Republic of the Philippines
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UNIVERSAL HEALTH CARE

PHILHEALTH CIRCULAR
No. 0044 - 0015

TO : PHILHEALTH ACCREDITED HEALTHCARE PROVIDERS, PHILHEALTH REGIONAL OFFICES, BRANCHES, LOCAL HEALTH INSURANCE OFFICES, AND ALL OTHERS CONCERNED

SUBJECT : Criteria for Coverage of Drugs Used in the Management of COVID-19 that are not in the Philippine National Formulary

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I. RATIONALE

PhilHealth aims to provide all Filipinos with the mechanism for financial risk protection and accessibility of healthcare especially during the public health emergency due to COVID-19. Further, Section 3 of Republic Act (RA) No. 11223, also known as the Universal Health Care (UHC) Act, ensures that all Filipinos are guaranteed equitable access to quality and affordable health care goods and services, and protected against financial risk. The declared state of calamity was extended to September 12, 2022 by the President of the Republic of the Philippines.[1]

Per Section 34 of the UHC Act, investments on any health technology or development of any benefit package by the Department of Health (DOH) and PhilHealth shall be based on the positive recommendations of the Health Technology Assessment (HTA). As provided in Section 4 of RA No. 3720, as amended by RA No. 9711, the Food and Drug Administration (FDA), as the National Regulatory Authority (NRA), has the power to issue certificates of compliance with technical requirements to serve as basis for the issuance of appropriate authorization.[2] Section 1 of Executive Order No. 121 s. 2020, provides that the Director General of the FDA is authorized to issue an Emergency Use Authorization (EUA) which shall implement reliance and recognition process for emergency use of drugs and vaccines for which may accept the regulatory decisions of the World Health Organization (WHO), and established regulatory authorities.[3]

Section 37 of RA No. 7875, as amended, states that "Drugs for which payments will be made shall be those included in the Philippine National Formulary (PNF) unless explicit exception is granted by the Corporation."[4] Thus, the PhilHealth Board of Directors approved PhilHealth Board Resolution (PBR) No. 2667 s. 2021, which sets the criteria for exemption of non-PNF drugs that are used for treatment of COVID-19.

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[1] Proclamation No. 1218, s. 2021: "Further Extending the Period of a State of Calamity Throughout the Philippines due to Corona Virus Disease 2019 Declared Under Proclamation No. 1021, s. 2020"
[2] RA No 9711: The Food and Drug Administration Act of 2009
[3] Executive Order No. 121, s. 2020: "Granting Authority to the Director General of the Food and Drug Administration to Issue Emergency Use Authorization for COVID-19 Drugs and Vaccines, Prescribing Conditions Therefor, and Other Purposes"
[4] RA No. 7875, as amended by RA Nos. 9241 and 10606: The National Health Insurance Act of 2013

II. OBJECTIVES

This PhilHealth Circular aims to:

A. Establish the criteria for the coverage of non-PNF drug use for the treatment of COVID-19 cases; and

B. Define the guidelines determining how exemption will be granted for non-PNF drug use in the management of COVID-19 prior to its reimbursement.

III. SCOPE

This PhilHealth Circular shall apply to drugs used for the treatment of COVID-19 that are not listed in the PNF subject to the criteria established for PhilHealth reimbursement.

IV. DEFINITION OF TERMS

A. **Classification of Regulatory Authorization:**

1. Certificate of Product Registration (CPR)[5] – is an authorization issued by FDA upon the approval of an application to register a health product prior to engaging in marketing, importation, exportation, sale, offer for sale, distribution, transfer, promotion, advertisement, and/or sponsorship thereof.

2. Drug products under Emergency Use (DEU)[6] – is an authorization issued for drug products with positive recommendation in the COVID-19 Living Recommendation and have a registered counterpart with the FDA at the time of application.

3. Emergency Use Authorization (EUA)[7] – is an authorization issued for unregistered drugs and vaccines in a public health emergency. The EUA is not a Certificate of Product Registration (CPR) or a marketing authorization. The evaluation process of the product may be facilitated by reliance and recognition principles, but stricter conditions on the use and monitoring following authorization shall be imposed.

B. **Investigational Product (IP)[8]** – A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assemble (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

C. **Philippine National Formulary (PNF)** – List of essential medicines that can be procured by the government and serves as the basis for PhilHealth's reimbursement for both public and private health facilities.

[5] https://www.fda.gov.ph/wp-content/uploads/2021/04/CPR-FAQS-HUHS.pdf
[6] FDA Circular No. 2021-0008: Updated Guidelines for the Registration of Drug Products under Emergency Use (DEU) for the Coronavirus Disease 2019 (COVID-19)
[7] FDA Circular No. 2020-0036: Guidelines on the Issuance of Emergency Use Authorization for Drugs and Vaccines for COVID-19
[8] Administrative Order No. 2020-0010: Regulations on the Conduct of Clinical Trials for Investigational Products

V. POLICY STATEMENTS

A. Criteria for the exemption of non-PNF drugs used for COVID-19 treatment

The grant of exemption for non-PNF drug use for COVID-19 treatment shall be based on all of the following:

1. The Health Technology Assessment Council has a positive recommendation for the use of the non-PNF drug for the clinical management of COVID-19;
2. The non-PNF COVID-19 drug should have a valid regulatory authorization from the FDA, which could be any of the following:
   a. Emergency Use Authorization (EUA); OR
   b. Certificate of Product Registration (CPR) including Certificate of Product Registration for Drugs under Emergency Use (DEU) for COVID-19 use.
3. The non-PNF COVID-19 drug is listed in the local COVID-19 treatment guidelines issued or adopted by the Department of Health (DOH).

   For non-PNF COVID-19 drug that is not included in the local COVID-19 treatment guidelines, PhilHealth Management may give preference to drugs recommended by the World Health Organization (WHO) for the treatment of COVID-19.

B. Process for Exemption

1. PhilHealth shall conduct consultation with experts and relevant stakeholders, as needed;
2. PhilHealth shall regularly review current standards for COVID-19 management based on the positive recommendation of the HTA Council (HTAC), FDA issuances or regulatory authorization, local treatment guidelines, WHO issuances, and critically appraised medical literature to determine the need to assess non-PNF COVID-19 drugs for possible reimbursement by PhilHealth.

   The non-PNF drugs for the clinical management of COVID-19 shall be reviewed and assessed based on all of the criteria mentioned in Section V.A.
3. The non-PNF COVID-19 drug that meets all of the criteria in Section V.A shall be approved for exemption by PhilHealth as emanated in Section 37 of RA No. 7875, as amended, to be eligible for reimbursement; and
4. PhilHealth shall issue corresponding advisory/ies containing the list of exempted non-PNF COVID-19 drugs with the following information:
   a. All of the required criteria mentioned in Section V.A. of this PhilHealth Circular;
   b. Generic name;
   c. Drug preparations including its dosage form and strength;
   d. HTAC recommended use or indication of drugs for COVID-19 treatment;
   e. Additional requirements for claims monitoring and processing, if applicable;
   f. Conditions that will suspend, terminate or revoke its exemption, if applicable; and
   g. Any other relevant matters that PhilHealth may deem necessary.

C. PhilHealth, as deemed necessary and reasonable, may suspend or terminate such exemption when attended by any of the following circumstances:

1. Expiration, revocation, suspension, or termination of the issued certificates or authorizations by the FDA;
2. Revision on the HTAC recommendations;
3. Exclusion of drugs from the COVID-19 local treatment guidelines of the Philippines and/or by the World Health Organization (WHO) for the treatment of COVID-19.

D. PhilHealth shall immediately deny the payment of the non-PNF COVID-19 drug upon suspension or termination of its exemption. The public shall be informed through a PhilHealth advisory posted on its official website: www.philhealth.gov.ph.

E. Monitoring

The monitoring of the implementation of this policy shall be in accordance with current monitoring rules and regulations of PhilHealth and other relevant policies of the DOH. Provider compliance shall be subject to PhilHealth's Health Care Provider Performance Assessment System (HCPPAS).

F. Policy Review

A regular policy review shall be conducted on the exemption granted for non-PNF COVID-19 drugs in collaboration with all relevant stakeholders and technical representatives in the Corporation in consideration of updates in guidelines or scientific evidence, and issuances.

VI. PENALTY CLAUSE

Any violation of this PhilHealth Circular shall be dealt with and penalized in accordance with the pertinent provisions of RA No. 11223 and RA No. 7875, as amended by RA Nos. 9241 and 10606, and their respective Implementing Rules and Regulations.

VII. SEPARABILITY CLAUSE

If any provision of this PhilHealth Circular shall be declared invalid, unconstitutional, or unenforceable, the validity of the remaining parts or provisions not affected shall remain in full force and enforceable.

VIII. REPEALING CLAUSE

All PhilHealth Circulars, issuances, rules and regulations or parts thereof which are contrary to and inconsistent with this PhilHealth Circular are hereby repealed, amended, or modified accordingly.

IX. DATE OF EFFECTIVITY

This PhilHealth Circular shall take effect immediately upon the completion of its publication in any newspaper of general circulation or in the Official Gazette. A copy shall thereafter be deposited to the Office of the National Administrative Register (ONAR) at the University of the Philippines Law Center.

ATTY. DANTE A. GIERRAN, CPA
President and Chief Executive Officer (PCEO)

Date signed: 6/29/2022

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DC: Date: 7/4/22

Criteria for Coverage of Drugs Used in the Management of COVID-19 that are not in the Philippine National Formulary