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Presentation of Custom Medication Therapy Management (MTM) Eligibility Criteria and Service Delivery Methods for the Provision of MTM services to a HIV-Infected Population

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Abstract

Background: MTM services are desired to improve clinical outcomes in many specialty areas beyond the core chronic conditions identified by CMS for Part D programs. A centralized MTM solution for the Oregon AIDS Drug Assistance Program (ADAP) known as CAREAssist for HIV – infected patients, was implemented utilizing customized entry criteria and service methodologies to meet its unique needs.

Objective: To develop a service model and eligibility criteria for MTM services that meets the unique clinical needs of an HIV-infected population

Methods: Oregon CAREAssist contracted with Ramsell Corporation for use of the RamsellMTM® solution for the delivery of MTM services. Claims data and limited clinical HIV disease measures were available for screening. Standard CMS enrollment criteria were not appropriate for this HIV infected population, therefore, modified criteria were created. Patients had to meet the following criteria to receive services: adherence (MPR) <80%; history of claims for ARV medications in the previous 45 days. Patients were prioritized when the following were present: diagnosis of mental health issue (other than depression) or substance abuse; claims for tipranavir, valganciclovir or enfuvirtide; or a medical provider referral. MTM services were based on the 2010 CMS criteria of a baseline CMR and a TMR every 12 weeks. Additional interactions were allowed in specific instances. Patients were enrolled in an opt-out manner. MTM Services were provided by in-house pharmacists with HIV experience. Specific modifications to the RCC™ web-based system were made to accommodate the specific clinical data capture needs for this patient population. Enrollment outreach was customized to include an initial enrollment letter followed by pharmacist telephone outreach at 14 and 30 days post letter mailing. Total enrollment was capped at 250 patients. Phased enrollment occurred with 50 patients being enrolled in October 2011, 100 patients in November 2011 and 100 in December 2011.

Results: Initial enrollment runs identified 437 of 2876 total enrollees (15.2%) as eligible for MTM with 22 (0.8%) patients meeting prioritized criteria. Enrolled patients had an average adherence by MPR of 63.46%; prioritized patients had an MPR of 63%. Demographics of current enrollees are: 388 Male (88.8%), 47 female (10.8%) and 3 transgender (0.7%); Caucasian 324 (74.1%), African American 45 (10.3%), Asian 4 (0.9%), Native American/Hawaiian 11 (2.5%) and unknown or other 24 (5.5%). 223 (51%) of enrollees reside in the city of Portland. The enrollment demographics approximated the overall demographic make-up of the overall program. The current rate of non-response to letters and calls is 23%. The Current Opt out rate is 46.2% and is declining. Net participation rate is 47% of all patients identified and contacted to date.

Conclusion: Custom enrollment criteria and methodologies allow the centralized RamsellMTM solution to tailor service to the HIV patients enrolled in Oregon CAREAssist and to deliver quality MTM services to meet their unique clinical needs. Opt out rates are in line with reported Part D norms and are currently declining.

Background

Recent budgetary pressures have put heavy emphasis on cost effective delivery of healthcare dollars for many public health entities. State AIDS Drug Assistance Programs (ADAP), funded by Ryan White Part B federal funding, are no different. The Health Resources and Service Administration (HRSA) has also mandated that the ADAP program implement specific quality assurance measures around the use of the medications paid for by ADAP programs as well as patients adherence to prescribed medication regimens through the required implementation of quality management plans by each state ADAP program.

The state ADAP programs have responded to this requirement in different ways. The primary way states have responded is through aggressive DUR and DUE processes that attempt to quantify and correct any deviations for current treatment guidelines. Other programs have looked at Medication Therapy Management (MTM) programs as a way to ensure quality delivery of healthcare to their clients. MTM programs are an ideal way to address the unique and challenging quality assurance issues faced by state ADAP programs. MTM encompasses both comprehensive and ongoing reviews of medication regimens, it encompasses aggressive adherence counseling and it involves follow up on identified issues to ensure a high quality of delivered care.

In late 2010 and early 2011, Oregon CAREAssist (ADAP) contracted with Ramsell corporation to design and implement an MTM program for their highest need clients. To the best of the participants knowledge, while MTM programs had been developed previously for HIV infected patients, this was to be the first statewide program and the potentially longest running. Unique challenges that were identified included:

- Enrollment criteria
- Service delivery
- MTM provider training
- Follow up
- Documentation

We attempt here to describe the Oregon CAREAssist/Ramsell Corporation MTM program and its results to date.

Methods - Enrollment

The primary issues that were identified were enrollment and service delivery model. For other aspects of the program, it was decided to follow the CMS model for Part D MTM programs. Ramsell utilized its proprietary, in-house developed MTM software solution (RamsellMTM) as its record keeping and screening platform. Ramsell Corporation was also serving as the PBM and 340B program administrator for Oregon CAREAssist so the Ramsell MTM system had ready access to claims starting as of June 1, 2011. Oregon CAREAssist has not previously adjudicated claims prior to June 1, 2011 and the manual records prior to June 1, 2011 were not able to be used by the MTM program. Implementation of the MTM program was started on October 2, 2011. Enrollment was to be capped at 250 patients (approximately 10% of the total population served by Oregon CAREAssist).

A review of current CMS Part D MTM requirements showed them to be inadequate for identifying patients in need of MTM services in an HIV specialty population because current thresholds were too common (dollar threshold and disease state thresholds) or non-contributory for screening of patients in need (numbers of prescriptions). It was felt that a full new set of screening criteria that marked the highest need HIV infected patients was needed. A comparison of the CMS MTM criteria and the arrived at screening criteria are shown in Tables 1A and 1B.

The decided upon enrollment criteria yielded 437 patients eligible for services. Patients who were screened in to participate were enrolled on a gradual basis with 50 patients in October being enrolled, 100 patients in November and 100 patients in December. There were 5 manual enrollees through provider and case manager recommendations that were processed over these same 3 months. Patients without prioritized enrollment were enrolled based on adherence calculated by MPR at the time of identification. Demographics and general enrollment numbers are detailed in Tables 2 and 3.

Table 1a and 1b - Comparison of CMS Part D MTM eligibility criteria and Oregon CAREAssist MTM Program eligibility criteria

TABLE 1A

2012 CMS Part D MTM enrollment criteria
Minimum Requirements
Take at least 8 Part D covered chronic medications
Have at least 3 or more chronic disease states
Have at least $3000 in medication expenditures per year for Part D covered medications

TABLE 1B

Enrollment Criteria OR CAREAssist MTM
Required (both required for enrollment)
• Have Received Antiretroviral Medications in past 45 days
• Adherence by MPR <80%*
Following patients were prioritized for enrollment
• Inferred Mental Health diagnosis (except major depression) by claims for relevant medications within past 45 days
• Receiving any of the following medications: Tipranavir, Efuvirtide, Valgancyclovir
• Identified substance abuse issues
Enrolled regardless of other criteria
• Manual enrollment on recommendation of medical provider

*An error was found in the adherence calculation used at screening that underestimated patient adherence. This resulted in an average adherence higher than allowed for at entrance. This also resulted in inaccurate data being reported in the submitted abstract. The error has now been corrected and all reported adherence numbers have been corrected to a standard MPR calculation.

Eligible Patient Demographics

TABLE 2

OR CAREAssist MTM Eligible Patients Demographics		
Sex	**n**	**Total eligible (n=437)**
Male	388	88.79%
Female	47	10.76%
Transgender	3	0.69%
Ethnicity		
Caucasian/Hispanic	324	74.14%
African American	45	10.30%
Asian	4	0.92%
Native American/Hawaiian	11	2.52%
Unknown/other	24	5.49%
Residence		
Portland	223	51.03%
Other	214	48.97%

Oregon CAREAssist MTM Program: General Enrollment scope and numbers

TABLE 3

OR CAREAssist Enrollment Breakdown				
		Total OR CAREAssist Enrollment (n-2876)	**Overall Total (n=437)**	**Contacted Patients (n=138)**
Total OR CAREAssist Patients	2876			
Eligible for MTM Services	437	15.19%		
Total Patients Successfully Contacted (as of 3/15/12)	138	4.80%	31.58%	
Total Enrolled patients	87	3.03%	19.91%	63.04%
Total Patients Opted Out	51	1.77%	11.67%	36.96%
Other Enrollment Data				
Mean Time in Program as of 3/15/12	n=87 enrolled patients	4.3 Months		

Oregon CAREAssist – Program Design

Managing HIV infected patients requires specialty knowledge on the part of the MTM providers due to their unique and complex needs. These patients require adherence levels of >95% for optimal clinical outcomes, which is not seen in other disease states. Ramsell clinical pharmacists have extensive training and experience in HIV care through Ramsell's long history of providing PBM, 340B and PBA services to multiple state ADAP programs. This may not always be the case in other circumstances and the need for training in HIV care was recognized.

Patients identified for enrollment were then attempted to be contacted for delivery of MTM services. Patients were sent an initial enrollment letter and, if they did not respond, were called via telephone approximately 14 days after the initial enrollment letter. Patients who could not be reached were then sent a second contact letter 28 days after the first letter and were contacted via telephone a second time. In patients where contact was successfully made, only 36% elected to opt out of services while 63% elected to receive program services.

The current CMS model for the delivery of MTM services, a comprehensive medication review (CMR) followed by quarterly targeted medication reviews (TMR) was adopted as the primary service model. Patients received both a personal medication record (PMR) and medication action plan (MAP) which followed current CMS templates after each interaction. An exceptions to allow monthly TMRs was given to patients on Hepatitis C therapy or those patients at high non-adherence risk (as determined by the MTM pharmacist) with sponsor approval.

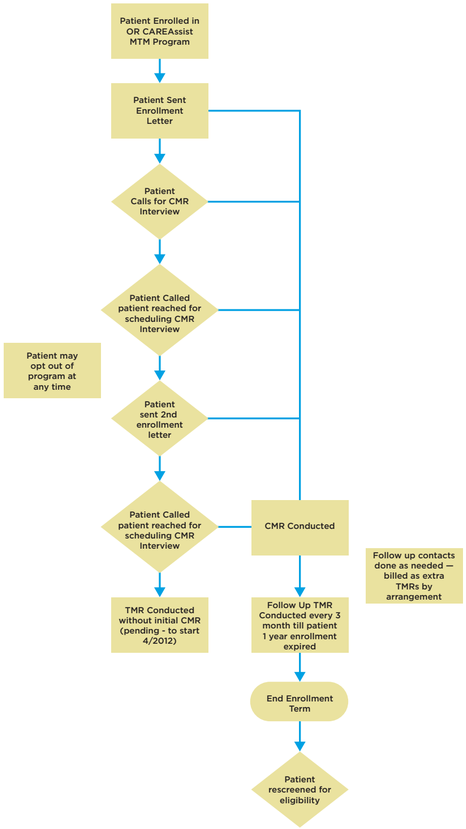
Given the 32% contact rate, it was decided that affective April 2012, that patients who could not be contacted via the current model would receive 4 TMRs without patient participation rather than a CMR and 3 TMRs as described in the revised 2012 CMS MTM guidelines. This decision was made based on the desire to have the adherence and medication quality assurance checks available to all identified patients regardless of their active participation.

Clinical outcomes were tracked via the RamsellMTM system along industry norms. Pharmacy claims data was collected as part of Ramsell Corporations PBM and 340B administrator contract with Oregon CAREAssist. As medical claims are not routinely collected as part of this arrangement, medical costs could not be used for analysis

A schematic of the contact schedule and service model is shown in Diagram 1. Service delivery and clinical outcomes are shown in Tables 4 and 5 respectfully.

OR CAREAssist MTM Service Overview

DIAGRAM 1



Results – Interventions Completed as of March 15, 2012

TABLE 4

Encounters		
Month	**CMR**	**TMR**
October	16	0
November	27	1
December	16	2
January	12	14
February	9	17
March (up to March 15, 2012)	0	5
Totals	80	39
No Shows	7 (8.0%)	N/A

TABLE 5

List of interventions identified		
Intervention	**Total**	**% of Total**
Adherence Counseling	63	34.43%
Adverse Event	16	8.74%
Drug-Disease Interaction	5	2.73%
Duplicate Therapy	12	14
Missing Therapy	9	17
Substitute Therapy	0	5
Non-Standard Dosing	80	39
Other/Not Specified	7 (8.0%)	N/A
Total	183	
Average interventions per enrolled patient (n=87)	2.1	
Status		
Open	149	81.42%
Closed/Resolved	14	7.65%
Pending	15	8.20%
No Action Required	5	2.73%
Adherence		
	On enrollment	**As of 3/15/12**
Adherence by MPR (enrolled patients, n=87)	83.1%*	86.30%
	Adherence Statistics	
Net Difference		+/-3.20%
Std Deviation	11.2	9.7
95% Confidence Intervals	+/-2.45	+/-2.12

*An error was found in the adherence calculation used at screening that net underestimated patient adherence. t-test (2 tailed, independent data) than allowed for at entrance. This also resulted in inaccurate data being reported in the submitted abstract. The error has now been corrected and all reported adherence numbers have been corrected to a standard MPR calculation.

Conclusions

Current CMS Part D MTM enrollment criteria do not adequately address the identification of HIV infected patients for MTM services in non-Part D health plans.

- New enrollment criteria should be used that address markers for:
  - Active Treatment
  - Adherence
  - Late Stage disease
- Manual enrollments, regardless of eligibility, should be allowed to account for patients who can benefit from services, but who may not screen in for care.

Current CMS Part D MTM service delivery models and documentation do meet the needs HIV MTM patients

- Exceptions in cases of difficult to tolerate regimens (e.g. Hepatitis C) or cases of gross non-adherence should be allowed
- More extensive follow up may be required in these cases

Participation levels in ADAP populations may be lower than what has been previously described in Medicare Part D populations.

- ADAP patients tend to have less stable housing and less stable support structures due to the nature of the programs
- Aggressive contact methods may be required to maximize participation
- Alternatives to full patient participation in the standard CMR based model should be considered

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