

 Saskatchewan Ministry of Health Drug Plan and Extended Benefits Branch	Section: <i>Pharmacy Professional Services</i>	Reference DP-PPS-22
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DIRECT OBSERVED THERAPY PROGRAM POLICY and PROCEDURES		

POLICY

- Drug Plan and Extended Benefits Branch (DPEBB) pays community pharmacies under the Direct Observed Therapy (DOT) Program a Direct Observed Therapy (DOT) fee for witnessing the administration of medications for the treatment of chronic hepatitis C infection to eligible patients.
- The DOT fee amounts are listed in Schedule B of the Pharmacy Proprietor Agreement that is in effect on the date the service was provided. DPEBB pays 100% of the DOT fee for eligible patients.
- **No incentives shall be provided** by the Proprietor or an agent on behalf of the Proprietor to any other person in relation to the provision of opioid agonist therapy (e.g., methadone).
"Incentives" means any money, gifts, donations to a charity, rebates, refunds, customer loyalty programs, points, coupons, discounts, goods, dividends, and/or rewards which can be redeemed for a gift or other benefit.

PROGRAM PURPOSE

- To ensure patient medication adherence to a select group of medications.

LEGISLATIVE AUTHORITY

- *The Health Administration Act, (Saskatchewan)*
- *The Pharmacy and Pharmacy Disciplines Act, 2015*
- *The Prescription Drugs Act (Saskatchewan)*
- *The Public Health Act, 1994*

PROGRAM DESCRIPTION

- Under the direct observation of a pharmacist, patients will be observed while they take their medication. Direct Observed Therapy (DOT) is designed to reduce the risk of treatment interruption and to ensure patient adherence.

ELIGIBLE PATIENTS

- All of the following criteria must be met to be eligible under the DOT Program:

- Patient is a Saskatchewan Resident with a valid Health Services Number who is not covered under Workers Compensation, Saskatchewan Government Insurance, Non-Insured Health Benefits (NIHB), Veteran Affairs or the Armed Forces.
- Patient's prescriber must request DOT therapy on patient's prescription.
- Patient must be approved for Exception Drug Status (EDS) for an eligible medication indicated for the treatment of chronic hepatitis C infection.

Exclusions:

- Residents of a Special-care Home are not eligible for the DOT Fee.
A Special-care Home, formerly referred to as a Long-term Care Facility, is defined as a designated facility that provides personal or nursing care to individuals who reside in the home on a temporary or permanent basis. The home may provide any of the following types of care: convalescent care; rehabilitation services; palliative care; respite care; and day programming. Special-care homes are operated by the Saskatchewan Health Authority or by a provider that has a contract with the Saskatchewan Health Authority.

PROCEDURES

The Pharmacist will:

- Confirm the patient is approved for Exception Drug Status for an eligible medication indicated for the treatment of chronic hepatitis C infection by checking the Pharmaceutical Information Program (PIP) or calling the Drug Plan and Extended Benefits Branch.
- Ensure the prescriber has requested DOT therapy on the prescription.
- Provide the medication daily through DOT to eligible patients.
- For twice daily regimen, the pharmacist will witness the administration of one of the daily doses (i.e. am dose) and provide the other dose (i.e. pm dose) as a carry.
- Document witnessed administration on the Direct Observed Therapy Form (Appendix II) or on a similar tracking form:
 - Pharmacist will indicate on the form whether the patient received the dose via DOT, carried a dose or if the patient missed the dose
 - Pharmacist will have the patient initial that they received the dose on the Direct Observed Therapy Form
 - If a patient misses a dose the pharmacist must document on the Direct Observed Therapy Form that they followed-up with the patient to determine cause and notified patient's prescriber.

The Pharmacy will:

- Submit the DOT fee electronically via the DPEBB on-line claim system ONCE weekly as per Appendix I. Paper claims will not be accepted. Pharmacies may submit the DOT fee for a missed dose but DPEBB will only pay for 5 consecutive missed doses.
- Retain copies of the Direct Observed Therapy Form or similar tracking form as per the SCPP Reference Manual - [Record Retention and Destruction](#) guidelines.
- Provide copies of the Direct Observed Therapy Form or similar tracking form upon DPEBB's request as part of the DPEBB's review of adherence to the DOT Program Policy and Procedure within two business days.

The Drug Plan and Extended Benefits Branch will:

- Provide pharmacies with the Direct Observed Therapy Policy and Procedures document and the Direct Observed Therapy Form (Appendix II).
- Pay the DOT fee upon receipt of the electronic claim.
- Request and review the Direct Observed Therapy form or similar tracking form to confirm pharmacies adhered to the DOT Program Policy and Procedures.
- Recover the DOT fee, if DPEBB determines, based on its review, there was non-adherence to the DOT Program Policy and Procedures.

Appendix I: Direct Observed Therapy Billing Procedure

1. DPEBB pays 100% of the Direct Observed Therapy Fee to the pharmacy
2. Paper claims will **not** be accepted.
3. Please ensure the following fields are

• PATIENT IDENTIFIER	= nine-digit Health Services Number (HSN)
• DISPENSING DATE	= date
• RX NUMBER	= enter the sequential RX#
• HEALTH PROVIDER ORGANIZATION ID	= SKCP
• HEALTH PROVIDER ID	= Pharmacist ID number (e.g. D1234)
• PHARMACIST ORGANIZATION ID	= SK
• PHARMACIST ID	= Pharmacist ID number (e.g. D1234)
• DIN	= 00951106
• COMPOUNDING FEE (CF)	= 0
• COMPOUND NAME	= blank
• QUANTITY (QTY)	= Up to a maximum of 7. This is the number of times where the pharmacist witnesses the patient taking the drug that week. For an example: if you witness your client taking the drug Mondays through Saturday, then your quantity should be 6 for that week
• DAYS SUPPLY	= 7
• ACQUISITION COST (AC)	= \$3.50
• DISPENSING FEE (DF)	= 0.00
• MARKUP	= 00 /00 /00
• TOTAL RX COST	= total fee
• PATIENT PAID	= \$0.00
• ADJUDICATION FLAG	= Y

- Use the **WEB page <https://www.drugplan.health.gov.sk.ca>** if unable to bill the fees electronically through the pharmacy's Practice Management System. Contact your pharmacy's software vendor if unsure how to install the WEB certificate. Refer to the DPEBB Pharmacy Reference Manual, Section VI to use the WEB page.
- The DOT billing codes will not appear on the:
 - Pharmaceutical Information Program (PIP);
 - Formulary; and
 - requested patient profiles.

DIRECT OBSERVED THERAPY FORM (Appendix II)

Patient's Name:	
Physician:	
Drug(s):	Dose:
Duration of Therapy:	Start Date:

Administration Code:

P- DOT at pharmacy C- Patient carried dose X- Patient did not come for required dose*

Please insert administration code. Please have patient initial for each dose received.

Month: _____	1	2	3	4	5	6	7
	8	9	10	11	12	13	14
	15	16	17	18	19	20	21
	22	23	24	25	26	27	28
	29	30	31				
Month: _____	1	2	3	4	5	6	7
	8	9	10	11	12	13	14
	15	16	17	18	19	20	21
	22	23	24	25	26	27	28
	29	30	31				
Month: _____	1	2	3	4	5	6	7
	8	9	10	11	12	13	14
	15	16	17	18	19	20	21
	22	23	24	25	26	27	28
	29	30	31				

*Pharmacist to initial that they spoke with the patient and their physician in the case of a missed dose

DIRECT OBSERVED THERAPY FORM – Twice Daily Regimens

Patient's Name:	
Physician:	
Drug:	Dose:
Duration of Therapy:	Start Date:

Administration Code:

**P- DOT at pharmacy
dose***

C- Patient carried dose X- Patient did not come for required

Please insert administration code. Please have patient initial for each dose received.

Month: _____	1- am pm	2	3	4	5	6	7
	8	9	10	11	12	13	14
	15	16	17	18	19	20	21
	22	23	24	25	26	27	28
	29	30	31				
Month: _____	1- am pm	2	3	4	5	6	7
	8	9	10	11	12	13	14
	15	16	17	18	19	20	21
	22	23	24	25	26	27	28
	29	30	31				
Month: _____	1- am pm	2	3	4	5	6	7
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*Pharmacist to initial that they spoke with the patient and their physician in the case of a missed dose