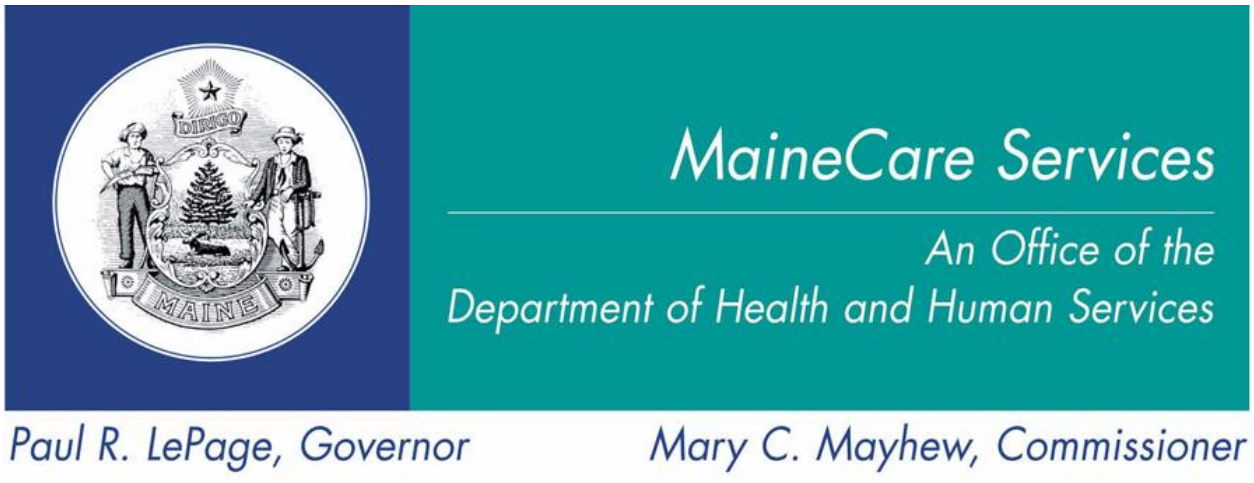

Maine Seal

Quarterly Report

HIV/AIDS 1115 Demonstration Project

SFY 2016 Quarter 4

DY 14 Quarter 4

(10/1/16 - 12/31/16)

MaineCare Services
An Office of the
Department of Health and Human Services
Paul R. LePage, Governor Mary C. Mayhew, Commissioner
Maine Seal

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 Relay)

February 27, 2017

Patricia Hansen
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 Ms. Hansen,

Please find enclosed, the quarterly report for the Maine HIV/AIDS Section 1115 Demonstration Waiver for the quarter ending 12/31/2016. 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

cc: Beth Ketch, Director of Policy and Provider Services
Aimee Campbell-O'Connor, CMS/CMCHO
Sheena Bunnell, PhD

Maine HIV/AIDS Demonstration

Section 1115 Quarterly Report

Demonstration Year: 14 (01/01/2016 - 12/31/2016)

Demonstration Quarter: 4 (10/01/2016 - 12/31/2016)

Maine Fiscal Quarter: 1/2017 (10/01/2016 – 12/31/2016)

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

Introduction

The MaineCare HIV/AIDS 1115 Demonstration project has completed the fourth quarter of its fourteenth 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 fourth quarter of the fourteenth year, there were 799 MaineCare and demonstration members enrolled in the demonstration project.

Enrollment Counts

There were 524 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 328 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	165	205	N/A	29	0	0	176
Enrollees above 100% FPL - Demonstration Enrollees	297	319	0	39	0	0	280
Members HIV Positive and MaineCare Eligible	312	328	N/A	16	N/A	0	312
Totals	774	852	0	84	0	0	768

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.

- Continuing with the new Emergency Department (ED) reporting process that incorporates a daily census from each hospital, in addition to the regular monthly report (which has a two month lag time).

- Sending the program's poster and brochure to 154 high schools and universities.

- The Nurse Coordinator and Program Manager attending and displaying program materials at four provider summits. The provider summits were organized by the Department of Health and Human Services Health Homes (HH), Behavioral Health Homes (BHH), and ED Care Management Collaborative programs. The goal of the summit was to transition MaineCare members with high costs and over utilization of services from the ED Care Management Collaborative to HHs and BHHs by January 1, 2017.

- Attending the Center for Disease Control and Prevention's Integrated HIV Prevention and Care Planning Body meetings. This planning body is in the early stages of development and will serve as the Integrated Planning meeting, the Ryan White Part B advisory meeting, the AIDS Drug Assistance Program (ADAP) advisory

meeting, and the HIV Prevention meeting. These meetings will discuss the Integrated Plan progress and collaboration, give updates, and seek feedback on any relevant aspects of Ryan White Part B and ADAP, and provide updates from HIV Prevention.

- The Nurse Coordinator attending a Quality Counts webinar titled “Get to Know the New PMP: An Orientation to Maine’s Updated Prescription Monitor Program.” The webinar discussed Maine’s newly enacted law (Chapter 488) which requires prescribers of opioids and benzodiazepines to keep track of the medications their patients are on by updating the statewide Prescription Monitoring Program (PMP) prior to prescribing opioids or benzodiazepines. The webinar showed what changed and what to expect on the new PMP.

- The Nurse Coordinator attending a Quality Counts webinar titled “Naloxone and Compassionate Care.” This webinar examined Maine’s opioid overdose epidemic, how to prescribe naloxone, how to talk to patients about the importance of having - and knowing how to use – naloxone, and how to access naloxone affordably.

- The Nurse Coordinator attending a Quality Counts webinar titled “Caring for ME: Compassionate Opioid Tapering: Case Studies.” This webinar explored case studies of common tapering scenarios, challenges, and techniques for effectively and compassionately tapering opioid dosages.

- The Nurse Coordinator attending a Quality Counts webinar titled “Opioid Dependence vs. Addiction: Different Conditions, Different Approaches.” This webinar examined the difference between addiction and dependence of opioids.

- The Nurse Coordinator attending a Quality Counts webinar titled “Understanding & Using MMEs to Comply with Maine’s Opioid Prescribing Law.” Under Maine’s new Opioid-Prescribing Law, Chapter 488, there are limits on how much opioids can be

prescribed. The webinar showed how providers can keep track of Morphine Milligram Equivalents (MME) that they prescribe to patients, while staying within the guidelines.

- The Nurse Coordinator attending a Quality Counts webinar titled “Marijuana: Medicinal or Malevolent.” The webinar explored the impacts that cannabinoids have on the developing brain, medicinal use of marijuana, and harm versus benefits.

- Sending the second lab data mailing to seven providers who had not responded to the first mailing.

- Meeting with a new case manager at the Horizon Program.

- The Program Manager and Nurse Coordinator attending the Annual Infectious Disease Conference. Presentations included: The Opioid Epidemic in Maine: Implications for Infectious Disease, Drug Diversion: Impacts and Challenges, The Rise of Antimicrobial Resistance and Antimicrobial Stewardship, and Environmental Changes and Their Impact on Infectious Diseases. Attended breakout sessions included: STDs in the US: Top 10 Updates and Epidemiology of STDs in Maine, The Bugs We Thought We’d Never See and Pre-Exposure Prophylaxis (PrEP) for HIV Prevention: Evidence, Guidelines, and Applications to Clinical Practice. The conference also included many exhibitors and poster topics.

- Sending an FDA medication alert to primary care providers regarding Selzentry. Letters were sent via mail and email, depending on provider preference (see Attachment A: Outreach). The alert was sent to approximately 333 providers.

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
co-pay is $20.00/90-day supply for brand name medications
(by mail order only)

- 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	October2016	November2016	December2016	Total for Quarter Ending 12/2016
Enrollees	462	458	456	1376
Members	312	313	312	937

Eligibility Group by Disease Stage	1 - ASX (asymptomatic)	2 - SX (symptomatic)	3 – AIDS	Total for Quarter Ending 12/16
Enrollees	978	313	85	1376
Members	600	269	68	937

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 no complaints received directly by the MaineCare 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 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 290 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 75 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 1,449 contacts were made in this quarter. Calls were the most common mode of communication, accounting for 89% of incoming contacts and 79% of outgoing contacts. Emails were the next most common; 9% and 13%, respectively

(refer to enclosure 6).

- Eligibility was the most common reason for contacts being made, accounting for 20% of incoming contacts and 22% 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 768 members included in the demonstration project at the end of the fourth quarter of the fourteenth 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 27, 2017

Attachment A: Outreach

Department of Health and Human Services
MaineCare Services
Nurse Coordinator
11 State House Station
Augusta, Maine 04333-0011
Tel.: (207) 624-4008; Fax: (207) 287-1864
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 em 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: _____

MaineCare Services
An Office of the
Department of Health and Human Services
Paul R. LePage, Governor
Mary C. Mayhew, 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 Relay)

November 28, 2016

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

On Friday November 4, 2016, FDA approved Selzentry (maraviroc) 20 mg/mL oral solution, Selzentry (maraviroc) 25 mg and 75 mg tablets and updated the label to include use in pediatric patients 2 years of age and older weighing at least 10 kg. The major changes to the label are summarized below.

INDICATIONS AND USAGE

SELZENTRY is indicated in combination with other antiretroviral agents for the treatment of only CCR5 tropic human immunodeficiency virus type 1 (HIV 1) infection in patients 2 years of age and older weighing at least 10 kg.

Limitations of Use:

- SELZENTRY is not recommended in patients with dual/mixed- or CXCR4-tropic HIV-1

DOSAGE AND ADMINISTRATION

Testing prior to Initiation of SELZENTRY

Prior to initiation of SELZENTRY, test all patients for CCR5 tropism using a highly sensitive tropism assay. SELZENTRY is recommended for patients with only CCR5-tropic HIV-1 infection. Outgrowth of pre-existing low-level CXCR4- or dual/mixed tropic HIV 1 not detected by tropism testing at screening has been associated with virologic failure on SELZENTRY.

Monitor patients for ALT, AST, and bilirubin prior to initiation of SELZENTRY and at other time points during treatment as clinically indicated.

Recommended Dosage in Pediatric Patients

The recommended dosage of SELZENTRY should be based on body weight (kg) and should not exceed the recommended adult dose. The recommended dosage also differs based on concomitant medications due to drug interactions (Table 2 and Table 3)

Before prescribing SELZENTRY tablets, assess children for the ability to swallow tablets. If a child is unable to reliably swallow SELZENTRY tablets, the oral solution formulation should be prescribed. Administer the oral solution using the included press-in bottle adapter and oral dosing syringe.

Table 2. Recommended Dosage in Pediatric Patients Aged 2 Years and Older Weighing at Least 10 kg (Tablets)

Concomitant Medications	Dosage of Selzentry Based on Weight			
	10 kg to <20 kg	20 kg to <30 kg	30 kg to <40 kg to <20g	≥40 kg
Potent CYP3A inhibitors (with or without a CYP3A inducer) protease inhibitors (except tipranavir/ritonavir) delavirdine elvitegravir/ritonavir ketoconazole, itraconazole, clarithromycin other potent CYP3A inhibitors (e.g., nefazodone, telithromycin)	50 mg twice daily	75 mg twice daily	100 mg twice daily	150 mg twice daily
Noninteracting concomitant medications, including tipranavir/ritonavir,	Not recommended	Not recommended	300 mg twice daily	300 mg twice daily

nevirapine, raltegravir, all NRTIs, and enfuvirtide [a]				
Potent CYP3A inducers (without a potent CYP3A inhibitor) including: efavirenz, rifampin, etravirine, carbamazepine, phenobarbital, and phenytoin	Not recommended			

[a] Noninteracting concomitant medications include all medications that are not potent CYP3A inhibitors or inducers.

Table 3. Recommended Dosage in Pediatric Patients Aged 2 Years and Older Weighing at Least 10 kg (Oral Solution)

	Dosage of Selzentry is based on weight			
Concomitant Medications	**10 kg to <20 kg**	**20 kg to <30 kg**	**30 kg to <40 kg**	≥40 kg
Potent CYP3A inhibitors (with or without a CYP3A inducer) including: protease inhibitors (except tipranavir/ritonavir) delavirdine elvitegravir/ritonavir ketoconazole, itraconazole,	50 mg (2.5 mL) twice daily	80 mg (4 mL) twice daily	100 mg (5 mL) twice daily	150 mg (7.5 mL) twice daily

clarithromycin other potent CYP3A inhibitors (e.g., nefazodone, telithromycin) boceprevir				
Noninteracting concomitant medications, including tipranavir/ritonavir, nevirapine, raltegravir, all NRTIs, and enfuvirtide [a]	Not recommended	Not recommended	300 mg (15 mL) twice daily	300 mg (15 mL) twice daily
Potent CYP3A inducers (without a potent CYP3A inhibitor) efavirenz, rifampin, etravirine,carbamazepine, phenobarbital, and phenytoin	Not recommended			

[a] Noninteracting concomitant medications include all medications that are not potent CYP3A inhibitors or inducers.

Hepatic Impairment

Pediatric Patients

There are no data to recommend specific doses of SELZENTRY in pediatric patients with mild or moderate renal impairment [see Use in Specific Populations (8.6)]. Additionally, SELZENTRY is contraindicated for pediatric patients with severe renal impairment or end-stage renal disease (ESRD) on regular hemodialysis who are receiving potent CYP3A inhibitors

ADVERSE REACTIONS

Clinical Trials Experience in Pediatric Subjects

Trial A4001031 is an open-label trial in which 103 treatment-experienced, CCR5-tropic, HIV-1–infected pediatric subjects aged 2 to less than 18 years weighing at least 10 kg

received SELZENTRY twice daily in combination with OBT. The dose of SELZENTRY was based on body surface area (BSA) and on whether the subject was receiving potent CYP3A inhibitors and/or inducers. The median duration of therapy with SELZENTRY was 131 weeks with 72% of subjects receiving study treatment for greater than 48 weeks and 62% of subjects receiving study treatment for 96 weeks.

In these 103 children and adolescents, the safety profile through 96 weeks was similar to that for adults. Most of the adverse reactions reported were mild to moderate; severe (Grade 3 and 4) adverse reactions occurred in 2% of subjects. The most common adverse reactions (all grades) reported with twice-daily therapy with SELZENTRY, were vomiting (12%), abdominal pain (4%), diarrhea (4%), nausea (4%), and dizziness (3%). Three subjects (3%) discontinued due to adverse events.

Maraviroc-related gastrointestinal adverse events through 48 weeks (nausea, vomiting, diarrhea, constipation, and abdominal pain/cramps) were observed more commonly in subjects who received the SELZENTRY oral solution (21%) compared with those who received SELZENTRY tablets (16%). Subjects were permitted to change formulations after Week 48.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Exposure Registry

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

Lactation

Risk Summary

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

There are no data on the presence of maraviroc in human milk, the effects on the breastfed infant, or the effects on milk production. When administered to lactating rats,

maraviroc was present in milk [see Data]. Because of the potential for (1) HIV transmission (in HIV-negative infants), (2) developing viral resistance (in HIV-positive infants), and (3) serious adverse reactions in a breastfed infant similar to those seen in adults, instruct mothers not to breastfeedif they are receiving SELZENTRY.

Pediatric Use

The safety, pharmacokinetic (PK) profile, and antiviral activity of SELZENTRY were evaluated in treatment-experienced, CCR5-tropic, HIV-1-infected pediatric subjects aged 2 to less than 18 years weighing at least 10 kg in an open-label, multicenter clinical trial, A4001031. Pharmacokinetics were evaluated in a total of 98 pediatric subjects: 85 subjects received SELZENTRY and concomitant medications that included potent CYP3A inhibitors with or without potent CYP3A inducers, 10 subjects received SELZENTRY and noninteracting medications (not containing potent CYP3A inhibitors or potent CYP3A inducers), and three subjects received SELZENTRY and medications that included potent CYP3A inducers without potent CYP3A inhibitors [see Clinical Pharmacology (12.3)].

See Dosage and Administration (2.4, 2.5) for dosing recommendations for pediatric patients aged 2 years and older and weighing at least 10 kg. The pharmacokinetics, safety, and efficacy of maraviroc in patients younger than 2 years have not been established. Therefore, SELZENTRY is not recommended in this patient population. Additionally, there are insufficient data to make dosing recommendations for use of SELZENTRY in pediatric patients concomitantly receiving noninteracting medications and weighing less than 30 kg or in pediatric patients concomitantly receiving potent CYP3A inducers without a potent CYP3A inhibitor.

CLINICAL STUDIES

Clinical Studies in Pediatric Subjects

Trial in CCR5 Tropic, Treatment Experienced Subjects

Trial A4001031 is an open-label, multicenter trial in pediatric subjects aged 2 to less than 18 years infected with only CCR5 tropic HIV 1. Subjects were required to have HIV

1 RNA greater than 1,000 copies per mL at screening. All subjects (n = 103) received SELZENTRY twice daily and OBT. Dosing of SELZENTRY was based on BSA and doses were adjusted based on whether the subject was receiving potent CYP3A inhibitors and/or inducers.

At 48 weeks, 48% of subjects treated with SELZENTRY and OBT achieved plasma HIV-1 RNA less than 48 copies per mL and 65% of subjects achieved plasma HIV-1 RNA less than 400 copies per mL. The mean CD4+ cell count (percent) increase from baseline to Week 48 was 247 cells per mm3 (5%).

How Supplied

SELZENTRY oral solution is a clear, colorless, strawberry-flavored liquid. Each mL of the solution contains 20 mg of maraviroc. It is packaged in plastic bottles as follows: Bottle of 230 mL (NDC 49702-237-55). Each bottle is packaged with one press-in bottle adapter and one 10–mL oral dosing syringe with 0.5–mL gradations. The press-in bottle adapter and oral dosing syringe are not made with natural rubber latex. This product does not require reconstitution.

SELZENTRY oral solution should be stored at 20oC to 25oC (68oF to 77oF); excursions permitted between 15oC and 30oC (59oF and 86oF) [see USP Controlled Room Temperature].

The complete product label is available on the FDAs website.

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

Kimberly Struble
Division of Antiviral Products
Food and Drug Administration

Richard Klein
Office of Health and Constituent Affairs
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	
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**	**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	$1,227,393,844.00
Population Group(s) (as identified in MBES From CMS 64 Waiver Expenditure Report Schedule C Summary) **Total Demo & Medicaid 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	$7,508,823.00	$7,693,624.00	$7,830,655.00	$8,251,832.00	$8,946,868.00	$7,873,455.00	$101,737,495.00
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	-$43,295,460.00	-$50,074,490.00	-$64,481,436.00	-$69,224,575.00	-$60,277,707.00	-$52,404,252.00	($1,125,656,349.00)

Note - FFY15 Q4 (Waiver DY 12 2014): Updated the "Annual Expenditure Targets" with the figures provided in an email from CMS forwarded by Emily Bean on 5/20/2015

Date: 2/10/2017

Maine HIV/AIDS: Overall Service Costs by Demonstration Year

Date Submitted to CMS:

Quarter Report Period: 01/01/2016 - 09/30/2015
MBES (Federal Fiscal Year) FFY 2016

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	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	$ 3,506,408	$ 5,083,460	$ 4,970,148	$ 4,998,250	$ 4,603,037	$41,786,745
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	$ 3,823,497	$ 4,187,216	$ 2,747,195	$ 3,281,684	$ 3,948,618	$ 3,270,418	$59,950,750
	$ 5,082,618	$ 7,737,499	$ 6,625,681	$ 5,139,905	$ 7,816,713	$ 8,068,145	$ 7,630,086	$ 5,531,591	$ 7,508,823	$ 7,693,624	$ 7,830,655	$ 8,251,832	$ 8,946,868	$ 7,873,455	$101,737,495

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

Date: 11/14/2016

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			
Medicaid	218	242			

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**	**1/01/14 - 3/31/14**	**4/01/14 - 6/30/14**	**Total Demo Year Partcipation YTD**
Expansion <=100% FPL	186	184	165	157	
Expansion >100% FPL	245	256	245	240	
Expansion Unknown FPL	33	37	43	49	
Medicaid	236	289	315	333	

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	
Expansion >100% FPL	235	230	224	206	
Expansion Unknown FPL	68	76	93	102	
Medicaid	312	314	338	326	

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	
Expansion >100% FPL	208	206	187	182	
Expansion Unknown FPL	119	126	132	138	
Medicaid	335	339	319	299	

*Some expansion members have an unknown FPL. This is due to the fact that the query for financial reporting is based on claims paid during the quarter. Therefore the service date on the claim can be from any point in time. We only have FPL data for claims with a service date of 1/1/2014 (the beginning of DY12) on. These financials are then reported based on the date of service.

Date: 11/14/2016

ADAP Funds Spent on MaineCare Clients

October 1, 2016 - December 31, 2016

	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"	$27.89	$1,952.21	N/A	N/A	$290.84	$581.68
"Enrollees" above 100% FPL: Demonstration "Enrollees"	$24.11	$3,784.92	$594.19	$15,448.85	$43.90	$439.00
"Members": HIV Positive and MaineCare eligible	$8.57	$1,293.87	N/A	N/A	$22.18	$22.18

Enclosure 5: Contact Tracking by Reason

Contact Reason	Total Contacts	Incoming	Outgoing
Adherence	290	70	220
Ambulance/Transportation	16	10	6
Case Management Services	198	106	92
Collaboration Care coordination	18	11	7
Compliance	75	14	61
Eligibility	305	90	215
ER	89	17	72
Family Planning	0	0	0
Inpatient	20	5	15
Introductory Call	44	10	34
Laboratory/X-ray	5	2	3
Mental Health/Substance Abuse	6	3	3
Medications	48	13	35
Member Survey	0	0	0
Other	171	82	89
Out Dated Contact	18	3	15
Pharmacy	13	1	12
Phone Call Follow Up	88	7	81
Policy	0	0	0
Provider Services	13	4	9
Unpaid Claim	31	6	25
Viral Loads	1	1	0

Enclosure 6: Contact Tracking by Method Used

Method Used	Total Contacts	Incoming	Outgoing
Call	1192	405	787
Email	177	43	134
Fax	3	3	0
Letter	77	4	73