



Rhode Island Executive Office of Health and Human Services

**Provisions for Stop Loss Claiming for Pharmacy
Expenditure in Treatment of Enrollees with Hepatitis C**

June 30, 2015
Revised July 18, 2014
Revised February 24, 2015
Revised February 9, 2015

This document delineates the provisions for stop loss claiming by contracted managed care organizations (MCOs) for pharmacy costs related to treatment of Enrollees with Hepatitis C. These include expenditures for Sovaldi, Olysio, and Harvoni and any medications or treatments otherwise included in the RI EOHHS “Medications for the Treatment of Hepatitis C: Pre-Authorization Guidelines”. These provisions are pursuant to the following section of the Agreement between the health plan and EOHHS:

ATTACHMENT N. SPECIAL TERMS AND CONDITIONS. This section is amended by adding the following: “Section 9: Stop-Loss Claiming for Pharmacy Expenditure in Treatment of Enrollees with Hepatitis C. Pharmacy expenditures for treatment of Enrollees with Hepatitis C are subject to EOHHS-established stop-loss provisions as set forth in the Rhode Island Executive Office of Health and Human Services document entitled *Provisions for Stop Loss Claiming for Pharmacy Expenditure Treatment of Enrollees with Hepatitis C (Provisions)*. Contractor may submit a stop-loss claim to EOHHS for enrollees with Hepatitis C when the actual average PMPM expenditure for pharmacy treatment exceeds the threshold PMPM as set forth in the *Provisions*. To qualify for Stop loss claiming contractor must comply with EOHHS-established clinical guidelines when authorizing a prescription for FDA approved direct acting antivirals. One hundred percent (100%) of the Contractor’s actual costs in excess of the per member per month level as set forth in the *Provisions* will be reimbursed by EOHHS to the Contractor”.

The provisions outlined below are effective for the contract period beginning July 1, 2015. These provisions apply to all managed care populations enrolled in the MCO including, as applicable:

- Rite Care
- Children with Special Health Care Needs
- Children in Substitute Care
- Rhody Health Partners
- Adult Medicaid Expansion
- Rhody Health Options (for non-dual, Medicaid-only enrollees only)

1. General Statement of Policy

These stop loss provisions pertain to pharmacy costs for persons with Hepatitis C without regard to whether a FDA approved Direct Acting Antiviral medications or treatments otherwise included in the RI EOHHS “Medications for Treatment of Hepatitis C: Pre-Authorization Guidelines” is part of the course of treatment for that person.

Based on initial research findings Sovaldi, for example, offers promise as an effective agent of treatment for certain persons with Hepatitis C. Sovaldi is also a high cost component of a treatment plan. Given both its newness and its high cost there is no base of experience to rely on in projecting its impact in capitation rate development. This policy also applies to subsequently approved

medications for the treatment of Hepatitis C currently in review for FDA approval. Pursuant to these circumstances EOHHS is taking the following actions:

- Approval of coverage of FDA approved medications for the treatment of Hepatitis C provided their use is fully consistent with the Rhode Island Executive Office of Health and Human Services “Medications for Treatment of Hepatitis C Pre-Authorization Guidelines” for authorization as issued by EOHHS and as revised from time to time by EOHHS.
 - Note that on March 14, 2014 the “Benefit Clarification for Hepatitis C Treatments” (Attachment A) was provided advising that health plans should not approve any new treatments of Sovaldi and Olysio. Any related costs for Sovaldi and Olysio prior to the date of release of the “Interim Pre-Authorization Guidelines for Direct Acting Antiviral medications for Treatment of Hepatitis C” are not included within these provisions and are not to be included in medical expense for the purpose of risk share or gain share submissions. The sole exception to this is the circumstance where an individual had initiated treatment prior to the March 14, 2014 release of the Benefit Clarification
- Establishing stop-loss provisions with MCOs wherein pharmacy expenditures for treatment of persons with Hepatitis C that exceed a defined “threshold PMPM” as set forth herein will be eligible for reimbursement by EOHHS at 100% of the expenditures above that threshold.

It is not a standard practice for EOHHS to develop stop loss arrangements for emerging treatment protocols. This action is an exception and developed based on recognition of both the uncertainty and the extraordinarily high cost exposure presented by the recent introduction of new treatment options.

These provisions apply to the contract period July 1, 2015 through June 30, 2016.

Expenditures for this new treatment are not otherwise recognized in the rate development for this period. However, rate development did incorporate MCO prior experience associated with treatment of persons with Hepatitis C. This experience is used as the basis for development of the threshold PMPM in this stop loss arrangement. Calculation of stop loss payments to MCOs will be based on expenditures in excess of the threshold PMPM for persons with Hepatitis C.

2. Definitions

- a. **Persons with Hepatitis C:** Persons with Hepatitis C means MCO members with a claim at any point during the contract period with a diagnosis code of “07041” or “07044”, or “07051” or “07054” or “07070” or “07071”. If a person meets this criteria at any point during the contract period, for the purpose of this stop loss arrangement he/she is regarded as a Person with Hepatitis C for the entire contract period or for the period of enrollment in the MCO if less than the full year.

- b. **Pharmacy Expenditure:** Pharmacy expenditures means the total pharmacy cost incurred by the MCO for a Person with Hepatitis C for all prescription drugs where the drug has been dispensed through a licensed pharmacy during the contract period and, except as noted above, not including any costs for Sovaldi and Olysio prior to the release date of the RI EOHHS Clinical Standards Protocol.
- c. **Pharmacy Expenditure PMPM:** Pharmacy expenditure PMPM is calculated as the actual total Pharmacy Expenditure during the contract period for persons with Hepatitis C divided by the total member months of enrollment of persons with Hepatitis C in the health plan during the contract period. A member month shall be calculated based on cumulative days of enrollment out of total days in a given month. A single member enrolled for the entire month would have a member month count of 1; a single member enrolled for part of the month would have a member month count of the number of days of enrollment divided by the total number of days in the month.
- d. **Threshold PMPM:** Threshold PMPM means the per person per month Pharmacy Expenditures for Persons with Hepatitis C as set forth in Table 1 below. The Threshold PMPM is calculated based on historical pharmacy expenditure for Persons with Hepatitis C prior to the availability of Sovaldi and other newly approved treatments for Hepatitis C trended forward to the contract period (see Attachment B). For the threshold PMPM a member month has been calculated based on cumulative days of enrollment out of total days in a given month. A single member enrolled for the entire month would have a member month count of 1; a single member enrolled for part of the month would have a member month count of the number of days of enrollment divided by the total number of days in the month. Threshold PMPM serves as the baseline for determining stop loss claiming amounts. The Threshold PMPMs for the contract period are shown in Table 1 below:

Table 1: Threshold PMPM By Enrolled Population	
Enrolled Population	Threshold PMPM for July 1, 2015 – June 30, 2016 Period
Rite Care (including children with special health care needs)	\$376.28
Rhody Health Partners	\$633.01
Rhody Health Options (for non-dual, Medicaid-only enrollees only)	\$841.91
Medicaid Expansion	\$571.63

3. Stop Loss Claiming

- a. For purposes of Stop Loss claiming EOHHS will be responsible for 100% of the Pharmacy Expenditure PMPM above the Threshold PMPM times the number of member months ((Pharmacy Expenditure PMPM -Threshold PMPM) x Number of Member Months)).
 - b. MCOs will submit invoices monthly within 45 days after the close of the calendar month using the “Monthly Tracker and Monthly Statement for Stop Loss for Pharmacy Expenditure in Treatment of Enrollees with Hepatitis C” (Attachment C) or as amended from time to time by EOHHS.
 - i. Stop loss payments will be on claims paid basis only.
 - ii. Invoices may be submitted monthly based on claims paid.
 - 1. Stop loss invoices must be accompanied by sufficient detail satisfactory to EOHHS to confirm that the submission is for Pharmacy Expenditures for Persons with Hepatitis C and that the health plan has incurred the expense.
 - 2. Stop loss payments shall be based on the aggregate experience for all business lines combined for the enrolled populations as shown on the attached Claim Form.
 - 3. Based on EOHHS review, payments will be made to the health plan on an interim basis subject to final settlement.
 - c. Final settlement for Stop-Loss claiming is for the aggregate experience for the full contract period. Please refer to Attachment D for final settlement invoice format and claims level data reporting requirements. This format may be amended from time to time at the discretion of EOHHS.
 - i. EOHHS will allow inclusion of claims for a period not to exceed twelve (12) months from the date of service. The final settlement invoice will include a report detailing all of the recoveries, rebates, and reinsurance etc., related to Pharmacy Expenditures for Persons with Hepatitis C.
4. Adjustments to Pharmacy Expenditure for the Purpose of Stop Loss Claiming
- a. Exclusion of Pharmacy Expenditures for Persons with Hepatitis C that are associated with any other stop loss claiming pursuant to this Agreement. This includes, for example, stop loss related to transplants.
 - b. Pharmacy related TPL collections by contractor or receivables, including those related to subrogation are to be included as offsets to Pharmacy Expenditure.
 - c. Pharmacy related reinsurance payments or receivables for Persons with Hepatitis C are to be included as offsets to Pharmacy Expenditures.
 - d. Rebates received or receivable by Contractor for drugs provided to Persons with Hepatitis C are to be included as offsets to Pharmacy Expenditures.

- e. With any invoice submitted to EOHHS pursuant to these provisions, MCOs shall submit, in a format determined by EOHHS, a report of all dollar recoveries, rebates, subrogation, reinsurance etc. received or identified as receivable by the plan for Pharmacy Expenditures for Persons with Hepatitis C.
5. Exclusion of Hepatitis C related Stop Loss claims from all other risk share/gain share related claiming Between the Health Plan and EOHHS.
- a. All pharmacy related expenditures pursuant to this stop loss arrangement shall be excluded from any risk share or gain share related claims submitted by the health plan.

ATTACHMENT A

March 14, 2014 Benefit Clarification for Hepatitis C Treatments

Revised June 30, 2015
Revised July 18, 2014
Revised February 24, 2015
Revised February 9, 2015



BENEFIT CLARIFICATION MEMORANDUM

TO: Patrice Cooper, UnitedHealthcare Community Plan
Beth Marootian, Neighborhood Health Plan of Rhode Island

FROM: Deborah Florio, Administrator 

CC: Toushoua Xiong
Alison Croke
Kristin Sousa
Marianea Peabody

DATE: 3/14/14

RE: Benefit Clarification for Hepatitis C Treatments

Background: EOHHS is currently reviewing and developing guidelines for the utilization of the new treatment regimens for Hepatitis C.

Clarification: We are currently requesting that the health plans do not approve any new persons on Sovaldi and Olysio. If a member has already begun the above treatment, we are requesting that they continue to receive this treatment.

Questions regarding this benefit clarification should be directed to your Health Plan Liaison. Contact information is included below:

NHPRI:	Kristin Sousa	401-462-2395	kristin.sousa@ohhs.ri.gov
	Toushoua Xiong	401-462-3516	toushoua.Xiong@ohhs.ri.gov
UHCP-RI:	Alison Croke	401-462-3497	alison.croke@ohhs.ri.gov
	Marlanea Peabody	401-462-3521	marlanea.peabody@ohhs.ri.gov

ATTACHMENT B

Calculation of Stop Loss Threshold PMPMs for Pharmacy Expenditures in Treatment of Enrollees with Hepatitis C

June 30, 2015

Calculation of Stop Loss Threshold PMPMs for Pharmacy Expenditure in Treatment of Enrollees with Hepatitis C

June 30, 2015
Revised July 18, 2014
Revised February 24, 2015
Revised February 9, 2015

Prepared by:
HealthCare Analytics
PO Box 41408
Providence, RI 02940-1408

1. Introduction

This document and the calculations contained within is in support of a document prepared by the Rhode Island Executive Office of Health and Human Services (EOHHS) titled “Provisions for Stop Loss Claiming for Pharmacy Expenditure in Treatment of Enrollees with Hepatitis C”, dated July 18, 2014. Said, referenced document delineates the provisions for stop loss claiming by contracted managed care organizations (MCOs) for the contract period July 1, 2015 – June 30, 2016 for pharmacy costs, including Sovaldi, Olysio, Harvoni, or treatments otherwise included in the RI EOHHS 'Medications for Treatment of Hepatitis C: Pre-Authorization Guidelines', related to the treatment of enrollees with Hepatitis C in all managed care populations in the MCOs, including:

- Rlte Care
- Children with Special Health Care Needs and Children in Substitute Care
- Rhody Health Partners
- Medicaid Expansion
- Rhody Health Options – for non-dual, Medicaid-only enrollees only

2. Methodology

This document presents the threshold PMPM amounts and their development effective July 1, 2015 through June 30, 2016, for each of the managed care populations listed above. In general, we followed an approach similar to the rate development of each of the listed managed care products (for rates effective July 1, 2015) for the selection of the base period and trend assumptions, and were guided by the definitions established in the said, referenced EOHHS document above.

We relied on data produced by Xerox State Healthcare for the identification of enrollees with Hepatitis C and their total pharmacy expenditures, to develop the threshold PMPM amounts effective 7/1/2015. This data is based on historical experience for dates of service during state fiscal years 2013 and 2014. The data provided to us conformed to the definitions as provided in the *Provisions* document to which this report is Attachment B. These definitions pertain to:

- Persons with Hepatitis C
- Pharmacy Expenditure
- Threshold PMPM

We assumed that the data provided to us for this period specific to Hepatitis C expenses and enrollees are also currently reflected in the data that was provided for the development of managed care rates for the respective populations listed above effective July 1, 2015 through June 30, 2016.

3. Calculation of Hepatitis C Stop Loss Threshold PMPMs

Hepatitis C Stop Loss Threshold PMPM for SFY 2016

Rite Care (RC)	SFY '13	SFY '14
Enrollees with Hepatitis C (Avg. Members)	229	239
<u>Total Rx Expenses of Hep C enrollees</u>	<u>\$ 1,262,130</u>	<u>\$ 778,984</u>
Rx PMPM: 1	\$ 458.76	\$ 271.63
Selected Trend: 2	1.1%	1.1%
<u>Trend Period (years):</u>	<u>3.00</u>	<u>2.00</u>
SFY '16 Projected Rx PMPM:	\$ 474.68	\$ 277.87
Blending Weight	50%	50%
SFY '16 Stop Loss Threshold PMPM for Rite Care:		\$ 376.28

1 To address potential year-to-year volatility in Hep-C related Rx expenses, a blend of the last 2 years will be used to set the threshold

2 Selected Trend for Rite Care is the Rx-specific trend that was part of the composite trend used for rating all RC rate cells

Rhody Health Partners (RHP)	SFY '13	SFY '14
Enrollees with Hepatitis C (Avg. Members)	907	781
<u>Total Rx Expenses of Hep C enrollees</u>	<u>\$ 6,642,637</u>	<u>\$ 5,804,660</u>
Rx PMPM: 1	\$ 610.41	\$ 619.50
Selected Trend: 2	1.2%	1.2%
<u>Trend Period (years):</u>	<u>3.00</u>	<u>2.00</u>
SFY '16 Projected Rx PMPM:	\$ 631.99	\$ 634.02
Blending Weight	50%	50%
SFY '16 Stop Loss Threshold PMPM for RHP:		\$ 633.01

1 To address potential year-to-year volatility in Hep-C related Rx expenses, a blend of the last 2 years will be used to set the threshold

2 Same as Selected Rx Trend for RHP rating for all RHP rate cells

Rhody Health Options (RHO) - Medicaid-only

	SFY '13	SFY '14
Enrollees with Hepatitis C (Avg. Members)	45	39
<u>Total Rx Expenses of Hep C enrollees</u>	<u>\$ 427,505</u>	<u>\$ 421,143</u>
Rx PMPM: 1	\$ 794.19	\$ 889.62
Selected Trend: 2	0.0%	0.0%
<u>Trend Period (years):</u>	<u>3.00</u>	<u>2.00</u>
SFY '16 Projected Rx PMPM:	\$ 794.19	\$ 889.62
Blending Weight	50%	50%
SFY '16 Stop Loss Threshold PMPM for RHO:		\$ 841.91

1 To address potential year-to-year volatility in Hep-C related Rx expenses, a blend of the last 2 years will be used to set the threshold

2 Selected Trend for RHO MA-only is the Rx-specific trend that was part of the composite trend used for rating RHO MA-only

Medicaid Expansion

	SFY '13	SFY '14
Enrollees with Hepatitis C (Avg. Members)	1,156	1,199
<u>Total Rx Expenses of Hep C enrollees</u>	<u>\$ 8,411,227</u>	<u>\$ 7,251,055</u>
Rx PMPM: 2	\$ 606.50	\$ 503.82
Selected Trend: 3	1.2%	1.2%
<u>Trend Period (years):</u>	<u>3.00</u>	<u>2.00</u>
SFY '16 Projected Rx PMPM:	\$ 627.74	\$ 515.52
Blending Weight	50%	50%
SFY '16 Stop Loss Threshold PMPM for Medicaid Expansion:		\$ 571.63

1 Since Medicaid Expansion is new, with very little experience data available, EOHHS estimated expenses based on a "look-alike" population

2 To address potential year-to-year volatility in Hep-C related Rx expenses, a blend of the last 2 years will be used to set the threshold

3 Since Medicaid Expansion is new and there is very little experience data available, the trends used represent the average of Rite Care and Rhody Health Partners

Revised June 30, 2015
Revised July 18, 2014
Revised February 24, 2015
Revised February 9, 2015

ATTACHMENT C

Monthly Tracker and Monthly Statement for Stop Loss for Pharmacy Expenditure in Treatment of Enrollees with Hepatitis C

June 30, 2015

ATTACHMENT D

Invoice for Stop Loss for Pharmacy Expenditure in Treatment of Enrollees with Hepatitis C

June 30, 2015