for the Use of Vasopressin

(Year) Title of Guidelines	Guideline developer	Recommendation on the use of Vasopressin	Reference
(2020) Clinical Practice Guidelines for Sepsis and Septic Shock in Adults in the Philippines	Philippines Society for Microbiology and Infectious Diseases (PSMID) in partnership with Philippine Academy of Family Physicians (PAFP), Philippine College of Emergency Medicine (PCEM), Philippine College of Physicians (PCP), Philippine College of Surgeons (PCS), Philippine College of Chest Physicians (PCCP), Philippine Heart Association (PHA), Philippine Medical Association (PMA), Philippine Neurological Association (PNA), Philippine Society of Critical Care Medicine (PSCCM), Philippine Society of Endocrinology, Diabetes, and Metabolism (PSEDM), Philippine Society of Gastroenterology (PSG), Philippine Society of general Internal Medicine (PSGIM), Philippine Society of Hematology and Blood Transfusion (PSHBT), Philippine College of Hematology & Transfusion Medicine (PCHTM), Philippine Society of Nephrology (PSN) Philippine Society for Parenteral & Enteral Nutrition (PhilSPEN)	Recommended the use of vasopressin (titrated up to 0.03 U/min) as the second vasopressor of choice on top of norepinephrine in patients with septic shock, with the intent of raising mean arterial pressure to target or decreasing norepinephrine dosage (conditional recommendation, low quality of evidence)	<a href="https://www.psmid.org/wp-content/uploads/2020/03/2020-CPG-for-Sepsis-in-Adults-Full-Manuscript.pdf">https://www.psmid.org/wp-content/uploads/2020/03/2020-CPG-for-Sepsis-in-Adults-Full-Manuscript.pdf</a> ● Page 59, Question 16

<b>(2021) Unified COVID-19 Algorithms</b>	Philippines Society for Microbiology and Infectious Diseases (PSMID) and Healthcare Professionals Alliance Against COVID-19 (HPAAC) Steering Committee	Recommended to apply vasopressors when shock persists in the form of: norepinephrine, vasopressin, or dobutamine (if with signs of poor perfusion and cardiac dysfunction).	<a href="https://www.psmid.org/unified-covid-19-algorithms-5/">https://www.psmid.org/unified-covid-19-algorithms-5/</a> <ul style="list-style-type: none"> <li>● Page 29, Figure F2.3. Critical COVID-19 - Management of Sepsis</li> </ul>
(2021) Living guidance for clinical management of COVID-19	World Health Organization (WHO)	For adults with critical disease with sepsis with persistent hypotension despite volume resuscitation, vasopressin is required to maintain mean arterial pressure (MAP) of $\geq 65$ mmHG and serum lactate level of $\geq 2$ mmol/L.	<a href="https://files.magicapp.org/guideline/0a6099d8-72d5-4d1d-9438-ecfb7417a16b/published_guideline_5852-3_0.pdf">https://files.magicapp.org/guideline/0a6099d8-72d5-4d1d-9438-ecfb7417a16b/published_guideline_5852-3_0.pdf</a> <ul style="list-style-type: none"> <li>● Pages 24-25, Table 6.3 COVID-19 disease severity classification</li> <li>● Page 43, Management of Critical COVID-19: septic shock</li> </ul>

## Annex C. Costing Analysis

### Cost of Vasopressin treatment regimen per patient

Notes:

- Same treatment regimen for COVID-19 and non-COVID-19 patients
- No comparator was used for this costing analysis as vasopressin is the standard second-line treatment for septic shock in COVID and non-COVID patients.

Parameter	Value	Reference
<b>Cost of Vasopressin</b>		
<b>Unit Cost of Vasopressin</b>	Php 1,690.00 (1 ampoule contains 20 units/mL)	Quotation from Philcare Pharma
<b>Treatment Regimen</b>	Standard preparation: Mix vasopressin 20 units/100 mL Dextrose 5% in Water (D5W) or Normal Saline Solution (NSS)  Average use: 3 ampoules in 24 hrs	2020 CPG (titrated up to 0.03 U/min)  Expert opinion
<b>Duration of treatment course</b>	Titrated up to 0.03 units/min at 10-15 minutes intervals until the target blood pressure is reached  Target blood pressure is usually reached within 2 to 14 days	Expert opinion
<b>Number of units needed per treatment course</b>	3 ampoules per day for 2-14 days = 6 to 42 ampoules	
<b>COST OF VASOPRESSIN PER TREATMENT COURSE</b>	Php 10,140.00 to Php 70,980.00	
<b>Other direct costs associated with the implementation of the proposed HT</b>		
<b>Unit Cost of I.V. Fluids, 0.9% Sodium Chloride (NSS)</b>	Php 49.00 (I.V. Fluids, 0.9% Sodium Chloride (NSS) 100 mL Bag)	2021 Drug Price Reference Index (DPRI). Retrieved from <a href="https://dpri.doh.gov.ph/download/2021-DPRI-As-of-October-5.pdf">https://dpri.doh.gov.ph/download/2021-DPRI-As-of-October-5.pdf</a>
<b>Number units of I.V. Fluids, 0.9%</b>	1 unit of 100mL-bag of NSS is needed for 1 ampoule of Vasopressin	

<b>Sodium Chloride (NSS) needed per treatment course</b>	<i>= 6 to 42 units of 100mL bags of NSS for the whole treatment course</i>	
<b>COST OF OTHER COSTS PER TREATMENT COURSE</b>	Php 294.00 to Php 2,058.00	
<i>Total cost of treatment per patient</i>		
<b>TOTAL COST OF VASOPRESSIN TREATMENT PER PATIENT</b>	<b>Php 10,434.00 to Php 73,038.00</b>	