Maine Seal

Quarterly Report

HIV/AIDS 1115 Demonstration Project

SFY 2017 Quarter 3

DY 15 Quarter 3

(7/1/17 – 9/30/17)

Department of Health and Human Services
Maine People Living
Safe, Healthy and Productive Lives

Paul R. LePage, Governor Ricker Hamilton, Commissioner

Department of Health and Human Services
MaineCare Services
Nurse Coordinator
11 State House Station
Augusta, Maine 04333-0011
Tel.: (207) 624-4008; Fax: (207) 287-8601
Toll Free (866) 796-2463; TTY Users: Dial 711 (Maine

Maine Seal

November 29, 2017

Emmett Ruff
Division of State Demonstrations and Waivers
Center for Medicaid and CHIP Services, CMS
Mail Stop S2-01-26
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Mr. Ruff,

Please find enclosed, the quarterly report for the Maine HIV/AIDS Section 1115 Demonstration Waiver for the quarter ending 9/30/2017. Please contact Emily Bean at (207) 624-4005 or emily.bean@maine.gov if further information is needed.

Sincerely,

[redacted]

Stefanie Nadeau, Director
Office of MaineCare Services
11 State House Station, Augusta, ME 04333-0011
Phone: 207-287-2093

Maine HIV/AIDS Demonstration

Section 1115 Quarterly Report

Demonstration Year: 15 (01/01/2017 - 12/31/2017)

Demonstration Quarter: 3 (07/01/2017 - 9/30/2017)

Maine Fiscal Quarter: 4/2017 (07/01/2017 – 09/30/2017)

Federal Fiscal Year (FFY) 17: (10/01/16 – 09/30/17)

Introduction

The MaineCare HIV/AIDS 1115 Demonstration project has completed the third quarter of its fifteenth year. This demonstration was implemented on July 1, 2002 and has been approved through December 31, 2017. The demonstration's goal is to provide critical services to people living with HIV/AIDS in order to delay, prevent, or reverse the progress of their disease.

Enrollment Information

During the third quarter of the fifteenth year, there were 800 MaineCare and demonstration members enrolled in the demonstration project.

Enrollment Counts

There were 472 demonstration enrollees included in the quarter. These members qualified by having a diagnosis of HIV/AIDS and income at, or below, 250% of the Federal Poverty Level (FPL). There were 333 Medicaid members included in the quarter. Medicaid members are identified as either the original cohort of members who are receiving MaineCare, or MaineCare members where 25% or more of their Medicaid claims are HIV-related.

Demonstration Populations (as hard coded in the CMS-64)	Count of members enrolled at Start of Quarter	Count of members enrolled During the Quarter	Number of Persons Disenrolled during Quarter for non-payment of premiums*	Number of Persons Disenrolled during the Quarter**	Number of Members who Changed FPL	Members who Switched Rate Codes	Count of members enrolled at End of Quarter
Enrollees at or below 100% FPL - Demonstration Enrollees	173	193	N/A	36	20	5	157
Enrollees above 100% FPL - Demonstration Enrollees	280	307	0	15	17	1	292
Members HIV Positive and MaineCare Eligible	315	333	N/A	21	N/A	0	312
Totals	768	833	0	72	37	6	761

Note: The numbers in the above chart come from different data sources; therefore, they may not reflect accurate enrollment counts, as they are based on FPL.

*Enrollees who fail to pay premiums within the 60-day grace period could lose coverage until premiums are paid. If the coverage is reinstated with no lapse, they will not be considered "disenrolled." (Example: a member has unpaid premiums and their coverage is closed on July 31st. On August 8th, the balance is received and the member is reopened with an August 1st start date. Since the coverage was retroactively opened, they would not be counted as disenrolled).

**Reasons an individual disenrolls could include: moving out of state, going over income, becoming deceased.

Outreach/Innovative Activities

Outreach is ongoing. Methods used for outreach during this period included:

- Attending weekly Decision Support System (DSS) User Group meetings to discuss the DSS and system issues, workarounds, and resolutions.

- The Nurse Coordinator making calls to members who had not been contacted in six (6) months or more (see enclosure 5).

- Referring more members to Consumers for Affordable Health Care to help with their unmet healthcare needs/coverage.

- Sending an FDA medication alert to primary care providers regarding Prezcobix, Kaletra, Norvir, Truvada, Emtricitabine and Tenofovir, Stribild, and Tybost. Letters were sent via mail and email, depending on provider preference (see Attachment A: Outreach). Alerts were sent to approximately 268 providers.

- Sending a clinical data collection letter to 26 providers. This mailing goes to the providers with members for whom MaineCare Services needs CD4 and viral load data (because we were unable to get recent results from the CDC).

- The Nurse Coordinator attending a webinar titled “Caring for ME Webinar – Opioid Prescribing Regulations.” This webinar discussed updates on Chapter 488, which is the new opioid regulation law, and related rules. The key note speaker also stressed the importance of pharmacy/provider communication in relationship to the opioid medications.

- The Nurse Coordinator and Program Manager attending a training held by the Center for Disease Control and Prevention. This training was for the Ryan White and MaineCare Targeted Case Managers. The agenda included CAREWare updates, ADAP and open enrollment, Data to Care program, Ryan White Part B financial assistance, and a presentation about MaineCare/the Special Benefit Waiver by the

Program Manager and MaineCare Targeted Case Management (by the policy writer).

- Sending the mammography reminder letter to seventy (70) members.

- Sending the cervical exam reminder letter to eighty-six (86) members.

Operational/Policy Development/Issues

Co-payments and premiums (for waiver enrollees)

Waiver enrollees pay all of the regular Medicaid co-payments except for:

- Physician visit: co-pay is $10.00
- Prescription drugs: co-pay is $10.00/30-day supply for generic medications

- The Maine ADAP pays deductibles, premiums, and co-pays (for medications on the ADAP's formulary). This coverage wraps around MaineCare, Medicare Part D, and private insurance. The ADAP covers medications to treat: HIV, mental illness, high blood pressure, high cholesterol, hepatitis, diabetes, thyroid disease, heartburn, nausea, diarrhea, antibiotics, contraceptives, estrogen, and vaccines. The full ADAP formulary can be found at: http://www.maine.gov/dhhs/mecdc/infectious-disease/hiv-std/provider/documents/adap-quarterly-formulary.pdf.
- The ADAP assists with co-pays in the following way:
    - The ADAP pays 100% of the co-pay (for formulary medications) for members with MaineCare (up to $10 per 30-day supply).
    - The ADAP pays 100% of the co-pay (for formulary medications) for members with MaineCare and Medicare Part D (up to $5 per 30-day supply as this is the maximum co-pay amount).

- Enrollees with an individual income of 150% of the FPL or higher are required to pay a monthly premium to receive services under the waiver. If a member submits their premium bill to the ADAP, the program will assist them with these payments. The premium amounts are as follows:

INCOME LEVEL	MONTHLY PREMIUM
Equal to, or less than, 150% of Federal Poverty Level	0
150.1% - 200% of Federal Poverty Level	$34.22
200.01% - 250% of Federal Poverty Level	$68.43

*Note: premiums are inflated by five percent (5%) annually

Financial/Budget Neutrality Development/Issues

Member numbers are based on distinct member paid claims of actual participation (refer to enclosure 3), as compared to the enrollment data that is based on member eligibility. Consequently, the number of members calculated in the financial shell does not match exactly to the number of members enrolled.

The figures reported in enclosures 1 and 2 (“Budget Neutrality” and “Overall Service Costs by Demonstration Year,” respectively) come from the Medicaid Program Budget and Expenditure System (MBES): “CMS 64 Schedule C Report for 1115 Waivers.” The data from previous quarters is updated in each enclosure with approved adjustments.

ADAP funds spent on MaineCare clients for this quarter can be seen in enclosure 4.

Member Month Reporting

Eligibility Group by Month	July 2017	August 2017	September 2017	Total for Quarter Ending 6/2017
Enrollees	453	447	449	1,349
Members	315	311	312	938

Eligibility Group by Disease Stage	1 - ASX (asymptomatic)	2 - SX (symptomatic)	3 – AIDS	Total for Quarter Ending 6/17
Enrollees	902	357	90	1,349
Members	560	286	92	938

Consumer Issues

The MaineCare Member Services help desk is the first point of contact for all MaineCare members, including those living with HIV/AIDS. Based on our monthly reports from Member Services, there were no complaints this quarter.

There were four complaints received directly by the MaineCare Program Manager and Nurse Coordinator.

Type	Contact Note	Resolution
Incoming	Member's case manager called to report that member missed a dental appointment as her ride through the transportation broker was late. Case manager is concerned that member can't be seen for 3 months now. Case manager is also concerned as this member has had transportation issues in the past.	Program Manager worked with our Non-Emergency Transportation unit, the member, the dentist's office, and the transportation broker. We were able to work with the provider to get the member an appointment within the week. The transportation broker agreed to send one of their drivers

Type	Contact Note	Resolution
		for the rescheduled appt. The broker agreed to monitor this member's future appts and rides to ensure the taxi company does a better job going forward.
Incoming	Member called to report that he is meeting with his case manager and her supervisor as he feels he was given incorrect information from them regarding his dental coverage.	The Nurse Coordinator followed up with the member after his meeting with his case manager and her supervisor. The Nurse Coordinator reviewed member's dental coverage with him.
Incoming	Member called to report that he is at the lab getting his blood drawn. He states this is the 3rd time his provider had the wrong labs done. Member wanted to know what he could do.	The Nurse Coordinator spoke with the member and referred him to his provider's office. The member said they haven't been receptive. She let him know he can register a complaint with the hospital if desired.
Outgoing	Member called and reported that he is having issues with his case manager. He reports that she doesn't return his calls (or if she does, that it takes days). He reports that she doesn't follow through with anything and he doesn't feel comfortable with her.	The Nurse Coordinator recommended to the member that he talk with his case management agency to see if he can get a different case manager. Upon follow up, the member was assigned to a new case manager.

Quality Assurance/Monitoring Activity

- Quality indicators continue to be monitored through claims data. These indicators include cost data, number and appropriateness of anti-retroviral medications,

hospitalization, physician and ED utilization rates, death rates, compliance with guidelines on prophylactic medications for opportunistic infections, ophthalmology exams, and pap smear exams, including visits to provider offices.

- One of the waiver's primary roles is to establish a close link with provider offices in order to obtain disease progression data, including CD4 and viral load results that will allow tracking of disease state progression and targeted interventions.

- An adherence report was designed based on our members' prescription pick-up dates. A link has been established between CD4 data and the adherence report to help target interventions. Based on this report, daily calls are made to members to remind them about their prescription pick-up dates. We project that this proactive approach will improve our members' compliance with their anti-retroviral medication. There were 110 adherence calls during the quarter (refer to enclosure 5).

- Member compliance with anti-retroviral medication continues to be tracked via their prescription refills. A link has been established between CD4 data and the compliance report to help target interventions. There are three phases of calls. The first phase is of the greatest concern, where calls are made to members whose CD4 counts are below 200 and they are late picking up their medications. In the second phase, calls are made to members whose CD4 counts are between 200 and 350 and they are late picking up their medications. In the third phase, calls are made to members whose CD4 counts are above 350 and they are late picking up their medications. There were 81 compliance calls during the quarter (refer to enclosure 5).

- Frequent address changes and disconnected phones for this population continue to make it difficult to contact members for adherence and compliance interventions. Ongoing efforts continue by contacting the regional Offices for Family Independence

(OFI), case managers, pharmacies, and providers for members' most updated addresses and phone numbers.

- A contact tracking system which includes calls, letters, emails, faxes, complaints, and grievances has been underway since February 6, 2003, with daily data entry by the Nurse Coordinator and Program Coordinator. This system allows us to note the number of calls per day, week, month, and year, and gives us a detailed map of calls by contact entity and reason.

- A total of 1,517 contacts were made in this quarter. Calls were the most common mode of communication, accounting for 90% of incoming contacts and 77% of outgoing contacts. Emails were the next most common; 7% and 17%, respectively (refer to enclosure 6).

- Eligibility was the most common reason for contacts being made, accounting for 13% of incoming contacts and 19% of outgoing contacts (refer to enclosure 5).

- Demonstration Evaluation

The HIV/AIDS project is fully operational. Analysis of quality and cost data is continually underway. Enrollment is ongoing with 761 members included in the demonstration project at the end of the third quarter of the fifteenth year. Reports to CMS have been provided as specified in the Special Terms and Conditions

Enclosures/Attachments

Attachment A: Outreach

Financial

Enclosure 1: Budget Neutrality Assessment

Enclosure 2: Overall Service Costs by Demonstration Year

Enclosure 3: Actual Participation by Demonstration Quarter

Enclosure 4: ADAP Funds Spent on MaineCare Clients

Communications

Enclosure 5: Contact Tracking by Reason

Enclosure 6: Contact Tracking by Method Used

State Contact

Emily Bean, Program Manager

Office of MaineCare Services

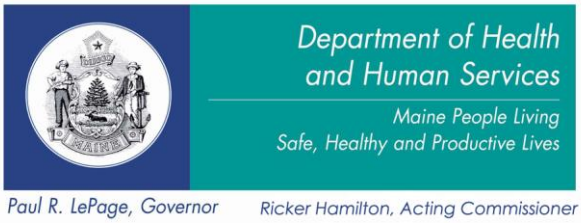
11 State House Station, Augusta, ME 04330

emily.bean@maine.gov

207-624-4005

Date submitted to CMS: November 29, 2017

Attachment A: Outreach



Department of Health and Human Services
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Nurse Coordinator
11 State House Station
Augusta, Maine 04333-0011
Tel.: (207) 624-4008; Fax: (207) 287-8601
Toll Free (866) 796-2463; TTY Users: Dial 711 (Maine Relay)

Authorization to Release Information

We are committed to the privacy of your health information. Please read this form carefully.

☒ Office of Maine Care Services	❒ Substance Abuse and Mental Health Services
❒ Office for Family Independence	❒ Office of Child and Family Services
❒ Maine Centers for Disease Control and Prevention	❒ Office of Aging and Disability Services
❒ Dorothea Dix Psychiatric Center	❒ Other:
❒ Riverview Psychiatric Center	

Your Name:	Your Date of Birth: Your Social Security Number:

Your Address:

Street Town/City State Zip Code

Records to be released, including written, electronic and verbal communication:

☒ All Healthcare, including treatment, services, supplies and medicines

☒ Billing, payment, income, banking, tax, asset, and/or other information regarding financial eligibility for DHHS program benefits such as MaineCare

❒Other:_____

❒ Limit to the following date(s) or type(s) of information:
(e.g. “lab test dated June 2, 2013” or “hospital records from 1/1/12- 1/15/12”)

I authorize the DHHS office(s) checked above to:
☒ Release my information to: ☒Obtain my information from:

Ryan White or named Case Management Agency: _____

Address:

_____

Street Town/City State Zip Code **Infectious Disease Specialist:**_____

Address:

_____

Street Town/City State Zip Code

If requesting that electronic information be transmitted by email, please clearly print the email address be

_____

☒ I understand that DHHS systems may not be able to send my information securely through email. I understand that email and the internet have risks that DHHS cannot control and that the information poter could be read by a third party. I accept those risks and still request that DHHS send my information by en Initials _____

Please allow the office(s) named above to disclose my information for the following purpose(s):

❒ Legal ☒Insurance ☒Coordination of Care ❒ Personal Request ❒ Other:

By initialing below, I wish for my release to include the following types of records:

_____ **Mental health treatment provider or program**
(initials)

_____ **Substance/Alcohol/drug abuse treatment provider or program**
(initials)

_____ **HIV infection status or test results:** Maine law requires us to tell you that releasing this information
(initials) may have implications. Positive implications may include giving you more complete care, and negative implications may include discrimination if the data is misused. **DHHS will protect your HIV data, and all your records, as the law requires.**

I (individual/personal representative of individual named above,) give permission to the DHHS office(s) listed above to release and/or share my records as written on this form. This form will remain in effect for one year from the date below. Other releases of my information are permitted during that time unless I revoke this form.

I further understand and agree that:

- DHHS will not condition my treatment, payment for services, or benefits on whether I sign this form, unless I need to sign this form so that the right offices of DHHS can make eligibility or enrollment decisions.

- I have the right to make a written request to access and copy my healthcare or billing information, and a copy fee will be charged as permitted by law.

- If I want a review of my mental health program or provider records before they are released, I can check here. ❒ I understand that the review will be supervised.

- I may take back my permission to share the records listed on this form at any time by contacting the Privacy Officer of the specific DHHS office: Beth Glidden 207-624-6913

- I understand that taking back my permission does not apply to the information that was already shared, as a result of my signing this form. If I revoke my permission, it may be the basis for denial of health benefits or other insurance coverage.

- I may refuse to disclose all or some health care information, but that refusal may result in improper diagnosis or treatment, denial of coverage or a claim for health benefits or other insurance, or other adverse consequences.

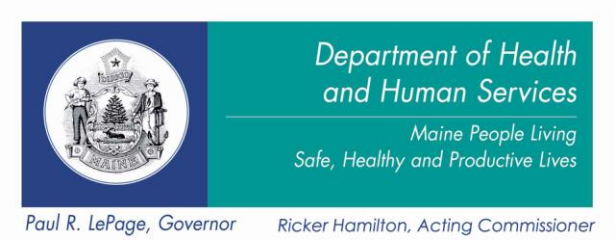
- DHHS offices will keep my information confidential as required by law. If I give my permission to share my records with people who are not required by law to keep them private, they may no longer be protected by confidentiality laws.

- If alcohol or drug provider or program records are included in this release, DHHS will tell the person receiving the records that they may not be shared with others who are not on this form without my written permission, unless required or permitted by law.

- I am signing this form voluntarily, and I have the right to a signed copy of this form if I request one.

Date: _____ Signature_____

Personal Representative's authority to sign: _____



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July 14, 2017

Dear MaineCare Provider:

You are receiving this informational letter because you have been identified as a provider for one or more MaineCare members living with HIV. The Department of Health and Human Services has developed quality initiatives to improve care for these MaineCare members. One of these quality initiatives is to provide timely, important information to providers on certain aspects of HIV care. The Department finds it important to provide information to you, as a Primary Care Provider (PCP), because not all PCPs who see MaineCare members living with HIV are experienced in the use of anti-retroviral medication.

Enclosed, please find information from the FDA regarding HIV medication changes and alerts. For more information, please refer to the FDA's website.

Please contact Sherry Boochko, RN at 207-624-4008 if you currently have no patients with HIV.

If you have any questions, you may contact me by sending an email to beth.ketch@maine.gov or the Nurse Coordinator, Sherry Boochko, RN at sherry.boochko@maine.gov.

Sincerely,

[redacted]

Beth Ketch, Director
Policy and Provider Services
Office of MaineCare Services

The FDA recently approved changes to the Prezcobix (darunavir and cobicistat) tablet label. The following changes were made:

1. To update DRUG INTERACTIONS section with MATE1 transporter information and Potentially Significant Drug Interactions Table 2 with corticosteroid information. A new subsection (section 7.4) was created to include drugs without clinically significant interaction with Prezcobix – see below.
2. To update USE IN SPECIFIC POPULATIONS sections 8.1 through 8.4 to be compliant with the "Pregnancy and Lactation Labeling Rule" (PLLR), and to revise relevant parts of Section 13, NONCLINCAL TOXICOLOGY accordingly.
3. To abridge CLINICAL PHARMACOLOGY sub-section on Darunavir Cardiac Electrophysiology and to update Drug Interactions sub-section with MATE1 transporter information.

Specifically Section 7: DRUG INTERACTIONS was updated to include MATE1 transporter information and the Potentially Significant Drug Interactions Table 2 was also updated with corticosteroid information as follows:

7.1 Potential for PREZCOBIX to Affect Other Drugs

Darunavir co administered with cobicistat is an inhibitor of CYP3A and CYP2D6. Cobicistat inhibits the following transporters: P-glycoprotein (P-gp), BCRP, MATE1, OATP1B1 and OATP1B3. Therefore, co-administration of PREZCOBIX with drugs that are primarily metabolized by CYP3A and/or CYP2D6 or are substrates of P-gp, BCRP, MATE1, OATP1B1 or OATP1B3 may result in increased plasma concentrations of such drugs, which could increase or prolong their therapeutic effect and can be associated with adverse events (see Table 2).

Table 2:Potentially Significant Drug Interactions: Alterations in Dose or Regimen May Be Recommended Based on Drug Interaction Trials or Predicted Interaction(see Contraindications (4) for a complete list of contraindicated drugs)

Concomitant Drug Class: Drug Name	Effect on Concentration of Darunavir, Cobicistat, or Concomitant Drug	Clinical Comment
Systemic/Inhaled/ Nasal/Ophthalmic Corticosteroids: **e.g.** betamethasone budesonide ciclesonide dexamethasone fluticasone methylprednisolone mometasone prednisone triamcinolone	↓ darunavir ↓ cobicistat ↑corticosteroids	Co-administration with systemic dexamethasone or other systemic corticosteroids that induce CYP3A may result in loss of therapeutic effect and development of resistance to PREZCOBIX. Consider alternative corticosteroids. Co-administration with corticosteroids of which exposures are significantly increased by strong CYP3A inhibitors can increase the risk for Cushing's syndrome and adrenal suppression. Alternative corticosteroids including beclomethasone and prednisolone (for which PK and/or PD are less affected by strong CYP3A inhibitors relative to other steroids) should be considered, particularly for long term use.

The updated labels will soon be available on the FDAs website.

Steve Morin
Office of Health and Constituent Affairs
Food and Drug Administration

Richard Klein
Office of Health and Constituent Affairs
Food and Drug Administration

Kimberly Struble
Division of Antiviral Products
Food and Drug Administration

The FDA approved changes to the Kaletra (lopinavir/ritonavir) tablet and oral solution labels. These changes include updates to the following sections:

- Section 2: DOSAGE and ADMINISTRATION with information about use of the oral solution with a feeding tube

2.1 General Administration Recommendations

Because KALETRA oral solution contains ethanol, it is not recommended for use with polyurethane feeding tubes due to potential incompatibility.

Section 4: CONTRAINDICATIONS was updated with the anti-angina drug, ranolazine

Drug Class	**Drugs Within Class That are Contraindicated with KALETRA**	**Clinical Comments**
Antianginal	Ranolazine	Potential for serious and/or life-threatening reactions.

Section 7: DRUG INTERACTIONS was updated as follows:

Concomitant Drug Class: Drug Name	**Effect on Concentration of Lopinavir or Concomitant Drug**	**Clinical Comments**
Anticancer Agents: venetoclax	↑ anticancer agents	Coadministration of venetoclax and KALETRA may increase the risk of tumor lysis syndrome. Refer to the venetoclax prescribing information for dosing instructions.

Concomitant Drug Class: Drug Name	Effect on Concentration of Lopinavir or Concomitant Drug	Clinical Comments
Systemic/Inhaled/ Nasal/Ophthalmic Corticosteroids: e.g., betamethasone budesonide ciclesonide dexamethasone fluticasone methylprednisolone mometasone prednisone triamcinolone	↓ lopinavir ↑ glucocorticoids	Coadministration with oral dexamethasone or other systemic corticosteroids that induce CYP3A may result in loss of therapeutic effect and development of resistance to lopinavir. Consider alternative corticosteroids. Coadministration with corticosteroids whose exposures are significantly increased by strong CYP3A inhibitors can increase the risk for Cushing's syndrome and adrenal suppression. Alternative corticosteroids including beclomethasone and prednisolone (whose PK and/or PD are less affected by strong CYP3A inhibitors relative to other studied steroids) should be considered, particularly for long-term use.

The MEDICATION GUIDE's "Who should not take KALETRA?" section was updated with ranolazine information, and the "Tell your doctor all the medicines you take" section with triamcinolone and venetoclax information

Similar changes were made to the Kaletra (lopinavir/ritonavir) Capsule label. Additionally subsections 8.1 through 8.3 were updated to be compliant with the " Pregnancy and Lactation Labeling Rule" (PLLR). Additionally Section 12, CLINCAL PHARMACOLOGY sub section 12.3 with was updated with pregnancy information as follows:

Pregnancy

In an open-label pharmacokinetic study, 12 HIV-infected pregnant women received KALETRA 400 mg/100 mg (two 200/50 mg tablets) twice daily as part of an antiretroviral regimen. Plasma concentrations of lopinavir were measured over 12-hour periods during the second trimester (20-24 weeks gestation), the third trimester (30 weeks gestation) and at 8 weeks post-partum. The C12h values of lopinavir were lower during the second and third trimester by approximately 40% as compared to post-partum, but this decrease is not considered clinically relevant in patients with no documented KALETRA-associated resistance substitutions receiving 400 mg/100 mg twice daily.

The updated labels will soon be available on the FDAs website.

Steve Morin
Office of Health and Constituent Affairs
Food and Drug Administration

Richard Klein
Office of Health and Constituent Affairs
Food and Drug Administration

Kimberly Struble
Division of Antiviral Products
Food and Drug Administration

On June 7, 2017, the Food and Drug Administration approved a new Norvir (ritonavir) oral powder formulation, 100 mg packet. This approval provides for the use of Norvir (ritonavir) oral powder (only for >100 mg dose increments) in combination with other antiretroviral agents for the treatment of pediatric patients with HIV-1 infection. Norvir oral powder dosage form is free of alcohol and propylene glycol, both of which are present in the currently marketed Norvir oral solution, making it safer for use in the pediatric population.

Additionally, labeling was revised for the Norvir tablet for oral use and oral solution to reflect the new powder formulation.

The complete revised labeling will be available soon on the FDAs website.

Norvir is manufactured by AbbVie Inc.

Richard Klein
Office of Health and Constituent Affairs
Food and Drug Administration

Kimberly Struble
Division of Antiviral Products
Food and Drug Administration

Steve Morin
Office of Health and Constituent Affairs
Food and Drug Administration

On June 8, 2017, the U.S. Food and Drug Administration approved the first generic version of Truvada for the treatment of HIV-1, in combination with other antiretroviral agents, and for pre-exposure prophylaxis (PrEP) in combination with safer sex practices to prevent sexually-acquired HIV infection in adults at high risk.

PrEP may be part of a comprehensive HIV prevention strategy that includes safer sex practices, such as consistent and correct condom use, regular HIV testing and risk reduction counseling. As part of PrEP, HIV-uninfected individuals who are at high risk of sexually acquired HIV infection take antiretroviral medication daily to try to lower their chances of becoming infected with HIV if they are exposed to the virus.

The most common side effects reported by HIV-1 infected individuals using emtricitabine and tenofovir disoproxil fumarate in clinical trials included diarrhea, nausea, fatigue, headache, dizziness, depression, insomnia, abnormal dreams, and rash. HIV-1 uninfected individuals taking Truvada for PrEP reported headache, abdominal pain, and decrease of weight.

Emtricitabine and tenofovir disoproxil fumarate must be dispensed with a Medication Guide for patients, which provides important information about the medication's use and risks. Emtricitabine and tenofovir disoproxil fumaratemust be used as directed by the physician and should be taken by mouth only. If you have kidney problems, your healthcare provider may tell you to take emtricitabine and tenofovir disoproxil fumarate less often. Do not change your dose or stop taking emtricitabine and tenofovir disoproxil fumarate without first talking with your healthcare provider. Stay under a healthcare provider's care when taking emtricitabine and tenofovir disoproxil fumarate. Emtricitabine and tenofovir disoproxil fumarate used for PrEP must only be prescribed to individuals confirmed to be HIV-negative immediately prior to initial use and periodically during use. Drug-resistant HIV-1 variants have been identified with the use of emtricitabine and tenofovir disoproxil fumarate for PrEP following undetected acute HIV-1 infection. Do not initiate emtricitabine and tenofovir disoproxil fumarate for a PrEP indication if signs or symptoms of acute HIV infection are present unless negative infection status is confirmed. Women infected with HIV-1 should be instructed not to breastfeed while taking emtricitabine and tenofovir disoproxil fumarate.

More information on emtricitabine and tenofovir disoproxil fumarate may be found within the drug label.

Generic drugs approved by the FDA have the same high quality and strength as brand-name drugs. The generic manufacturing and packaging sites must pass the same quality standards as those of brand-name drugs.

On June 8, 2017, the Food and Drug Administration approved the first generic version of emtricitabine and tenofovir disoproxil fumarate tablets, 200 mg/300 mg, determined to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Truvada Tablets, 200 mg/300 mg.

The drug is indicated for the treatment of HIV-1, in combination with other antiretroviral agents in adults and pediatric patients weighing at least 17 kg, and for pre-exposure prophylaxis (PrEP) in combination with safer sex practices to prevent sexually-acquired HIV infection in adults at high risk.

Emtricitabine and tenofovir disoproxil fumarate must be dispensed with a Medication Guide for patients, which provides important information about the medication's use and risks.

Emtricitabine and tenofovir disoproxil fumarate must be used as directed by the physician and should be taken by mouth only. If you have kidney problems, your healthcare provider may tell you to take emtricitabine and tenofovir disoproxil fumarate less often. Do not change your dose or stop taking emtricitabine and tenofovir disoproxil fumarate without first talking with your healthcare provider. Stay under a healthcare provider's care when taking emtricitabine and tenofovir disoproxil fumarate.

Emtricitabine and tenofovir disoproxil fumarate used for PrEP must only be prescribed to individuals confirmed to be HIV-negative immediately prior to initial use and periodically during use. Drug-resistant HIV-1 variants have been identified with the use of emtricitabine and tenofovir disoproxil fumarate for PrEP following undetected acute HIV-1 infection. Do not initiate emtricitabine and tenofovir disoproxil fumarate for a PrEP indication if signs or symptoms of acute HIV infection are present unless negative infection status is confirmed.

Women infected with HIV-1 should be instructed not to breastfeed while taking emtricitabine and tenofovir disoproxil fumarate.

More information on emtricitabine and tenofovir disoproxil fumarate may be found within the drug label on the FDAs website.

The generic formulation is a product of Teva Pharmaceuticals USA.

Richard Klein
Office of Health and Constituent Affairs
Food and Drug Administration

Kimberly Struble
Division of Antiviral Products
Food and Drug Administration

Steve Morin
Office of Health and Constituent Affairs
Food and Drug Administration

The STRIBILD and TYBOST labels were updated to include revised text regarding corticosteroids as follows

STRIBILD

Section 7 Drug Interaction, Table 6 was revised for systemic, inhaled, nasal, and ophthalmic corticosteroids as follows.

Table 6 Established and Other Potentially Significant Drug Interactions: Alteration in Dose or Regimen May Be Recommended Based on Drug Interaction Studies or Predicted Interaction

Concomitant Drug Class: Drug Name	**Potential Effect[b]**	**Clinical Comment**
Systemic/Inhaled/Nasal/Ophthalmic Corticosteriods: e.g. betamethasone budesonide ciclesonide dexamethasone fluticasone methylprednisolone mometasone prednisone triamcinolone	↓elvitegravir ↓cobicistat ↑corticosteroids	Coadministration with oral dexamethasone or other systemic corticosteroids that induce CYP3A may result in loss of therapeutic effect and development of resistance to elvitegravir. Consider alternative corticosteroids. Coadministration with corticosteroids whose exposures are significantly increased by strong CYP3A inhibitors can increase the risk for Cushing's syndrome and adrenal suppression. Alternative corticosteroids including beclomethasone and prednisolone (whose PK and/or PD are less affected by strong CYP3A inhibitors relative to other studied steroids) should be considered, particularly for long-term use [see Drug Interactions (7.6)].

Beclomethasone and prednisolone were added to section 7.6 Drugs Without Clinically Significant Interactions with STRIBILD

TYBOST

Section 7 Drug Interaction, Table 6 was revised for systemic, inhaled, nasal, and ophthalmic corticosteroids as follows. Additionally section 7.4 was added as shown below.

Table 6 Established and Other Potentially Significant Drug Interactions: Alteration in Dose or Regimen May Be Recommended Based on Drug Interaction Studies or Predicted Interaction.

Concomitant Drug Class: Drug Name	**Potential Effect[b]**	**Clinical Comment**
Systemic/Inhaled/Nasal/Ophthalmic Corticosteriods: e.g. betamethasone budesonide ciclesonide dexamethasone fluticasone methylprednisolone mometasone prednisone triamcinolone	↓cobicistat ↓atazanavir ↓darunavir ↑corticosteroids	Coadministration with oral dexamethasone or other systemic corticosteroids that induce CYP3A may result in loss of therapeutic effect and development of resistance to atazanavir or darunavir. Consider alternative corticosteroids. Coadministration with corticosteroids whose exposures are significantly increased by strong CYP3A inhibitors can increase the risk for Cushing's syndrome and adrenal suppression. Alternative corticosteroids including beclomethasone and prednisolone (whose PK and/or PD are less affected by strong CYP3A inhibitors relative to other studied steroids) should be considered, particularly for long-term use [see Drug Interactions (7.4)].

7.4 Drugs without Clinically Significant Interactions with TYBOST

No clinically significant drug interactions have been either observed or are expected when TYBOST is combined with the following drugs: beclomethasone and prednisolone.

The updated labels will soon be available on the FDAs website.

Steve Morin
Office of Health and Constituent Affairs
Food and Drug Administration

Richard Klein
Office of Health and Constituent Affairs
Food and Drug Administration

Kimberly Struble
Division of Antiviral Products
Food and Drug Administration

Budget Neutrality Assessment

(This page automatically calculates entered data.)

DY - 13: 1/1/15 - 12/31/15	DY - 14: 1/1/16 - 12/31/16	DY - 15: 1/1/17 - 12/31/17

Annual Assessment																
	DY - 1 FFY: 10/01/02 - 9/30/03	DY - 2 FFY: 10/01/03 - 9/30/04	DY - 3 FFY: 10/01/04 - 9/30/05	DY - 4 FFY: 10/01/05 - 9/30/06	DY - 5 FFY: 10/01/06 - 9/30/07	DY - 6 FFY: 10/01/07 - 9/30/08	DY - 7 FFY: 10/01/08 - 9/30/09	DY - 8 FFY: 10/01/09 - 9/30/10	DY - 9 FFY: 10/01/10 - 9/30/11	DY - 10 FFY: 10/01/11 - 9/30/12	DY - 11 FFY: 10/01/12 - 9/30/13	DY - 12 FFY: 10/01/13 - 9/30/14	DY - 13 FFY: 10/1/14 - 09/30/15	DY - 14 FFY: 10/1/15 - 09/30/16	DY - 15 FFY: 10/1/16 - 09/30/17	Total Computable Ceiling
Cumulative Expenditure Targets	$8,706,056.00	$18,949,248.00	$30,707,947.00	$43,937,686.00	$58,571,556.00	$67,382,817.00	$78,965,794.00	$93,255,027.00	$104,436,521.00	$118,909,175.00	$141,146,776.00	$154,141,747.00	$154,141,747.00	$154,141,747.00	$154,141,747.00	$1,381,535,591.00
Total Demo Costs	$5,082,618.00	$7,737,499.00	$6,625,681.00	$5,139,905.00	$7,816,713.00	$8,068,145.00	$7,630,086.00	$5,531,591.00	$7,508,833.00	$7,693,637.00	$7,830,655.00	$8,251,718.00	$8,946,723.00	$9,255,570.00	$6,153,344.00	$109,272,718.00
Costs Over/Under Target	-$3,623,438.00	-$6,129,131.00	-$11,262,149.00	-$19,351,983.00	-$26,169,140.00	-$26,912,256.00	-$30,865,147.00	-$39,622,789.00	-$43,295,450.00	-$50,074,467.00	-$64,481,413.00	-$69,224,666.00	-$60,277,943.00	-$51,022,373.00	-$44,869,029.00	-$1,272,262,873.00

Note - FFY15 Q2 (Waiver DY 12 2014): Updated the "Annual Expenditure Targets" with the figures provided in an email from CMS forwarded by Emily Bean on 5/20/015

Date: 11/14/2017

Maine HIV/AIDS: Overall Service Costs by Demonstration Year

Date Submitted to CMS:

Quarter Report Period: 07/01/17 - 09/30/2017
MBES (Federal Fiscal Year) FFY 2017

DY - 13: 1/1/15 - 12/31/15	DY - 14: 1/1/16 - 12/31/16	DY - 15: 1/1/17 - 12/31/17

Population Group(s) (as identified in the MBES)	DY - 1 FFY: 10/01/02 - 9/30/03	DY - 2 FFY: 10/01/03 - 9/30/04	DY - 3 FFY: 10/01/04 - 9/30/05	DY - 4 FFY: 10/01/05 - 9/30/06	DY - 5 FFY: 10/01/06 - 9/30/07	DY - 6 FFY: 10/01/07 - 9/30/08	DY - 7 FFY: 10/01/08 - 9/30/09	DY - 8 FFY: 10/01/09 - 9/30/10	DY - 9 FFY: 10/01/10 - 9/30/11	DY - 10 FFY: 10/01/11 - 9/30/12	DY - 11 FFY: 10/01/12 - 9/30/13	DY - 12 FFY: 10/01/13 - 9/30/14	DY - 13 FFY: 10/1/14 - 09/30/15	DY - 14 FFY: 10/1/15 - 09/30/16	DY - 15 FFY: 10/1/16 - 09/30/17	Total Demo Year Costs
Expansion	$ 864,930	$ 1,443,819	$ 2,633,167	$ 765,645	$ 1,721,128	$ 2,381,941	$ 2,341,356	$ 2,788,130	$ 3,685,326	$ 3,506,421	$ 5,083,460	$ 4,970,034	$ 4,998,374	$ 5,764,852	$ 3,555,981	$ 46,504,564
Medicaid	$ 4,217,688	$ 6,293,680	$ 3,992,514	$ 4,374,260	$ 6,095,585	$ 5,686,204	$ 5,288,730	$ 2,743,461	$ 3,823,507	$ 4,187,216	$ 2,747,195	$ 3,281,684	$ 3,948,349	$ 3,490,718	$ 2,597,363	$ 62,768,154
	$ 5,082,618	$ 7,737,499	$ 6,625,681	$ 5,139,905	$ 7,816,713	$ 8,068,145	$ 7,630,086	$ 5,531,591	$ 7,508,833	$ 7,693,637	$ 7,830,655	$ 8,251,718	$ 8,946,723	$ 9,255,570	$ 6,153,344	$ 109,272,718

Date: 11/14/2017

Actual Participation by Demonstration Quarter

Demonstration Year 1: 7/01/02 - 6/30/03

	Quarter 1	Quarter 2	Quarter 3	Quarter 4	
Population Group(s)	**7/01/02 - 9/30/02**	**10/01/02 - 12/31/02**	**1/01/03 - 3/31/03**	**4/01/03 - 6/30/03**	**Total Demo Year Participation**
Expansion	79	89	110	112	133
Medicaid	244	249	252	254	288

Demonstration Year 2: 7/1/03 - 6/30/04

	Quarter 1	Quarter 2	Quarter 3	Quarter 4	
Population Group(s)	**7/01/03 - 9/30/03**	**10/01/03 - 12/31/03**	**1/01/04 - 3/31/04**	**4/01/04 - 6/30/04**	**Total Demo Year Participation**
Expansion	122	125	136	138	166
Medicaid	255	254	255	253	303

Demonstration Year 3: 7/01/04 - 6/30/05

	Quarter 1	Quarter 2	Quarter 3	Quarter 4	
Population Group(s)	**7/01/04 - 9/30/04**	**10/01/04 - 12/31/04**	**1/01/05 - 3/31/05**	**4/01/05 - 6/30/05**	**Total Demo Year Particpation**
Expansion	132	130	164	189	187
Medicaid	270	272	304	310	332

Demonstration Year 4: 7/1/05 - 6/30/06

	Quarter 1	Quarter 2	Quarter 3	Quarter 4	
Population Group(s)	**7/01/05 - 9/30/05**	**10/01/05 - 12/31/05**	**1/01/06 - 3/31/06**	**4/01/06 - 6/30/06**	**Total Demo Year Participation**
Expansion	173	210	225	251	280
Medicaid	311	309	317	324	365

Demonstration Year 5: 7/1/06 - 6/30/07

	Quarter 1	Quarter 2	Quarter 3	Quarter 4	
Population Group(s)	**7/01/06 - 9/30/06**	**10/01/06 - 12/31/06**	**1/01/07 - 3/31/07**	**4/01/07 - 6/30/07**	**Total Demo Year Partcipation**
Expansion	263	275	268	325	363
Medicaid	318	302	264	269	375

Demonstration Year 6: 7/1/07 - 6/30/08

	Quarter 1	Quarter 2	Quarter 3	Quarter 4	
Population Group(s)	**7/01/07 - 9/30/07**	**10/01/07 - 12/31/07**	**1/01/08 - 3/31/08**	**4/01/08 - 6/30/08**	**Total Demo Year Partcipation**
Expansion	296	305	310	306	380
Medicaid	249	263	261	269	330

Demonstration Year 7: 7/1/08 - 6/30/09

	Quarter 1	Quarter 2	Quarter 3	Quarter 4	
Population Group(s)	**7/01/08 - 9/30/08**	**10/01/08 - 12/31/08**	**1/01/09 - 3/31/09**	**4/01/09 - 6/30/09**	**Total Demo Year Partcipation**
Expansion	330	306	317	329	395
Medicaid	290	275	281	270	337

Demonstration Year 8: 7/1/09 - 6/30/10

	Quarter 1	Quarter 2	Quarter 3	Quarter 4	
Population Group(s)	**7/01/09 - 9/30/09**	**10/01/09 - 12/31/09**	**1/01/10 - 3/31/10**	**4/01/10 - 6/30/10**	**Total Demo Year Partcipation**
Expansion	340	351	354	367	428
Medicaid	271	267	281	316	362

Demonstration Year 9: 7/1/10 - 6/30/11

	Quarter 1	Quarter 2	Quarter 3	Quarter 4	
Population Group(s)	**7/01/10 - 9/30/10**	**10/01/10 - 12/31/10**	**1/01/11 - 3/31/11**	**4/01/11 - 6/30/11**	**Total Demo Year Partcipation**
Expansion	383	401	403	408	471
Medicaid	313	270	274	283	367

Demonstration Year 10: 7/1/11 - 6/30/12

	Quarter 1	Quarter 2	Quarter 3	Quarter 4	
Population Group(s)	**7/01/1 - 9/30/11**	**10/01/11 - 12/31/11**	**1/01/12 - 3/31/12**	**4/01/12 - 6/30/12**	**Total Demo Year Partcipation**
Expansion	428	460	469	448	548
Medicaid	275	281	167	187	323

Demonstration Year 11 7/1/12 - 6/30/13

	Quarter 1	Quarter 2	Quarter 3	Quarter 4	
Population Group(s)	**7/01/12 - 9/30/12**	**10/01/12 - 12/31/12**	**1/01/13 - 3/31/13**	**4/01/13 - 6/30/13**	**Total Demo Year Partcipation YTD**
Expansion	399	408	409	418	488
Medicaid	203	196	212	206	269

Demonstration Year 11 plus 7/1/13 - 12/31/13

	Quarter 5	Quarter 6			
Population Group(s)	**7/01/13 - 9/30/13**	**10/01/13 - 12/31/13**			**Total Demo Year Partcipation YTD**
Expansion	408	449	0	0	492
Medicaid	218	242	0	0	257

Demonstration Year 12 01/01/14 - 12/31/14

	Quarter 1	Quarter 2	Quarter 3	Quarter 4	
Population Group(s)	**1/01/14 - 3/31/14**	**4/01/14 - 6/30/14**	**7/01/14 - 9/30/14**	**10/01/14 - 12/31/14**	**Total Demo Year Partcipation YTD**
Expansion <=100% FPL	186	184	165	157	188
Expansion >100% FPL	245	256	245	240	265

Expansion Unknown FPL	34	37	43	49	77
Medicaid	236	289	315	333	361

Demonstration Year 13 **01/01/15 - 12/31/15**

	Quarter 1	Quarter 2	Quarter 3	Quarter 4	
Population Group(s)	**1/01/15 - 3/31/15**	**4/01/15 - 6/30/15**	**7/01/15 - 9/30/15**	**10/01/15 - 12/31/15**	**Total Demo Year Partcipation YTD**
Expansion <=100% FPL	155	157	156	145	174
Expansion >100% FPL	235	230	224	206	253
Expansion Unknown FPL	68	76	93	102	129
Medicaid	312	314	338	326	378

Demonstration Year 14 **01/01/16 - 12/31/16**

	Quarter 1	Quarter 2	Quarter 3	Quarter 4	
Population Group(s)	**1/01/16 - 3/31/16**	**4/01/16 - 6/30/16**	**7/01/16 - 9/30/16**	**10/01/16 - 12/31/16**	**Total Demo Year Partcipation YTD**
Expansion <=100% FPL	143	145	135	129	165
Expansion >100% FPL	208	206	187	182	224
Expansion Unknown FPL	119	126	132	138	172
Medicaid	335	339	319	299	386

Demonstration Year 15 **01/01/17 - 12/31/17**

	Quarter 1	Quarter 2	Quarter 3	Quarter 4	
Population Group(s)	**1/01/17 - 3/31/17**	**4/01/17 - 6/30/17**	**7/01/17 - 9/30/17**	**10/01/17 - 12/31/17**	**Total Demo Year Partcipation YTD**
Expansion <=100% FPL	131	124	118		
Expansion >100% FPL	180	174	168		
Expansion Unknown FPL	141	147	150		
Medicaid	312	323	320		

Date: 11/22/2017

ADAP Funds Spent on MaineCare Clients

July 1, 2017 - September 30, 2017

	FEDERAL DOLLARS				STATE DOLLARS	
Demonstration Populations	**Average ADAP Expenditures for Prescription Drugs**	**Total ADAP Expenditures for Prescription Drugs**	**Average ADAP Expenditures for Premiums**	**Total ADAP Expenditures for Premiums**	**Average ADAP Expenditures for Copay Reimbursement**	**Total ADAP Expenditures for Copay Reimbursement**
"Enrollees" at or below 100% FPL: Demonstration "Enrollees"	$54.31	$3,367.23	$1,376.21	$6,881.05	N/A	$0.00
"Enrollees" above 100% FPL: Demonstration "Enrollees"	$83.33	$9,499.55	$541.76	$12,460.37	$59.40	$297.00
"Members": HIV Positive and MaineCare eligible	$9.32	$1,556.63	$600.96	$600.96	N/A	$0.00

Enclosure 5: Contact Tracking by Reason

Contact Reason	Total Contacts	Incoming	Outgoing
Adherence	110	34	76
Ambulance/Transportation	52	25	27
Case Management Services	237	119	118
Collaboration Care coordination	54	24	30
Compliance	81	19	62
Eligibility	251	69	182
ER	121	28	93
Family Planning	0	0	0
Inpatient	17	1	16
Introductory Call	50	16	34
Laboratory/X-ray	4	1	3
Medications	49	26	23
Member Survey	163	43	120
Mental Health/Substance Abuse	1	1	0
Other	159	84	75
Out Dated Contact	6	1	5
Pharmacy	7	3	4
Phone Call Follow Up	71	9	62
Policy	0	0	0
Provider Services	36	12	24
Unpaid Claim	38	11	27
Viral Loads	0	0	0

Enclosure 6: Contact Tracking by Method Used

Method Used	Total Contacts	Incoming	Outgoing
Call	1244	485	759
Email	203	38	165
Fax	5	5	0
Letter	65	8	57