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| ISSUE DATE November 8, 2021 | EFFECTIVE DATE January 3, 2022 | NUMBER *See below |
| SUBJECT Prior Authorization of HIV/AIDS Antiretrovirals – Pharmacy Services | | BY  Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs |

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISE to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: <https://www.dhs.pa.gov/providers/Providers/Pages/PROMISE-Enrollment.aspx>.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for HIV/AIDS Antiretrovirals submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of HIV/AIDS Antiretrovirals will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of HIV/AIDS Antiretrovirals to the appropriate MCO.

BACKGROUND:

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| *01-21-49 | 09-21-48 | 27-21-40 | 33-21-48 |
| 02-21-36 | 11-21-38 | 30-21-43 | |
| 03-21-36 | 14-21-39 | 31-21-51 | |
| 08-21-51 | 24-21-46 | 32-21-36 | |

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs website at <https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 15, 2021, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of HIV/AIDS Antiretrovirals:

- Clarification of the prescriptions that require prior authorization for therapeutic duplication;
- Addition of medical necessity guidelines for Cabenuva (cabotegravir/rilpivirine); and
- Clarification of the guideline for a non-preferred HIV/AIDS Antiretroviral that a current history of being prescribed the same non-preferred HIV/AIDS Antiretroviral does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred.

The revisions to the guidelines to determine medical necessity of prescriptions for HIV/AIDS Antiretrovirals submitted for prior authorization, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of HIV/AIDS Antiretrovirals are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to HIV/AIDS Antiretrovirals) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of HIV/AIDS Antiretrovirals

A. Prescriptions That Require Prior Authorization

Prescriptions for HIV/AIDS Antiretrovirals that meet any of the following conditions must be prior authorized:

1. A non-preferred HIV/AIDS Antiretroviral. See the Preferred Drug List (PDL) for the list of preferred HIV/AIDS Antiretrovirals at: <https://papdl.com/preferred-drug-list>.
2. A prescription for Cabenuva (cabotegravir/rilpivirine).
3. An HIV/AIDS Antiretroviral with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
4. A non-nucleoside reverse-transcriptase inhibitor (NNRTI) when there is a record of a recent paid claim for another NNRTI in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
5. A protease inhibitor when there is a record of a recent paid claim for another protease inhibitor (exception: Norvir [ritonavir]) in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
6. An integrase strand transfer inhibitor when there is a record of a recent paid claim for another integrase strand transfer inhibitor in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
7. A single product regimen when there is a record of a recent paid claim for another single product regimen in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an HIV/AIDS Antiretroviral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred HIV/AIDS Antiretroviral, **one** of the following:
 - a. Has a current history (within the past 90 days) of being prescribed the same non-preferred HIV/AIDS Antiretroviral (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)
 - b. **All** of the following:

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- i. Has a documented history of contraindication, intolerance, or lab test results showing resistance to the preferred HIV/AIDS Antiretrovirals with the same mechanism of action as the requested agent,
- ii. Is prescribed the HIV/AIDS Antiretroviral for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,
- iii. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

AND

2. For Cabenuva (cabotegravir/rilpivirine), **both** of the following:
 - a. Is prescribed Cabenuva (cabotegravir/rilpivirine) for an indication that is included in the FDA-approved package labeling OR a medically accepted indication
 - b. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

AND

3. For therapeutic duplication, **one** of the following:
 - a. For an NNRTI, is being transitioned to another NNRTI with the intent of discontinuing one of the medications,
 - b. For a protease inhibitor, is being transitioned to another protease inhibitor with the intent of discontinuing one of the medications,
 - c. For an integrase strand transfer inhibitor, is being transitioned to another integrase strand transfer inhibitor with the intent of discontinuing one of the medications,
 - d. For a single product regimen, is being transitioned to another single product regimen with the intent of discontinuing one of the medications,
 - e. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

4. If a prescription for an HIV/AIDS Antiretroviral is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

B. Clinical Review Process

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Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an HIV/AIDS Antiretroviral. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

C. References

1. DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents – A Working Group of the Office of AIDS Research Advisory Council (OARAC). Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Last Updated: December 18, 2019; Last Reviewed: December 18, 2019.
2. DHHS Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. Last Updated: December 24, 2019; last reviewed December 24, 2019.