Maine Seal

Quarterly Report
HIV/AIDS 1115 Demonstration Project
SFY 2018 Quarter 4
DY 16 Quarter 4
(10/1/18 – 12/31/18)

Janet T. Mills
Governor

Jeanne M. Lambrew, Ph.D.
Commissioner

Maine Department of Health and Human Services
MaineCare Services
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February 28, 2019

Athena Cymrot
Centers for Medicare & Medicaid Services (CMS)
Center for Medicaid and CHIP Services (CMCS)
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Cymrot,

Please find enclosed, the quarterly report for the Maine HIV/AIDS Section 1115 Demonstration Waiver for the quarter ending 12/31/2018. Please contact Emily Bean at (207) 624-4005 or emily.bean@maine.gov if further information is needed.

Sincerely,

Michelle Probert, Director
Office of MaineCare Services
11 State House Station. Augusta, ME 04333-0011
Phone: 207-287-5875

Maine HIV/AIDS Demonstration
Section 1115 Quarterly Report

Demonstration Year: 16 (01/01/2018 - 12/31/2018)
Demonstration Quarter: 4 (10/01/2018 - 12/31/2018)
Maine Fiscal Quarter: 4/2018 (10/01/2018 – 12/31/2018)
Federal Fiscal Year (FFY) 19: (10/01/18 – 09/30/19)

Introduction

The MaineCare HIV/AIDS 1115 Demonstration project has completed the fourth quarter of its sixteenth year. This demonstration was implemented on July 1, 2002 and has been approved through March 31, 2019. The demonstration's goal is to provide critical services to people living with HIV/AIDS to delay, prevent, or reverse the progress of their disease.

Enrollment Information

During the fourth quarter of the sixteenth year, there were 808 MaineCare and demonstration members enrolled in the demonstration project.

Enrollment Counts

There were 484 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 331 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	152	10	N/A	22	16	3	152
Enrollees above 100% FPL - Demonstration Enrollees	313	6	1	17	14	2	311
Members HIV Positive and MaineCare Eligible	315	13	N/A	16	N/A	4	311
Totals	780	29	1	55	30	9	774

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:

- 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 Intelence, Symtuza, Genvoya, Stribild, Tybost, Pifeltro, Tivicay, Triumeq, Juluca, Odefsey & Complera. Alerts were sent via mail and email, depending on provider preference (see Attachment A: Outreach). Alerts were sent to approximately 365 providers.

- Sending a clinical data collection letter to thirty (30) infectious disease specialists. This mailing goes to providers of members for whom MaineCare Services needs CD4 and viral load data.

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 per 30-day supply for generic medications

- The Maine AIDS Drug Assistance Program (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	$35.93
200.01% - 250% of Federal Poverty Level	$71.85

*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	October 2018	November 2018	December 2018	Total for Quarter Ending 12/2018
Enrollees	465	458	463	1,386
Members	315	312	311	938

Eligibility Group by Disease Stage	1 - ASX (asymptomatic)	2 - SX (symptomatic)	3 – AIDS	Total for Quarter Ending 12/2018
Enrollees	931	364	91	1,386
Members	596	242	100	938

Consumer Issues

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

There were also no complaints received directly by the MaineCare Program Manager and/or Nurse Coordinator.

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 Emergency Department (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 213 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 151 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 to obtain 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 1,411 contacts were made in this quarter. Phone calls were the most common mode of communication, accounting for 91% of incoming contacts and 79% of outgoing contacts. Emails were the next most common; 7% and 13%, respectively (refer to enclosure 6).

- Case management services were the most common reason for contacts being made, accounting for 32% of incoming contacts and 13% 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 774 members included in the demonstration project at the end of the third quarter of the sixteenth 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:
February 28, 2019

Attachment A: Outreach

PAUL R. LEPAGE
GOVERNOR

Maine Department of Health and Human Services
MaineCare Services
Nurse Coordinator
11 State House Station
Augusta, Maine 04333-0011

BETHANY L. HAMM
ACTING COMMISSIONER

November 14, 2018

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 regarding FDA HIV product approval, safety warnings, product labeling changes and other pertinent information. For more information, please refer to the FDA's website.

If you have any questions, or if you currently have no patients with HIV, please contact the Nurse Coordinator, Cindy M. Robbins, RN at Cynthia.M.Robbins@maine.gov or 207-624-4008.

Sincerely,

Beth Ketch

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

The following information is from July and October 2018. For more information, please refer to the FDA's website.

- The FDA approved changes to the **INTELENCE** (etravrine) label to expand the population to pediatric patients 2 years to less than 6 years of age weighing at least 10 kg. The major changes include the following.

  The dosage of INTELENCE for patients greater than or equal to 10 kg to less than 20 kg is 100 mg twice daily. The method of administration section was updated to state:

  Patients should be instructed to swallow the INTELENCE tablet(s) whole with a liquid such as water. Patients who are unable to swallow the INTELENCE tablet(s) whole may disperse the tablet(s) in a glass of water. The patient should be instructed to do the following:

  - Place the tablet(s) in 5 mL (1 teaspoon) of water, or at least enough liquid to cover the medication,
  - Stir well until the water looks milky,
  - Add approximately 15 mL (1 tablespoon) of liquid. Water may be used but other liquids, such as orange juice or milk, may improve taste. Patients should not place the tablets in orange juice or milk without first adding water. The use of warm (temperature greater than 104°F [greater than 40°C]) or carbonated beverages should be avoided.
  - Drink the mixture immediately,
  - Rinse the glass several times with orange juice, milk or water and completely swallow the rinse each time to make sure the patient takes the entire dose.

- The FDA approved **SYMTUZA™** (darunavir 800 mg, cobicistat 150 mg, emtricitabine 200 mg, and tenofovir alafenamide 10 mg) tablets. SYMTUZA is a four-drug combination of darunavir (DRV), a human immunodeficiency virus (HIV-1) protease inhibitor, cobicistat (COBI), a CYP3A inhibitor, and emtricitabine (FTC) and tenofovir alafenamide (TAF), both HIV-1 nucleoside analog reverse transcriptase inhibitors, and is indicated as a complete regimen for the treatment of HIV-1 infection in adults:

  - Who have no prior antiretroviral treatment history or
  - Who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months and have no known substitutions associated with resistance to darunavir or tenofovir.

  DOSAGE AND ADMINISTRATION

  <u>Testing Prior to Initiation</u>:

  - Prior to or when initiating SYMTUZA, test patients for HBV infection.
  - Prior to or when initiating SYMTUZA, and during treatment with SYMTUZA, on a clinically appropriate schedule, assess serum creatinine, estimated creatinine

clearance, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, also assess serum phosphorus.

Recommended dosage: One tablet taken once daily with food.

Renal Impairment: SYMTUZA is not recommended in patients with estimated creatinine clearance below 30 mL/min.

Hepatic Impairment: SYMTUZA is not recommended in patients with severe hepatic impairment.

Pregnancy: SYMTUZA is not recommended during pregnancy because of substantially lower exposures of darunavir and cobicistat during pregnancy.

SYMTUZA should not be initiated in pregnant individuals. An alternative regimen is recommended for those who become pregnant during therapy with SYMTUZA.

WARNINGS AND PRECAUTIONS

Drug-induced hepatitis (e.g., acute hepatitis, cytolytic hepatitis) including some fatalities can occur with SYMTUZA. Monitor liver function before and during therapy, especially in patients with underlying chronic hepatitis, cirrhosis, or in patients who have pre-treatment elevations of transaminases).

Severe skin reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug rash with eosinophilia and systemic symptoms, and acute generalized exanthematous pustulosis may occur with SYMTUZA. Discontinue treatment if severe skin reaction develops.

Patients receiving SYMTUZA may develop new onset or exacerbations of immune reconstitution syndrome.

Monitor in patients with a known sulfonamide allergy.

Discontinue treatment in patients who develop symptoms or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity.

Patients receiving SYMTUZA may develop new onset or exacerbation of diabetes mellitus/hyperglycemia and redistribution/accumulation of body fat.

Patients with hemophilia may develop increase bleeding events.

ADVERSE REACTIONS

The most common adverse reactions (all grades, incidence greater than or equal to 2%) were diarrhea, rash, nausea, fatigue, headache, abdominal discomfort, and flatulence.

Please refer to the package insert for further details regarding laboratory abnormalities, renal laboratory tests, and bone mineral density outcomes from the two Phase 3 trials.

- The **Genvoya** (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide), **Stribild** (elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate) and **Tybost** (cobicistat) labels were recently updated to include drug-drug interaction data with direct oral anticoagulants. The specific changes to each label include the following.

  Genvoya and Stribild are both expected to increase the exposures of apixaban, rivaroxaban, betrixaban, dabigatran and edoxaban. The specific recommendations are as follows:

  Apixaban: Due to potentially increased bleeding risk, dosing recommendations for coadministration with Genvoya or Stribild depends on the apixaban dose. Refer to apixaban dosing instructions for coadministration with strong CYP3A and P-gp inhibitors in apixaban prescribing information.

  Rivaroxaban: Coadministration of rivaroxaban with Genvoya or Stribild is not recommended because it may lead to an increased bleeding risk.

  Betrixaban, dabigatran, edoxaban: Due to potentially increased bleeding risk, dosing recommendation for coadministration of betrixaban, dabigatran or edoxaban with a P-gp inhibitor such as Genvoya or Stribild depends on the direct oral anticoagulant indication and renal function. Refer to the direct oral anticoagulant dosing instructions for coadministration with P-gp inhibitors in the direct oral anticoagulant prescribing information.

  Tybost coadministered with atazanavir or darunavir:

  Apixaban: Due to potentially increased bleeding risk, dosing recommendations for coadministration of apixaban with Tybost depends on the apixaban dose. Refer to apixaban dosing instructions for coadministration with strong CYP3A and P-gp inhibitors in apixaban prescribing information.

  Rivaroxaban: Coadministration of rivaroxaban with Tybost is not recommended because it may lead to an increased bleeding risk.

  Tybost coadministered with atazanavir:

  Betrixaban, dabigatran and edoxaban: Due to potentially increased bleeding risk, dosing recommendations for coadministration of betrixaban, dabigatran, or edoxaban with a P-gp inhibitor such as Tybost coadministered with atazanavir depends on DOAC indication and renal function. Refer to DOAC dosing instructions for coadministration with P-gp inhibitors in DOAC prescribing information.

  Tybost coadministered with darunavir:

  Betrixaban, dabigatran and edoxaban: No dose adjustment.

- The FDA recently approved **PIFELTRO** (doravirine) tablets, a non-nucleoside reverse transcriptase inhibitor (NNRTI), indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adult patients with no prior antiretroviral treatment history and

DELSTRIGO, a fixed dose combination tablet containing doravirine, lamivudine, and tenofovir disoproxil fumarate indicated as a complete regimen for the treatment of HIV-1 infection in adult patients with no antiretroviral treatment history. A summary of the dosing, contraindications, adverse reactions and clinical studies for the respective products is provided below.

DOSAGE AND ADMINISTRATION

PIFELTRO

- One tablet taken orally once daily with or without food in adult patients.
- Dosage adjustment with rifabutin: One tablet taken twice daily (approximately 12 hours apart)

DELSTRIGO

- Testing: Prior to or when initiating DELSTRIGO, test for HBV infection. Prior to or when initiating DELSTRIGO, and during treatment with DELSTRIGO, on a clinically appropriate schedule, assess serum creatinine, estimated creatinine clearance, urine glucose and urine protein in all patients. In patients with chronic kidney disease, also assess serum phosphorus.
- One tablet taken orally once daily with or without food in adult patients.
- Renal impairment: Not recommended in patients with estimated creatinine clearance below 50 mL per minute.
- Dosage adjustment with rifabutin: Take one tablet of DELSTRIGO once daily, followed by one tablet of doravirine 100 mg (PIFELTRO) approximately 12 hours after the dose of DELSTRIGO

CONTRAINDICATIONS

- PIFELTRO and DELSTRIGO are contraindicated when co-administered with drugs that are strong cytochrome P450 (CYP)3A enzyme inducers as significant decreases in doravirine plasma concentrations may occur, which may decrease the effectiveness of PIFELTRO and DELSTRIGO. These drugs include, but are not limited to, the following:

    - The anticonvulsants carbamazepine, oxcarbazepine, phenobarbital, phenytoin
    - The androgen receptor inhibitor enzalutamide
    - The antimycobacterials rifampin, rifapentine
    - The cytotoxic agent mitotane
    - St. John's wort (*Hypericum perforatum)*

DELSTRIGO is contraindicated in patients with a previous hypersensitivity reaction to lamivudine

WARNINGS AND PRECAUTIONS

PIFELTRO

- Monitor for Immune Reconstitution Syndrome.

DELSTRIGO

- New onset or worsening renal impairment: Prior to or when initiating DELSTRIGO, and during treatment with DELSTRIGO, on a clinically appropriate schedule, assess serum creatinine, estimated creatinine clearance, urine glucose, and urine protein in all patients. Avoid administering DELSTRIGO with concurrent or recent use of nephrotoxic drugs.
- Bone loss and mineralization defects: Consider monitoring BMD in patients with a history of pathologic fracture or other risk factors of osteoporosis or bone loss.
- Monitor for Immune Reconstitution Syndrome

Most common adverse reactions (incidence greater than or equal to 5%, all grades) are nausea, dizziness, headache, fatigue, diarrhea, abdominal pain, and abnormal dreams.

- FDA approved revisions to the **TIVICAY** (dolutegravir), **TRIUMEQ** (abacavir, dolutegravir, and lamivudine) and **JULUCA** (dolutegravir, rilpivirine) labels to include information on the risk of neural tube defects. Below is a summary of changes to the TIVICAY label. Similar changes were made to the TRIUMEQ and JULUCA labels. In addition, weight gain was added to the Postmarketing Experience subsection for each label.

2 DOSAGE AND ADMINISTRATION

2.1 Pregnancy Testing before Initiation of TIVICAY

Perform pregnancy testing before initiation of TIVICAY in adolescents and adults of childbearing potential.

5 WARNINGS AND PRECAUTIONS

5.3 Embryo-Fetal Toxicity

Preliminary data from an observational study showed that TIVICAY was associated with increased risk of neural tube defects when administered at the time of conception and in early pregnancy. As there is limited understanding of reported types of neural tube defects associated with dolutegravir use and because the date of conception may not be determined with precision, avoid use of TIVICAY at the time of conception through the first trimester of pregnancy.

If there are plans to become pregnant or if pregnancy is confirmed within the first trimester while on TIVICAY, if possible, switch to an alternative regimen.

Perform pregnancy testing before initiation of TIVICAY in adolescents and adults of childbearing potential to exclude use of TIVICAY during the first trimester of pregnancy.

Advise adolescents and adults of childbearing potential to consistently use effective contraception.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in individuals exposed to TIVICAY during pregnancy. Healthcare providers are encouraged to register patients by calling the Antiretroviral Pregnancy Registry (APR) at 1-800-258-4263.

8.2 Lactation

Risk Summary

The Centers for Disease Control and Prevention recommends that HIV 1 infected mothers in the United States not breastfeed their infants to avoid risking postnatal transmission of HIV-1 infection.

8.3 Females and Males of Reproductive Potential

Pregnancy Testing

Perform pregnancy testing in adolescents and adults of childbearing potential before initiation of TIVICAY.

Contraception

Adolescents and adults of childbearing potential should avoid use of TIVICAY at the time of conception through the first trimester of pregnancy because of the potential risk of neural tube defects.

Advise adolescents and adults of childbearing potential who are taking TIVICAY to consistently use effective contraception.

- The FDA approved revisions to the **ODEFSEY** (emtricitabine, rilpivirine, and tenofovir alafenamide) and **COMPLERA** (emtricitabine, rilpivirine, and tenofovir disoproxil fumarate) labels to add safety and pharmacokinetic data in HIV-1 infected pregnant women, to align with the recently approved
EDURANT (rilpivirine) USPI. Listed below are the specific changes to the labels.

Section 2: DOSING AND ADMINISTRATION

2.3 Recommended Dosage During Pregnancy

For pregnant patients who are already on ODEFSEY prior to pregnancy and are virologically suppressed (HIV-1 RNA less than 50 copies per mL), one tablet of ODEFSEY taken once daily may be continued. Lower exposures of rilpivirine, a component of ODEFSEY, were observed during pregnancy, therefore viral load should be monitored closely.

The same recommendations were added to the COMPLERA label.

Section 8: USE IN SPECIFIC POPULATIONS

Updates were made with respect to APR data. In general, available data from the APR show no increase in the risk of overall major birth defects with first trimester exposure for rilpivirine (RPV). In a clinical trial, total rilpivirine exposures were generally lower during pregnancy compared to the postpartum period.

Section 12: Clinical Pharmacology
12.3 Pharmacokinetics

Pregnancy and Postpartum was updated to provide the pharmacokinetic results of total rilpivirine exposures during the second and third trimester of pregnancy and postpartum.

- The FDA approved revisions to the **GENVOYA** (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide), **STRIBILD** (elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate) and **TYBOST** (cobicistat), labels regarding use during pregnancy. Additional edits were made with respect to drug interactions. Highlights of the changes to the labels are summarized below.

GENVOYA AND STRIBILD
The GENVOYA labeling is highlighted below and the same information is included in the STRIBILD label.

SECTION 2: DOSAGE AND ADMINISTRATION
2.5 Not Recommended During Pregnancy
GENVOYA is not recommended for use during pregnancy because of substantially lower exposures of cobicistat and elvitegravir during the second and third trimesters.
GENVOYA should not be initiated in pregnant individuals. An alternative regimen is recommended for individuals who become pregnant during therapy with GENVOYA.

TYBOST

SECTION 2: DOSAGE AND ADMINISTRATION
2.4 Not Recommended During Pregnancy

TYBOST coadministered with darunavir is not recommended for use during pregnancy because of substantially lower exposures of darunavir and cobicistat during the second and third trimesters.

TYBOST coadministered with atazanavir is not recommended for use during pregnancy because of substantially lower exposures of cobicistat during the second and third trimesters.

TYBOST coadministered with darunavir or atazanavir should not be initiated in pregnant individuals. An alternative regimen is recommended for individuals who become pregnant during therapy with TYBOST coadministered with darunavir or atazanavir.

SECTION 8: USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Risk Summary

TYBOST coadministered with darunavir or atazanavir is not recommended during pregnancy. In a clinical trial of individuals taking cobicistat coadministered with darunavir, exposures of cobicistat and darunavir were substantially lower during the second and third trimesters of pregnancy.

PAUL R. LEPAGE
GOVERNOR

Maine Department of Health and Human Services
MaineCare Services
Nurse Coordinator
11 State House Station
Augusta, Maine 04333-0011

BETHANY L. HAMM
ACTING COMMISSIONER

October 11, 2018

Dear ,

The MaineCare HIV/AIDS 1115 Demonstration Waiver has completed the second quarter of its sixteenth year. MaineCare Services is continuing a series of initiatives aimed at improving the care of members who are HIV positive. In order to fulfill the quality care initiatives required by the Centers for Medicare and Medicaid Services (CMS), we collect lab data, such as viral loads and CD4 counts, which are used to establish baseline data for tracking disease progression.

According to our records, you are the provider for the member(s) on the enclosed form. This form outlines the lab results we need from you. Please complete all the requested information with the most recent results, and return it in the enclosed self-addressed envelope. We will repeat this mailing semi-annually to update any necessary information.

If you have any questions, call Sherry A. Boochko, RN, Nurse Coordinator in the Division of Health Care Management at 207-624-4008.

Thank you in advance for your help with this quality initiative.

Sincerely,

Beth Ketch

Beth Ketch, Director
Director of Policy and Provider Services
MaineCare Services
11 State House Station
Augusta, ME 04333-0011